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Melamine food recalls: Effects of melamine on animal/human health, food safety and economic trade

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Abstract

Revelations of significant safety threats posed by melamine contaminated imported foods have dramatically heightened public concern and triggered food control measures. Melamine is a synthetic chemical used in a variety of industrial applications. It is high in nitrogen and has been added to animal feeds to disguise the protein content, lower costs and increase manufacturers' profits. It is not naturally occurring and is not allowed to be added to food. Though melamine is considered metabolically inactive and low in toxicity, excessive exposure to the substance has been found to cause urinary tract stones, and crystals in the urine. The current level set by the US Food and Drug Administration in food is 2.5 ppm ingested by a person weighing 60kg. Given that little is known about the long-term ill-effects of consuming melamine, and the associated risks of this imported food products to the Caribbean and the developing world, it is important to examine the probable health and economic risks associated with melamine tainted food products. Since the Chinese scandal, a number of countries have adopted food control measures to prevent the product from entering the food chain. This paper focuses on melamine as a chemical hazard, cases of melamine food poisoning, effects of melamine on animal and human health, food safety and quality control measures, institutional structure and capacity to test and control melamine entry into the food chain, impact on International and Regional Trade and recommendations for better food control and protection of consumers from unsafe foods.

Key words: melamine, health effects, food control, food recall, economic, tolerable daily limits

Introduction

Globalization is generally characterized by increased international trade, more integrated markets, more rapid adoption of new technologies, increased market concentration and information transfer. It also means that food safety incidents are widely reported internationally. One result is that food safety incidents can negatively impact products where no food safety issue exists as consumers lose trust in both foreign and domestic food safety institutions.

Food terrorism has been defined by the World Health Organization (WHO) as an act of threat of deliberate contamination of food for human consumption with chemical, biological or radio-nuclear agents for the purpose of causing injury or death to civilian populations and/or disrupting social, economic or political stability (WHO, 2003). There would always be unscrupulous people who would think of making profits through adulteration of foods than caring for the health of the consumers of those foods

The most recent, and still evolving, example is the epidemic of melamine poisoning stemming from tainted infant formula in China. More than 294,000 children in China have reportedly been affected by adulterated formula (Ingelfinger, 2008). This adulteration had caused great impact on public health and the milk industry in China.

This paper focuses on the chemical hazard melamine, reports on food scares, cases of melamine food poisoning, effects of melamine on animal and human health, testing and control of melamine entry into the food chain, impact on International and Regional Trade and recommendations for better food control and protection of consumers from unsafe foods.

History of Food scares

The term 'food scare' describes contemporary anxiety about the consumption of food. There is no doubt that recent food scares have become global media events. The term first appears in print media in the mid-1980s following an episode of malicious lacing of Tylenol tablets with cyanide in the US (Campbell and Fitzgerald 2001). Since then its use has become widespread in spite of no greater incidence of food-related crises (Wansink, 2004).

Several cases of food sabotage have occurred in the United States. In 1984, a cult contaminated salad bars with salmonella to disrupt a local election. The case caused 751 illnesses, including 45 hospitalizations. The British 'curried eggs' fiasco of 1988 involving allegations of salmonella contamination of British eggs, for example, resulted in a lingering downturn in their consumption (North and Gorman 1990). In 2003, a Michigan supermarket worker contaminated 200 pounds of hamburger with a nicotine-based pesticide making 92 people sick (Begley, 2007).

What is melamine?

Melamine ($C_3H_6N_6$) is an organic compound that is often combined with formaldehyde to produce melamine resin, a synthetic polymer which is fire resistant and heat tolerant. It is a synthetic chemical with a variety of industrial uses including the production of resins and foams, food containers, fabrics, glues, cleaning products, fertilizers and pesticides. It does not occur naturally in food (CDC, 2008). Melamine is a triazine compound and is an essential component of materials such as flame retardants, glues, and plastics.

Aside from common commercial uses, melamine became a topic of much discussion in early 2007, when veterinary scientists determined it to be the cause of hundreds of pet deaths, because of pet food contamination. Prior to these reports, melamine had been regarded as non-toxic or minimally toxic (Green Home, 2008). The chemical has a high nitrogen content that makes it possible for unscrupulous food manufacturers to boost the protein content of food products, which can deceive certain quality-control checks that are standard in the food industry (Ghosh, 2008). The unexplained presence of melamine in wheat gluten added to mass-produced dog and cat foods was the most likely cause. Pet owners reported symptoms that are

commonly associated with renal failure, which could be explained by the ammonia that may result from the digestion of the melamine (Food Insight, 2007).

