Risk assessment and risk management in action: case study - Benzo[a]pyrene in Cooking Oil

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Risk Analysis Framework

Four components:
- Hazard identification
- Hazard characterisation
- Exposure assessment
- Risk characterisation

Risk Analysis

Risk Assessment
* Science based

Risk Management
* Policy based

Risk Communication
* Interactive exchange of information and opinions concerning risks
Food incident identification

In mid-December 2012, there was a report in the newspaper alleging that

- a suspected unlicensed food processing establishment had been supplying cooking oil of substandard quality to 13 restaurants

- the content of Benzo[a]pyrene (B[a]P), a human carcinogen, in the cooking oil concerned exceeded the limit set by the European Union (EU) (2 μg/kg)
Food incident identification

- What is the major problem?
  - The existing Hong Kong legislation does not stipulate a statutory limit on BaP in food. How to establish a reasonable action level?
  - What is the extent of this problem?
  - How to determine the types, frequency and number of food samples to be taken for testing (surveillance programme)?
Risk Assessment - Hazard identification

- Benzo[a]pyrene (B[a]P)
  - is a type of polycyclic aromatic hydrocarbons (PAHs)
    - PAHs is ubiquitous in the environment
    - PAHs may be found in trace amounts in various types of food, including cereals
    - Level of PAHs in uncooked food may range from 0.01 to 0.1 microgram/kg
Risk Assessment - Hazard identification

- Source of B[a]P
  - The two major sources of B[a]P in food
    - deposition and uptake of B[a]P from polluted air on food crops and
    - formation and deposition of B[a]P during heat processing using methods such as roasting, smoking, and grilling
Risk Assessment - Hazard identification

- Occurrence of B[a]P in oil
  - Drying of cereals and plants used for production of crude vegetable oils
    - using direct application of combustion gases,
      - combustion products may come into contact with the grain and oil seeds
  - The level of B[a]P in oil may increase after repeated use
**Risk Assessment - Hazard identification**

- **Occurrence of B[a]P in oil**
  - The level of B[a]P in oil much reduced after oil refining processes e.g. deodorisation step
  - The ultimate level of B[a]P would depend on the conditions under which refining takes place and quality control
B[a]P in oil and Gutter Oil

- there is no definition of “gutter oil” internationally
- generally, it refers to discarded oil recovered from gutters and ditches

Presence of B[a]P in oil does not mean that the oil is gutter oil as B[a]P may be present in oil as mentioned above

- the quality of cooking oil could be monitored by conducting chemical tests to ascertain the amount of harmful substances contained
Risk Assessment – Hazard characterisation

- BaP is toxic to genes and may cause cancer in humans

- The International Agency for Research on Cancer (IARC) (2009)
  - B[a]P is classified as “carcinogenic to human” (i.e. Group 1 agent)

A safety reference value cannot be determined
Risk Assessment – Hazard characterisation

- For contaminants that are both genotoxic and carcinogenic
  - JECFA recommended the use of the benchmark dose approach for hazard characterisation
  - In 2005, the JECFA established a benchmark dose lower confidence limit (BMDL$_{10}$) equivalent to 100 μg of B[a]P/kg body weight/day for PAHs in food
Risk Assessment – Exposure assessment


  - The major contributors to dietary exposure of PAHs
    - cereals and cereal products (owing to high consumption in the diets) and
    - vegetable fats and oils (owing to higher concentrations of PAHs in this food group)
Risk Assessment – Exposure assessment

- Margin of exposure (MOE) approach

- MOE = BMDL_{10}/ estimated exposure

- MOE is used to assess the degree of health concern. The smaller the MOE, the higher the health concern, and vice versa

- JECFA considered that an MOE value of lower than 10,000 indicated public health concern
Risk Assessment – Exposure assessment

○ Consumption data:
  ● Hong Kong Edible Oils Association (HKEOA)
    ○ estimated the oil consumption/capita using the edible vegetable oil usage data and the Hong Kong population in 2007
    ○ the estimated oil consumption amount was 11.22 kg per annum (30.74 g/day)
Risk Assessment – Exposure assessment

- Assumption:
  - an average adult consumed 30.74 g of edible vegetable oil per day and
  - only the concerned oil with the highest level of B[a]P detected (17 μg/kg) among samples collected was consumed everyday
Risk Assessment – Risk characterisation

- The MOE calculated for edible vegetable oil containing B[a]P at the level of 17 μg/kg is higher than 10,000.
  - CFS considered that the health risk concern for consuming the above mentioned vegetable oil should not be high.

