



Emerging Risks Identification: an appraisal of the approaches trialled by EFSA

Andrea Altieri, 3-4/06/2014

OUTLINE

1. Mandate of EFSA on Emerging Risks
2. Approach to emerging risks identification
3. Results
4. Lessons learnt
5. Feedback to IRGC protocol





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



... THROUGHOUT THE WORKFLOW



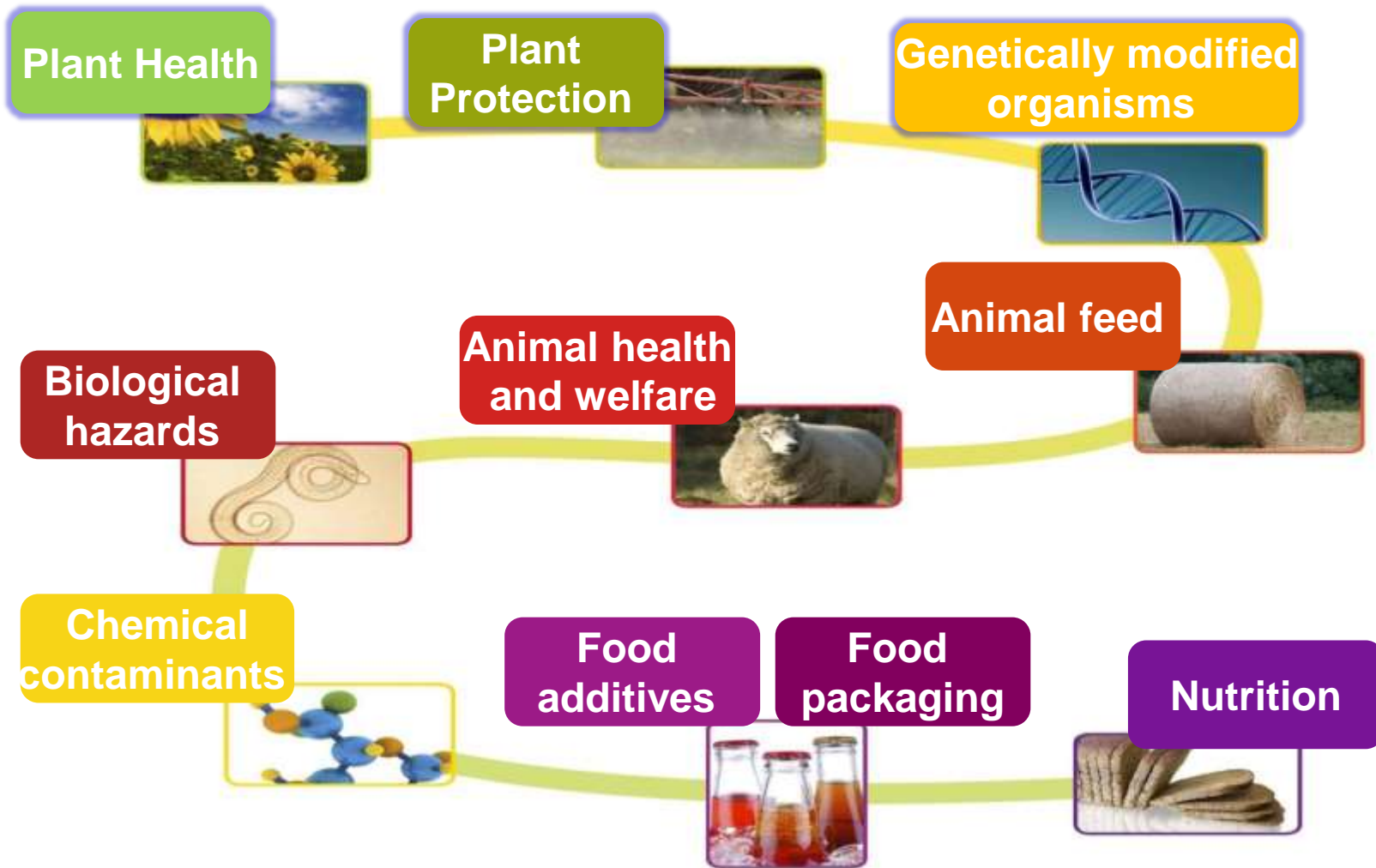
EFSA
receives question

EFSA's scientists evaluate, assess, advise

Adoption and
communication



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



LEGAL BASIS ON EMERGING RISKS


REG. 178/2002 Laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety

Article 34

Identification of emerging risks

1. The Authority shall establish **monitoring** procedures for systematic searching for, **collecting, collating** and **analysing** information and data **with a view to the identification of emerging risks** in the fields within its mission.