Contaminated Foods and Food Recalls

The crisis over melamine may have been one of the most serious scare to the food industry (Food Insight, 2007). The 2007 melamine adulteration of pet food resulted in many deaths of cats and dogs in the United States and elsewhere (Turnipseed *et al*. 2008). The pet food was manufactured with melamine-adulterated wheat gluten and rice concentrate obtained from China. The discovery of melamine in infant formula manufactured and sold in China has revitalized concerns about the possible presence of the chemical in other products, particularly processed foods such as cookies and candy that contain milk ingredients (WHO, 2008; Dutch Food Authority, 2008). On April 20th, 2009 FDA inspectors in the USA announced that traces of melamine, a toxic industrial chemical used to make plastics, fire retardant, and fertilizers, had been found in Diamond Pet Foods feed given to pigs at California's American Hog Co.

Food recalls in each category are divided on the basis of the degree of harm and social impact or could be classified as proactive or compulsory (Liu et al., 2008). First-level recalls apply to unsafe food that has induced or may result in serious harm, or where the product has been widely distributed or has a great social influence. For the latter, read the potential to cause considerable collateral damage to a range of Chinese products. Second-level recalls are used in the case of unsafe foods that cause moderate harm, or that have a limited distribution or moderate negative social influence. Third-level recalls are applied to unsafe food that can cause a small degree of harm or whose labels do not provide sufficient information on the ingredients contained.

Further, food recalls are classified into proactive or compulsory under different situations (Liu et al. 2008). For proactive recalls, once the food is confirmed as unsafe, the manufacturer must immediately ceased to produce or sell its product, and must recall it in the following specified manner: (1) after the food is confirmed as being unsafe, distributors must be told to stop selling the food within one day. Consumers must also be notified within one day for first-level recalls, two days for second-level recalls, and three days for third-level recalls; (2) after the food is confirmed as being unsafe, the manufacturer must submit a food recall plan to the supervisory authorities within three days for first-level recalls, five days for second-level recalls, and seven days for third-level recalls; and (3) after the recall is implemented, the manufacturer must submit progress reports on the recall to the supervisory authorities within three days for first-level recalls, seven days for second-level recalls, and fifteen days for third-level recalls.

Deliberate Act

Melamine is not approved for direct addition to human and animal foods and no manufacturer is allowed to deliberately add it to any food for U.S. consumers (Mermelstein, 2009). Many food products were adulterated with melamine to increase their apparent protein content (Mermelstein, 2009) and at less cost (Yang et al. 2009). But why would one intentionally add a non-nutritious substance such as melamine to food? Nitrogen content has long been used as a surrogate for assessing the protein content of foods, and melamine contains a substantial amount of nitrogen — 66% by mass. Melamine had been illegally added to food products in order to increase the

apparent protein content as standards tests for estimation of protein level depends on measuring total nitrogen content (Yang et al., 2009). Before the current melamine disaster, the marked dilution of infant formula in China had resulted in marasmus in some infants (Ingelfinger, 2008) which led to government directives to increase the protein content of such preparations or risk severe penalties. Thus, it is possible that the adulteration was conceived in response to a well-intentioned government directive. The fact that melamine could increase the apparent protein content and, furthermore, make the product look milky may have been irresistible to those who would adulterate. In the mainland of China, makers of baby formula, for example, watered down the product, then added melamine to the milk, which was a cheap fool test which allowed the milk to appear rich in protein (Lam et al. 2008; Mc Williams, 2008) in order to pass the food quality nutrition test (AsiaNews.it,2008; Yuan and Batle, 2008).

Health Effects

More than 6200 babies have become ill in China as a result of drinking infant formula made from milk contaminated with the industrial chemical melamine (Parry, 2008).

Melamine, when associated with cyanuric acid can cause renal failure (WHO, 2008b; Parry, 2008). While there are very few data on the nephrotoxic effects of melamine in humans, studies on animals have shown that melamine, particularly in combination with cyanuric acid, causes deposition and precipitation of birefringent crystals thereby causing renal failure (Yang and Batlle, 2008). The main adverse effects shown in studies on animals were kidney related, including renal calculi, renal tubular necrosis, melamine crystalluria, and haematuria (Cianciolo et al., 2008; WHO, 2008b). The kidneys are designed to filter toxins from the body and causes crystals of melamine cyanurate to be formed. These are highly insoluble and end up blocking the tubules, which can eventually lead to kidney stones. Unable to purge itself, the body gradually accumulates toxins and death may result (AntiguaSun, 2008; Ho, 2008).

