

An Introduction to the role of EFSA in risk assessment

Laurence Castle. CSL York

DISCLAIMER

- This presentation uses some slides kindly provided by EFSA.
- The presenter (Laurence Castle) is NOT a staff member of EFSA.
- Rather, I am an independent expert appointed to one the the EFSA Panels (the AFC-panel)
- This presentation and any subsequent Q&A discussions should not be taken as the official position of EFSA.

Overview

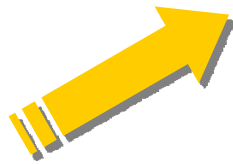
- Creation of EFSA
- What EFSA does
- Structure of EFSA
- Risk assessment process
- Communications
- Challenges
- Further information

Origins

- Series of food scares (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

EFSA has three main goals

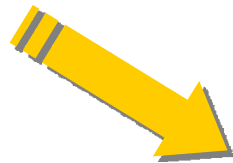
Make a
significant
contribution to:



Improving EU food safety



Re-building consumer
confidence in EU food safety



Re-building confidence of
trading partners in the EU
food supply

Legal basis

Regulation EC 178/2002 – January 2002

- General principles / requirements of Food Law
- Establishment of EFSA
- Rapid alert system, crisis management and emergencies

Mandate

- Provision of scientific advice and support for Community legislation/policies in all fields with direct/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 answerable to it
- EFSA has independent Management Board
- EFSA works in close co-operation with national authorities
- EFSA to actively consider and meet stakeholder needs (in particular 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

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 such as 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**

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. consumer, government, agriculture, industry, retail as well as scientific experience)

1 Member representing the European Commission (DG SANCO)

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

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)

