中国检科院食品风险管理与应用研究所
Food Risk Management and Application Institute of CAIQ

Risk Analysis and Risk-benefit Assessment Application in China

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Main contents

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- Risk analysis framework in China

Establishment for risk analysis framework in China

- 《Food Safety Act》 was enforced since June 1st, 2009
- GB/T 23811-2009 Guideline for food safety risk analysis procedures

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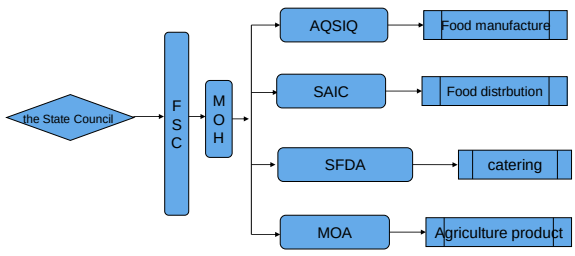
Food safety management model in China



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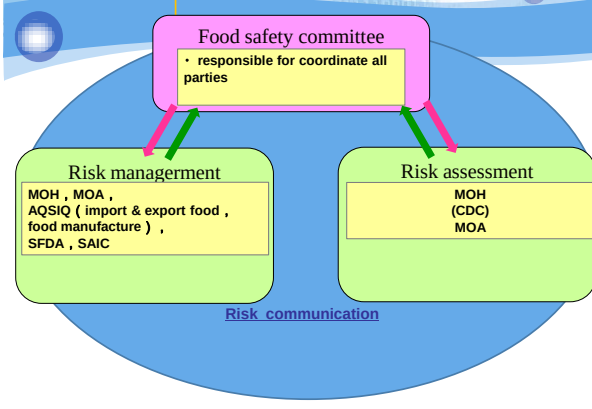
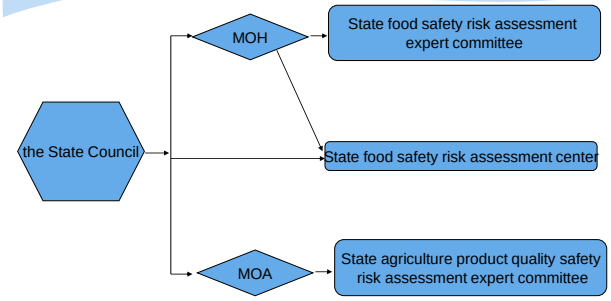
Food risk management in China



Risk assessment department in China



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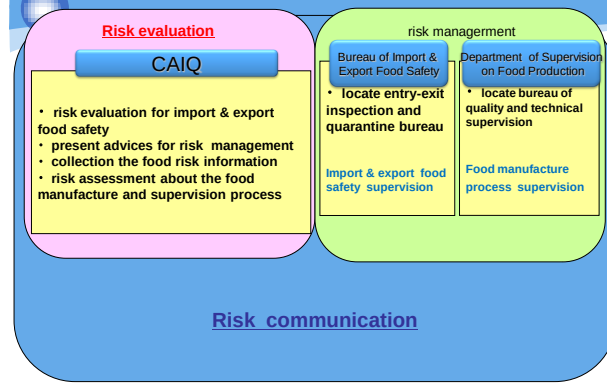
Food risk management in AQSIQ



Food risk management in MOH

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Food risk management in MOA

- Presenting advices about risk assessment policy for national agricultural products
- Drawing national risk assessment planning and guideline of agricultural products
- Providing risk assessment reports for agricultural products
- Organizing domestic and overseas academic communication of agricultural products

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Food risk management in SFDA & SAIC

SFDA

- To direct relevant local work regarding food and drug administration, emergency response, inspection and informationalization
- To carry out international exchanges and cooperation related to food and drug regulation

SAIC

To take charge of food hygiene licensing and food safety supervision at consumption stage

To formulate good practice for food safety at consumption stage and supervise its implementation, carry out investigation and monitoring work of food safety at consumption stage, and release information related to supervision on food safety at consumption stage

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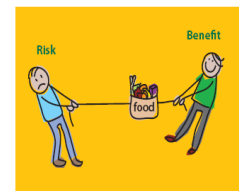
- Introduction of risk-benefit assessment



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Definitions

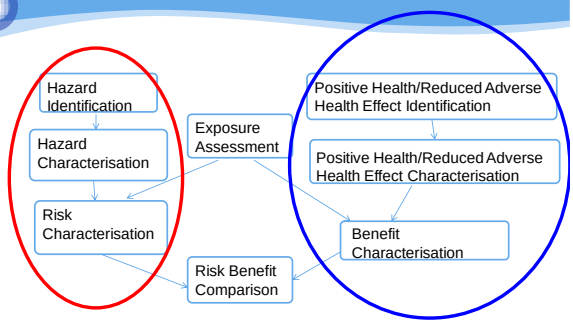
- Risk: The probability of an adverse effect in an organism, system, or (sub)population in reaction to exposure to an agent.
- Benefit: The probability of a positive health effect and/or the probability of a reduction of an adverse health effect in an organism, system, or (sub)population, in reaction to exposure to an agent.

