

# NATIONAL COORDINATED SURVEY OF MELAMINE IN FOOD AND BEVERAGES

## SUMMARY

In 2008, in response to an increasing numbers of infants in China presenting with kidney stones, Chinese authorities investigated and found a link to the consumption of infant formula manufactured in China. This investigation suggested that raw milk had been adulterated with melamine. In response to this international incident, the National Food Incident Response Protocol (the Protocol)<sup>1</sup> was activated.

Food Standards Australia New Zealand (FSANZ), in consultation with Australian States and Territories, conducted a survey of food and beverages containing milk products or having a high protein component, manufactured in China and imported into Australia. The results of this survey confirmed the presence of melamine in a limited range of milk products at unsuitable levels. These products were consequently withdrawn from retail sale in Australia. Currently, the melamine incident is in the 'stand down' phase under the Protocol, with ongoing monitoring/testing of foods identified by FSANZ to pose a risk by the Australian Quarantine and Inspection Service (AQIS).

## BACKGROUND

Melamine (also known as 1,3,5-triazine-2,4,6-triamine) is an organic base chemical most commonly found in the form of white crystals rich in nitrogen. It is a chemical compound that has a number of industrial uses, including the production of laminates, glues, dinnerware, adhesives, moulding compounds, coatings and flame retardants (WHO, 2009). Melamine is the common term used for both the chemical and for the plastic produced from it (WHO, 2009). There are no approved food uses for melamine in the Australia New Zealand Food Standards Code (the Code), nor are there any provisions for melamine use in the Codex Alimentarius, although Codex is currently establishing a Maximum Level (ML) for melamine in certain foods.

In early September 2008, the Department of Agriculture, Fisheries and Forestry, through AQIS, alerted FSANZ to the possible adulteration of infant formula in China, resulting in an increased number of infant cases of kidney stones. Reports from China indicated that melamine and its analogues (including cyanuric acid) had been added to raw milk prior to processing into milk powder. On occasion, water is added to raw milk to increase its volume; however as a result of this dilution, the milk has a lower protein concentration. Companies using milk for further processing, such as milk powder and powdered infant formula, check the milk for adequate protein levels by using a test which measures nitrogen content. In this instance, melamine was added to the diluted raw milk to increase the nitrogen level and imitate higher protein content (WHO, 2009).

On 12 September 2008, the Protocol was triggered to inform jurisdictions of these international events. On 16 September 2008, the International Food Safety Authorities Network (INFOSAN) issued an Emergency Alert to inform members of the event and of the possibility of contaminated milk powder being used in other products and available in other markets (WHO, 2009). By 22 September 2008, other dairy products and foods containing dairy ingredients from China were also implicated in the melamine adulteration incident. The Protocol provides clear guidance to member agencies of the Food Regulation Standing Committee's Implementation Sub-Committee<sup>2</sup> (ISC) for responding to a range of national food incidents in a timely, appropriate, consistent and coordinated manner. It provides a link between the protocols of Australian Government and State

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<sup>1</sup> The Protocol formalises current arrangements between agencies for responding to national food incidents. The Protocol does not override existing response protocols of individual agencies or jurisdictions. Instead it provides a link between the protocols of Australian Government and State and Territory agencies responsible for food safety and food issues. For more information on the National Food Incident Response Protocol please refer to the Department of Health website ([www.health.gov.au](http://www.health.gov.au)).

<sup>2</sup> The Food Regulation Standing Committee's Implementation Sub-Committee (ISC) was established to develop guidelines on food regulations, standards implementation and enforcement activities. ISC comprises representatives from the Commonwealth, each State and Territory jurisdiction and New Zealand and includes representation from the Australian Quarantine and Inspection Service, FSANZ and a representative of Australian local government. ISC members are responsible for food safety and food issues and include the government agencies in each jurisdiction with statutory responsibility for food safety.

and Territory agencies responsible for food safety and food issues. In response to the Protocol activation, the Food Surveillance Network<sup>3</sup> (FSN) convened and agreed to conduct a national survey to investigate melamine levels in foods containing milk based products or products with a high protein content imported from China.

AQIS confirmed that no infant formula manufactured in China was imported into Australia<sup>4</sup>, which subsequent jurisdictional investigations at the retail level confirmed. Further information was sought from AQIS regarding other imported food products which may contain milk products or powders from China. AQIS also confirmed that while dairy products from China were heavily restricted by quarantine requirements, products with minor dairy ingredients (less than 10%) and some other exempt foods could be imported (e.g. biscuits and chocolate).

