#### Second Report of the Expert Group on Melamine Incident

# Submitted to the Chief Secretary for Administration (21 January 2009)

#### **Introduction**

The Expert Group on Melamine Incident (the Group), chaired by the Secretary for Food and Health, was set up on 26 September 2008 to address public health and food safety concerns arising from reports earlier that month of melamine being found in infant formula produced in the Mainland and causing renal stones and kidney failure in some infants and children. The Group first met on 26 September 2008 and set up three Sub-groups to look into different issues. They are the Health Services Sub-group, the Treatment Sub-group and the Food Safety, Supply and Control Sub-group. After its second meeting on 20 October 2008, the Group submitted its first Report to the Chief Secretary for Administration and released it to the public on the same day. <sup>1</sup>

2. The Group has made a number of recommendations concerning health services, medical treatment and food safety in relation to the melamine incident for its three respective Sub-groups to take forward. The Sub-groups were asked to report progress to the Group in three months. All three Sub-groups continued their work during this time and have made good progress in taking forward the recommendations. This second report of the Group summarises their work progress in the last three months.

#### **Present Situation**

3. In the period after the release of the Group's first Report on 20 October 2008, the situation regarding the melamine incident has become more stabilized. With the Group taking the lead, our public health services have fully met the demands and food testing has also been conducted in a strategic manner to address public concern.

#### **Health Services**

4. The Group noted that the number of enquiries made to the telephone enquiry hotline operated by the Centre for Health Protection (CHP) of the Department of Health (DH) has decreased substantially. The Designated Clinics

<sup>&</sup>lt;sup>1</sup> Please visit the Food and Heath Bureau's website for access to the first Report of the Expert Group on Melamine Incident, the Terms of Reference and Membership of the Expert Group and its three Sub-groups at <a href="http://www.fhb.gov.hk/melamine/doc/report20081020.pdf">http://www.fhb.gov.hk/melamine/doc/report20081020.pdf</a>.

(DCs) and Special Assessment Centres (SACs) of the Hospital Authority (HA) have operated smoothly and been able to meet the demands for screening and assessment of Hong Kong children at or under 12 years of age. HA has also provided treatment for children with renal stones suspected to be related to the consumption of melamine tainted milk products (MTMP) or dairy products detected in SAC/DC. The demands for their services have also been decreasing.

#### Report Cases

5. CHP continues its surveillance function. In the light of the latest information available from the World Health Organization (WHO), CHP updated the case definition on 9 December 2008. As at 19 January 2009, CHP has received 13 reported cases of children with renal stones suspected to be related to MTMP.

#### Research

- 6. With the development of the incident and accumulation of scientific knowledge, the Expert Group noted that several studies on the health effects of melamine have been published. A Mainland China hospital published a review of cases with acute renal failure and urinary stones. Local studies include a review of the local screening programme and a cross-sectional study. A case-control study on the epidemiological link between urine melamine levels and renal stone formation has been conducted in collaboration with a Mainland university. Please refer to **Annex 1** for a list of these studies, their areas of research and other details.
- 7. To assess the potential medium to long term effects of melamine exposure and as recommended by the Group, the Food and Health Bureau (FHB) is commissioning research on the priority areas specified. In response to FHB's invitation for submission, proposals have been received and are being assessed for their scientific quality and relevance.

#### **Food Safety**

- 8. Regarding food safety, the Centre for Food Safety (CFS) has been conducting food surveillance and sampling in accordance with the programme endorsed by the Group, with suitable adjustments in the light of the prevailing developments and the latest testing results. The Government Laboratory has continued to devote resources for melamine testing of food samples. The CFS continues to operate a telephone hotline while the number of enquiries is on the decrease.
- 9. The Group noted that in response to public concerns regarding

whether animal feeds might be tainted with melamine, the Agriculture, Fisheries and Conservation Department (AFCD) has set the detection limit of melamine in animal feeds at 2.5 mg/kg feed with effect from 7 November 2008. After setting the detection limit of melamine, AFCD collected samples of feed used in local farms for melamine testing.

#### **Public Communication**

10. Also as endorsed by the Group, the CHP, HA and CFS have continued to issue press releases to keep the public informed of the latest numbers of telephone enquiries, reported cases, attendances at the DCs and SACs, food and feed samples tested and their results.

#### **Implementation of the Group's Recommendations**

11. In respect of the recommendations made by the Group in its first Report released on 20 October 2008 concerning provision of health services, medical treatment and food safety in relation to the melamine incident, their implementation progress is detailed in the ensuing paragraphs.

