Emerging food safety risks: Melamine-tainted milk in China[1]

In September of 2008, media reports emerged that thousands of infants in China had fallen ill from drinking infant formula tainted with dangerous quantities of melamine. An industrial chemical commonly used in plastics and resins, melamine had been intentionally added to milk as a "fake" protein, allowing producers to dilute the product but fraudulently pass nutrition tests. Rather than testing directly for protein, these tests measure nitrogen, which makes up 67% of melamine by mass [WHO, 2009a]. Infants who drank the melamine-contaminated infant formula developed kidney stones and other renal problems that lead to at least six deaths, 51,900 hospitalizations, and an estimated 294,000 illnesses in China, Taiwan, Macau, and Hong Kong [Yang et al., 2009; WHO, 2009b]. Food products containing melamine were then exported internationally.

The melamine scandal is an example of a global food safety risk and the generic factors that contributed to its amplification or attenuation could be relevant for a wide range of other potential food safety risks.

When any substance is considered as a potential food additive, the first step in any risk assessment is the gathering of knowledge in order to solve as many ***scientific unknowns*** as possible – knowledge related to its chemical composition and properties, its toxicity, how it is metabolised or biodegrades, how it can be detected etc. However, when a substance is novel or is not a designated food additive – as was the case with melamine – there are many unknowns, and knowledge of this kind is often incomplete or not adequately sought out. Such a lack of knowledge can amplify risks. When melamine was first discovered in milk in China, there was a rush to find toxicological information about the chemical, but little was found. The few pre-existing laboratory analyses of melamine had determined that it has a low toxicity in animals, and is rapidly eliminated from the body in urine [Wong et al., 2008].

Although one US study on rats in 1983 had shown that very high doses of melamine (3161 parts per million by body weight) caused harm or even death from urinary bladder inflammation and bladder stones and crystals in the urine [WHO, 2009b; NTP, 1983], without knowledge of this study, Chinese producers would have had little or no reason to believe melamine could inflict harm. To the contrary, there was a prevalent belief in the industry at the time that melamine was essentially non-toxic, since it had been used for years as an additive in the animal-feed industry to feign a higher protein content (this was something of an 'open secret' in China) [Ingelfinger, 2008; Yang et al., 2009; Kuehn, 2009; Barboza et al., 2007].

The ***complexity*** of the food supply chain was another factor that increased the likelihood of risk emergence. The dairy industry in China, as is the case with many large food industries these days, has followed the trend of agribusiness industry consolidation, in that a few large processors now compete within a more complicated chain. This means that numerous, dispersed actors (from small farmers, to independent brokers, to brand-name processors) have input into the final product and there are more potential points at which contamination could take place. What happened in the Chinese dairy industry was further complicated by large increases in demand (which suppliers could barely keep up with, pushing them to compete in ever more uncoordinated supply chains [Yang et al., 2009]); as well as the influence of global trade putting pressure on the industry to produce as cheaply as possible (which provided one incentive to look for a cheap protein substitute).

A complex food chain also allows for food contaminants to become more widely spread and more difficult to trace. Once it emerged in China that melamine could be toxic to humans, concern understandably began to mount about what other kinds of products could be

[1] This paper is based on a draft case-study prepared by Farah Abi-Akar, a member of IRGC's secretariat in 2009. It aims to illustrate some of the contributing factors to the emergence of risks described in the IRGC report "The Emergence of Risks: Contributing Factors". This report is part of phase 1of IRGC's project on Emerging Risks. More information can be found online at http://irgc.org/Project-Overview,219.html

contaminated. The fact that melamine had been added to animal feed made it more likely that other parts of the food chain would be affected – at least four brands of eggs were later found to contain melamine [BBC, 2008].