- Based on the “as low as reasonably practicable” (ALARP) principle,
  - efforts should be made to minimise exposure to B[a]P.
Risk Management Actions

- **Immediate actions**
  - Inspected the
    - suspected unlicensed food processing establishment
    - alleged supplier of the cooking oil
    - restaurants involved
  - Collected a total of 39 cooking oil samples
    - tested for B[a]P
      - the highest level of B[a]P detected is 17 µg/kg
**Risk Management Actions**

- **Immediate actions**
  - Marked and sealed the concerned oil to restrict their movement pending the result of testing
  - Requested the supplier concerned to stop selling and recall the product
Risk Management Actions

- **Tracing the source and distribution of substandard cooking oil**

  - The cooking oil found to have a BaP level exceeding the mainland limit was the product of a mainland manufacturer

  - contacted the State General Administration of Quality Supervision, Inspection and Quarantine (AQSIQ)
Risk Management Actions

- Tracing the source and distribution of substandard cooking oil

- The relevant mainland authority ordered the manufacturer to:
  - suspend supply of the products to Hong Kong
  - stop production and take improvement measures
  - recall the products in question
Risk Management follow-up actions

- **Review of the Food Surveillance Programme**
  
  - CFS will review the testing of cooking oil under the Food Surveillance Programme, in terms of
    
    - frequency
    - the number of samples to be taken for testing
    - the types of laboratory analyses to be conducted
      - including B[a]P in its routine testing
Risk Management follow-up actions

- Review of regulation on B[a]P in oil in different countries/region
  - The Codex Alimentarius Commission
    - has not established any standard on B[a]P in food
  - Many developed countries
    - the United States, Australia, New Zealand, Japan and Singapore, etc.
    - have not at present set any limits on B[a]P in food
Risk Management follow-up actions

- Review of regulation on B[a]P in oil in different countries/region
  - **EU** established limits on B[a]P at 2 μg/kg for
    - oils and fats (excluding cocoa butter and coconut oil) intended for direct human consumption or use as an ingredient in food
  - **Mainland China** established limits on B[a]P at 10 μg/kg for
    - fats/oil and their products (油脂及其製品) in GB2762-2012
Setting local action level

Risk assessment input using MOE approach:

- If a B[a]P level higher than 10 μg/kg but lower than 20 μg/kg * is detected in edible vegetable oil, the MOE calculated will be higher than 10000.

- If a B[a]P level at 20 μg/kg is detected in edible vegetable oil, the MOE calculated will be lower than 10000.

*the MOE value would still be larger than 10,000 for oil sample containing 19.5 μg/kg of B[a]P
Risk Management follow-up actions

- Setting local action level

  - CFS suggested and Expert Committee on Food Safety adopted an action level of 10 μg/kg for B[a]P in edible vegetable oil
    - with reference to the standards of different countries / jurisdictions and
    - taking into account the results of risk assessment using the MOE approach
Local action level - enforcement

- If a BaP level higher than 10 μg/kg but lower than 20 μg/kg is detected in cooking oil,
  - CFS may take enforcement action in accordance with Section 52 of the Cap. 132
  - Section 52 of the Ordinance provides that if any person sells to the prejudice of a purchaser any food which is not of the nature, or not of the substance, or not of the quality, of the food demanded by the purchaser, he shall be guilty of an offence
Local action level - enforcement

- If a BaP level at 20 μg/kg is detected in cooking oil,

  - CFS would take enforcement action in accordance with Section 54 of the Public Health and Municipal Services Ordinance (Cap. 132 of Laws of Hong Kong),

  - Section 54 of the Ordinance stipulates that all food (including cooking oil) for sale must be fit for human consumption.

  - Initiate a mandatory recall of the cooking oil concerned
Involvement of Risk Communication

- Issued press releases
- Meeting with representatives of the trade to
  - brief them on the testing results
  - remind them
    - using cooking oil satisfying safety and quality requirements
    - maintaining proper records in accordance with the Food Safety Ordinance (Cap. 612) to allow source tracing
    - sourcing food from reliable suppliers
Involvement of Risk Communication

- Source food from reliable suppliers, including –
  - checking whether the suppliers possess the relevant food business licenses;
  - checking whether they have been registered as food importers or distributors under the Food Safety Ordinance (Cap. 612); and
  - checking the source and quality of the food ingredients
Experience Gained
Experience Gained

- Prompt response to the report in the newspaper by stepping up surveillance immediately;

- Proactive communication and transparency in releasing testing results and other related information;

- Open dialogue with the trade to enlist their co-operation in obtaining food product from reliable source and keeping proper record for tracing of source of food;
Experience Gained

- Timely engagement of members of the Expert Committee on Food Safety in seeking their independent advice on the risk assessment as well as the risk management plan;

- Comprehensive surveillance coverage – import, wholesale and retail to be considered; and

- Review of the food surveillance plan
Thank you