#### **Health Services**

- 12. The Group recommended that the operating hours of CHP's telephone hotline and those of the DCs and SACs should continue while they may be adjusted if the demand warrants. The CHP's notification arrangement of cases and daily announcement of the above should also continue. The implementation is set out below:
  - (a) CHP's telephone enquiry hotline: As at 19 January 2009, the CHP hotline has received a total of 10,744 telephone enquiries. The daily average between 2 and 19 January 2009 was 4 enquiries. Between 1 and 21 November 2008, the daily average was 12, compared with an average of over 1,000 enquiries from 23 to 27 September 2008 each day after the hotline was set up on 21 September 2008. In view of the changed demands, the hotline's operating hours have been adjusted. With effect from 22 November 2008, CHP has ceased the hotline service on Saturday morning. Such arrangement is similar to those of most of DH's other hotline services. A brief history of the operating hours of the hotline is as below and recording service has been available outside the operating hours
    - (i) 21 September to 17 October: from 9 am to 5 pm daily;
    - (ii) 18 October to 21 November: from 9 am to 5 pm on Monday to

Friday, and from 9 am to 1 pm on Saturday; and

(iii) 22 November to the present : from 9 am to 5:45 pm on Monday to Friday.

The CHP will maintain the telephone hotline service for the convenience of the public but keep it under review.

- (b) **CHP case reports:** As at 19 January 2009, CHP received reporting of a total of 15 cases of children with renal stones suspected to be related to MTMP. However, CHP announced on 9 December 2008 that two of these cases had been verified as non-melamine related following HA's detailed investigations showing that the renal stones were most likely attributable to underlying hypercalciuria, and therefore the two cases were discounted. Taking the above into consideration, there remains 13 melamine related case reports as at 19 January 2009, of which 2 were reported by private doctors and the rest by HA. CHP continues to issue daily press releases on the number of cases reported and also the number of telephone enquiries received.
- (c) **DCs and SACs :** HA set up 18 DCs and 7 SACs on 23 September 2008 to provide free assessment for eligible children at or under 12 years of age. While the number of DCs has remained the same, the number of SACs has been adjusted as below
  - (i) 23 to 25 September : 7 SACs;
  - (ii) 26 September to 22 October: 9 SACs; and
  - (iii) 23 October to the present : 8 SACs.

As at 19 January 2009, DCs and SACs have provided screening and assessments to 55,714 and 26,584 children respectively. The number of attendances is released by HA daily. The DCs will be in operation for at least six months until March 2009 in the light of actual needs so as to ensure that the service demands are well met. As at 19 January 2009, the number of appointments made for assessment at SACs up to 31 January 2009 was 160. This was partly to cater for the parents' preferences regarding appointment time. The SACs will continue to run until the end of March 2009 to ensure that the referrals from the DCs will be adequately assessed. If there is no further increase of patients for assessment, thereafter, children may seek initial assessment at General Out-patient Clinics and those who need subsequent follow ups will be seen at the appropriate paediatric or

surgical specialist out-patient clinics. To help monitor the demand for the services, FHB continue to receive summary daily reports on the cross border traffic movement, especially during Mainland holiday periods, for example, the coming Chinese New Year holidays to ensure that should there be any unusual surge in demand for services, it would be taken care of expeditiously.

13. The Group will continue to monitor the provision of services above. Should circumstances so warrant, CHP and HA may implement changes to their respective services after consulting the Group or Health Services Sub-group members.

#### **Medical Treatment**

- 14. The Group highlighted in its first Report the need for revisiting the case definition as necessary upon availability of new scientific information. The Group emphasized promulgation of screening, diagnosis and treatment protocols to private clinicians and that HA should analyse data collected from DCs and SACs and update its referral criteria. The Group also recommended FHB to commission research on health effects and to maintain close liaison with the Mainland Ministry of Health (MoH) on new developments. The progress is set out below:
  - **Case definition**: To facilitate disease surveillance, CHP adopted on (a) 18 September 2008 a set of reporting criteria, based on that issued by As endorsed by the Group, CHP further adopted a set of case definitions in October 2008 to assess the real burden of disease. case definition comprised three categories, namely "suspected" case, "probable" case and "confirmed" case. CHP communicated with WHO and MoH on this set of case definitions. On 5 December 2008, WHO announced its establishment of the Tolerable Daily Intake (TDI) of melamine at 0.2 mg/kg body weight for people of all ages. subsequent to WHO's Expert Meeting convened in Ottawa from 1 to 4 December 2008 to review the toxicology aspects of melamine and In view of this development, CHP revised on 9 evanurie acid. December the case definition of "probable" case by updating the TDI as follows:

#### **Previous definition**

- A "probable" case is a "suspected case" with melamine intake exceeding the tolerable daily intake threshold of 0.63 mg/kg for those over 36 months of age or 0.32 mg/kg body weight for those 36 months or younger, for a significant duration.