2. Where the Authority has information leading it to **suspect an emerging serious risk**, it shall request additional information from the Member States, other Community agencies and the Commission.
3. The Authority shall **use all the information it receives** in the performance of its mission to identify an emerging risk.
4. The Authority shall **forward the evaluation and information collected** on emerging risks to the European Parliament, the Commission and the Member States.

DEFINITION OF EMERGING RISK

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- New hazard
 - New exposure
 - Increased susceptibility
 - Differentiation between
 - Emerging issue = suspicious of a serious risk
 - Emerging risk
 - Risk

ESFA, 2007. Definition and description of « emerging risks » within the EFSA' s mandate. Statement of the Scientific Committee, 10 July 2007.

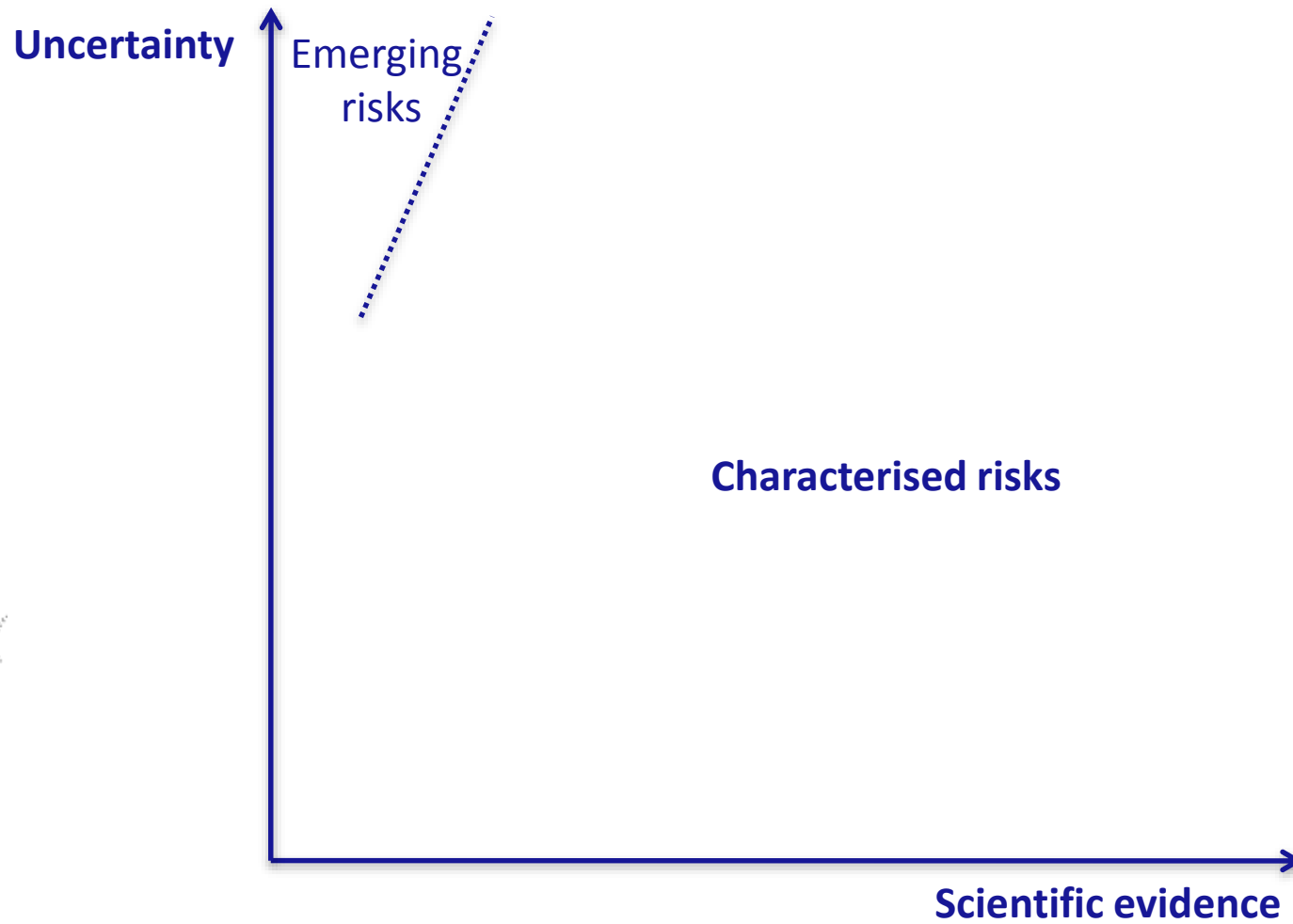
WHAT DO WE HOPE TO ACHIEVE ?

