Risk Analysis

Case Example on Contaminants in Food
Melamine

Seminar on Food Safety Risk Analysis in ASEAN

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Melamine Crisis

- March 2007: Reports from China indicated the adulteration of pet food in China with Melamine with possible implication on feed.

- Gluten protein in pet foods sourced from China were adulterated – over 1000 products recalled by Canadian pet food manufacturer “Menu Foods”.

- It was the tip of the Iceberg

- In September 2008: Reports from China indicated findings of levels of Melamine from 20 to 900 ppm (mg/kg) in milk powder (included in infant formula)

Role of the Regulator

- Oversight on Managing the Interaction between Food Producers and Consumers

- Delegated Authority from Consumers as to Protect them (from Health Concerns and Fraud)

- Empowered to Make Decisions on behalf of the Public (Consumers)

- Is the Centre of Attention in Case of Deficiencies in Food Safety
  - e.g., Food Safety Incidents

Outline

- Review of a Food Fraud Crisis with International Dimensions:
  - Melamine Incident (deliberate contamination of foods)
    - Applying the Risk Analysis Principles for Decision Making

- Illustration of Decision-Making following a structured and Collaborative Approach

- Importance of Concerted Action at the Domestic and International Level
What is Melamine

- Melamine is 1,3,5-triazine-2,4,6-triamine, a synthetic chemical used in industrial applications incl. resins and foams, cleaning products, fertilizers and pesticides.
- 67% nitrogen by weight
- Protein content of food measured through Readings of nitrogen content (derivative of Kjeldhal method that dates back to 1883)
- Low ppm range of melamine would increase the apparent protein content by a few %
- Milk contains about 3.0–3.4% protein content
- Addition of Melamine increases substantially “false readings” of protein: FOOD FRAUD

The Incident: A Food Fraud Case that turns bad...

- Companies and a number of milk-collection depots were diluting milk with water
  - Melamine was added to cheat protein assays
- Melamine can, at high levels, lead to Kidney stones and renal lesions
- 54,000 cases at first – raised to 300,000 illnesses at the end of the incident (mostly children)
- 6 deaths (Babies) due to adulteration of infant formula
- Major Loss of confidence in safety of infant formula and other food products

Initial Risk Management Activities Domestically and Internationally
Challenge: Importance of Relying on Robust Information

- Melamine can contaminate any product where milk powder is an ingredient
  - Extent of contamination: Broad and unlimited
- Crucial need: Reliance on a network of trusted regulators to gather facts/information
- Initial information came from the New Zealand Food Safety Authority (NZ FSA) – Needed far more information

Activated a Network of Information Exchange

- International Food Chemical Safety Liaison Group: IFCSLG
  - Most reliable source of information
  - Rapid, Responsive and Reliable

INFOSAN: International Food Safety Authorities Network

Raison d’Être

- Continued trend of Globalization of food/feed supply chains
  - Incidents tend to be international
- Dealing with food safety events requires rapid access and exchange of food safety information at national and international levels
- Clear, reliable and authoritative information about food safety has been recognized as an essential need for prevention and response measures
  - Confidence in the Food Supply

INFOSAN: Goals and Mandate

GOAL

- Prevent international spread of contaminated food and foodborne disease and strengthen food safety systems globally

ROLE

- Promote rapid exchange of information during food safety related events
- Share information on important food safety related issues of global interest
- Promote partnership and collaboration between countries on food safety
- Support to strengthening countries’ capacity to manage food safety risks

In 2004: Codex Alimentarius Commission revised principles and guidelines on exchange of information in food safety emergency situations

- Guidelines requested that member states designate official contact points from their food competent authorities to exchange information during food safety emergency situations
- WHO: responsible for keeping list of official contacts up to date
- Birth of INFOSAN: International Food Safety Authorities Network
Continued Efforts of Data Collection:

- Methods of analysis for Melamine in food were not prevalent/available
- Data on occurrence of Melamine in food was not available:
  - Baseline information
  - Occurrence as a result of the adulteration incident

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Move to Scientific Assessment

Pre-requisites to reach robust risk Analysis Decisions

- LC-ESI-MS/MS
- HILIC silica column
- ACN + (NH₄HCOO+HCOOH)
- 3 transitions monitored for MEL:
  - 127→85
  - 127→68
  - 127→43

Need for a Common Foundation of Risk Assessment

- Canada supported an expert consultation under the auspices of FAO/WHO to lead to a global risk assessment
- Common Risk Assessment used the latest information available internationally
- Allowed to leverage resources

<table>
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<th>Country</th>
<th>Key Study</th>
<th>NOAEL (mg/kg bw)</th>
<th>SF</th>
<th>UF</th>
<th>TRD (mg/kg bw)</th>
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Early Days of the Crisis: Multiple Attempts for Risk Assessments

- Inefficient use of resources

Multiple outcomes

Divergent Risk management measures

Inefficient use of resources

Toxicological and Health Aspects of Melamine and Cyanamic Acid

Report of a WHO/Expert Meeting in collaboration with FAO
Supervised by Health Canada
Health Canada, Ottawa, Canada
1-4 December 2008

Consumers, industry and other interested parties
Summarizing the Outputs of the Risk Assessment

- Dose Response Assessment of Subchronic Rat Studies modeling Incidence of Bladder Stones and Application of a 200 safety factor led to TDI 0.2mg/kgbw/day for Melamine
- Previously established TDI for analogue Cyanuric Acid: 1.5 mg/kgbw/day
- Available data indicates simultaneous exposure to Melamine and analogues more toxic than to Melamine alone
- Data Gaps/uncertainties: Inability to establish health based guidance for co-exposure