#### **New definition**

- A "probable" case is a "suspected case" with melamine intake exceeding the tolerable daily intake threshold of 0.2 mg/kg body weight for a person of any age and for a significant duration.

The definitions for "suspected" and "confirmed" cases above and the reporting criteria remained the same. The revised case definition was promulgated to local doctors by CHP on 9 December 2008 (Annex 2).

The Group understands that being the first place in the world to develop case definitions on melamine related disorders, and that the scientific knowledge of melamine and analogues is very limited and rapidly evolving, the case definition will be reviewed as necessary from time to time subject to availability of new scientific evidence.

- (b) **Promulgation of protocols:** HA conducted symposia on 4, 5 and 18 October 2008 at HA Headquarters and at the Princess Margaret Hospital, in collaboration with the Hong Kong Society of Nephrology, the Hong Kong Paediatric Society and the Hong Kong Paediatric Nephrology Society. The symposia shared with local medical professionals the screening programme and clinical management of children affected by MTMP and laboratory testing of clinical specimens. The HA guideline was also discussed at the HA's Melamine Treatment Group to collect input from representatives of the universities and the private sector. Through HA's existing public private interface mechanism, the finalized version was disseminated to private partners to update them on the current management guidelines.
- (c) Clinical management: HA issued its revised operational guideline on 6 October 2008 for use by its DCs, SACs and Accident and Emergency Departments, explicitly delineating the ultrasound criteria for reporting melamine associated renal stones and medical advice based on available evidence and practicability. HA is closely working with its experts to observe new progress and development, and is prepared to update the information regularly.
- (d) **Data analysis**: The Group noted that analysis of DCs and SACs data so far showed that the yield of ultrasound scanning for renal stones in children was low, at a rate of about 0.034 percent. The results of the blood and urine tests performed so far did not indicate a noticeable alternative pathology. The Group considers that the overall findings suggest that selection of children at risk would be a more cost-effective approach for the screening programme.

- (e) Commission of research: Given the novel nature of melamine related disorders, the Group recommended commissioning research to assess the potential medium and long term health effects associated with melamine exposure. The Treatment Sub-group has provided expert advice on the research initiatives. FHB invited submission of project proposals on 18 November 2008. Priority areas as set out in the invitation include:
  - (i) Follow-up studies of affected persons, particularly those assessed to be at higher risk of adverse health outcomes;
  - (ii) Laboratory testing of melamine and analogues; and
  - (iii) Animal models or other basic science research.

The Group noted that proposals received will be subject to peer review in order to ensure that funded projects will be of high scientific quality and relevance. Taking into account the time required for necessary logistics, the Group expects that the approved research projects will commence in February/March 2009.

15. The Group endorsed that FHB and CHP should continue to maintain communications with the MoH and WHO on the latest developments and scientific knowledge, including case definitions, reporting criteria, diagnosis and management. FHB and the experts in HA will also monitor the developments of treatment and other related aspects with the Mainland.

#### Food Safety

- 16. In its first Report, the Group recommended enlarging the focus of CFS's surveillance strategy, extending the scope of testing to cover Mainland raw materials and conducting a review of the testing programme after three months. CFS should require certification on the melamine content of the imported food products which previously failed the legal limit. CFS should also closely monitor international development on setting of standards and FHB should accord top priority to the relevant legislative exercise. The recommendations have been taken forward as set out below:
  - (a) Surveillance and sampling programme: CFS has been conducting surveillance and sampling in accordance with the programme endorsed by the Expert Group, with suitable adjustments in the light of prevailing developments and the latest testing results. While the Government Laboratory conducts the actual testing of food samples, the CFS conducts its risk-based surveillance and sampling programme

#### in three phases:

- (i) <u>First Phase</u> (mid September to late October 2008): focused on products most directly at risk, in particular infant formula/infant food, milk and milk-related products, including testing every consignment of raw milk and pasteurized/UHT milk from the Mainland since 25 September 2008. Testing results of about 80-100 samples were announced daily.
- (ii) Second Phase (late October to mid November 2008): focusing on source control, testing was extended to Mainland raw materials commonly used by local food manufacturers including eggs, flour, baking powder, custard cream powder, egg white powder and cake mix, as well as fresh produce including meat, fish and vegetables. Furthermore, testing of infant formula and food for pregnant/lactating women and every consignment of Mainland milk continued. Testing results of about 60 samples were announced daily.
- (iii) Third Phase (mid November 2008 to mid February 2009): in this phase, surveillance and sampling are focused on products identified to pose higher risk from the previous testing and any other relevant food types. Items included in the food groups are milk, eggs, frozen confections, baby food and bakery products. About 100 samples are tested each week and the test results are announced twice weekly, although unsatisfactory results will be announced once available.

