

**The European Food Safety
Authority**
The role of EFSA in risk assessment

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- Rather, I am an independent expert appointed to one of the EFSA Panels (the CEF-panel)
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Overview

- Creation of EFSA
- What EFSA does
- Structure of EFSA
- Risk assessment process
- Communications
- Challenges
- Further information

Creation of EFSA

Origins

- Series of food scares and scandals in Europe (e.g. BSE, dioxins)
- Loss of consumer confidence in safety of food chain and damaged trust in public authorities
- Creation of agencies to handle food issues at national level
- ➔ Need to strengthen EU food safety system and policy

Creation of EFSA

Legal basis

Regulation EC 178/2002 – January 2002

- Establishment of EFSA in 2002 and located in Parma, Italy
- General principles / requirements of Food Law
- Rapid alert system, procedures for crisis management and emergencies

Creation of EFSA

EFSA has three main goals



What EFSA does

Mandate

- Provision of scientific advice and support for Community legislation/policies in all fields with direct or indirect impact on food and feed safety
- Provision of independent information on all matters within these fields
- Risk communication

What EFSA does

The main changes

- Risk assessment separated from risk management
- EFSA not part of European Commission nor is it answerable to it
- EFSA has independent Management Board
- EFSA works in close co-operation with national authorities
- EFSA actively considers and meet stakeholder needs, especially consumers

What EFSA does

EFSA's tasks

1. Provide scientific advice, opinions, information, and technical support for Community legislation and policies
2. Collect and analyse data to allow characterisation and monitoring of risks
3. Promote and coordinate development of uniform risk assessment methodologies
4. Communicate risks related to all aspects of EFSA's mandate

What EFSA does

Who can task EFSA?

- European Commission
- European Parliament
- Member States
- EFSA can also task itself

What EFSA does

Core values

- Scientific excellence**
- Independence**
- Openness**
- Transparency**
- Responsiveness**

Observation

Having an independent science-based risk assessment authority that is EFSA, fits well with the general and specific provisions of the agreement on SPS Measures

EFSA structure

Management Board

Advisory Forum

EFSA Directorate and Staff

Scientific Committee and Panels

EFSA structure

MB Composition

14 Members

- Selected on basis of individual expertise and competence through an open call
- Members do not represent EU Member States
- Widely range of backgrounds (e.g. consumers, government, agriculture, industry, retail, as well as scientific experience)

1 Member representing the European Commission (DG SANCO)

EFSA structure

MB Role

Ensure EFSA works effectively and efficiently

- Establish budget, agree work programmes and monitor implementation
- Ensure Authority stays within remit of Founding Regulation
- Appoint Executive Director, Scientific Committee and Panels

EFSA structure

Advisory Forum

- Representatives from national food safety authorities/bodies with role equivalent to EFSA
- One representative per Member State (special representatives for animal health and plant health)
- Commission and European Parliament invited as observers
- Special invitees (accession countries, observers from Norway, Iceland, Switzerland)

EFSA structure

AF Role

- Advise EFSA on scientific matters, work programme/priorities and emerging risks
- Ensure close collaboration between national bodies and EFSA
- Assist in resolving contentious scientific issues and avoiding divergent views on food/feed safety issues
- Avoid duplication of scientific effort
- Play a key role in sharing and disseminating information
- Assist in increasing scientific co-operation between Member States

EFSA structure

EFSA Staff

- Over 400 staff (2009)
- + temporary agents, contract agents, national experts on detached-duty, etc.
- + independent experts



Risk Assessment

10 Scientific Panels

- Food additives and nutrient sources (ANS)
- Food contact materials, enzymes, flavourings and processing aids (CEF)
- Animal Health and Welfare (AHAW)
- Biological hazards (BIOHAZ)
- Contaminants in the food chain (CONTAM)
- Additives and products in animal feed (FEEDAP)
- Genetically modified organisms (GMO)
- Dietetic products, nutrition and allergies (NDA)
- Plant health (PLH)
- Plant Protection Products (PPR)