The following symptoms were observed in infants affected by the melamine-contaminated infant formula in the current outbreak in China (WHO, 2008c) 29th September, 2008. Unexplained fever arising from urinary tract infections, bacteraemia secondary to urine stasis resulting from urinary tract obstruction; Unexplained crying in infants, especially when urinating; possible vomiting; Macroscopic or microscopic haematuria; acute obstructive renal failure: oliguria or anuria; dysuria (pain on urinating) and passage of stones while urinating (for example, a baby boy with urethral obstruction with stones normally has dysuria); high blood pressure, oedema, pain over the kidneys.

In a study to investigate the renal outcomes of children after exposure to low dose melamine in Hong Kong indicated no severe adverse renal outcomes, such as acute renal failure or urinary tract obstruction, were detected in children after exposure to low dose melamine (Lam et al., 2008). Exposures to high doses of melamine over long periods have been associated with cancer of the bladder (CDC, 2008).

Risk and Tolerable Daily Intake (TDI)

Risk is an important determinant of food choice and correspondingly, estimates of risk are strongly related to estimates of consumption (Raats and Sparks, 1995). It has become particularly salient in the wake of a decade of 'food scares'.

Regulatory decisions concerning the continued or prospective use of chemicals that may enter the food supply are

influenced by the results of risk assessments (Winter, 2003). A safety/risk assessment is a scientifically based methodology used to estimate the risk to human health from exposure to specified compounds. It is based on available data and certain scientific assumptions in the absence of data (FDA, 2008). The three components of risk analysis are risk assessment, risk management, and risk communication. Food chemical exposure = food consumption x residue level (Winter, 2003).

A food safety standard is a description of a specified amount of product relating. In determination of 'safety' standards based on science, one would need to know the dose-response relationships on the highest amount of hazardous agent (Coleman and Marks, 2003). International experts have established a tolerable daily intake (TDI) for melamine. The TDI is an estimate of the maximum amount of an agent to which an individual could be exposed on a daily basis over the course of a lifetime without an appreciable health risk (FDA, 2008). The WHO indicated that the new TDI is meant to help national authorities set safe limits in food for withdrawal purposes should melamine be detected as a result of intentional adulteration

The World Health Organization indicated that tiny traces of the chemical melamine are not harmful in most foods, but it joined the U.S. and EU in setting a strict limit that regulators should impose before pulling products off the shelf (Jordans, 2008).

This TDI for melamine has been set at 0.2 mg/kg body weight (bw) and for cyanuric acid as 1.5 mg/kg body weight is the outcome of a meeting organized by the World Health Organisation (WHO) in Ottawa, Canada (CFIA, 2008). The executive summary stated that the TDI is 'applicable to the whole population, including infants'. However, exposure to both melamine and cyanuric acid may confer a higher risk, and there are unknowns about long-term renal and other risks. The current limit set by the FDA for melamine in food is 2.5 parts per million (ppm) calculated on the basis of ingestion by a person weighing 60 kg. This conclusion assumes a worst case exposure scenario in which 50% of the diet is contaminated at this level, and applies a 10-fold safety factor to the Tolerable Daily Intake (TDI). To account for any uncertainties, the US Food and Drug Administration (FDA) indicated the 2.5 parts-per-million standard was intended to address situations where the chemical accidentally comes into contact with food, such as where it is used for industrial purposes in a factory that makes food products (Ghosh, 2008). US Federal guidelines allow for only 1 ppm in infant formula (Schellhaass, 2009).The European Commission has decided that all products originating from China and containing more than 15% of milk as an ingredient must be checked for the presence of melamine. In order to protect the European citizen, products containing more than 2.5 mg/kg are to be immediately destroyed (Ghosh, 2008).