The Group noted that as at 19 January 2009, a total of 5 137 samples have been tested, with 40 samples found to contain melamine at levels exceeding the legal limits. Sale of all relevant products was stopped. The overall unsatisfactory rate is less than 1%. Summary of the testing results is at **Annex** 3. A review of the testing programme will be conducted after completion of the Third Phase. Testing of melamine will be incorporated into CFS's regular surveillance plan thereafter.

(b) **CFS's telephone enquiry hotline:** As at 19 January 2009, CFS has handled about 7,730 telephone enquiries since the hotline's operation on 16 September 2008. In the first two weeks of the hotline's operation, it handled 265 calls on average per day. The number of enquiries handled then declined substantially. Between 1 and 21 November 2008, the daily average was 38 enquiries. In view of the

steady decline, the operating hours of the hotline have been adjusted. With effect from 22 November 2008, the CFS hotline operates from 9 am to 6 pm on Monday to Friday, ceasing operation on Saturday mornings. Between 2 and 19 January 2009, the number of calls was 7 on average per day.

- (c) Certification requirement: While certain products like milk and frozen confections with previous unsatisfactory test results of melamine are subject to "hold and test" by the CFS until their test results are satisfactory, CFS has written to the importers and sole agents for the other products failing the melamine test previously, requiring them to provide quality verification or laboratory certificate before importing the same products into Hong Kong. CFS will continue to sample the failed products that have resumed import.
- (d) International development in setting standards for melamine: CFS has been monitoring closely the international development in the setting of limits on melamine and melamine analogue level in food. The levels adopted by various overseas national authorities for melamine are summarized in Annex 4. The limits adopted in the other jurisdictions are generally similar to the standards set in Hong Kong. On 5 December 2008, WHO announced that the limits for melamine in infant formula (1 mg/kg) and in other food (2.5 mg/kg) introduced by many countries and places, including Hong Kong, provide a sufficient margin of safety as compared to the TDI established by WHO. As for melamine analogues, WHO also announced that there were currently inadequate data to allow the calculation of a health-based guidance value for the co-exposure to melamine and its analogues.
- (e) Harmful Substances in Food (Amendment) Regulation 2008: The Group noted that the Amendment Regulation was gazetted on 23 September 2008 and came into force the same day. It set the legal limits of melamine at 1 mg/kg for milk and food for children under the age of 36 months, pregnant and lactating women, and at 2.5 mg/kg for other food. To more clearly reflect the policy intention in the law that all liquid milk and milk beverage (for persons of any age) should comply with the 1 mg/kg requirement, definitions for the terms "milk" and "milk beverage" were added in the Amendment Regulation. The latest amendment came into force on 28 November 2008.
- (f) Public Health and Municipal Services (Amendment) Bill 2008: As recommended in the Group's first Report, the Secretary for Food and Health introduced the Public Health and Municipal Services

(Amendment) Bill 2008 into the Legislative Council on 5 November 2008. It seeks to empower the Director of Food and Environmental Hygiene to make orders administratively under the law to prohibit the import and supply of any problem food and direct a recall on reasonable grounds. The Amendment Bill is an important measure proposed to help tackle food safety incidents like the melamine incident in a timely and effective manner. The Bill is undergoing Committee Stage scrutiny in the Legislative Council.

#### **Detection Limit for Melamine in Animal Feed**

- 17. The Group noted that in the light of detection of exceeded level of melamine in fresh shell eggs imported from the Mainland and reports of animal feed being tainted with melamine in the Mainland in late October 2008, AFCD has set the detection limit of melamine in animal feed at 2.5 mg/kg feed, with effect from 7 November 2008. The detection limit is set with reference to the guidelines and practices promulgated by the World Health Organization (WHO), the European Union (EU) and the Mainland.
- 18. AFCD then tested a total of 27 feed samples and 139 animal (fish, pig and chicken) samples collected from local farms. Only one sample of marine fish feed was found to contain melamine exceeding the detection limit. All of the other feed and animal samples were found to be satisfactory, including fish samples from farms that had also used the unsatisfactory feed. The overall satisfactory rates for feed and farmed animals are 96.3% and 100% respectively. The Group observed that nonetheless AFCD has asked local fish farmers to stop using the feed concerned, and informed the Mainland authorities of the finding. AFCD has also advised local fish and livestock farmers, when sourcing, to request their feed suppliers to ascertain that the feed they supply does not contain melamine and they should report any irregularities of their stock suspected to be related to melamine tainted feed. AFCD will continue to closely monitor the situation.

