Implementing General Principles and Approaches in Chemical RA in the EU since the adoption of Regulation (EC) 178/2002

Djien Liem
Lead Expert in International Scientific Cooperation

efsa
European Food Safety Authority

www.efsa.europa.eu

OUTLINE

1. Chemical RA in EFSA
2. General principles
3. Challenges 2017-2020

OUTLINE

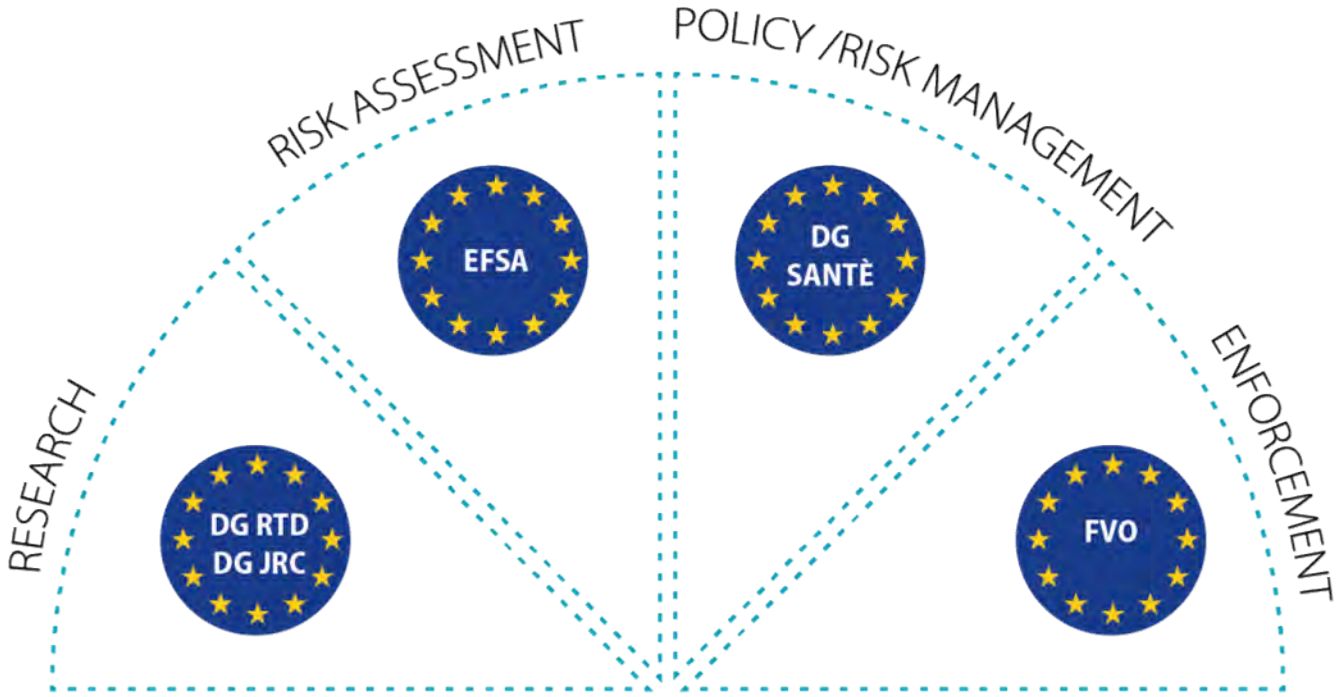
1. Chemical RA in EFSA
2. General principles
3. Challenges 2017-2020

EU FOOD SAFETY POLICY – MAIN ELEMENTS

- From **Farm to Fork** approach
- Based on sound **scientific advice**
- Comprehensive **legislation** on:
  - food & animal feed safety;
  - food hygiene; animal health & welfare;
  - plant protection;
  - clear information on content and origin of food
- **Enforcement** & checks

RISK ANALYSIS PRINCIPLE AT EU LEVEL

FOOD SAFETY INSTITUTIONAL SET UP IN THE EU



HEADQUARTERS
in the **heart of Parma**

EFSA IS TASKED TO

EFSA'S ROLE

WHAT Efsa does

- Scientific advice on:
  - food-related risks,
  - dietary issues,
  - animal health & welfare and plant health
- Risk communication

EFSA DOES NOT DO

- Food safety policies and standards
- Pre-market authorization of new products
- Enforcement/control
- Labelling
- Food quality