In the analysis of melamine, the US FDA is applying liquid chromatography triple quadrupole tandem mass spectrometry (LC-MS/MS), gas chromatography/mass spectrometry (GC/MS) and other approaches such as amino acid analysis, protein tagging and a novel method of Surface-Enhanced Raman spectroscopy (SERS) coupled with various nanosubstrates (Ghosh, 2008; Mermelstein, 2009). SERS is a sensitive technique based on the phenomenon that Raman scattering signals of probed molecules on nanostructures can be enhanced by more than a million times as a result of electromagnetic field and chemical enhancement. SERS is able to rapidly detect 2 ppm of melamine in milk using zinc

oxide nanosubstrates. The major advantage of SERS is that melamine contamination can be detected on-site and in real-time (less than 15 min/sample) (Mermelstein, 2009). Infrared lasers and light spectroscopy methods were able to detect trace amounts of melamine in baby formula at 1 ppm in about 5 minutes (Schellhaass, 2009).

Trade Policy Responses

According to the provisions of the Agreement on Sanitary and Phytosanitary Measures (SPS) of the World Trade Organization, importing regulations should be 'science based' and incorporate a risk assessment (Kerr, 2003). Each country is allowed to specify its own acceptable level of risk but that level of risk cannot discriminate among trading partners and should be consistent across products (Kerr and Hobbs, 2005).

The importing country should remove the 'unsafe' product from its domestic market and all imports of that product should be embargoed until the government in the exporting country makes the changes necessary to satisfy the importing government that future shipments meet or exceed an acceptable threshold of product safety.

International food standards are adopted by the Codex Alimentarius Commission, an international organization jointly run by the Food and Agriculture Organization and the World Health Organization. In general, Trinidad and Tobago follows internationally accepted food standards and guidelines (i.e. those developed by the Codex Alimentarius Commission and the International Organization for Standardization), and may refer to U.S., Canadian, and Europeanstandards as well. The output of Codex includes standards, guidelines, and codes of practice. SPS regulations are a concern at the WTO because of their potential to serve as non-tariff barriers to trade, that is, barriers that do not take the form of a tariff or tax on imported goods.

Food Control

FAO/WHO (2003) defines the food chain approach as recognition that the responsibility for the supply of food that is safe, healthy and nutritious is shared along the entire food chain - by all involved with the production, processing, trade and consumption of food. Generally, the orientation of many food safety systems tends to be reactive and defined by enforcement criteria instead of preventive and holistic in the approach to risk assessment and reduction (Food Chain, 2001). Effective national food control systems are essential to protect the health and safety of domestic consumers. There is a strong interest in promoting national food control systems that are based upon scientific principles and guidelines, and which address all sectors of the food chain. In many countries, effective food control is undermined by the existence of fragmented legislation, multiple jurisdictions, and weaknesses in surveillance, monitoring and enforcement.

The foremost responsibility of food control is to enforce the food law (s) protecting the consumer against unsafe, impure and fraudulently presented food by prohibiting the sale of food not of the nature, substance or quality demanded by the purchaser.

Increasing consumer concerns and the consequential costs imposed on society as a result of food safety incidents have led to an increased public focus on the causes, effects, and prevention of both microbiological and non-microbiological hazards (Fearne et al., 2001).

In two surveys of how Americans feel about globalization of food Since 9/11,

Americans harbour serious concerns that the food supply could become a target of terrorists (Mey, 2004)

Finally,85% of the respondents participating in the nationwide survey after the terrorist attacks indicated they agree that hits on the American food supply might be one way that terrorists could attack Americans.

Chinese exports to the United States have surged. China's agricultural exports to the United States reached $2.26 billion in 2006, up from $453 million in 1993, according to the United States Department of Agriculture. In the past five years (2002-2007) total food imports to the United States have risen by about 50% while the number of FDA food import inspectors has fallen by roughly 20 % (Deseret News, 2007).

Trinidad and Tobago Food Safety Agency

The Ministry of Health/Chemistry Food and Drugs Division and the Ministry of Food Production & Marine Resources: Plant Quarantine Service are responsible for ensuring the safety and quality of foods exported to Trinidad and Tobago (USDA Gain Report, 2005). The Trinidad and Tobago Food and Agricultural Import Regulations requires a Health Certificate/Sanitary Certificate for food safety, food quality and food processing (USDA Foreign Agricultural Service, 2005). A Certificate of Analysis is required by the Ministry of Health requires this certificate for the purposes of food safety, food quality, heavy metals, and inorganic/organic standards.

The Food and Drug Act of 1960, the Pesticide & Toxic Chemical Act of 1979, the Animal Disease Importation Act of 1954, and the Plant Protection Act of 1975, are the laws that govern the importation of food and agricultural products into Trinidad and Tobago. However, these food laws are outdated. In general, Trinidad and Tobago follows internationally accepted food standards and guidelines (i.e. those developed by the Codex Alimentarius Commission and the International Organization for Standardization), and may refer to U.S., Canadian, and European standards as well.