For the purpose of establishing the risk to public health and safety from melamine consumption, FSANZ established a referral level of 2.5 mg/kg for melamine in dairy-based foods other than infant formula. This referral level was established because detections at or above this level were considered to be adulteration and therefore fulfil the definition of being unsuitable. A risk assessment, including exposure, was undertaken for all food above the melamine referral level of 2.5 mg/kg. Concentrations below the referral level may have arisen through leaching from food contact materials during processing and are of no toxicological concern.

International agreement on an ML of 2.5 mg/kg (equivalent to the referral level set by FSANZ) for melamine in food other than infant formula was supported by other food regulatory bodies such as the European Food Safety Authority (EFSA), US Food and Drug Administration (US FDA) and Health Canada. Subsequent to this national and international action, new work for considering ML's for melamine in food and feed was approved at the 32<sup>nd</sup> Session of the Codex Alimentarius Commission in June 2009. The 4<sup>th</sup> Session of the Codex Committee on Contaminants in Food, held in April 2010, agreed on a proposed ML of 1.0 mg/kg for melamine in powdered infant formula and an ML of 2.5 mg/kg in all other food and animal feed (CCCF, 2010). The MLs for powdered infant formula and all other foods and feed were adopted at the 33<sup>rd</sup> Session of the Codex Alimentarius Commission, with the ML for melamine in liquid infant formula (0.5 mg/kg) sent to Step 3 for comments and consideration at the next session.

For more information on Codex Committees and the Step process please refer to the Department of Agriculture, Fisheries and Forestry website (<http://www.daff.gov.au/agriculture-food/codex/resources/faq>).

## **OBJECTIVE**

The objectives of this survey were:

- To determine the level of melamine in food and beverages with dairy ingredients or those which contained some dairy products that had been manufactured in China and imported into Australia.
- To determine whether melamine was present in other high protein foods (e.g. soy-based foods) manufactured in China and imported into Australia.
- To assess whether there were any potential health and safety risks associated with melamine in foods where levels were detected.

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<sup>3</sup> FSANZ coordinates the Food Surveillance Network (FSN), which facilitates the planning and coordination of the food surveillance and monitoring activities undertaken by government health agencies in Australia and New Zealand. The FSN comprises representatives from all State and Territory jurisdictions and the Australian and New Zealand governments.

<sup>4</sup> Australian quarantine regulations do not permit the importation of infant formula from China.

## METHODOLOGY

### Sampling

A two tiered approach was adopted for the survey with the first including high priority foods which were sampled and tested immediately. These foods were considered potentially high risk for melamine adulteration as they were dairy-based or contained dairy based products which reported positive detections for melamine overseas. The second tier included a wider range of lower priority high protein foods as they were mixed foods containing soy, gluten or egg ingredients.