#### **Publicity**

19. As endorsed by the Group in its first Report, daily press releases have continued to be issued to keep the public informed of the number of enquiries handled by CHP's telephone hotline, attendances at HA's DCs and SACs and the number of cases reported to CHP with related information provided. CFS has also been issuing daily releases on its latest surveillance results and uploaded all testing results onto CFS's website since 16 September 2008. As the number of tested samples has gradually been reduced from 100 per day to about 100 samples each week, the test results are announced twice weekly since mid November 2008, except for unsatisfactory results which will be announced at

once. To keep the public informed, the above publicity arrangement may continue.

#### **Way Forward**

- 20. The Group notes that about four months since the melamine incident, the situation has become more stabilized and the demands for the various services concerned have been fully met. With the Group taking a lead, the government bureaux and departments concerned and HA have mobilized their resources, worked smoothly and effectively to provide a range of services, including case surveillance, health screening, assessment and treatment, and surveillance and testing of food samples, to address public concerns. The Group has committed to provide the services at the DCs and SACs until the end of March 2009. food surveillance strategy, as endorsed by the Group, should also continue and a review should be conducted upon completion of its Third Phase in mid February Barring unforeseen developments, the testing of melamine will be incorporated into the routine surveillance programme and a risk-based approach will continue to be employed with special attention given to products with unsatisfactory results from previous testing. The testing results will be promulgated to the public at a regular interval. The Group will continue to closely monitor the situation.
- 21. The Group considers that food safety will remain a challenge. While recognizing the concerted actions taken by the Government in relation to food safety in this incident, the Group considers that the Government should remain vigilant and continue to strengthen its rapid response capacity in handling any major food safety incidents. The Group emphasizes the importance of triparte collaboration between the Government, the trade and the public in enhancing food safety and is pleased to note that the local food trade has responded positively to the Government's call for cooperation in the current incident. The Government will also continue to maintain close liaison and exchange information with the Mainland and other regulatory authorities.
- 22. The Group is pleased to note that preparation for the research studies to assess the potential medium to long term health effects associated with melamine exposure is making progress and the actual studies will commence in February/March 2009. The Group is particularly keen that FHB should continue to keep an active interest in the development of the incident in the Mainland and maintain close liaison with international health and food authorities and local scientific community for the latest information.
- 23. The Group is keenly aware of the public concerns, especially among parents when infants and young children are more likely to be affected. To alleviate their concerns, the Group has placed much emphasis on timely

communication with the public by clear announcements on CFS's food testing results, attendances at SACs and DCs and number of case reports, and by providing telephone enquiry hotlines. While these arrangements will continue, the Group considers that the experience of handling the melamine incident has helped strengthen risk communication strategies, particularly in the early stage of an incident to help ease public anxieties.

24. The three Sub-groups will continue to monitor the implementation of the above measures and report progress to the Group in around another three months. The Group will then further review the latest situation and consider whether the various services may be incorporated into the regular and routine services provided by the various departments and HA. To keep the Chief Secretary for Administration apprised of the progress of work, the Group will provide the next report in March 2009.

#### **Note of Thanks**

- 25. The Group Chairman would like to thank the local food trade for their cooperation with Government on food testing to enhance food safety; and the medical profession and clinical staff both in the private and public sectors for their professionalism and dedication in meeting the service needs of the public. He is also grateful to the food, medical and scientific experts for their expert advice.
- 26. The Group Chairman is also grateful to the experts, academics and representatives of government bureaux and departments who serve on the Group as members and contribute invaluable advice to its work.

Expert Group on Melamine Incident Food and Health Bureau Government Secretariat January 2009

