Role of risk assessment within risk analysis framework

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Identifying hazards, assessing risks

Risk = f (hazard, exposure)

What risk assessors do … ?

• Evaluate studies performed by third parties
  – Chemical, analytical, toxicological, clinical
• Discuss validity of study results and data
  – Meeting general and specific criteria to allow assessment of hazards

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### What risk assessors do ... ?

- Draw conclusions about risk(s) presented by a hazard
  - Apply general and specific scientific rules when doing so
- Provide recommendations how to address a risk
  - In accordance with risk assessment policy
- Communicate main findings
  - Using language that target audiences understand

### What risk assessors do not do ...?

- Draft and adopt laws or regulations
- Define the environment for risk assessment
  - Policies, priorities, resources
- Decide on an agreed level of protection of the consumer
- Decide what risks are acceptable or not acceptable
- Implement measures to control risks
- Develop strategies that address stakeholders in the food chain and their role to mitigate a risk

### Four activities of risk assessment (Codex!)

<table>
<thead>
<tr>
<th>Hazard identification</th>
<th>The identification of biological, chemical and physical agents capable of causing adverse health effects and which may be present in a particular food or group of foods.</th>
</tr>
</thead>
<tbody>
<tr>
<td>Hazard characterization</td>
<td>The qualitative and/or quantitative evaluation of the nature of the adverse health effects associated with biological, chemical and physical agents, which may be present in food. For chemical agents, a dose-response assessment is performed. For biological or physical agents, a dose-response assessment should be performed if the data are obtainable.</td>
</tr>
<tr>
<td>Exposure assessment</td>
<td>The qualitative and/or quantitative evaluation of the likely intake of biological, chemical and physical agents via food, as well as exposures from other sources if relevant</td>
</tr>
<tr>
<td>Risk characterization</td>
<td>The qualitative and/or quantitative estimation, including attendant uncertainties, of the probability of occurrence and severity of known or potential adverse health effects in a given population based on hazard identification, hazard characterization and exposure assessment</td>
</tr>
</tbody>
</table>
Example of a hazard / risk

Hazard identification & characterization
Example acrylamide (AA)

- Chemical properties of AA (e.g. volatility)
- Chemical reactions leading to formation of AA
- Food items and food processing conditions
- In vitro genotoxicity studies (e.g. AMES)
- In vivo toxicity studies (e.g. neurotoxicity)
- In vivo cancer studies (e.g. in rats)
- Epidemiological studies in humans (working place)

Exposure assessment: example acrylamide

- Analytical methods to determine AA in food
- Fate of acrylamide in the food chain
- Survey of food items and their levels of AA
- Food consumption studies for target populations
- Total diet study
- Statistical evaluation of available data
- Statistical extrapolation

Risk management, risk communication (AA)

- Feasibility of setting maximum limits
- Identification of foods that are main contributors
  - Priorities for research
  - Priorities for risk mitigation
- Private sector voluntary measures
- Intervention strategies (asparaginase treatment)
- Advice to consumer food processing at home
- Areas for future regulatory actions
Risk assessment: various scientific disciplines

- Chemistry, human medicine, toxicology, analytical chemistry, food technology, epidemiology, biochemistry, cell biology, microbiology, veterinary medicine, plant biology, zoology, nutritionists
- Risk assessment work is team work: team members represent those scientific disciplines needed to address a question
- All team members are appointed and work as scientists

It is scientific work …

- Takes into account relevant previous data
- Undertakes testing to assess the results
- Based on evidence
- Is undertaken openly and in communication with others
- Application of high standards with honesty, integrity, and objectivity

http://undsci.berkeley.edu/article/0_0_0/whatisscience_09

Risk assessment: fair and honest

- Provides a fair and honest description of a food hazard and the associated risks for identified groups of consumers
- Fairness and honesty are laid down in the legal framework
- They are also a result of risk assessment’s scientific approach and procedures
- Using consistent data requirements, endpoints, criteria etc. are important elements
- Risk assessments shall survive scientific based challenges by others (= scientists)
- Valid until challenged by new data/revised evaluation

Risk assessment & risk analysis framework

- Contributes to other activities of risk analysis framework
  - Participates in drafting risk assessment policies
  - Defines resources needed
  - Profiles of risk assessors
  - Monitoring of risk management measures
  - Undertakes/contributes to risk communication
Role of risk assessment in risk analysis

• Risk assessment
  – assesses scientifically the evidence about the hazards,
  – discusses its relevance for human health,
  – gives an estimate of the risk for consumers if they are exposed to the hazard

• Content and format of a specific risk assessment allows for further use for risk management and risk communication

• Iterative interaction with risk management