Early identification of new problems (not necessarily incidents or crises), to better anticipate risk assessment needs:

- New and emerging hazard or drivers
- New research issues
- New risk assessment methodologies



EMERGING RISKS VS. CHARACTERISED RISKS



KEY PLAYERS

- The Member States **Network** is currently composed of delegates from 21 Member States and Norway and observers from the European Commission, EU pre-accession countries, the FDA and FAO.
- **StaCG-ER** is composed of EU-wide stakeholder organisations working in areas related to the food chain. The selection of members for StaCG-ER was based on the individual expertise of the nominees, and to ensure a balanced representation of both industry and consumers.
- The **SC's SWG on Emerging Risks** was created in 2013 and includes representatives from EFSA Panels.
- **EC**

CAPACITY DEVELOPMENT

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- **Emerging Risks Identification (ERI)**
 - Develop methodology and procedures (e.g. best practices for ERI);
 - Data collection and tool development (e.g. Sc. Lit, RASFF, Media, Experts);
 - Evaluation and prioritisation;
 - Exchange of information (e.g. MS-Network, Stakeholders, Experts);
 - **Preparedness for Urgent Advice**
 - EFSA crisis handling procedures;
 - EFSA crisis preparedness activities;

APPROACH PROPOSED BY WG ON METHODOLOGY

1. Identification of priority issues

Performed by SCER and Scientific Committee WG

Emerging issues are identified through e.g. Consultations with experts, MS Network, Stakeholders

Prioritization based on a set of agreed criteria, including the EFSA definition of ER

Output 1: first priority list

2. Identification of Data Sources and Data collection

Performed by EMRISK

Data collection focused on selected emerging issues identified and resources available

Prioritization based on a set of agreed criteria, including the EFSA definition of ER

Output 2: first priority list

3. Final Evaluation: Emerging Risks Identified

Performed by EMRISK and Scientific Committee WG

Output 3: emerging risks and recommendations for possible actions



RESULTS

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- **1st pilot (~16 months):**
 - 75 data sources monitored
 - Criteria (Novelty, Soundness, Imminence, Scale, Severity)
 - ~ **2200** issues evaluated using an expert judgment approach
 - **158 issues** identified
 - **12 signals** prioritised for follow-up activities
 - **2nd pilot (~20 months):**
 - Non systematic monitoring of sc. literature and expert consultations
 - Criteria (Novelty, Soundness, Imminence, Scale, Severity)
 - **45 issues** evaluated using an expert judgment approach
 - **14 issues** prioritised for follow-up activities