### Annex 1

# **List of Recent Publications on Melamine Incident**

	Date	Title	Institution	Journal	Major Area of Research
1.	November 2008	Melamine related urinary calculus and acute renal failure in infants 婴幼儿三聚氰胺相关泌尿系结石致急性肾衰竭诊疗分析	Division of Urology & Dept of Pediatric Surgery, Beijing Children' Hospital (affiliated to Capital Medical University, Beijing)	Zhonghua Er Ke Za Zhi 中华儿科杂志	Case review of infants with urinary calculus and acute renal failure due to melamine tainted milk formula admitted to the Beijing Children's Hospital and the Xuzhou Children's Hospital in 2008. Major findings are:  • Stones composed of melamine and uric acid, molecular ratio 2:3;  • Renal failure was relieved in all 34 patients, after different modes of treatment;  • Stones usually widely distributed in the urinary tract, bilateral, sand and sediment like;  • 2 major treatments were regulation of hyperkalemia and electrolyte disturbance and relief of urinary obstruction.  • http://www.cma.org.cn/uploadfiles/20081014/sanlu3.doc.
2.	December 2008	Melamine-tainted milk product (MTMP) renal stone outbreaks in humans	Dr CHIU Man Chun, Princess Margaret Hospital	HK Medical Journal	<ul> <li>This is an editorial, describing the screening programme in Hong Kong. The author discussed that:</li> <li>In Hong Kong, after mass screening by ultrasound, only very few patients with stones were encountered;</li> <li>There was a background rate of symptomatic paediatric renal stones admitted to HA, therefore Hong Kong has no outbreak;</li> <li>Current testing of melamine in urine and stones are too sensitive, making interpretation difficult;</li> <li>It was postulated that melamine served as a nidus for deposition of other chemicals such as uric acid.</li> <li><a href="http://www.hkmj.org/article_pdfs/hkm0812p424.pdf">http://www.hkmj.org/article_pdfs/hkm0812p424.pdf</a>.</li> </ul>
3.	December 2008	Renal screening in children after	Dept of Paediatrics &	British Medical Journal	Cross-sectional study of 3170 children seen at SACs of New Territories East.  Major findings are:

	Date	Title	Institution	Journal	Major Area of Research
		exposure to low dose melamine in Hong Kong: cross sectional study	Dept of Radiology, CUHK		<ul> <li>Prevalence of suspected melamine related abnormalities on ultrasound was only 0.2%;</li> <li>Overall prevalence of microscopic haematuria was less than 1%;</li> <li>No adverse renal outcomes;</li> <li>Estimated melamine intake was low and did not exceed tolerable daily intake;</li> <li>Large scale and urgent screening programmes may not be informative and cost effective for populations who have been exposed to low dose melamine.</li> <li><a href="http://www.bmj.com/cgi/content/full/337/dec18_4/a2991?q=rss_home_">http://www.bmj.com/cgi/content/full/337/dec18_4/a2991?q=rss_home_</a></li> </ul>
4.	January 2009	Diagnosis and Spectrum of Melamine-related Renal Disease: Plausible Mechanism of Stone Formation in Humans	Dept of Chemical Pathology, HKU	Clinica Chimica Acta	<ul> <li>Case-control study on 15 exposed children in China, showing that:</li> <li>More than 50% of cases had predisposing urinary metabolic urinalysis which may serve as triggers of stone formation;</li> <li>Strong correlation between renal stone size and urinary melamine concentration;</li> <li>Urinary cyanuric acid was not significantly different between cases and controls;</li> <li>The spectrum and severity of disease appeared to be dose-related;</li> <li>Urine melamine level might be an indicator of residual melamine load in the body and thus is useful for following-up and monitoring of the confirmed cases.</li> <li>http://www.sciencedirect.com/science?_ob=ArticleURL&amp;_udi=B6T57-4VBDKM7-3&amp;_user=10&amp;_rdoc=1&amp;_fmt=&amp;_orig=search&amp;_sort=d&amp;view=c&amp;_acct=C000050_221&amp;_version=1&amp;_urlVersion=0&amp;_userid=10&amp;md5=99ab5911de5127663fd9837_88cc67114.</li> </ul>

監測及流行病學處



Surveillance And Epidemiology Branch

9 December 2008

本署檔號 Our Ref.: DH DEB NCD/9/12/2008

Dear Doctor,

# Revised case definitions of renal diseases associated with consumption of melamine tainted milk products (MTMP)

Upon receiving the latest information from the World Health Organization regarding the tolerable daily intake of melamine, I would like to inform you about the revised case definitions of renal diseases associated with MTMP as follows:

#### Suspected case (懷疑病例)

Individuals having consumed food that is tainted with melamine (according to the lists of unsatisfactory/tainted foods promulgated by Centre for Food Safety, Hong Kong and/or AQSIQ#, China and/or other official agencies overseas);

AND either of the following conditions:-

Having a positive ultrasound finding of renal stone(s) \* where other potential causes have been excluded by differential diagnosis;

#### OR

Having a verified, positive history of passing renal stone(s), sand or filtrated residues, where other potential causes have been excluded by differential diagnosis.

#### Probable case (臨床病例)

A "suspected case" with melamine intake exceeding the tolerable daily intake threshold of 0.2 mg/kg body weight for a person of any age and for a significant duration.

#### Confirmed case (確診病例)

A "probable case" with laboratory confirmation.\*\*\*

 Exact radiological criteria@ defining a positive ultrasound examination as per the Hospital Authority Expert Group on milk products tainted with melamine. If ultrasound was performed outside Hong Kong, a written report or ultrasound film should be available to confirm the finding.