Dose Response Assessment of Subchronic Rat Studies modeling Incidence of Bladder Stones and Application of a 200 safety factor led to TDI 0.2mg/kgbw/day for Melamine

Dietary Exposure Resulting from Deliberately Contaminated Infant Formula was 40 to 120 times the TDI – Catastrophic effects

Dietary Exposure Resulting from Foods Containing Deliberately Contaminated Milk ranged from was 0.8 to 3.5 times the TDI

Estimates of Exposure to Baseline Levels: 13 Micrograms/kgbw/day

Well below the TDI

Early /Proposed Limits Introduced by Countries for Risk Management (1 ppm for Infant Formula and 2.5 ppm for other foods) allowed adequate protection

Need to Stand Behind the Common Assessment

- Several countries / authorities:
  - adopted the proposed Toxicological Reference Values
  - Amended their Measures, based on the outputs of FAO/WHO Risk Assessment
  - Called for Common Risk Management Values

Considering the Outputs of the Assessment
Coordination of Risk Management Action

International Food Chemical Safety Liaison Group: IFCSLG

- Avoid unjustified measures by regulators
- Support a Concerted Approach

Call for Codex Guidance

- Dairy products and milk powder are part of several processed foods.
- Guidance was needed to mitigate possible multiplication of Tolerances for Melamine
- Maximum Levels were developed to help discriminate products where Melamine is present as a result of "background / environmental" occurrence and instances of deliberate addition: adulteration.
- Melamine standards were amongst the fastest moving Codex standards to date.
  - 2.5 PPM standard developed and adopted in one year

Adopted Codex Standards for Melamine: Basis for Domestic Standards

- Codex standards adopted in 2010 and 2012/13:
  - 2.5 PPM for all foods except infant formula
  - 0.5 PPM for Powdered infant formula
  - 0.15 PPM for Liquid Infant formula

Levels reflect background levels that may be due to possible use of tri-chloromelamine in disinfectant agents and Cyromazine: authorized pesticide derived from melamine.

Ensure Continued Engagement and Collaboration
Strength Comes from Collaboration

- Swift Response
- Coordinated at Domestic and International Levels

Risk Analysis ... Offers the Structure For

ROBUST FOOD DECISIONS

Risk Assessment
Scientific Advice & Information Analysis

Risk Management
Regulation & Control

Risk Communication
Dialogue with All Stakeholders

Annexes – Additional Information on INFOSAN
Towards the Formation of INFOSAN

1. In 2000: World Health Assembly adopted a resolution calling for improved communication between the WHO and member states on food safety matters
2. In 2002: Several conferences on food safety organized by the FAO and the WHO recommended the creation of an international food safety network
3. In 2003: WHO report on potential terrorist threat to food recommended the establishment of prevention and response systems
   - Identified food safety emergency network as one of the basic measures of preparedness internationally
4. In 2004: Codex Alimentarius Commission revised principles and guidelines on exchange of information in food safety emergency situations
   - Guidelines requested that member states designate official contact points from their food competent authorities to exchange information during food safety emergency situations
   - WHO: responsible for keeping list of official contacts up to date
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Management of INFOSAN

- In 2010, INFOSAN became a WHO / FAO joint programme (co-managed by the FAO and WHO)
- INFOSAN secretariat
  - Coordination of INFOSAN emergency activities conducted mainly by the WHO in close communication with the FAO
  - Advocacy, fundraising, strategic planning
  - Routine management of the network, production and dissemination of relevant information
- INFOSAN Advisory Group
  - Established in 2006: group of experts from national food safety authorities across the globe (with adequate geographical and food safety expertise coverage)
  - Advises secretariat on operations of network, engagement of members, strategic plan / workplan and advocacy groups

INFOSAN Actions

Routinely
- Develops information notes by the secretariat on emergent or important food safety issues
- Shares food safety guidelines, questionnaires, newsletters and fact sheets
- Supports strengthening of food control systems through aid to in-country information sharing

In Emergency Situations
- Identifies, verifies and shares information on food safety events and foodborne illness outbreaks that go beyond one country’s boundaries
- Provides technical assistance to national governments in managing food safety events or emergencies (through secretariat)
- Engages emergency contact points to provide updated information on food safety events to support timely exchange of information with countries potentially importing or exporting the implicated food
- Operates a secure web platform for confidential information sharing

INFOSAN: Structure

- Voluntary membership
- Focal Points from countries: point of contact for information sharing / dissemination
  - Provide input in developed material
  - Engage in sharing relevant information at times of “food safety peace”
  - May not reflect / be from the national agency in charge of managing food safety emergencies
- Emergency Contact Points:
  - Should come from the national authority responsible for food safety emergency coordination
  - Report urgent food safety events of potential international significance to INFOSAN secretariat
  - Collaborate with IHR national focal point on food safety events falling under the IHR
  - Request international assistance through INFOSAN secretariat to respond to a food safety incident or emergency
INFOSAN: Final Notes

- An information exchange network is as effective as:
  - the engagement commitment of its members
  - the accuracy and timeliness of information provided

- Some informal structures can be excellent avenues to promote information sharing and collaboration between responsible authorities at times of emergencies, e.g. International Food Chemical Safety Liaison Group

- To ensure effectiveness of coordination and collaboration in emergencies, structures and collaborations should be established and working well at times of “food safety peace”