The increasing complexity of the food supply chain is in large part a consequence of changing ***technological advances*** and ***social dynamics***. Technological innovation in the form of food technology has changed the industry quite significantly – processing, preserving and packaging techniques have revolutionised the way that food is prepared, transported and sold. Chemical processes are now routinely applied to foodstuffs (e.g., freeze drying, irradiation, addition of inert gases) and the use of food additives (both natural and artificial) has greatly increased. These extra processes and supplementary ingredients amplify risks related to food safety – for example, numerous food additives have been found to have adverse effects on health, leading their use to be heavily regulated in some countries.[2] At the same time, urbanisation, modernisation and the spread of prosperity have drastically changed the lifestyle of the majority of people so that populations are now much more *reliant* on these processed, packaged foods than they used to be. The melamine scandal is evidence of this, as most of the harm originated from the consumption by infants of infant formula, a processed product which may be highly modified.

Globalisation and the rapid growth of international trade have played a similarly influential role in risk amplification. Melamine-tainted products produced in China were exported to other countries, making this food safety risk a global issue. In the US, products found and later recalled due to measured or suspected melamine contamination included certain brands of candy, biscuits, cookies, milk, flavored drink, and coffee (although no cases of health problems have been reported in the US) [Ingelfinger, 2008; FDA, 2008b]. Europe was minimally affected because it is illegal to import dairy products and infant formula into the EU from China, but it had nevertheless imported products containing milk powder including cookies, toffees and chocolates [Rosenthal, 2008; EFSA, 2008]. After the scandal surfaced, 68 countries banned or recalled goods suspected to contain melamine. Given today's globalised trading system, this situation could easily be repeated for future food safety risks [Bhalla et al., 2009]. The trend towards more free trade may also be a contributor to risk amplification if it leads to fewer inspections of imported foods - in the US, an advocacy organisation reports that the FDA's border inspections of regulated foods may have been as low as 0.6% in 2007. In comparison, before trade agreements were updated in the mid 1990s with the founding of the WTO and prior to the North American Free Trade Agreement, 8% were inspected [Public citizen, 2007].

Despite the above factors contributing to the wide spread of melamine-contaminated goods, the adverse effects of their consumption were much more concentrated. The great majority of the victims were from mainland China, with a handful of cases each in neighbouring Hong Kong, Macau and Taiwan. There are two notable details about the victims of the melamine-tainted food products. Firstly, they were all infants or young children under the age of three, which indicates that there were important ***varying susceptibilities*** to this food safety risk. The root of this susceptibility turned out to be that infants have higher concentrations of naturally-occurring uric acid than do adults, and this combines with melamine to form kidney stones. Because many infants are on a diet of almost exclusively infant formula, this also contributed to them accumulating large amounts of melamine in their systems [FDA, 2008c]. However, infants (because of their under-developed immune systems) and children (because they consumer larger amounts of food relative to body weight) may, in general, be more susceptible to any number of food safety risks [Ingelfinger, 2008]. Secondly, most of the victims came from poor, rural areas [Yang et al., 2009], suggesting that poverty and a lower level of development acted as factors that amplified risk in this instance - poor rural populations would have a more restricted choice of products and would not be able to afford the much more expensive foreign-made brands.

[2] For example, the consumption of foods containing sodium benzoate (used as a preservative) and some artificial colours have been linked with increased hyperactivity in children [McCann et al., 2007]; and sodium nitrite (used as a preservative and colour fixing agent in meat and fish) is toxic in high amounts and has the potential to form carcinogenic nitrosamines. Its use is therefore highly regulated [Scanlan, 2000].