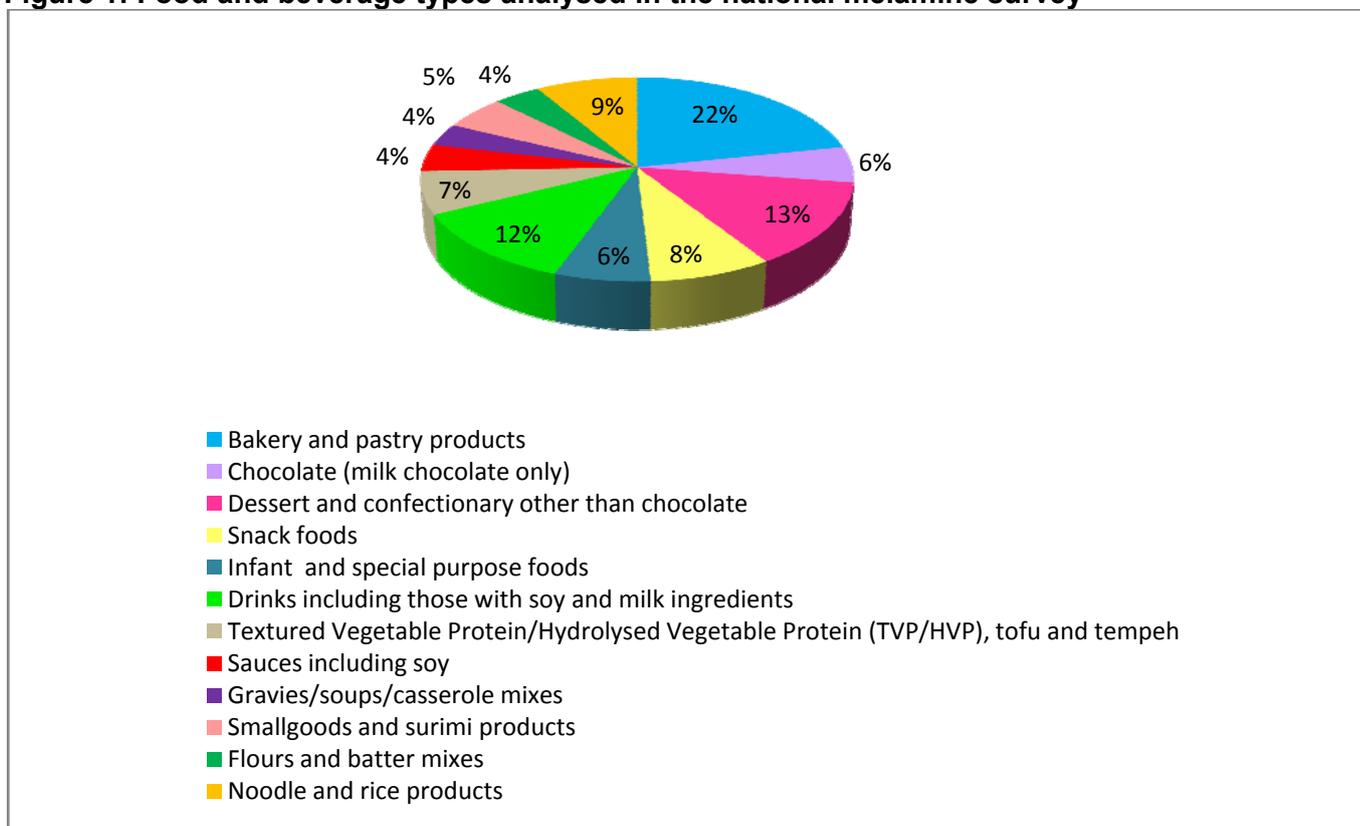
Samples for analysis were collected by food regulatory agencies in all Australian States and Territories from October 2008, with a total of 293 samples collected for analysis. The range of foods and beverages sampled in the national melamine survey are outlined in Figure 1.

For each food type, the products available on retail/wholesale shelves or at the importer, were reviewed and purchased only if they contained milk products or were high protein foods manufactured in China. Where possible, two samples of the same product, each with different batch numbers/date markings were purchased to account for variation between batches. At the time of sample collection, all sample information was recorded prior to being dispatched to the laboratory. Primary samples were retained by the laboratory for any follow up analysis.

From these purchased foods, analytical samples were prepared as follows:

- 272 individual samples.
- 8 composite samples, composited from either identical products with different batch codes, or different varieties of the same brand.

**Figure 1: Food and beverage types analysed in the national melamine survey**



## *Analysis*

FSANZ engaged Leeder Consulting to conduct the melamine analysis for tier one products. Leeder Consulting used a NATA accredited method for the analysis of melamine in food and beverages using Liquid Chromatography Tandem Mass Spectroscopy (LC/MS/MS), with a Limit of Reporting (LOR) of 1.0 mg/kg. Leeder consulting analysed 134 samples for melamine under tier one of the survey. Advanced Analytical Australia undertook melamine analysis of 21 samples collected in Queensland for this survey, also using a LC/MS/MS method with LOR 1.0 mg/kg.

For tier two samples, FSANZ engaged Symbio Alliance to undertake the melamine analysis. Symbio Alliance used a NATA accredited LC/MS/MS method, with a LOR of 1.0 mg/kg. Symbio Alliance analysed 125 samples for melamine. Since traces of melamine can occur in foods from sources other than intentional contamination at low levels (e.g. herbicides/pesticides, fertilisers [WHO, 2008]), the same samples were re-analysed at a more sensitive LOR 0.05 mg/kg using a method that could quantify low levels to determine background melamine levels.