HOW EFSA WORKS

ADVISE

EU Commission

EU Parliament

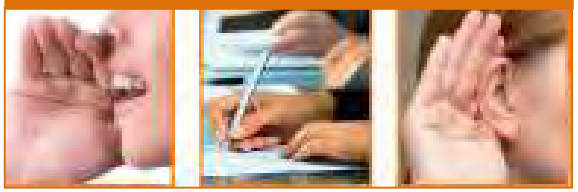
Member States

EFSA self mandate

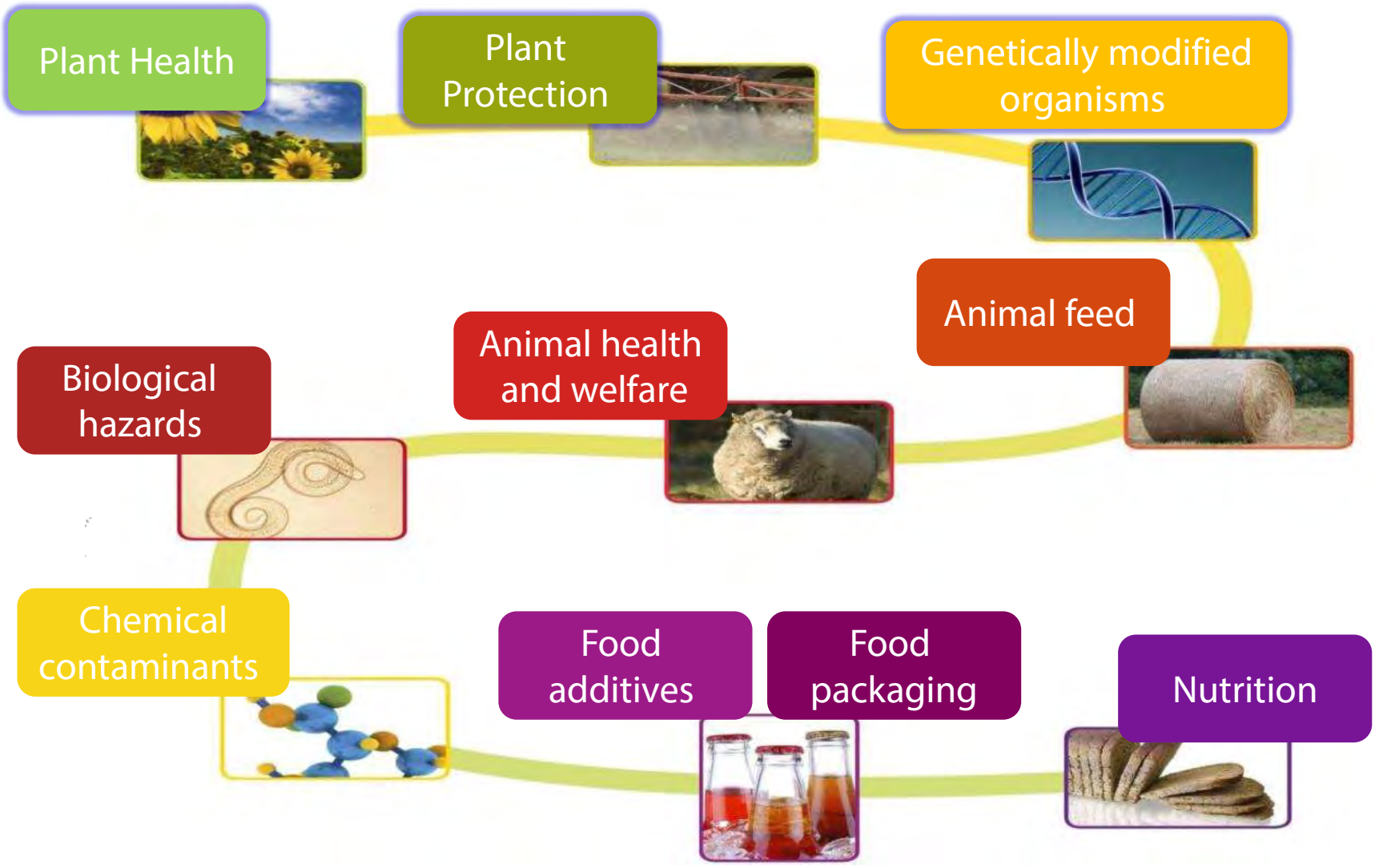
EFSA receives a question

EFSA's scientists evaluate, assess, advise

Adoption and communication



THE SCIENTIFIC PANELS



SCIENTIFIC COMMITTEE AND PANELS

Scientific Panels

- 10 Scientific Panels (thematic remit)
- 21 scientists selected on the basis of proven excellence
- Open meetings, transparent work
- Mandatory commitment to independence

Scientific Committee

- 10 Chairs of Scientific Panels plus 6 top level independent scientists
- Horizontal scientific issues, consistency of scientific opinions, harmonised methodologies

EFSA'S SCIENTIFIC OUTPUTS

Advice on:

- Generic Health Issues
- Regulated Products
- Emerging Risks

Tools for Risk Assessment:

- Guidance
- Methods

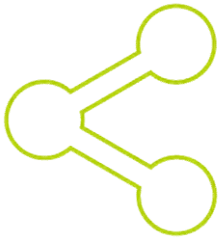
Reports

WHO'S BEHIND EFSA'S ACTIVITIES?