Temporal complications also amplified risk in this case – it took some time for the melamine contamination to be discovered, because harmful effects only became evident following a gradual build-up of melamine (due to chronic consumption) in the systems of the infants. Nevertheless, the lack of early warning was an important governance failure, given that there had been recent indications of melamine's potential toxicity and of the fact that it was being used as a protein 'substitute' in food well before the contaminated milk scandal – in 2007, pet food exported from China to the US was found to be contaminated with melamine and other chemicals after it killed at least 1,000 cats and dogs, maybe thousands more, through renal failure [AP, 2007a]. The discovery instigated "the largest recall in FDA history" and the source was traced to wheat flour from China, which had been intentionally adulterated to reflect higher perceived protein content and therefore higher value [Kuehn, 2009]. What's more, although reports of melamine-tainted milk did not appear until mid-September, 2008, it later emerged that awareness of the problem had existed since at least the beginning of August – one Chinese manufacturer, Sanlu, confirmed on August 2 that its infant formula was poisoned. However, no action was taken because, the week before the Beijing Olympics were due to begin, the Chinese government "issued orders to suppress 'bad news', including about health scares, during the period of the Olympic Games" to protect "social stability" [Spencer, 2008]. It was not until more than one month later on September 9 that the government of New Zealand revealed the melamine-contamination problem, as the New Zealand company Fonterra, which owned 43% of Sanlu stock, had learned about the contamination and, with delay, alerted their ambassador. Different sources state that doctors and citizens in some parts of China knew well before, as far back as early 2007, though the timeline is unclear [Economist, 2008b; Spencer, 2009]. China may have filtered out online "information about tainted milk from as long ago as December, in order to protect China's reputation during the run-up to the Olympics" [Economist, 2008b].

Although there were regulations in place to try to protect food safety and prevent this sort of incident occurring, one common problem with regulation (and one which applies not only to China) is that the rate of regulation implementation and adaptation often lags behind that of industry process. This is especially the case under circumstances of fast economic growth, as experienced by China. In the melamine case, the speed of development of the Chinese dairy industry after the turn of the century quickly outpaced regulations. Milk processors and retailers became concentrated into large companies and production went from small to industrial scale, but China's regulations remained "thin" [Gereffi, 2009].

Another potential problem with regulations is that they can have unintended secondary effects. A failure to anticipate these secondary effects can lead to risks being amplified. Well-meaning regulations implemented in China with the aim of protecting infant health actually ended up creating ***perverse incentives*** for manufacturers of infant formula to falsify protein content. These regulations imposed strict nutrition requirements on infant formula and were implemented in response to a 2004 scandal when 13 babies died from drinking infant formula made from starch and sugar [Reuters, 2008; Ingelfinger, 2008]. Because the required protein and nutrients were expensive, producers searched for cheaper ways to seemingly adhere to the set levels – this led to the addition of melamine.

One reason why it may have been difficult to foresee the secondary effects of this regulation may have been that "too many departments are in charge of food safety [in China], which causes overlapping of responsibilities and creates problems for law enforcement, and there are often conflicts of interest within agencies and governments at various levels" [Yang et al., 2009]. This led to poor coordination between ministries and agencies, which "may have prolonged the outbreak of melamine poisoning" [Reuters, 2008].

When responsibilities are not clearly divided, authority is not clearly designated and organisations do not have the capacity to anticipate and respond to emerging risks, it is also more challenging to resolve ***conflicts of interests***. How the inevitable trade-offs are made can have a significant impact on risk amplification or attenuation. With regards to food safety risks, at the local/national level, a trade-off must be made between the costs and

inconvenience of testing for contaminants, conducting inspections, enforcing regulations etc., and the benefits of minimising risks of contamination. With global trade in food products being so important, there are trade-offs to be made at the international level, too. When it comes to deciding whether to import food products from other countries (which may have different food safety standards and regulations), countries must make a trade-off between the possibility of food safety risks on the one hand, and the economic benefits of trade (e.g., access to cheaper goods) and the maintenance of politically favourable relationships on the other.

Concentrated interests – notably those of domestic industries – must be carefully dealt with when making these trade-offs. The imposition of high safety standards on food imports (a non-tariff trade barrier) is becoming increasingly popular in many countries. Though these standards aim to ensure food safety and protection of health, they have also been used less transparently as tools of exclusion to improve a country's global economic competition, boost domestic industry, or promote political goals [Fan et al., 2009; Athukorala, 2004]. The fact that "China has some of the toughest food safety standards regarding imported food," but does not necessarily require domestic producers to abide by them [Fan et al., 2009], could be evidence of the latter.