## **RESULTS**

The survey identified 7% (n=280) of food products had positive detections for melamine above the LOR of 1.0 mg/kg. The samples with melamine detections included: four samples of milk based tea drinks, milk drinks and drink powders with dairy ingredients, with a range of melamine concentration of 2.0 – 12.0 mg/kg; one sample of crackers and crisps; and one sample of cakes and muffins. The sample of cakes and muffins which was identified as containing melamine was a composite of three varieties of the same cake brand. Additional analysis was undertaken on the individual purchases for this composite. This additional analysis determined that all three individual purchases were positive for melamine at a concentration above the LOR, with a range of melamine concentration of 3.0 – 16.0 mg/kg. A summary of results from this survey are provided in Table 1.

For the 125 samples analysed for melamine at LOR 0.05 mg/kg, 13 samples had melamine detections above the LOR but below 1.0 mg/kg.

**Table 1: Food categories analysed for melamine and the mean and range in concentration.**

Food category	Number of samples analysed	Number of samples with concentrations $\geq$ LOR	Mean concentration for samples $\geq$ LOR (mg/kg)	Concentration Range (min – max) (mg/kg)
Biscuits, wafers and similar products	35	0	N/A	$\leq 1.0$
Buns, rolls and dumplings	6	0	N/A	$\leq 1.0$
Cakes and muffins	14	2 <sup>#</sup>	9.5	$\leq 1.0 - 16.0$
Chocolate (milk chocolate only)	15	0	N/A	$\leq 1.0$
Confectionary other than chocolate	16	0	N/A	$\leq 1.0$
Crackers and crisps <sup>‡</sup>	17	1	3.0 <sup>†</sup>	$\leq 1.0 - 3.0^{\dagger}$
Desserts and custards (including custard buns and pastries)	15	0	N/A	$\leq 1.0$
Ice confection and other frozen desserts	7	0	N/A	$\leq 1.0$
Infant rusks	3	0	N/A	$\leq 1.0$
Milk based tea drinks, milk drinks and drink powders with dairy ingredients	27	4	6.0	$\leq 1.0 - 12.0$
Special purpose foods/meal replacement powders <sup>‡</sup>	10	1	0.1 <sup>†</sup>	$\leq 0.05 - 0.1^{\dagger}$
Textured Vegetable Protein/Hydrolysed Vegetable Protein (TVP/HVP) <sup>‡</sup>	9	5	0.3	$\leq 0.05 - 0.5$
Soy drinks <sup>‡</sup>	7	0	N/A	$\leq 0.05$
Soy infant formula <sup>‡</sup>	5	0	N/A	$\leq 0.05$
Tofu and tempeh <sup>‡</sup>	10	0	N/A	$\leq 0.05$
Soy sauce <sup>‡</sup>	9	0	N/A	$\leq 0.05$
Sauces other than soy <sup>‡</sup>	3	0	N/A	$\leq 0.05$
Gravies/soups/casserole mixes <sup>‡</sup>	10	1	0.06 <sup>†</sup>	$\leq 0.05 - 0.06^{\dagger}$
Smallgoods <sup>‡</sup>	7	3	0.2	$\leq 0.05 - 0.4$
Surimi products <sup>‡</sup>	8	0	N/A	$\leq 0.05$
Extruded snack foods <sup>‡</sup>	6	1	0.5 <sup>†</sup>	$\leq 0.05 - 0.5^{\dagger}$
Flours/premixes <sup>‡</sup>	5	0	N/A	$\leq 0.05$
Batter mixes <sup>‡</sup>	6	0	N/A	$\leq 0.05$
Egg noodle/egg pasta <sup>‡</sup>	9	1	0.07 <sup>†</sup>	$\leq 0.05 - 0.07^{\dagger}$
Flavoured noodles and noodles with sauce <sup>‡</sup>	11	1	0.11 <sup>†</sup>	$\leq 0.05 - 0.11^{\dagger}$
Non-dairy pastry products <sup>‡</sup>	6	0	N/A	$\leq 0.05$
Frozen and shelf stable fried rice <sup>‡</sup>	4	0	N/A	$\leq 0.05$

N/A: Not applicable given there were no detects  $\geq$ LOR.

<sup>#</sup> Further analysis for melamine concentration in each individual purchase was conducted for one composite sample of cakes and muffins with a detection of melamine above the LOR.

<sup>†</sup> Only one sample with detected level of melamine.

<sup>‡</sup> Some products in this category were manufactured in Malaysia.

