European Food Safety Authority

Assessment Methodology Unit
Activities carried out and ways of cooperation

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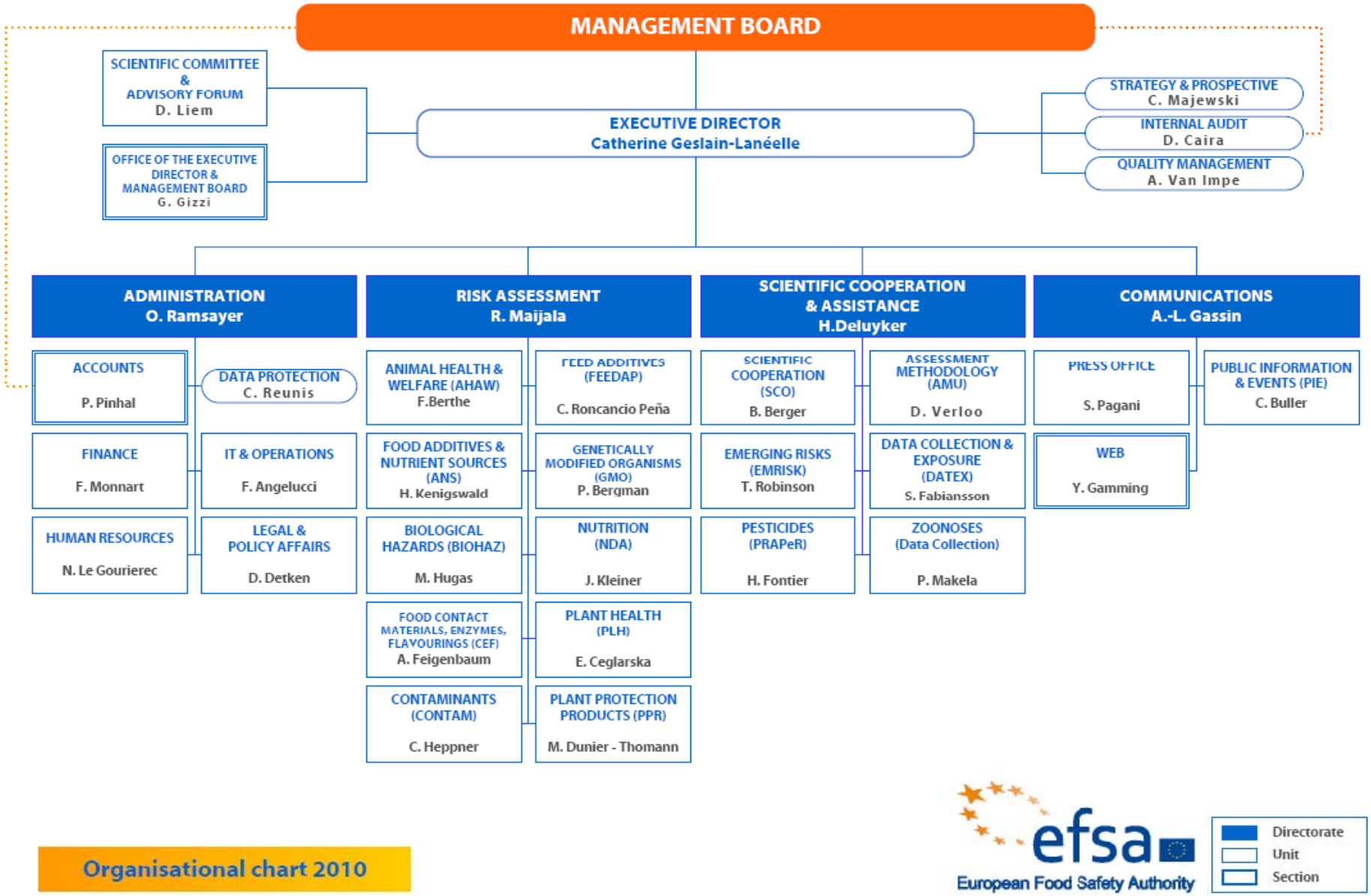
Head of Assessment Methodology Unit