450 staff

1 Scientific Committee &
10 Panels

1500 experts



1 Advisory Forum &
15 Scientific Networks

400 Research Institutes/Academia

SCIENTIFIC COOPERATION

Individual experts

National food safety organisations

International organisations

Research institutes & academia

efsa
European Food Safety Authority

PEOPLE

OUTLINE

1. Chemical RA in EFSA
2. General principles
3. Challenges 2017-2020

KEY CHEMICALS ASSESSED IN EFSA

- Contaminants
- Pesticides
- Vitamins and minerals
- Food additives and nutrient sources
- Feed Additives
- Food contact materials, Enzymes
- Flavourings and processing aids
- Proteins used in GMOs

CHEMICAL RISK ASSESSMENT: A BRIEF OVERVIEW

The four pillars of Risk Assessment

Hazard Identification

Hazard Characterisation

Exposure Assessment

Risk Characterisation

CHEMICAL RISK ASSESSMENT: A BRIEF OVERVIEW

HAZARD IDENTIFICATION

What health problems are caused by the chemical?

EXPOSURE ASSESSMENT

Levels in food, dietary exposure, relevant food groups, relevant populations, time trends

HAZARD CHARACTERISATION

ADME, acute to chronic toxicity, human data, genotox, reprotox, etc. Derivation of a health based guidance value (*e.g.* ADI)

RISK CHARACTERISATION

Relate **exposure** to **Health Based Guidance Value**

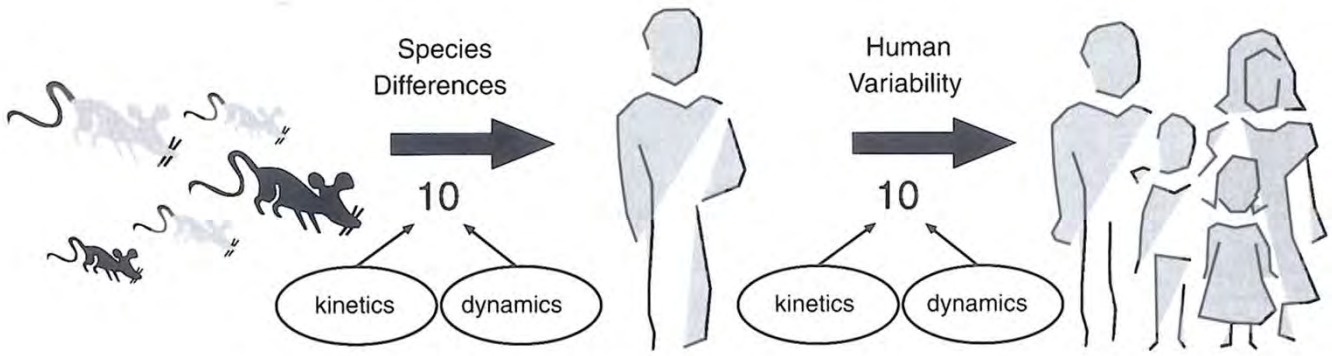
Risk Managers

Overview of the types of studies

- ADME – absorption, distribution, metabolism and excretion (toxicokinetics)
- Acute, sub-acute, and sub chronic in vivo studies
- Gene mutation and chromosome damage studies
- Carcinogenicity
- Fertility, Development, parturition, and post-natal development
- Special studies (e.g. hypersensitivity studies, local toxicity studies)

Typical approach

1. Take the most sensitive endpoint and species from a range of toxicological hazards.
2. Take the highest dose tested that does **not** cause toxicity (using the above endpoint).
3. Apply Uncertainty Factors (typically 100)



4. ADI = NOAEL/(UF)

EXPOSURE ASSESSMENT

Dietary exposure

Indirect methods

- Levels in food
- Food consumption
- Intake assessment
- Adults, children, etc

Direct methods

- Duplicate portion
- Adults, children, etc.

Non-dietary exposure

Inhalation

Ingestion

Dermal

EXPOSURE ASSESSMENT

Dietary exposure

Indirect methods

- Levels in food
- Food consumption
- Intake assessment
- Adults, children, etc

Direct methods

- Duplicate portion
- Adults, children, etc.

