

Advisory Council on Food and Environmental Hygiene

**Summary Report on the Incident of Melamine
in Milk Powder and Milk-related Products**

PURPOSE

This paper briefs Members on the food safety related measures taken by the Administration to tackle the incident of melamine being detected in milk powder and milk-related products.

BACKGROUND

2. Earlier in September 2008, melamine was found in the infant formula produced by the Mainland's Sanlu brand and there were infants in the Mainland who suffered from kidney stones and kidney failure after consuming Sanlu infant formula.

3. Melamine is an industrial chemical used for the production of melamine resins, which are used in laminates, glues, adhesives, paper, textiles, etc., and should not be added to food products. In the present Mainland food incident, unscrupulous traders had added melamine to make the milk appear to be high in protein, causing the contamination of a range of dairy products by the chemical.

4. The Joint Food and Agriculture Organization (FAO)/World Health Organization (WHO) Expert Committee on Food Additives (JECFA) had not evaluated the safety of melamine. Human data on oral exposure to melamine was not available until the recent infant kidney stone cases in the Mainland. While melamine has low oral acute toxicity, excessive and prolonged exposure to melamine has been found to cause bladder stones, crystals in urine and proliferation of epithelial cells of urinary bladder in experimental animals.

5. The US Food and Drug Administration (USFDA) considered melamine to be metabolically inactive or inert. When combined with another chemical, such as cyanuric acid which might also be present in melamine powder, the combination of melamine and cyanuric acid could form crystals which could give rise to kidney stones. In 1999, the International Agency for Research on Cancer (IARC) of WHO evaluated the carcinogenicity of

melamine and considered that there was inadequate evidence in humans for the carcinogenicity of melamine. The European Food Safety Authority (EFSA) also did not consider melamine to be genotoxic or carcinogenic in 2007.

FOLLOW-UP MEASURES

6. The Administration has taken a series of measures to effectively tackle the incident, and those related to food safety are elaborated in the ensuing paragraphs.

Introducing Legal Limits of Melamine in Food

7. The Administration introduced the Harmful Substances in Food (Amendment) Regulation 2008 to prohibit inappropriate level of melamine in food, and the statutory standards came into effect on 23 September 2008. In setting the legal limits, we have researched into international practices and standards and taken into consideration the following –

- (a) melamine is not a food additive and the addition of melamine into food is not approved by the Food and Agriculture Organisation (FAO)/World Health Organisation (WHO) Codex Alimentarius or by any national authorities;
- (b) traces of melamine may be present in food due to migration of melamine from utensils/ packaging made of melamine-formaldehyde resin;
- (c) melamine can also be an environmental contaminant and small amount may be present as an environmental metabolite of pesticide;
- (d) a Tolerable Daily Intake of 0.63 mg/kg body weight/day for melamine is established by the US Food and Drug Administration; and
- (e) a Tolerable Daily Intake of 0.32 mg/kg body weight/day for melamine should be applied to infants and young children of 36 months old or below, as they are more vulnerable to kidney stone formation and an additional safety factor of 2 is introduced.

8. Having taken into account all the above factors, we have set the maximum concentration of melamine under the Harmful Substances in Food Regulations (Cap 132AF) as follows –

Milk Food intended to be consumed principally by persons of an age group into which children under the age of 36 months fall	1 milligram per kilogram of the food
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Food intended to be consumed principally by pregnant or lactating women	
Any other food	2.5 milligrams per kilogram of the food

9. The approach in the Amendment Regulation was considered adequate to protect public health, while taking into account the possible and unavoidable presence of melamine in food in some cases, due to environmental contamination and migration during the manufacturing process. Hong Kong was the first place to establish a legal standard for melamine, and Hong Kong's legal limits are in general consistent with the standards subsequently promulgated by many other jurisdictions, e.g. Canada and New Zealand.

Expert Group on Melamine Incident and the Food Safety, Supply and Control Sub-group

10. The Expert Group on Melamine Incident was set up in September 2008 to assess the health and food safety effects of melamine exposure in the medium to longer term and make recommendations on the appropriate follow up and surveillance of those who have been affected. The Food Safety, Supply and Control Sub-group of the Expert Group on Melamine Incident (Sub-group) was tasked to work out the strategy for effective monitoring and inspection on dairy products and food contaminated by melamine; to study the problem of the contamination of food supply by melamine in Hong Kong; and to conducting risk assessment in regard to the impact of the incident on general food safety. The Sub-group met on 2 October and provided valuable advice on the directions on the surveillance strategy and relevant risk assessment. The Expert Group on Melamine submitted its report to the Chief Secretary on 20 October.

