General tasks and structure of the EFSA and its role on risk assessment for microbiological hazards

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Food Safety Challenges for Mediterranean Products (Zaragoza, Spain; 10-11 June 2014)
PRESENTATION PLAN

- Introduction to EFSA, its structure and function.
- The role of the Biological Hazards Panel (BIOHAZARDS).
- Examples of some recent/ongoing BIOHAZ opinions.
EFSA WAS SET UP IN JANUARY 2002 AS

- an independent source of scientific advice and communication on risks associated with the food chain
- part of a comprehensive programme to:
  - improve EU food safety system
  - help ensure a high level of consumer protection
  - restore and maintain confidence in the EU food supply
  - clearly separating risk assessment and risk management functions
2003: scientific work starts

2005: moved to Parma from Brussels

Since 2003 more than 3,300 scientific outputs including 2,330 scientific opinions

Budget 2014: EUR 79.6 million

Over 450 staff, 60% engaged in the production of scientific advice
EFSA IS TASKED TO

- Provide independent scientific advice and support for EU law/policies on food and feed safety
- Provide independent, timely risk communication
- Promote scientific cooperation
...BUT NOT TO

- develop food safety policies and legislation
- adopt regulations, authorise marketing of new products
- enforce food safety legislation
- take charge of food safety/quality controls, labelling or other such issues, like inspections and traceability
... SCIENTIFIC EXCELLENCE IN RISK ASSESSMENT

- > 3,300 outputs
  > 2,330 opinions
  - 500th opinion: 2007
  - 1000th opinion: 2009
  - 2000th opinion: 2012
- Scientific expertise across Europe
- Impartiality of scientific advice
- EFSA Journal, Scientific Colloquia, international cooperation...
... THROUGHOUT THE WORKFLOW

EFSA’s scientists evaluate, assess, advise

Adoption and communication
INDEPENDENCE...

- From risk managers (EU Commission, Member States)
- From private interests

Guaranteed through a comprehensive policy covering all actors and working processes:

- Organisational governance: different roles of Management Board, Advisory Forum, Panels and staff
- Governance of scientific processes: mandates, selection of experts, data and literature review, collegial decision making, transparency
- Declaration of Interests
…THROUGHOUT THE WORKFLOW

- Procedure for Expert selection
- Accepted mandates (Register of Questions)
- Names of panel and working group members
- Declaration of interest of experts
- Agendas of plenary meetings
- Minutes of plenary and working group meetings
- Access to data
- Open panels meetings
- Consultations
- Adopted opinions
- Press releases and web stories
EFSA HAS A ROBUST GOVERNANCE...

Management Board + Advisory Forum + EFSA Staff + Scientific Committee and Panels = EFSA

European Food Safety Authority
EFSA MANAGEMENT BOARD...

14 Members
- Selected on basis of individual expertise and competence through an open call
- Appointed by the Council of the EU based on suggestions from Parliament
- Members do not represent EU Member States and are appointed in a personal capacity
- Wide range of backgrounds

1 Member representing the European Commission
... WHOSE ROLE IS TO

- Primary role: ensure Authority functions 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
- Audit Authority’s operations

The Management Board is not involved in scientific advice
EFSA ADVISORY FORUM...

- Representatives from national food safety authorities/bodies with role equivalent to EFSA
- One representative per Member State; may bring specialist support
- Commission represented as observer
... WHOSE ROLE IS TO

- 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
EXPERTS ARE CAREFULLY SELECTED

EFSA seeks high-calibre experts to serve on its Scientific Committee and Scientific Panels

- Open call to scientists from all EU Member States and beyond
- EFSA choses candidates with proven excellence in one or more scientific fields within its remit
- Open, transparent selection procedure
10 Scientific Panels and Scientific Committee

Mainly opinions on applications

1. Food additives and nutrient sources (ANS)
2. Food contact materials, enzymes, flavourings (CEF)
3. Feed additives (FEEDAP)
4. Genetically modified organisms (GMO)
5. Nutrition (NDA)