In conclusion, the case of melamine-tainted milk in China shows both how a national food safety risk can now easily spread across the globe and how inadequate or ill-conceived regulation in conjunction with concentrated political or economic interests can amplify emerging food safety risks.

References

[AP, 2007a] Thousands of Pets Probably Sickened by Food, Associated Press, 9 April 2007, http://www.msnbc.msn.com/id/18029173/

[Athukorala et al., 2004] Athukorala, Prema-Chandra and Jayasuriya, Sisira; Food Safety Issues, Trade and WTO Rules: A Developing Country Perspective; Chapter 7 within *The World Economy: Global Trade Policy 2003*, edited by David Greenway; Wiley-Blackwell, http://books.google.com/books?hl=en&lr=&id=MiHfUpEoUAIC&oi=fnd&pg=PA141&dq=wto+ban+food+china&ots=3zDrn0eQnt&sig=mlUS3PkIe3hCE_P6k3kjxurgml0

[Barboza et al., 2007] Barboza, David and Barrionuevo, Alexi, Filler in Animal Feed Is Open Secret in China, *New York Times*, 30 April 2007, http://www.nytimes.com/2007/04/30/business/worldbusiness/30food.html

[BBC, 2010] Chinese Dairy Executives Charged in Tainted Milk Case, 6 January, 2010, http://news.bbc.co.uk/2/hi/asia-pacific/8443437.stm

[BBC, 2008] BBC News, Chinese Melamine Scandal Widens, 31 October 2008, http://news.bbc.co.uk/2/hi/7701477.stm

[Bhalla et al., 2009] Bhalla, Vivek, Grimm, Paul C., Chertow, Glenn M., and C. Pao, Alan. Melamine Nephrotoxicity: An Emerging Epidemic in an Era of Globalization, *Kidney International*, 75, 774-779.

[Economist, 2008b] The Poison Spreads, *The Economist,* 25 September 2008, http://www.economist.com/businessfinance/displayStory.cfm?story_id=12304845

[EFSA, 2008] European Food Safety Authority, Statement of EFSA on Risks for Public Health Due to the Presences of Melamine in Infant Milk and Other Milk Products in China, *The EFSA Journal* 807, 1-10, http://www.efsa.europa.eu/cs/BlobServer/Statement/contam_ej_807_melamine,0.pdf?ssbinary=true

[Ellwein and Cohen, 1990] Ellwein, L.B. and Cohen, S.M., The health risks of saccharin revisited, *Critical Reviews in Toxicology*, 20 (5), 311-326

[Fan et al., 2009] Fan, Saina and Boyd, Milton, Understanding Canada-China Food Trade: Behind-the-Border Barriers, Asia Pacific Foundation of Canada, June 2009, http://asiapacific.ca.c11.previewyoursite.com/files/Analysis/2009/ChinaFoodTrade.pdf

[FDA, 2008b] US Food and Drug Administration, Melamine Contamination in China, 18 October 2008, http://www.fda.gov/ohrms/dockets/ac/08/briefing/2008-4386b3.pdf

[FDA, 2008c] US Food and Drug Administration, Update: Interim Safety and Risk Assessment of Melamine and Its Analogues in Food for Humans, 28 Nov 2008, http://www.fda.gov/Food/FoodSafety/FoodContaminantsAdulteration/ChemicalContaminants/Melamine/ucm164520.htm

[Gereffi, 2009] Gereffi, Gary, A Global Value Chain Approach to Food Safety and Quality Standards, Duke University, Prepared for the Global Health Diplomacy for Chronic Disease Prevention, 4 February 2009, http://www.cggc.duke.edu/pdfs/GlobalHealth/Gereffi_Lee_GVCFoodSafetyI_4Feb2009.pdf

[Ingelfinger, 2008] Ingelfinger, Julie R., Melamine and the Global Implications of Food Contamination, *The New England Journal of Medicine* 359 (26), 2745-2748.