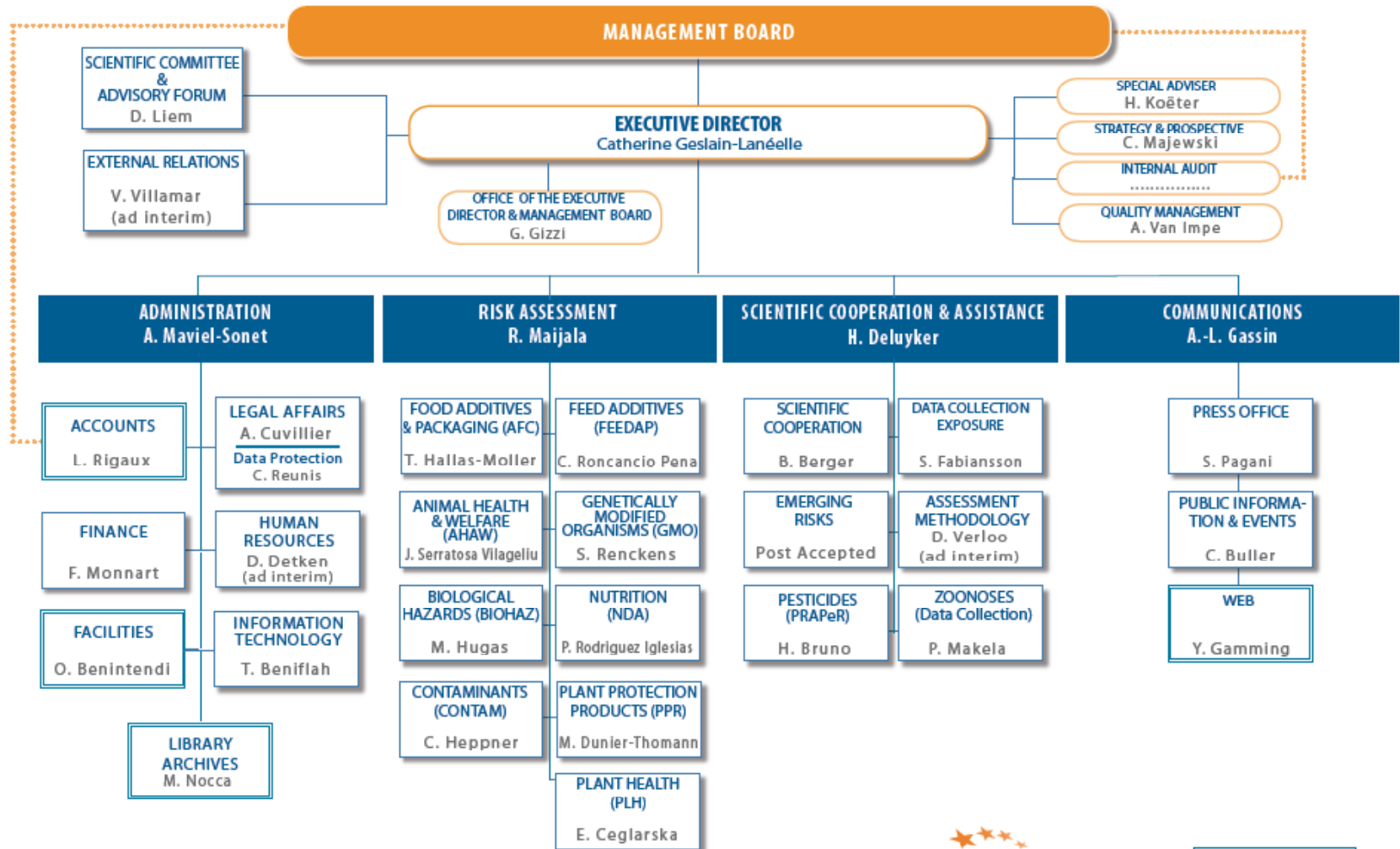
AF Role

- 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 Staff

- Over 300 in February 2008
- Genuinely multinational and multicultural
- Temporary agents, contract agents, national experts

EFSA Structure



Scientific Panels

- Food additives, flavourings, processing aids, materials in contact with food (AFC)
- 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)

Scientific Panels

The AFC Panel has the highest workload and assessed more than 1300 applications since 2003.

In 2008 the AFC Panel will be replaced by:

- ANS Panel - food additives and nutrient sources added to food
- CEF Panel - food contact materials, enzymes, flavourings and processing aids

.....giving then 10 panels

Scientific Panels

- Structure defined in Founding Regulation and carried over from Commission
- Cover whole food chain
- Members appointed by Management Board following open call for applications
- Selected on basis of proven scientific excellence, experience in relevant fields, specialised expertise
- Geographical balance and gender also taken into account
- Maximum 21 members per panel
- Composition re-established every three years

Scientific Committee

COMPOSITION

- Chairs of nine 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

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?

HAZARDS

- Chemical agent
- Biological agent
- Physical agent

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

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



BIOLOGICAL HAZARDS

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

PHYSICAL HAZARDS

- Glass, stones, insects, and other debris in food

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

Context

27 Member States with different attitudes and perceptions regarding:

- Nutrition and health
- Food safety
- Risk



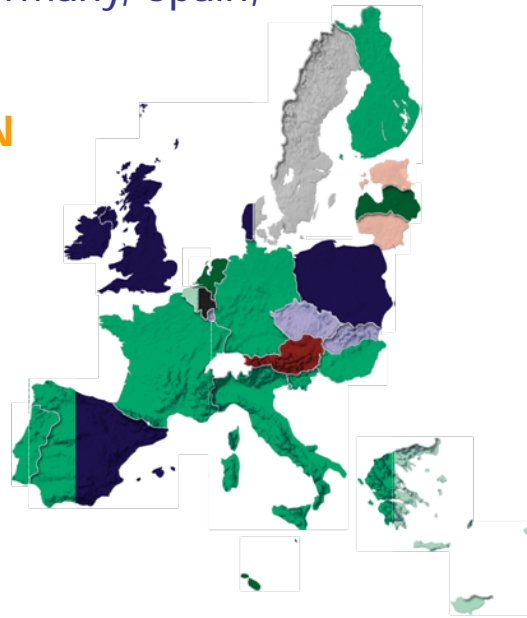
Risk perceptions: Top Concerns

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

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>

AHAW Panel. Basic Information for the Development of the Animal Welfare Risk Assessment Guidelines

FEEDAP Panel. Guidelines for the assessment of additives in animal nutrition

GMO Panel. Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed

PPR Panel. Guidance documents -for the implementation of Council Directive 91/414/EEC (Plant Protection Products)

.....etc.