Mainly generic opinions

6. Animal health and welfare (AHAW)
7. Biological hazards (BIOHAZ)
8. Contaminants (CONTAM)
9. Plant health (PLH)
10. Plant protection products (PPR)

Scientific Committee (SC)
EFSA today

... WHOSE ROLE IS TO PROVIDE SCIENTIFIC ADVICE FROM FARM TO FORK

- Plant Health
- Animal health and welfare
- Biological hazards
- Chemical contaminants
- Food additives
- Food packaging
- Genetically modified organisms
- Animal feed
- Nutrition
... AS WELL AS TALENTED STAFF
...WITH DIFFERENT ROLES

Panels
• Owners of scientific opinions

Scientific Committee
• Ensures consistency
• Issues guidance
• Assess emerging risks

Staff
• Support panel work
• Produce scientific and technical advice
• Communication
WITHIN EUROPE...

- National food safety agencies / research organisations (Art. 36)
- 400 research institutes
- 1,500 experts
- EU Agencies:
OUTSIDE EUROPE...

Working with national food safety organisations:

- US: FDA, USDA APHIS, USDA FSIS, ARS, EPA
- Health Canada
- Food Safety Commission of Japan
- Food Standards Australia
- New Zealand Food Safety Authority

Working with international organisations:
THE BIOHAZ PANEL

Remit

The Panel on Biological Hazards (BIOHAZ Panel) deals with questions on biological hazards relating to Food Safety and Food-borne Diseases, including:

- Food-borne Zoonoses
- Food Hygiene
- Microbiology
- Transmissible Spongiform Encephalopathies (TSE)
- Associated Waste Management
Provision of Scientific Opinions
- General questions: providing guidance and advice in response to questions
- Investing in food safety science: development, promotion and application of new and harmonized scientific approaches and methodologies for (quantitative) RA

Evaluation of Products (or Processes):
- Decontamination treatments: assessing the efficacy to remove microbial contamination
- Animal By-Products: assessing effectiveness of new disposal methods
- TSE Tests: assessing if the performance of the tests meet requirements
Work activities (cntd)

- **Data Collection**
  - Networking: collaboration with national authorities/bodies on microbiological risk assessment and TSEs
  - Procurement: literature review, data collection or development of RA models
THE BIOHAZ PANEL

From the question to the answer

European Commission
European Parliament
Member States
EFSA (“self mandate”)

Question?

Opinion

Risk Assessment

Risk Communication

Consumers
Media
Industry
Professionals

Risk Management
Microbial risk assessment activities of the BIOHAZ Panel: recent and ongoing activities

THE BIOHAZ PANEL

From the question to the answer

SCIENTIFIC Panel

Opinion adopted

Mandate

Working Group

Draft Opinion
Microbial risk assessment activities of the BIOHAZ Panel: recent and ongoing activities

THE BIOHAZ PANEL

Steps BIOHAZ risk assessment

1. Identifying external experts
2. Declaring interests
3. Working group set up
4. Stakeholder involvement?
5. Reviewing data
6. Scientific co-operation with other partners?
7. Draft Opinion
8. Public consultation?
9. Amended opinion
Outcome of the opinion

- Publication on EFSA website
- Communicated to originator of question (EC, MS, Parliament), provides support for changes of legislation
- In the published opinion
  - Background and explanation of the Terms of Reference (ToR)
  - Assessment (detailed report of the Panel)
  - Conclusions
  - Set of recommendations:
    - Reduce data gaps and scientific uncertainty
    - Usually advice for future research topics
    - Communicated to Risk Manager and DG Research of the EC
ToR 1: to identify and rank the main risks for PH that should be addressed by meat inspection at EU level.