Non-dietary exposure

Inhalation

Ingestion

Dermal

DIETARY EXPOSURE ASSESSMENT - INDIRECT

Market basket/Individual foods method

Levels in *all* foods eaten by a *representative* consumer

DIETARY EXPOSURE ASSESSMENT - INDIRECT

Food consumption survey

Market Basket Survey

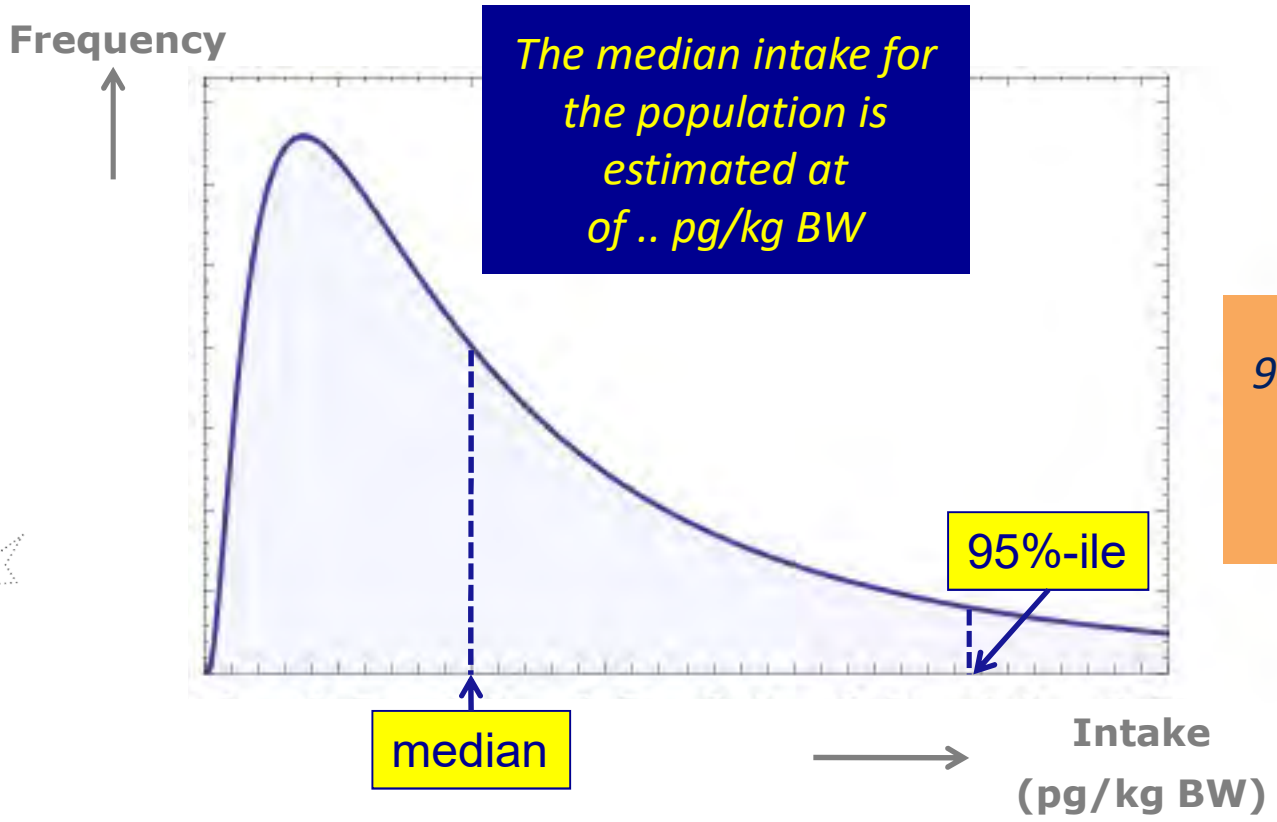
Food group	Concentration (pg/g fat)	Consumption (g of fat/day)	Intake (pg/day)
Beef	2.6	5	13
Pork	0.28	15	4.2
Poultry	2.3	1	2.1
Eggs	1.5	1.5	2.3
Fatty sea fish	35	0.4	14
…			
Total			115

A health concern?

Many critical issues

- **Food consumption:** age, representativity, within & between person variability, food supply, food habits, food choice, socio-economic factors, time trends
- **Sampling strategy:** representativity of foods selected, geographical distribution, proportion of imported vs primary production
- **Analytical measurements:** specificity, sensitivity, within and between lab reproducibility
- **Intake calculations:** mean, median, 95%-ile, age group, distribution, subpopulations, handling of nondetects

DIETARY EXPOSURE ASSESSMENT



95% of the population has an intake of up to .. pg/kg BW

CHEMICAL RISK ASSESSMENT: A BRIEF OVERVIEW

HAZARD IDENTIFICATION

What health problems are caused by the chemical?