Like most countries, the Government of Trinidad and Tobago is concerned about food Safety, food Security and achieving HACCP standards, especially in this global economy where small developing economies could aim at being competitive by adding value to raw material and seeking niche markets globally. The main issues faced as outlined by Davis (2002) however are:

- Little or no coordination between agencies responsible;
- Very little capabilities for HACCP and trace back ;
- Lack of accredited diagnostic capabilities, particularly in residue analysis;
- Double standards - local vs. export products;
- Private sector is not always aware of the importance of food safety issues;
- Few cost recovery programmes.

The Government of the Republic of Trinidad and Tobago has embraced the highly regarded ‘Jagdeo Initiative’ endorsing the creation of the Caribbean Agricultural Health and Food Safety Authority (CAHFSA). From a national point of view, the establishment of the National Agricultural Health and Food Safety Agency (NAHFSA) of Trinidad and Tobago - with which it will partner is in harmony with the mission and Vision 2020 approach of the Ministry and work towards revitalizing, modernising and transforming our nation’s

agricultural sector. This multi-faceted, regulatory body NAHFSA is being formed to monitor what is going on internationally in agricultural health and food safety and co-ordinate a national approach, so that Trinidad and Tobago can ensure compliance with the latest standards and technologies (Piggott, 2008).

Economic impact

Collateral damage arises as a result of a product safety incident or a series of product safety incidents that occur in other products from a particular country but where consumers experience a general loss of trust in products sourced from that country. In other words, the exporting country's label is damaged or the equity of the national brand is diminished (Innes et al., 2007).

In addition to its catastrophic health effects, the contamination has had major economic effects, with the United States and other countries banning the importation of milk and other food products from China. The U.S. Food and Drug Administration (FDA) has opened an office in Beijing (and will open others in Shanghai and Guangzhou and in other countries) that will examine food exports destined for the United States (Ingelfinger, 2008).

On September 19, 2008, the day after the contamination on liquid milk, the sale volume of milk fell to the lowest and 8311.7 ton of unqualified milk products were withdrawn from the market (Yang et al., 2009). By November 6, 2008, about 130 Chinese milk producers were closed, representing about 20% of dairy producers.

Since the March 16, 2006 announcement by Canada's Menu Foods it that it has various kinds of pet foods that used Chinese produced gluten, a protein extracted from grains such as wheat, corn, and rice and used as a binding element (Grigg, 2007). Within a few weeks, some 60 million cans of pet food, marketed under 95 brand names, had been recalled across North America. 'One pound of tainted wheat gluten could, if undetected, contaminate as much as a thousand pounds of food'. Americans consume an estimated 400 million pounds of wheat gluten annually, and according to a U.S. Customs survey, more than 13% of imported wheat gluten comes from China. In other words, the same poison that crippled thousands of pets could eventually find its way into bagels, pizza, pasta, and pancakes (Grigg, 2007).

Consumer reactions

When faced with a food crisis, a consumer can respond along a continuum of passive and aggressive responses. Passive response involves simply modifying one's behavior to avoid the danger. Consumers can also take a more aggressive response, which might be to demand restitution or to try and change the market structure by campaigning for new laws, guidelines, or regulatory systems (Wansink 2004). Behavior related to food crises are based on risk perceptions and on risk attitudes related to the crisis (Wildavsky and Dake 1990).

A basic, but misguided view of how consumers respond to food is often characterized in Fig. 1 as a linear process - There's a crisis, there are crisis-related communications (from an company, industry, or government), consumers hear these messages, and they respond (Wansink, 2004). In reality, consumer response is more sophisticated. Different segments respond differently, and pre-crisis considerations (such as consumer's previous knowledge and pre-crisis communication) need to be accounted for. Therefore, a more complete and useful framework of how they respond to food

crises is presented on Fig. 2 (Wansink, 2004).

The Ministry of Consumer Affairs in Trinidad & Tobago posted a full page advertisement (ad) in the Sunday Guardian newspaper warning consumers about foodstuffs from China and Japan which may be hazardous to their health. The ad mentioned ham and sausages manufactured by Itoham Foods, were under suspicion of cyanide contamination (AntiguaSun, 2008). Food safety is something often taken for granted - until something goes wrong.