- Hazards from scientific literature were ranked qualitatively using a decision tree.
<table>
<thead>
<tr>
<th>Species</th>
<th>Main biological hazards</th>
</tr>
</thead>
<tbody>
<tr>
<td>Swine</td>
<td><em>Salmonella, Toxoplasma, Trichinella</em> and <em>Yersinia</em></td>
</tr>
<tr>
<td>Poultry</td>
<td><em>Campylobacter, Salmonella, ESBL-AmpC carrying Escherichia coli</em> and <em>Salmonella</em></td>
</tr>
<tr>
<td>Cattle</td>
<td>Verocytotoxin-producing <em>E. coli</em> (VTEC), <em>Salmonella</em></td>
</tr>
<tr>
<td>Sheep and Goats</td>
<td>VTEC, <em>Toxoplasma</em></td>
</tr>
<tr>
<td>Solipeds</td>
<td><em>Trichinella</em></td>
</tr>
<tr>
<td>Farmed game (Deer)</td>
<td><em>Toxoplasma</em></td>
</tr>
<tr>
<td>Farmed game (Wild boar)</td>
<td><em>Salmonella, Toxoplasma</em></td>
</tr>
<tr>
<td>Farmed game (Reindeer, rabbits and ostriches)</td>
<td>None</td>
</tr>
</tbody>
</table>
Conclusions on hazards currently not covered by meat inspection

To ensure effective control of the hazards of relevance, a comprehensive meat safety assurance, combining measures applied on-farm and at-abattoir, is necessary. A prerequisite for this system is setting targets.

1. Risk-Categorisation of batches/herds/flocks/farms for the main hazards: based on on-farm indicators and FCI

2. Risk-Categorisation of slaughterhouses according to their capacity to control the hazard: based on on trends of data derived from process hygiene assessments, HACCP

3. Control measures both on farm and at the slaughterhouse
Key Strengths and Weaknesses of current meat inspection?

> Food chain information (FCI) provides information on disease occurrence and veterinary treatments, enabling a **focused inspection** of animals with problems;

> **Ante-mortem** inspection allows the detection of observable abnormalities and of animals heavily contaminated with faeces;

> **Post-mortem** inspection enables the detection of **carcass faecal contamination**, which is an indicator of slaughter hygiene.

> The use FCI for food safety purposes is limited because the data that it contains is very general and does not address specific hazards of public health importance;

> Current **ante- or post-mortem** visual inspection are **not able to detect any of the public health hazards** identified as the main concerns for food safety;

> Palpation and incision techniques used during **post-mortem** inspection can cause **bacterial cross-contamination**.
Conclusions on adaptation of current meat inspection methods

- FCI could be used for risk categorisation of farms/batches. To achieve this, the system needs further development to include additional information, e.g. appropriate indicators for the main public health hazards.

- *Ante-mortem* inspection can help to detect animals heavily contaminated with faeces, and to assess their general health status, therefore no adaptations are required.

- It is proposed that palpation and incision used in current *post-mortem* inspection should be omitted in animals subject to routine slaughter, as they don’t contribute to control the main meat-borne hazards, and because of the potential risk of microbial cross-contamination.

- Elimination of abnormalities on aesthetic/meat quality grounds can be ensured through *meat quality assurance* systems.
1. To propose a definition of carbapenemase-producing bacterial strains and genes relevant for PH and linked to FP-animals

2. To review the information on the epidemiology

3. To analyse the methods for detection (isolation and identification) and characterisation of bacteria, encoding genes and associated mobile elements.

4. To make recommendations for a harmonised monitoring

5. To identify possible means of preventing or minimising the further emergence and spread of carbapenem-resistant bacterial strains transmitted via the food chain, including advantages and disadvantages of different options.
Resistance to carbapenems is an emergent and highly sensitive public health issue, since it could leave few available therapeutic options for human patients

So far only a few studies have reported carbapenem-resistant bacteria in food-producing animals and none in derived food

Transmission of carbapenemase-producing bacteria or resistance genes through the food chain has not been reported but is considered likely

Specific targeted surveys should be conducted at EU level

Measures to prevent and minimising further emergence of this resistance need to be taken
METHODS