Risk-based Surveillance and Testing

11. A risk-based surveillance programme, with systematic and extensive testing of milk and related products available in the local market, has been an important tool adopted by the Government to tackle the melamine incident. As at 20 October, 2 758 samples of various milk and related products were tested. 33 samples involving 16 brands were found to contain melamine at levels exceeding the legal limits, with the detected levels ranging from 1.4

ppm to 68 ppm. Sale of all relevant products was stopped. The overall unsatisfactory rate is about 1%. Testing results of about 60 to 100 samples have been announced on a daily basis.

12. Through its risk-based surveillance programme, the Centre for Food Safety (CFS) aims to effectively protect public health, assess the extent of melamine contamination in the local market, identify the risk factors (e.g. probability of melamine contamination having regard to milk content, brand, origin, source of ingredients etc.) and assess the potential impact on public health. The CFS aims at removing the uncertainty on a food-type-by-food-type basis, beginning with the food types most likely to be contaminated by melamine. The CFS takes into account a range of factors in drawing up its surveillance programme, including the probability of melamine contamination of a food, vulnerability of the target consumer group, the consumption pattern and dietary habit of the population, and public concern. With the endorsement of the Sub-group, the surveillance programme of the CFS is divided into three phases –

(i) First Round of Surveillance and Testing: from mid-September to mid-October 2008

13. Having regard to the above considerations, the CFS accorded top priority to infant formula, baby food and milk in the first round of its testing. As there were concerns from the public on the consumption of milk imported from the Mainland, the CFS has since 25 September 2008 started to conduct test on all consignments of raw milk, pasteurized milk and UHT milk imported from the Mainland to ensure that they meet the legal requirement on melamine in food before they are put to the market. Testing was then expanded to cover other types of dairy products and products with milk powder as ingredient which are commonly consumed by the public, e.g. dairy-based confectioneries, beverages and bakery products. Testing of all the highest risk food groups was completed in the first round and the results are summarized at **Annex I**.

(ii) Second Round of Surveillance and Testing: from late October to early November

14. While the first round of the surveillance programme focused mainly on the testing of final products, which have the most direct impact on consumers, the CFS attempted in the second round to devote more resources to the testing of Mainland raw materials commonly used in the local food products, for greater control at source. In order to identify the relevant raw materials, the CFS secured the support of the following food trade associations to appeal to their members to provide the Administration with information/

samples on Mainland milk-related ingredients that are commonly available in Hong Kong: Hong Kong & Kowloon Provisions, Wine & Spirit Dealers' Association; Hong Kong & Kowloon Confectionery, Biscuit & Preserved Fruit Wholesalers Association Limited; Hong Kong Food Council Ltd; Federation of Hong Kong Industries; Confectioners and Bakers Association of Hong Kong and Kowloon; and the Hong Kong Beverage Association.

15. The Administration has encountered difficulties in obtaining a comprehensive picture of the estimated number of pre-packaged milk-related products that were manufactured in the Mainland, especially for snack food like chocolates, biscuits, candies, beverages, and hence the proportion tested. The CFS has therefore sought the support of several major food retailers/importers to provide information on pre-packaged food from the Mainland that are likely to contain milk as an ingredient. That said, even the food trade acknowledged that it would be difficult to identify all Mainland food products that contain milk powder. Testing of these products will continue in the second round.

16. Given the relatively higher risk associated with infant formula and food for pregnant and lactating women, testing of the relevant products would continue in the second round. Testing of every consignment of raw milk and pasteurized/ UHT milk from the Mainland would also continue.

17. With a more targeted approach and greater emphasis on control at source in the second round, the quantity of samples tested would be adjusted so as to enhance the effectiveness of CFS' overall surveillance work. The number of samples to be tested each day would be adjusted from 100 to around 60, similar to the number CFS tested before moving on to a heightened state of surveillance in the first round.