<sup>‡</sup> Prior to analysis for melamine at LOR 0.05 mg/kg, this sample was analysed at LOR 1.0 mg/kg, with no positive detection of melamine above LOR.

## RISK ASSESSMENT

### *Health-based guidance value*

For all foods containing levels of melamine above 2.5 mg/kg, a Tolerable Daily Intake (TDI) for melamine and its analogues, established in 2007 by the US Food and Drug Administration (FDA), was used for the risk assessment. The TDI, based on a 13-week rat study, was 0.63 mg/kg bw/day (US FDA, 2008).

### *Dietary exposure and risk characterisation*

For the foods where melamine exceeded the referral level of 2.5 mg/kg, Table 2 shows the amount of food that could be consumed by infants (weighing 10 kg) and adults (70 kg) before the TDI for melamine would be exceeded. The calculations show that it is highly unlikely that adults or infants would consume the large amounts of food needed to exceed the TDI. For example, to reach the TDI:

- adults would have to consume 3-5 kg cakes and muffins or 15 kg of crisps and crackers every day; and
- infants would have to consume 400-700 g of cakes and muffins or 2 kg of crisps and crackers every day.

**Table 2: Amounts of melamine containing foods that could be consumed per day before exceeding the TDI\***

Food category	Amount (kg) per day to exceed the TDI <sup>†</sup>			
	Infant (10 kg bw) <sup>‡</sup>		Adult (70 kg bw)	
	Mean	Maximum	Mean	Maximum
Cakes and muffins	0.7	0.4	4.6	2.8
Crisps and crackers	2.1	2.1	14.7	14.7
Milk-based tea drinks and milk drinks	1.1	0.5	7.4	3.7

<sup>†</sup> TDI = 0.63 mg/kg bw/day

\* Estimated using the mean and maximum melamine concentration in samples where melamine was above the referral level.

<sup>‡</sup> An infant of 10 kg bodyweight would typically be around the age of 10-15 months (NHMRC & MoH, 2006).

## RISK MANAGEMENT

The coordination and risk management of the initial food incident involving adulteration of dairy products with melamine was managed under the Protocol, where a consistent risk management approach was agreed amongst the relevant regulatory agencies. The same risk management approach was applied to the findings of this survey.

In the national melamine survey, six food products were identified with melamine concentrations above the referral level (>2.5 mg/kg) and therefore considered to be unsuitable. Additional analysis of individual samples in a composite were also determined to contain unsuitable levels of melamine (>2.5 mg/kg).

As a result of this food incident, together with the findings of this survey and international testing, eight products were withdrawn from retail sale and one product recalled. Two additional products were withdrawn by industry as a precaution<sup>5</sup>. On 12 November 2008, it was agreed that the melamine incident go to the 'stand down' phase under the Protocol.

<sup>5</sup> Details of the action on these products are available on the FSANZ website at: <http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2008/melamineinfoodsfromchina/>.

FSANZ, together with national and international food regulatory agencies, for example INFOSAN colleagues, continue to collaborate and keep abreast of food safety issues involving melamine in food. AQIS continues to monitor food products imported into Australia from China based on FSANZ risk assessment advice. These include:

- other foods from China, for infants and young children; and
- foods that have been tested in Australia and found to contain melamine. These foods are listed on the FSANZ website and have been subject to withdrawal or recall by State and Territory food authorities.

Foods will fail inspection if analytical testing identifies melamine levels in excess of 2.5 mg/kg.

No food tested has returned a positive result (AQIS, 2009).

For more information on AQIS and Australian quarantine requirements/monitoring please refer to the AQIS website (<http://www.daff.gov.au/aqis>).

## **RISK COMMUNICATION**

Communication of the food withdrawals to the general public was a major component of this incident. The media played an important role in this communication, particularly the Asian media who assisted in translating material for relevant consumers.

For further information relating to this incident and melamine generally, please refer to the FSANZ website and relevant fact sheets at:

<http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2008/melamineinfoodfromchina/>

<http://www.foodstandards.gov.au/scienceandeducation/factsheets/factsheets2008/importedfoodproducts4015.cfm>

## **CONCLUSION**

The national coordinated survey of melamine in foods and beverages manufactured in China indicated that Australia had imported some food products which contained melamine at unsuitable levels. These products have subsequently been withdrawn from sale in Australia. AQIS continues to test for melamine, 'risk' food products as identified by FSANZ that are imported into Australia from China.

## REFERENCES

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