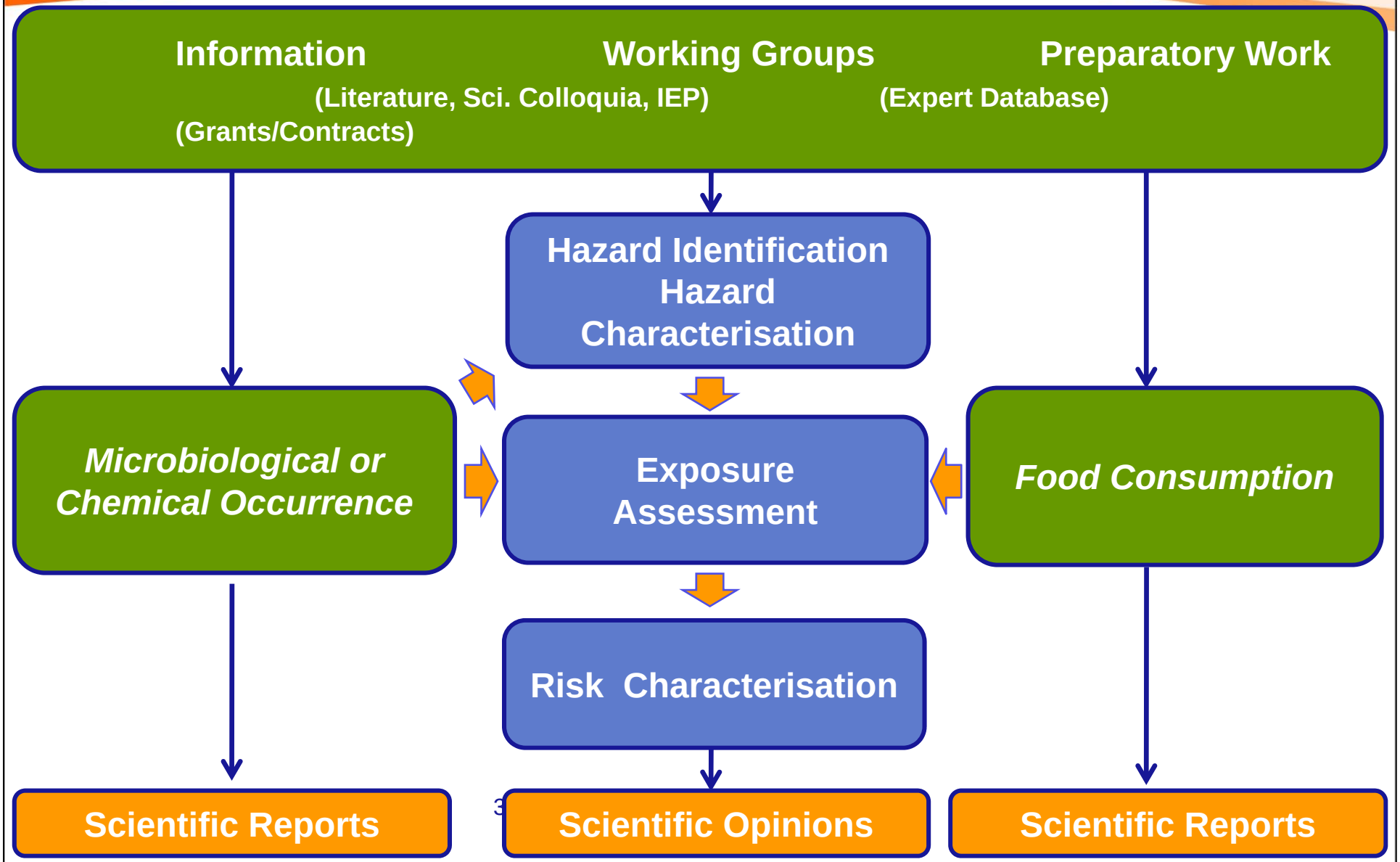
Stakeholders consultative platform, 22 June 2010, Parma



Organisational chart 2010

efsa
European Food Safety Authority

Workflow: SCA Support



Risk Assessment Workflow: SCA Support

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Information Work (Grants/Contracts) (AMU, SCO)

Working Groups (Literature, Sci. Colloquia, IEP) (SCO)