- @ Ultrasound criteria for reporting MTMP associated renal stone
  - (1) Ultrasonography is currently the preferred procedure for investigating MTMP associated renal stone. The criterion for reporting MTMP associated renal stone should be:
    - Criterion 1: "A strong echogenic lesion> or = 4 mm lying inside the renal calyx or renal pelvis, detected by multi-planar US scan (B-mode) using high frequency probe (5-10 MHz).", OR
    - Criterion 2: "An ultrasonographic abnormality not completely fulfilling criterion 1"
       AND "dilatation of either renal pelvis or renal calyx."
  - (2) Hydronephrosis alone does not imply the presence of a renal stone.
  - (3) Lesion not completely fulfilling criterion 1 or 2 should be reported as an inconclusive US scan. It is recommended to follow up these patients with an interval scan in 1 -3 months' time subject to clinical judgment. In consideration of radiation exposure risk and the potential benefits, CT, MR and IVU of the kidneys are not advisable unless otherwise justified.
- \*\* According to Centre for Food Safety, Hong Kong, China.
- \*\*\* Subject to further assessment of technical feasibility and scientific validity.
- # Administration of Quality Supervision, Inspection and Quarantine of the People's Republic of China

The above case definitions will be reviewed and updated from time to time as knowledge of the disease is evolving.

You are kindly reminded to report cases to the Central Notification Office of the Centre for Health Protection (CHP) via fax (24772770), phone (24772772) or CENO On-line (www.chp.gov.hk/ceno).

Yours faithfully,

(Dr. TH Leung)

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Consultant Community Medicine (Non-Communicable Disease)

Centre for Health Protection

Department of Health

# Annex 3

# Summary of Surveillance and Testing Results (as of 19 January 2009)

Food group	Sample Tested	Satisfactory Samples
Infant formula (all origins)	162	162 (100%)
Some 78 infant formula products involving 19 brands, none		
originated from Mainland China		
Baby food (all origins)	235	234 (99.6%)
Raw milk, Pasteurized/ UHT milk and milk beverage (Mainland)	728	723 (99.3%)
Pasteurized/ UHT milk and milk beverage (Local Milk Factories)	72	72 (100%)
Milk and Milk Beverages (Overseas)	276	276 (100%)
UHT Cream (all origins)	80	80 (100%)
Milk powder/ Evaporated Milk/ Condensed Milk (Mainland)	67	67 (100%)
Milk powder/ Evaporated Milk/ Condensed Milk (Overseas)	158	158 (100%)
Other major dairy products (all origins)	184	184 (100%)
Frozen Confections (Mainland)	117	112 (95.7%)
Frozen Confections from Local Frozen Confection Manufacturers	165	165 (100%)
Frozen Confections (Overseas)	476	476 (100%)
Bakery Products and Milk-related Snack Food (mainly Mainland and Southeast Asia origins)	1 243	1 218 (98%)
Beverage and Drinks (mainly Mainland and Southeast Asia origins)	169	169 (100%)
Raw Material (except eggs) (all origins)	162	162 (100%)
Egg (all origins)	347	343 (98.8%)
Meat and Meat Products (all origins)	90	90 (100%)
Poultry (all origins)	93	93 (100%)
Fish and Fish Products (all origins)	172	172 (100%)
Vegetables (Mainland)	30	30 (100%)
Others (e.g. prepackaged mixed dishes, salad dressing,	111	111 (100%)
condiments and sauces)		
Total	5 137	5 097 (99.2%)

#### Annex 4

## Limits set by overseas national authorities on melamine levels in food

(as of 19 January 2009)

Country/Region	Product	Limit (mg / kg)	<b>Publication date</b>	Link
Canada	Infant formula and sole source	0.5. <sup>a</sup>	05.12.08	http://www.hc-sc.gc.ca/fn-an/securit/chem-chi
	nutrition products, including			m/melamine-eng.php
	meal replacement products			
	Other food products containing	2.5. <sup>a</sup> .	03.10.08	
	milk and milk-derived			
	ingredients			
China	Formula for infant and young	1	07.10.08	http://www.moh.gov.cn/publicfiles/business/ht
(Mainland)	children			mlfiles/mohbgt/s3582/200810/38027.htm
	Liquid milk, (including raw	2.5		
	milk), milk powder, and other			
	formula			
	Other food containing more	2.5		
	than 15% of milk			

<sup>&</sup>lt;sup>a</sup>These levels apply to a combined concentration of melamine and cyanuric acid.