Risk⟷Benefit Hazard⟷Positive health effect

- Risk- Benefit: Where a food or food substance is recognised to have the potential to exert both health benefits and health risks it is important for risk-benefit managers to be able to weigh the risks against the benefits on the basis of a qualitative or quantitative risk-benefit assessment.

- The proposed procedure and examples of situations used in risk-benefit assessment

The risk-benefit assessment paradigm



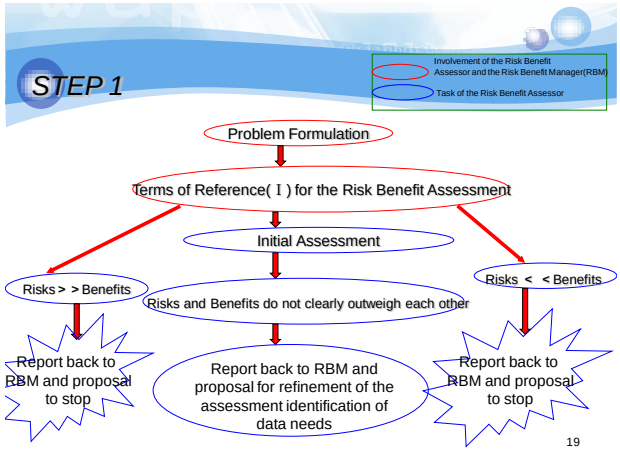
Examples of situations used in risk-benefit assessment

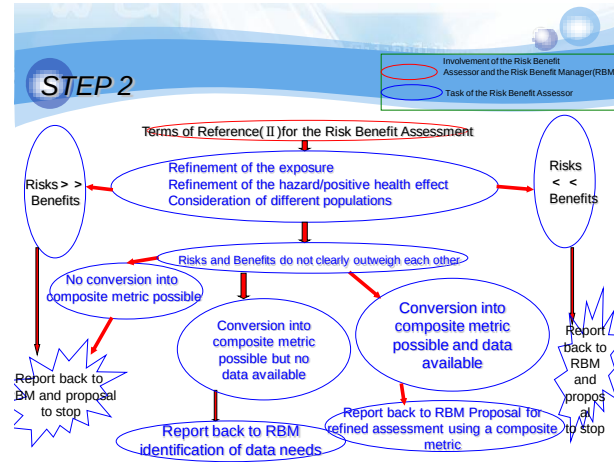
- Where a single compound or food constituent has both positive and negative health effects.
- Where similar levels of dietary exposures can be associated with both risk and benefit.
- Before the start of an intervention, such as folic acid fortification, or fluoridation of drinking water.
- Where a significant change of dietary consumption patterns has occurred or may occur in the future, e.g. substituting sugar by low-calorie sweeteners.
- Where chemicals are used to reduce microbial contamination, e.g. use of disinfection processes.

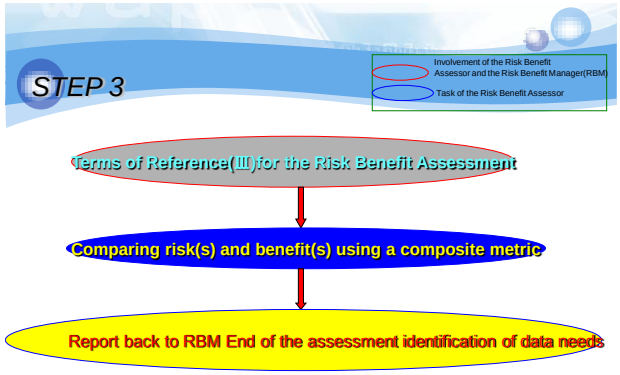
Examples of situations used in risk-benefit assessment

- Where the beneficial effect, such as enhanced retention of nutritional value resulting from improved processing procedures, requires to be assessed against the negative effects associated with a greater survival of foodborne pathogens.
- Where new knowledge emerges with major implications for either the risk(s) or the benefit(s) in a previous risk assessment, benefit assessment or risk-benefit assessment. For example the possible association between folic acid consumption and colon cancer.

- **Proposed approach for risk-benefit assessment**







- Situation and progress of risk-benefit assessment in China

Application of risk-benefit assessment used in the safety evaluation of drug quality in China

- Risk-benefit assessment including descriptive, semi-quantitative and quantitative methods is mainly used in the safety evaluation of drug quality in China.
- Benefits and risks can be described in relation to the Intensity (seriousness or severity) of the treated disease or adverse reaction, its duration or chronicity, and, especially in the case of a reaction, its incidence in the treated population.
- All of the contents above could be described as high, medium and low to further compare risk and benefit of drug.

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Thank You for Your Attention !