Preparatory (Expert Database) (SCO)

Hazard Identification (EMRISK-PRAPeR)
Hazard Characterisation (AMU-PRAPeR)

Chemical or Microbiological Occurrence (DATEX-PRAPeR-ZOONOSES)

Exposure Assessment (DATEX)

Food Consumption (DATEX)

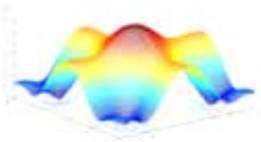
Risk Characterisation (AMU – PRAPeR)

Scientific Reports

Scientific Opinions

Scientific Reports

The Assessment Methodology Unit



The Assessment Methodology unit's mandates are to:

- develop and apply new or refined risk assessment and decision support approaches
- provide direct access to scientific literature for EFSA staff and experts

Task packages

- Quantitative decision support and statistical data analysis
- Advances in toxicological risk assessment methods
- Information retrieval from literature and classical library services
- Development of approaches to detect and predict emerging risks in animal health and plant

Hands on

- Collates and summarises data from scientific literature and existing databases
- Evaluates, revises and redo statistical and modelling methods used in risk assessments
- Carries out and supports epidemiological and statistical data analyses
- Develops or support the development of quantitative risk assessment and quantitative decision support tools for risk managers
- Contributes to the development and application of new or refined risk assessment approaches

The AMU team

15 persons

- Multidisciplinary (veterinary epidemiology, mathematics, statistics, toxicology, nutrition, chemistry, data management, information specialist)
- In 2008, 2009 and 2010 AMU had projects with ALL panels and units in EFSA
- ‘Methodological’ is common denominator

Outputs AMU

http://www.efsa.europa.eu/en/panels/amu.htm

Examples of ongoing projects in the different task packages



Quantitative decision support and statistical data analysis

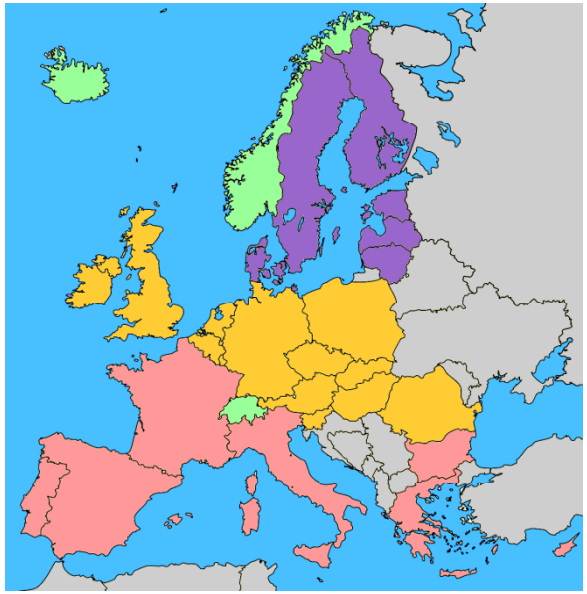
Ongoing projects: statistical support to different units

- Review of key studies for applicant dossiers:
  - Methods (e.g. randomization, blinding, sample size and statistical methods)
- Communication of findings (written and oral) to WG's, Panels.

Ongoing projects: data collection support to PPR protected crops WG

- Request to develop a new Guidance document on emissions from protected crop systems (greenhouses etc.)
- Definition of a data model to harmonize existing information and data collections
- Establishment of an inventory of protected crop structures in Europe
- Data were collected
  - from literature review (offical statistics)
  - through internet questionnaires (ongoing procurement for Central EU to Campden Technology Limited, UK)

Input from Growers and Growers Associations is important and necessary



European regions for data collection on protected crop systems:

North, Central and South



Advances in toxicological risk assessment methods

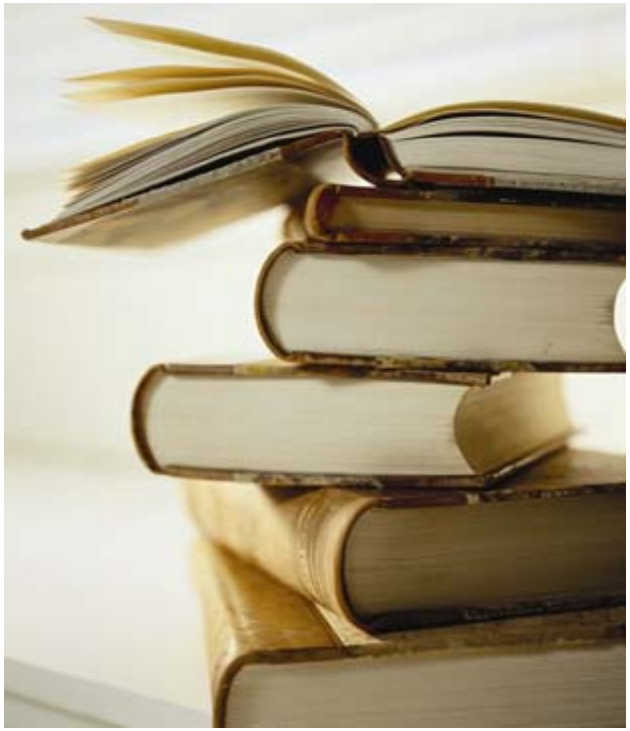
Ongoing project: Isoflavones WG

- Report characterising the potential hazards and health benefits associated with isoflavone consumption by December 2010;
- To serve a decision on a possible mandate for a full risk assessment of the consumption of isoflavones and isolated isoflavone supplements
- Should the review identify a lack of key information, the need for further research will be highlighted.

Data collection

- General horizon scanning of the European market for isoflavone rich products including soy infant formulae;
- Integration of questionnaire data provided by industry
- Market volume: data obtained from two market research organisations
- Dietary and supplement compositional information to be extracted from the database literature to inform report writing and future recommendations

Stakeholders involvement



Information retrieval from literature and classical library services

Ongoing project: Systematic review (SR)

- OBJECTIVES: to assess
  - if and how SR are applicable to risk assessment (RA) in food and feed safety
  - advantages and disadvantages of SR in this field
- DELIVERABLES:
  - EFSA Guidance document on the Application of SR methodology to food and feed safety assessments in support of decision making (published in May 2010)
  - Workshop for EFSA Panel members and staff (23-25 Feb 2010)
- SR IMPLEMENTATION PLAN:
  - EFSA-tailored SR trainings for EFSA experts and staff
  - EFSA-tailored web-based software for SR
  - Library support (Information Specialists and support in collecting information via EFSA Library information sources)
  - Repository for FAQ on SR and RA in food and feed safety

EFSA Guidance on Submission of scientific peer-reviewed open literature for the approval of pesticide active substances under Regulation (EC) No 1107/2009

- OBJECTIVE: to provide instructions on how to identify and select "scientific peer-reviewed open literature on the placing of plant protection products on the market and how to report it in a dossier.
- APPROACH: Guidance is based upon the principles of systematic review,

Compatible with existing OECD guidance for the preparation of active substances dossiers.

- COMPLETION of the Guidance: June 2010.