Country/Region	Product	Limit (mg / kg)	<b>Publication date</b>	Link
European Union	Composite products	Import into the	10.12.08	http://eur-lex.europa.eu/LexUriServ/LexUriSer
	containing milk or milk	EU Member		v.do?uri=OJ:L:2008:331:0019:0020:EN:PDF
	products, soya or soya	States prohibited		
	products, intended for the			
	particular nutritional use of			
	infants and young children,			
	originating or consigned			
	from China			
	All consignments originating	2.5		
	in or consigned from China			
	of ammonium bicarbonate			
	intended for food and feed			
	and of feed and food			
	containing milk, milk			
	products, soya or soya			
	products			

Country/Region	Product	Limit (mg / kg)	Publication date	Link
Japan	Baby Food	Should not be	16.10.08	http://www.fsc.go.jp/emerg/melamine1009.pdf
		detected		#search=.
		(limit of		
		quantitation: 0.5)		
	Milk, milk products and	Should not be		
	processed foods containing	detected		
	milk or milk products from	(limit of		
	China	quantitation: 0.5)		
	Other Foods	2.5		
Macau	Milk	1	28.10.08	http://www.gcs.gov.mo/showNews.php?PageLa
	All foods intended to be	1		ng=C&DataUcn=33372&Member=0&ach=∾
	consumed principally by			hYear=&PHPSESSID=f2a3qmoge48baq8760fs
	children under 36 months			sdsea5.
	All foods intended to be	1		
	consumed principally by			(Document issued by Serviços de Saúde,
	pregnant or lactating women			Governo da Região Administrativa Especial de
	All other foods	2.5		Macau)
Malaysia	Infant foods	1	11.10.08	http://fsq.moh.gov.my/uploads/NST_Interview.
	Other foods	2.5	]	<u>pdf</u>

Country/Region	Product	Limit (mg / kg)	Publication date	Link
New Zealand Food Safety Authority	Infant formula	1	29.9.08	http://www.nzfsa.govt.nz/publications/media-releases/2008/29-sep-melamine-statement.htm
(NZFSA)	For foods other than infant formula in their final form	2.5		
Food Standards Australia New	Infant formula	1	14.10.08	http://www.foodstandards.gov.au/newsroom/factsheets/factsheets2008/melamineinfoodsfromchina/index.cfm
Zealand (FSANZ)	For dairy-based foods and foods containing dairy-based ingredients	2.5		
Singapore	Foods for infants and children up to 3 years of age Food in general	2.5	18.12.08	http://www.ava.gov.sg/NR/rdonlyres/E1226BE 1-6D1A-4EC4-8E06-BF5C712C832B/22746/C ircularResumptionofChinamilkandmilkproducts
Taiwan	All food	"not detected"	26.9.08	18Dec0.pdf. http://www.doh.gov.tw/CHT2006/other/ShowC opy.aspx?doc_no=68731&class_no=25.

Country/Region	Product	Limit (mg / kg)	<b>Publication date</b>	Link
Thailand	Infant filled milk, infant	1.b.	27.10.08	( WTO notification G/SPS/N/THA/172,
	filled milk follow-up formula			08-5169 and G/SPS/N/THA/173, 08-5195)
	for infants and young			
	children, whole milk powder,			
	low fat milk powder,			
	skimmed milk powder, filled			
	whole milk powder and filled			
	low fat skimmed milk			
	powder			
	Foods, other than the above,	2.5 <sup>b</sup>		
	which contained milk and			
	milk-derived ingredients			
US Food and Drug	Infant formula	1. °.	28.11.08	http://www.cfsan.fda.gov/~dms/melamra4.html
Administration				
(FDA)				http://www.fda.gov/bbs/topics/NEWS/2008/NE
	Food products other than	2.5° b	3.10.08	<u>W01895.html</u>
	infant formula			http://www.cfsan.fda.gov/~dms/melamra3.html

b These levels apply to a combined concentration of melamine and melamine-related compounds including cyanuric acid, ammelide and ammeline.

<sup>&</sup>lt;sup>c</sup> These levels apply to melamine or one of melamine-related compounds (including cyanuric acid, ammelide and ammeline) alone.

Country/Region	Product	Limit (mg / kg)	Publication date	Link
Hong Kong	Milk, food intended to be	1	23.9.08	http://cfs.fehd.hksarg/english/whatsnew/whatsn
	consumed principally by			ew_fstr/whatsnew_fstr_harmful_substances_reg
	children under 36 months			<u>ulation.html</u>
	and pregnant or lactating			
	women			
	Other food	2.5		
World Heath	Tolerable daily intake (TDI) for melamine = 0.2		5.12.08	http://www.who.int/mediacentre/news/releases/
Organization	mg/kg body weight per day			2008/pr48/en/index.html
(WHO)				
	Tolerable daily intake (TDI) for cyanuric acid =			
	1.5 mg/kg body weight per day			

End