Risk Assessment

EFSA-managed projects

- Scientific cooperation
- Data collection
- Emerging risks
- Assessment methodology

Risk Assessment

Scientific Panels

- Cover whole food chain
- Members appointed by Management Board following open call for applications
- Selected on basis of scientific excellence, experience in relevant fields, specialised expertise, independence
- Maximum 21 members per panel
- Composition re-established every three years

Risk Assessment

Scientific Committee

COMPOSITION

- Chairs of ten Scientific Panels
- Six scientists not members of any Panel

ROLE

- General co-ordination of EFSA's scientific work, ensure consistency of opinions
- Guidance and scientific advice on multi-sectoral issues
- Establish expert working groups
- Advice on risk assessment and policies related to EFSA scientific work

Risk Assessment

RA – what is it?

Evaluation of the potential for adverse effects on human health arising from the presence of additives, contaminants, toxins or disease-causing organisms in food or feedstuffs

$$\text{Risk} = f[\text{hazard}] * [\text{exposure}]$$

- Hazard identification – what?
- Hazard characterisation – how bad?
- Frequency/level of occurrence – how often or how much?

Risk Assessment

HAZARDS

- Chemical agent
- Biological agent
- Physical agent

..... with the potential to cause an adverse health effect.

Risk Assessment

CHEMICAL HAZARDS

- Environmental contaminants – dioxins, PCBs, metals
- Natural toxicants – mycotoxins, phycotoxins
- Pesticides
- Veterinary drugs
- Processing contaminants
- Additives – to food & feed
- Packaging migration
- Allergens
- Deliberate adulteration



Risk Assessment

BIOLOGICAL HAZARDS

- Bacteria: Salmonella, Listeria, E.coli O:157, Clostridium botulinum
- Prions: TSEs (BSE, Scrapie)
- Viruses: norovirus
- Parasites: trichinella, cysticercosis, anisakis

Risk Assessment

PHYSICAL HAZARDS

- Glass, stones, insects, filth, and other debris in food
- Choking and suffocation hazard

Communications

Risk communication

Provide appropriate, consistent, accurate and timely communications on food safety issues to all interested parties, stakeholders and the public at large, based on the Authority's risk assessments and scientific expertise

Communications

Context

27 Member States with different attitudes and perceptions regarding:

- Nutrition and health
- Food safety
- Risk

Communications

Risk perceptions: Top Concerns (illustrative, 2006)

PESTICIDES: Greece, Italy, Hungary, France, Portugal, Slovenia, Germany, Spain, Finland

NEW VIRUSES LIKE AVIAN INFLUENZA: Malta, Latvia, The Netherlands

RESIDUES IN MEAT: Cyprus, Greece, Belgium

FOOD HYGIENE OUTSIDE HOME: Poland, United Kingdom, Denmark, Ireland, Spain

CONTAMINATION BY BACTERIA: Czech Republic, Luxembourg, Slovakia

POLLUTANTS LIKE MERCURY OR DIOXINS: Belgium

GMOs: Austria

ADDITIVES: Lithuania, Estonia

WELFARE OF FARMED ANIMALS: Denmark, Sweden



Communications

Communicating uncertainty

The risk assessment should also communicate:

- any Assumptions made
- any Uncertainties in the information used including Gaps
- any Limitations of the current state of understanding

The process of risk assessment and (in risk management) the determination of acceptable levels of risk implies the routine use of 'safety margins' to ensure adequate precautions are taken to protect health.

Challenges

- Re-evaluation of existing hazards (substances, processes etc) up to modern standards
- Immunotoxicity, reprotoxicity, new end-points?
- Human genetic variability and genetic factors in risk
- New technologies, e.g. nanotechnology, animal cloning, gene doping
- Emerging risks – chemical, biological

EFSA - further information

<http://www.efsa.europa.eu>