[Kuehn, 2009] Kuehn, Bridget M., Melamine Scandals Highlight Hazards of Increasingly Globalized Food Chain, *JAMA* 301(5), 473-475.

[McCann et al., 2007] McCann, D., Barrett, A., Cooper, A., Crumpler, D., Dalen, L., Grimshaw, K., Kitchin, E., Lok, K., Porteous, L., Prince, E., Sonuga-Barke, E., Warner JO and Stevenson J., Food additives and hyperactive behaviour in 3-year-old and 8/9-year-old children in the community: a randomised, double-blinded, placebo-controlled trial, *The Lancet*, 370(9598), 1560-7,

[NTP, 1983] Carcinogenesis bioassay of melamine (CAS No. 108-78-1) in F344/N rats and B6C3F1 mice (feed study), United States Department of Health and Human Services, Public Health Service, National Institutes of Health, National Toxicology Program (NTP Technical Report Series No. 245; NTP-81-86; NIH Publication No. 83-2501; http://ntp.niehs.nih.gov/ntp/htdocs/LT_rpts/tr245.pdf

[Public Citizen, 2007] Public Citizen, Trade Deficit in Food Safety: Proposed NAFTA Expansions Replicate Limits On U.S. Food Safety Policy that Are Contributing to Unsafe Food Imports, July 2007, http://www.citizen.org/documents/FoodSafetyReportFINAL.pdf

[Reuters, 2008] China Melamine Scandal Prompts Mass Chicken Cull, Reuters, 31 Oct. 2008, http://in.reuters.com/article/worldNews/idINIndia-36252520081031?feedType=RSS&feedName=worldNews&pageNumber=2&virtualBrandChannel=0

[Rosenthal, 2008] Rosenthal, Elisabeth, China's Milk Scandal Now Seen as a Risk in Europe, *New York Time*, 25 September 2008, http://www.nytimes.com/2008/09/26/world/asia/26melamine.html

[Scanlan, 2000] Scanlan, R., Nitrosamines and cancer, The Linus Pauling Institute, 2000, http://lpi.oregonstate.edu/f-w00/nitrosamine.html

[Spencer, 2008] Spencer, Richard, Chinese Ordered Cover-up of Tainted Milk Scandal, *Telegraph.co.uk*, 24 September 2008, http://www.telegraph.co.uk/news/worldnews/asia/china/3074986/Chinese-ordered-cover-up-of-tainted-milk-scandal.html

[Spencer, 2009] Spencer, Richard, Two Sentenced to Death over China Melamine Milk Scandal, *Telegraph.co.uk*, 22 January 2009, http://www.telegraph.co.uk/news/worldnews/asia/china/4315627/Two-sentenced-to-death-over-China-melamine-milk-scandal.html

[Wong et al., 2008] Wong, S.N. and Chiu, M.C., The Scare of Melamine Tainted Milk Products, Accessed 2 July 2009, *Hong Kong Journal of Paediatrics* 13, 230-234, http://hkjpaed.org/details.asp?id=672&show=1234

[WHO, 2009a] World Health Organization, Toxicological and Health Aspects of Melamine and Cyanuric Acid, Ottawa Canada, 1 - 4 December 2008, http://whqlibdoc.who.int/publications/2009/9789241597951_eng.pdf

[WHO, 2009b] World Health Organization; Expert Meeting to Review Toxicological Aspects of Melamine and Cyanuric Acid, 1-4 December 2008; Last reviewed/updated 16 April 2009; accessed 19 June 2009; http://www.who.int/foodsafety/fs_management/infosan_events/en/print.html

[Yang et al., 2009] Yang, Ruijia, Huang, Wei, Zhang, Lishi, Thomas, Miles, and Pei, Xiaofang, Milk Adulteration with Melamine in China: Crisis and Response, *Quality Assurance and Safety of Crops & Foods* 1(2), 111-116.