Guidance for applicants, MS's and EFSA

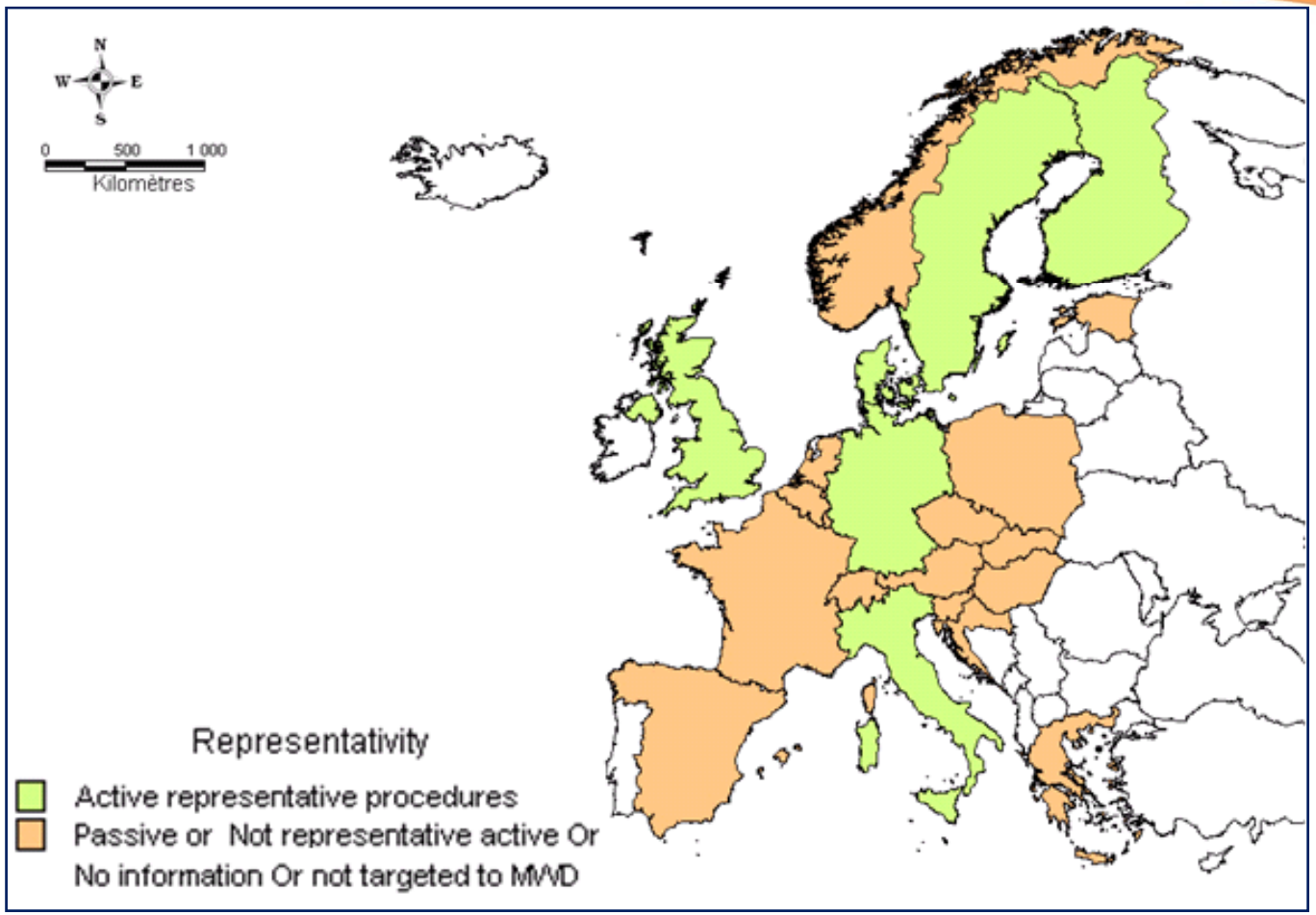


Development of approaches to detect and predict emerging risks in animal health and plant health

Example: Honey bees Colony losses

- Description and critical analysis of surveillance programmes; recommendations for the improvement and harmonisation at the European level
- Collection and analysis of the epidemiological dataset on colony collapse, weakening and mortality, stemming from the existing surveillance programmes
- Critical review and selection of relevant literature on the possible causes of honey bee colony collapse, weakening and mortality
- The global objective of the project was to facilitate future epidemiological research and surveillance programmes at EU level

Surveillance Networks Analysed



Recommendations

- Establishment of a sustainable European network for coordination and follow-up of surveillance on colony losses to underpin monitoring programmes
- Strengthen standardization at European level by harmonization of surveillance systems, data collected and by developing common performance indicators
- Build on the examples of best practice found in existing surveillance systems for communicable and notifiable diseases already present in some countries
- Undertake specific studies that build on the existing work in progress to improve the knowledge and understanding of factors that affect bee health
- The set up of the coordination team at European level.

Involvement of stakeholders

- Project coordinators –P. Hendrix, M-P. Chauzat, M. Debin (AFSSA)
- Experts from COLOSS – M. Brown, Y. Le Conte, F. Mutinelli, A. Gregorc, W. Ritter, P. Neumann, I. Fries
- COGECA “Honey working group”

Thank you for your attention

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Questions?