- **Targeted surveys** to detect CP producers **recommended**

- **Pre-enrichment** step in broth containing **meropenem**

- Determination of MICs:
  - for **meropenem**
  - based on epidemiological cut-off (ECOFF), as opposed to clinical breakpoints
    - = carbapenem non-susceptible

- Detection of **carbapenemase producers**

- Characterisation of **carbapenemases**
FOODS OF NON ANIMAL ORIGIN (FONOAO)

Risks posed by pathogens in FoNAO

- Part 1: outbreak data analysis and risk ranking of food/pathogen combinations (EFSA-Q-2012-00237)
- Part 2: specific food/pathogen combinations (EFSA-Q-2012-00238)
Conclusions ToR 1: to assess the PH risk posed by pathogens that may contaminate FoNAO and to compare the incidence of foodborne human cases linked to FoNAO and FoAO

<table>
<thead>
<tr>
<th>Outbreaks due to:</th>
<th>Total number of foodborne outbreaks (%)</th>
<th>Human cases (%)</th>
<th>Hospitalisations (%)</th>
<th>Deaths (%)</th>
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<tbody>
<tr>
<td>FoNAO</td>
<td>219 (10)</td>
<td>10,543 (26)</td>
<td>2,798 (35)</td>
<td>57 (46)</td>
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<tr>
<td>FoAO</td>
<td>2,065 (90)</td>
<td>30,230 (74)</td>
<td>5,090 (65)</td>
<td>68 (54)</td>
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<td>Total</td>
<td>2,284</td>
<td>40,773</td>
<td>7,888</td>
<td>125</td>
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</table>

- Excluding the VTEC O104 outbreak data, FoNAO still caused 10% of the outbreaks, 18% of cases, but only 8% of the hospitalisations and 5% of the deaths.

- General tendency for the outbreaks associated with FoNAO to involve more cases and to be less severe than those associated with FoAO.
Approach ToR 2: to identify and rank specific food/pathogen combinations most often linked to foodborne human cases from FoNAO in the EU

Multi criteria analysis model
risk ranking combinations of FoNAO commodities and specific pathogens
(adaptation of a Risk Ranking Tool developed by the US FDA)

Criteria
1. Strength of associations between food and pathogen
2. Incidence of illness
3. Burden of disease
4. Dose-response relationship
5. Consumption
6. Prevalence of contamination
7. Pathogen growth potential during shelf life

Per food/pathogen combination
score $Crit_1 + score Crit_2 + \ldots + score Crit_7 = \text{total risk score}$
FONAO: PART 1 (OUTBREAK DATA ANALYSIS / RISK RANKING)

ToR 2: Model output (reference scenario): Top 5 food/pathogen combinations

<table>
<thead>
<tr>
<th>Reference scenario 1 including all criteria</th>
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<tr>
<td><strong>Ranking position</strong></td>
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ToR 3: To identify the main risk factors for the specific food/pathogen combinations identified under ToR 2, including agricultural production systems, origin and further processing.

ToR 4: To recommend possible specific mitigating options and to assess their effectiveness and efficiency to reduce the risk for humans posed by food/pathogen combinations identified under ToR 2.

ToR 5: To recommend, if considered relevant, MC for the identified specific food/pathogen combinations throughout the production chain.
Timelines

EFSA is requested to provide opinions in line with the agreed terms of Reference 3 to 5 (EFSA-Q-2012-00237) for the following food/pathogen combinations with a similar production system:

1. The risk from *Salmonella* and *Norovirus* in leafy greens eaten raw as salads. Cutting and mixing before placing on the market should be included as potential risk factor and specific mitigation options proposed if relevant.