EXAMPLES OF ISSUES EVALUATED 2012-2013

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- Potential chemical contamination of food from recycled paper
 - Zoonotic viruses associated with illegally imported wildlife products
 - First report on indigenous ciguatera fish poisoning in the EU
 - *Salmonella* in paan (betel) leaves
 - Indian milk adulteration
 - Increased use of banned, unauthorised and counterfeit pesticides
 - Combined toxicity of melamine and cyanuric acid
 - Mycotoxins in Swedish crops
 - Under-reporting of foodborne norovirus in older adults
 - Drivers and pathways of antimicrobial resistance: foodborne extended-spectrum beta-lactamase (ESBL)
 - Zoonotic potential of Usutu virus
 - Colorectal cancer and possible link with dietary and cooking habits of red meat consumption
 - Animal illnesses linked to jerky pet treats
 - PPCPs in the environment and possible human exposure through the food chain
 - Potential contamination of the food/feed chain from industrial and environmental chemical contaminants with certain characteristics (i.e. volume of production, dispersive use..)
 - Insects used as food and feed
 - Alternatives to bisphenol A for food contact material applications
 - Food chain contamination from environmental pollution of micro plastic particles
 - Possible applications of synthetic biology in the food chain
 - *Clostridium difficile* as a potential zoonotic or foodborne pathogen
 - Lumpy skin disease
 - Cyanotoxins contamination in food
 - Masked mycotoxins
 - 3d-food printing
 - Extraintestinal pathogenic *Escherichia coli* (ExPEC)
 - *Opisthorchis felinus* in Italy
 - Cinnamon challenge: consumption of large quantities of cinnamon within a short time
 - Increased norovirus activity associated with emergence of a new variant of genotype II
 - Imported flowers as a vector for spreading honey bees infectious

ACTIVITIES


Closed

- Emergence of aflatoxins in cereals in the EU due to climate change Climate change
- European-wide survey on energy drinks
- Multiple stressors in bees

Ongoing

- Cyanotoxins in food
- Chemical mixtures
 - Toxicity of exposure to **multiple chemicals** in bees
 - **Metabolic interactions** and **synergistic effects** of chemical mixtures for human risk assessment
- Human biomonitoring and biomarkers
- Industrial chemical contaminants in the food chain (ECHA)
- Review of non-monotonic dose-responses of substances for human risk assessment

ACTIVITIES ON NEW METHODS AND TOOLS

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- **Medisys** customisation
 - Evaluation of a system for the scanning of Eurostat's data to detect **trends in trade**
 - **Omics** technologies in risk assessment
 - Pilot study for the identification of **emerging biological risks**
 - A procedure for the identification of **chemical risks**
 - Modern methodologies for **human chemicals hazard assessment**
 - **Chemical mixtures**
 - A framework for the risk assessment of **chemical mixtures**
 - **Combined toxicity of multiple chemicals:** Evidence-based approach for **Animal Health** and **Ecological Risk Assessment** using Systematic Review


"VALIDATION"

Issues identified recently addressed by the Scientific Committees of the European Commission or by EFSA:


- Synthetic biology (EC SCENIHR)
- Caffeine intake (NDA)
- Pollen and virus-like organisms (PLH)
- Micro-plastic particles in marine animals (CONTAM)
- Lumpy skin disease (AHAW)




WHAT HAS WORKED

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- Identification of some relevant **issues**
 - **Expertise and networking** are a vital part of the process, particularly for filtering signals
 - **Briefing notes** to exchange and evaluate information
 - **Sharing information** without creating unnecessary scares
 - **Focused monitoring** and **follow-up activities**

WHAT NEEDS TO BE IMPROVED

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- **Definitions** and **methodological approach**
 - “New” **hazard**
 - **Declaration of:** emerging risk identified
 - **Expert elicitation**
 - **Data gaps and uncertainty**
 - **Holistic monitoring** for signals of emerging risks is not very efficient (resource demanding, producing a modest number of signals)
 - The monitoring priority should be on **non-regulated areas** and not previously assessed hazards rather than changing exposure to known hazards.
 - **Buy-in**

COMMENTS TO IRGC PROTOCOL

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- Comprehensive
 - Risk Assessment and Risk Management
 - Definition of threats (hazard based)
 - Identification of threats
 - Data gaps and uncertainty
 - Corporate culture of future studies
 - Scenario development



Thank you very much for your attention!