In a 2004 study conducted in Trinidad which examined public awareness and perception to bio/food terrorism, 81.0% has heard of at least one term either 'bioterrorism' or 'food-terrorism' or 'agro-terrorism' and most (87.9%) felt that Trinidad and Tobago had no counterterrorism programmes (Badrie et al., 2005). In another study which explored consumer trusts in food in Australia, especially people's experiences that support or diminish trust in the food supply found that media coverage of food scares and scandals and personal experience of food-borne illness challenged respondents' trust in the food system and questionable marketing ploys by food manufacturers also decreased trust challenged respondents' trust in the food system (Coveney, 2008). It also emphasized the importance of a visible authoritative presence in the food system to strengthen trust and provide reassurance to consumers.

Trust in risk information about food related-hazards is an important determinant of public reactions to risk information. One of the central questions addressed by the risk communication literature is why some individuals and organizations are trusted as sources of risk information and others are not (Wansink, 2004). Factors such as hazard type and source credibility have been identified as important in the establishment of effective strategies for risk communication. (Frewer, et al. 1997). Risk perception may be influenced by a number of factors, such as unfamiliarity, lack of control, perceived consequences, and hazards being seen as catastrophic and having risk for future generations (Raats and Shepherd, 1995). When consumers perceive food risks to be well managed, this is often associated with established systems of control of which people are aware, such as the mechanisms for controlling a food poisoning outbreak,' reads the report (Koo and Mattson, 2003).

Conclusion and Recommendations

Until recently eating food was viewed as a low-risk activity and perceived risk surrounded matters of hygiene or lack of food. Recently, however, the safety of food supplies has been increasingly called in to question.

In the US, the Food and Drug Administration (FDA) provided more money for inspectors and passed the Bioterrorism Act of 2002 to stop or catch attacks on the food supply. But the 600 additional inspectors for imported food are gone, putting us back down to 2001 numbers, and the 2002 law failed its first real test when it took weeks to identify melamine as the pet-food culprit (Begley, 2007).

Some recommendations

A comprehensive, 'farm-to-fork approach' to food safety can help combat threats such as bio-terrorism and food scares. The improvement of food safety among producers and consumers;

The need for an effective food control system. Food producers need to implement systems to identify and secure points of vulnerability, such as storage tanks or

transport;

Managing the potential problems associated with any food safety issue involve the following five pre-crisis preparations: 1) promote a hierarchical understanding of food production, 2) Integrate distinct communication channels, 3) Accommodate consumer needs and concerns with packaging and labeling, 4) Position products as comparable alternatives, and 5) correctly address public concerns;

The need to strengthen coordination of multi-agency food safety system. Risks and recalls can be reduced by engaging a single source partner e.g. Centers of Disease Control, US (CDC), proposed Caribbean Agricultural Health and Food Safety Agency (CAHFSA) and proposed National Agricultural Health Food Safety Agency (NAHFSA of Trinidad and Tobago) who can help ensure higher standards of food safety and quality.

Consumers acquire food safety-related information from various sources such as government publications, consumer organizations, research institutes, and the media. Key to maintaining trust in the safety of food is a quick and transparent response. An integrative and coordinated communication effort by the multiple information sources is essential in increasing consumer acceptance.

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The Crisis **?** Crisis-related **?** Communication **?** Consumers Response

Figure 1: Stimulus Response Model of Crisis Communications (Wansink, 2004)

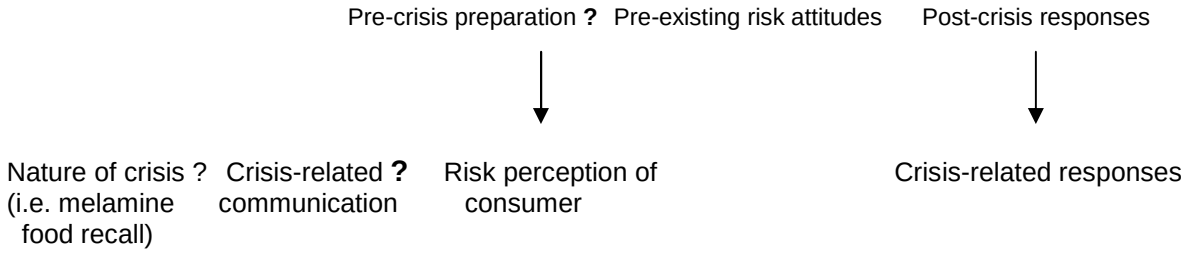

Figure 2: Consumer responses to food safety crises(Modified from Wansink, 2004)