2. The risk from *Salmonella*, *Yersinia*, *Shigella* and *Norovirus* in bulb and stem vegetables, and carrots.

3. The risk from *Salmonella* and *Norovirus* in tomatoes.

4. The risk from *Salmonella* in fruit and vegetables grown on soil, intended to be eaten raw (melons, cucumber).

5. The risk from *Salmonella* and *Norovirus* in berries.

**Deadlines:**
- 31 March 2014
- 31 December 2014
- 30 September 2014
- 30 September 2014
- 30 June 2014
QUALIFIED PRESUMPTION OF SAFETY (QPS)

- EFSA-Q-2013-00019: the maintenance of the list of QPS biological agents intentionally added to food and feed (2013 update) (opinion published)

- EFSA-Q-2013-00009: Anticipation of future notifications to EFSA of microbial taxonomic units intentionally introduced into the food chain (report published)

- EFSA-Q-2014-00189: The maintenance of the list of QPS recommended biological agents intentionally added to food or feed as notified to EFSA (ongoing activity)
TSE/BSE

- EFSA-Q-2013-00336: Application for a revision of the annual monitoring programme for BSE from Norway (report published)

- EFSA-Q-2012-00577: Application for a revision of the annual monitoring programme for BSE from Norway (report published)

- EFSA-Q-2012-00247: Quantitative evaluation of BSE risk in bovine intestines and mesentery (opinion published)

- EFSA-Q-2012-00647: Risk of transmission of scrapie via in vivo derived embryo transfer in ovine animals (opinion published)

- EFSA-Q-2012-00646: Scrapie situation in the EU after 10 years of monitoring and control in sheep and goats (ongoing activity)
APPLICATIONS

- Animal-By-Products
  - EFSA-Q-2013-00609: Application for EFSA approval sought for on-farm containment using BIOREDUCTION (opinion published)

- Decontamination treatments
  - EFSA-Q-2013-00601: Evaluation of the safety and efficacy of peroxyacetic acid solution for reduction of pathogens on poultry carcasses and meat (opinion published)
Two self task mandates from the BIOHAZ Panel

- Development of a risk ranking framework on biological hazards (EFSA-Q-2011-1178)
- Development of a risk ranking toolbox for the BIOHAZ Panel (EFSA-Q-2013-00014)
To evaluate the performance and the data requirements of the available risk ranking tools.

To investigate methodologies for introducing uncertainty and variability in the risk ranking models.

To design and develop a risk ranking toolbox for the EFSA BIOHAZ Panel

Ongoing activity; deadline: December 2014
MOLECULAR TYPING

Evaluation of molecular typing methods for major food-borne microbiological hazards and their use for attribution modelling, outbreak investigation and scanning surveillance

- Part 1 (evaluation of methods and applications (EFSA-Q-2013-00032)
- Part 2 (surveillance and data management activities) (EFSA-Q-2013-00906)
EFSA-Q-2012-00752: The public health risks related to the *mechanically separated meat (MSM)* derived from poultry and swine (opinion published)

EFSA-Q-2012-00576: *VTEC-seropathotype* concept and scientific criteria regarding pathogenicity assessment (opinion published)

EFSA-Q-2013-00646 and 00648: The public health risks related to the *maintenance of the cold chain* during storage and transport of meat

EFSA-Q-2013-00400: The public health risks of eggs due to deterioration and development of pathogens (ongoing activity)

EFSA-Q-2013-01026: The public health risks related to the consumption of *raw drinking milk* (ongoing activity)
ACKNOWLEDGEMENTS

■ The experts of the BIOHAZ Working Groups

■ The BIOHAZ Panel members:
  ■ Olivier Andreoletti, Dorte Lau Baggesen, Declan Bolton, Patrick Butaye, Paul Cook, Robert Davies, Pablo S. Fernandez Escamez, John Griffin, Tine Hald, Arie Havelaar, Kostas Koutsoumanis, Roland Lindqvist, James McLauchlin, Truls Nesbakken, Miguel Prieto Maradona, Antonia Ricci, Giuseppe Ru, Moez Sanaa, Marion Simmons, John Sofos and John Threlfall.

■ The current BIOCONTAM staff:
  ■ Liebana Ernesto, Messens Winy, Correia Sandra, Da Silva-Felicio Maria Teresa, Michaela Hempen, Romero-Barrios Pablo, Stella Pietro
Questions?