Risk Assessment vs Risk Management: The European Food Safety Authority and Competent Authorities

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Food safety hazards

- May 2011 Germany
- Shiga toxin-producing *E. coli* (STEC) O104:H4
- 4000 people ill
- More than 56 deaths
- Second cluster in Bordeaux-France caused by the same strain
- Sprouted seeds
Risk assessment: A scientifically based process consisting of the following steps:

- Hazard identification;
- Hazard characterization;
- Exposure assessment;
- Risk characterization.
Risk Analysis

- Risk management:

  Weighing policy alternatives in consultation with all interested parties, considering:

  - Risk assessment

  - Other factors relevant for the health protection of consumers and for the promotion of fair trade practices,

  - Selecting appropriate prevention and control options.
Risk Analysis

- **Risk communication:**
  Interactive exchange of information throughout the risk analysis process:
  
  - Risk, risk-related factors and risk perceptions,
  - Among risk assessors, risk managers, consumers, industry, the academic community and other interested parties,
  - Including the explanation of risk assessment findings and the basis of risk management decisions.
Food safety risk analysis is carried out by national, regional and international food safety authorities.

Risk Assessors

European Union: EFSA

National Food Safety Agencies

Risk Managers

Eur. Commission
Eur. Parliament
Members States

National Authorities

*Codex committees: Food safety standards

Joint FAO/WHO Expert bodies
Joint Expert Committee on Food Additives (JECFA)
Joint Meeting on Pesticide Residues (JMPR)
Joint Expert Meeting on Microbiol. RA (JEMRA)
Risk Management

- Internationally, *Codex committees that recommend food safety standards (Committees on Food Hygiene, Meat Hygiene, Food Additives, Contaminants, Pesticide Residues, and Residues of Veterinary Drugs in Foods)

- National authorities are responsible for ensuring food safety standards are respected by operators.
EFSA

- EFSA is an independent European agency funded by the EU budget

- Operates separately from the Risk Managers: European Commission, European Parliament and EU Member States

Functional separation between Risk assessment and Risk management

- On the requests for scientific advice from risk managers
- On its own initiative
Missions of EFSA

- Independant information and communication on risks associated with the food chain
- Scientific advice and technical support for the Community’s legislation and policies on food and feed safety issues
- Scientific advice and technical support on human nutrition and assistance concerning communication on nutritional issues within the framework of the community health programme
- Scientific opinion on other matters related to animal health and welfare and plant health
European Commission
Represents the interests of the Union

Members States

Law proposition

Law adoption

European Parliament
Represents the EU’s citizens

Council of EU
Represents the governments of the MS

Law implementation
EFSA Scientific Panels/Units

- Risk assessment and scientific assistance
- Scientific evaluation of regulated products
- Science strategy and coordination
Risk assessment and scientific assistance

**PANELS**
Animal health and welfare (AHAW)
Biological hazards (BIOHAZ)
Contaminants in the food chain (CONTAM)
Plant health (PLH)

**UNITS**
Biological monitoring (BIOCONTAM)
Evidence management (DATA Unit)
Assessment and methodological support (AMU)
Scientific evaluation of regulated products

PANELS
Genetically modified organisms (GMO)
Dietetic products, nutrition and allergies (NDA)
Food additives and nutrient sources added to food (ANS)
Food contact materials, enzymes, flavourings and processing (CEF)
Additives and products or substances used in animal feed (FEEDAP)
Plant protection products and their residues (PPR)

UNITS
Biological monitoring (BIOCONTAM)
Evidence management (DATA Unit)
Assessment and methodological support (AMU)
Science strategy and coordination

SCIENTIFIC COMMITTEE
Scientific Committee and Emerging risks Unit
Chairs of panels

UNITS
Advisory forum and scientific cooperation (AFSCO)
Members states: National Authorities of Food Safety

Stakeholder consultative platform:
- Grants/contracts
- Support projects on RA

Individual Experts
Expert database (4000)

Stakeholder consultative platform:
- Grants/contracts
- Support projects on RA

EU Institutions
European Medicines Agency
European Chemical Agency
EC Diseases and Control
EC Joint Research Centre

Advisory Forum:
Heads of national Authorities
- Advice on sc matters
- Emerging risks
- Coordination of R. Com.