(iii) Special Surveillance Project: from early November 2008 to early February 2009

18. On the basis that the upcoming test results will continue to indicate a positive trend by meeting the legal standards, we shall move on to a special surveillance project on melamine than to continue with the extensive testing, for more effective use of resources. During the 3-month special project, we shall continue testing every consignment of raw milk and pasteurized/ UHT milk from the Mainland, and about 100 samples of other relevant food products per week. We shall identify the products most at risk or worth further testing from the results of the second round of testing. With the testing of the top priority food groups drawing to an end, the CFS would later

begin testing more products with no milk content (e.g. meat, vegetables and processed food) but may have been subject to melamine contamination.

19. Subject to a review at the end of the 3-month special project, we shall continue to monitor the melamine situation in the local market through our routine surveillance programme. We shall analyze all our testing results from the previous phases and findings of overseas authorities before finalizing the types of products to be included and the number of samples involved. Apart from monitoring by testing, we will also require importers to provide us with appropriate certification on the melamine content of the food, should they intend to import products that have been found failing the legal standard under our surveillance. The CFS may also test samples of such products before their resumption of sale in the local market.

Communications and Partnerships

20. The melamine incident aroused major public concern and it was of vital importance that the Administration is able to alleviate worries of the community and to provide useful reference for making food choices. The CFS has been issuing daily press updates on its latest surveillance results since 16 September 2008, and has set up a public enquiry hotline. As at 20 October, the CFS has handled 5 968 telephone enquiries and 917 written ones. In addition, all testing results with photos of the samples have also been uploaded onto CFS' website since 16 September 2008.

21. Some members of the public suggested the CFS to announce levels of melamine found in samples that were nonetheless within legal limits. For the purpose of ensuring food safety, the Administration should advise the public on whether certain products meet the legal requirements on melamine, bearing in mind that samples in compliance with the legal requirements do not pose a public health risk. The local legal limits for melamine in food were promulgated with reference to considered risk assessment, and are set with the aim of protecting the health of adults and children alike. Announcing only the exact amount of melamine in products that are tested in excess of the legal limits for melamine is indeed in line with CFS' long-standing practice of making announcement of other food tests, so as to avoid public confusion.

22. Apart from communications with the general public, the Administration has also been working closely with the trade. The Administration has worked with the trade on the recall action whenever a food sample failing the legal standard is detected; traders' briefings were held for introducing the legal limits on melamine; meeting was held with milk powder

importers to ensure a stable supply of infant formula in the local market; and partnership has been built with the trade to obtain information on commonly used Mainland milk ingredients and popular milk-containing products from the Mainland.

23. Close liaison with the Mainland and overseas food authorities has also been a critical element in the Administration's strategy in tackling the incident. References to international research and studies have been made in drawing up the legal standards and exchanges with the Mainland and other overseas authorities have been maintained. The Administration will continue to monitor any relevant international developments.

24. Members are invited to note and comment on the food safety related measures taken by the Administration to tackle the melamine incident.

Centre for Food Safety

Food and Environmental Hygiene Department

Food and Health Bureau

October 2008

**First Round Surveillance and Testing Results
(As at 20 October 2008)**

Food group	Sample Tested	Satisfactory Samples
Infant formula (all origin) <i>Some 55 infant formula products involving 19 brands, none originated from Mainland China</i>	86	86 (100%)
Baby food (all origin)	90	89 (98.9%)
Raw milk, Pasteurized/ UHT milk and milk beverage (Mainland)	287	282 (98.3%)
Pasteurized/ UHT milk and milk beverage (Local Milk Factories)	72	72 (100%)
Milk and Milk Beverages (Overseas)	173	173 (100%)
UHT Cream (all origins)	75	75 (100%)
Milk powder/ Evaporated Milk/ Condensed Milk (Mainland)	52	52 (100%)
Milk powder/ Evaporated Milk/ Condensed Milk (overseas)	97	97 (100%)
Other major dairy products (all origin)	162	162 (100%)
Frozen Confections (Mainland)	95	90 (94.7%)
Frozen Confections from Local Frozen Confection Manufacturers	165	165 (100%)
Frozen Confections (Overseas)	436	436 (100%)
Bakery Products and Milk-related Snack Food (mainly Mainland and Southeast Asia origins)	702	680 (96.9%)
Beverage and Drinks (mainly Mainland and Southeast Asia origins)	141	141 (100%)
Others (e.g. prepackaged mixed dishes, salad dressing, condiments and sauces)	125	125 (100%)
Total	2758	2725 (98.8%)