Focal points:
- Share information
- RA expertise
- Collection of data
Sc opinion on the public health risk/pathogens of food of non-animal origin

European Commission → Terms of references → Food/pathogens combinations → Risks of Salmonella and Norovirus in leafy freen eaten raw salad → EFSA Biological hazards Panel

1/ Identify the main risk factors of contamination

2/ Recommend possible mitigations and assess their efficiency

3/ Recommend microbiological criteria for Salmonella and Norovirus in leafy greens

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1/ Main risk factors for *Salmonella*

**Primary production**
- Environment: animal rearing; heavy rainfall
- Contact w/ animal reservoir
- Use of untreated manure/compost
- Use of contaminated water in agriculture
- Post-harvest contaminations by food handlers/equipment

**Processing**
- Washing tanks, equipment; water, food handlers
- Bacterial biofilm, adherence

**Distribution, retail, catering**
- Direct or indirect contact of raw contaminated food of animal origin and leafy greens
2/ Recommend mitigations

Farm

- Food safety management systems: GAP, GHP, GMP
- Evaluation of farm environment
- Water treatment and sufficient drainage
- Testing faecal indicators for irrigation water
- Hygiene training to handlers
- Labelling for consumers (shelf-life indicators, preparation...)

Fork
3/ Recommend microbiological criteria

- No microbiological criteria at the primary production
- **Hygiene Criteria** to verify GAP/GHP: *E. coli*
  
  Functioning at pre-harvest, harvest and on farm post harvest production prior to processing

- **Process Hygiene Criterion:** *E. coli*
  
  Indication on GAP, GHP, GMP, HAACCP implementations

- **Food Safety Criterion:**
  
  - Absence of *Salmonella* on leafy greens intended to be eaten raw as salad
  
  - Testing for *Salmonella* in cases indicating failing of GAP, GHP, GMP or HACCP programmes
Risk management

- Regulation and Control

- Other legitimate factors relevant to the matter under consideration should be taken into account including societal, economic, traditional, ethical and environmental factors and the feasibility of controls.

- Precautionary principle is applied in risk management decisions when appropriate.
Risk management

- General Food Law (Regulation EC N° 178/2002)

- Regulatory aspects:
  - Legal framework for food safety
  - Legal framework for animal feed
  - Animal health and welfare
  - Holistic approach towards hygiene
  - Limits of contaminants and residus
  - Novel food
  - Additives, flavourings, packaging and irradiation
  - Emergency measures
  - Decision making process to ensure efficacy, transparency and rapidity
Risk management

- Business operators at all stages of production, processing and distribution should ensure that foods or feeds satisfy the requirements of food law.

- MS enforce food law and verify that the relevant requirements of food law are fulfilled by food and feed business operators.
  - System of official controls and inspections
  - Monitoring and surveillance programmes

- Measures and penalties applicable to infringements of food and feed law.
  - Effective, proportionate and dissuasive
Examples of regulations


Examples of Risk management options

- Ban from an imported food (prohibited ingredient, high levels of pathogens)
- Set MRL for chemicals (pesticides, antibiotics); re-evaluation of MRL
- Prohibition of some food additives
- Authorisation or not of GMOs
- Labelling, Traceability
- Rapid alert system covering food and feed.
Conclusion

- Risk Assessors
  - Work independently, openly and transparently
  - Functional separation with Risk Managers

- Risk Managers
  - Efficient and commensurate regulations and controls
  - Appropriate sanctions in cases of non compliance

- Risk communication
  - Interactive and transparent process involving all interested parties