EXPOSURE ASSESSMENT

Levels in food, dietary exposure, relevant food groups, relevant populations, time trends

HAZARD CHARACTERISATION

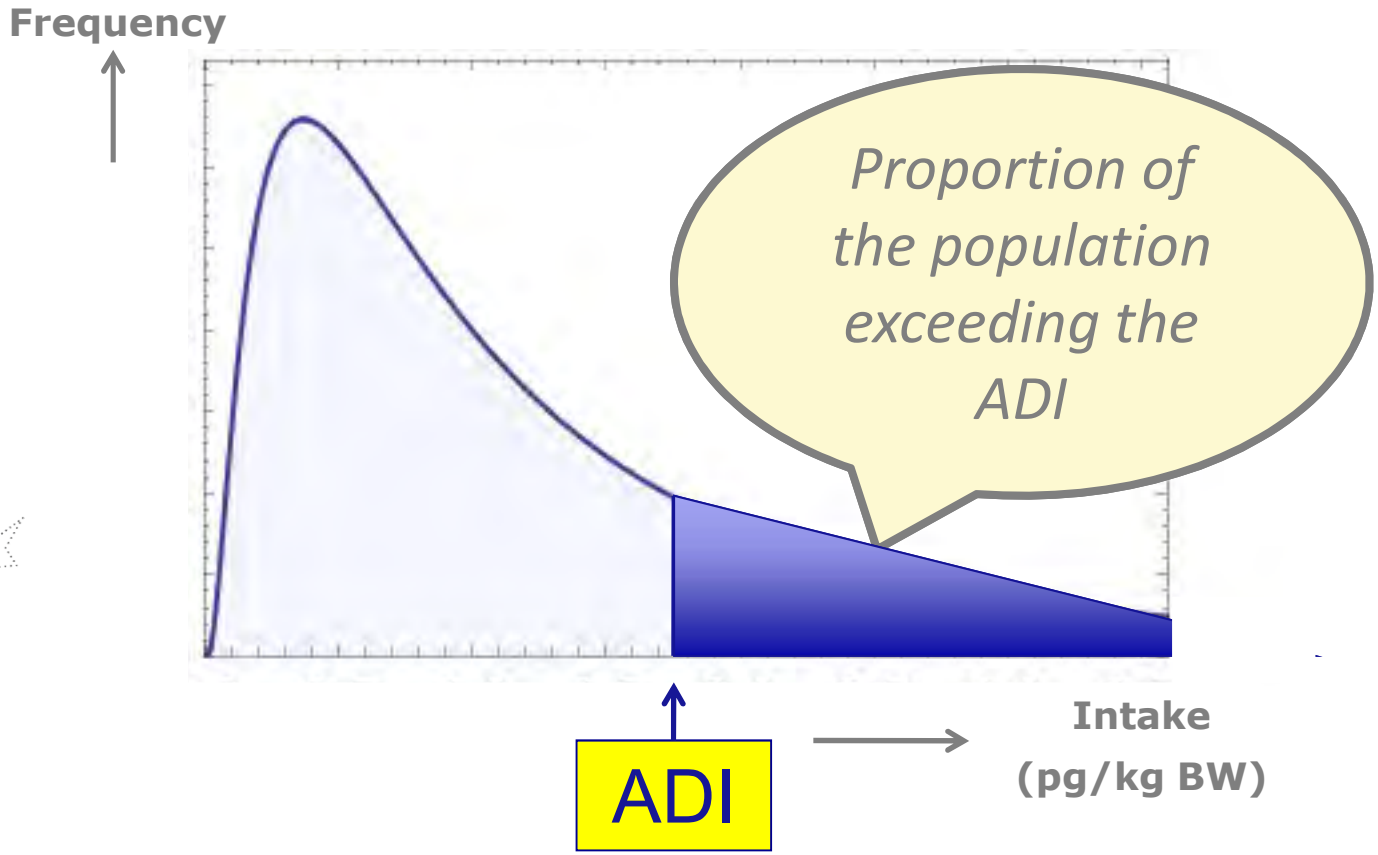
ADME, acute to chronic toxicity, human data, genotox, reprotox, etc. Derivation of a health based guidance value (*e.g.* ADI)

RISK CHARACTERISATION

Relate **exposure** to **Health Based Guidance Value**

Risk Managers

RISK CHARACTERISATION

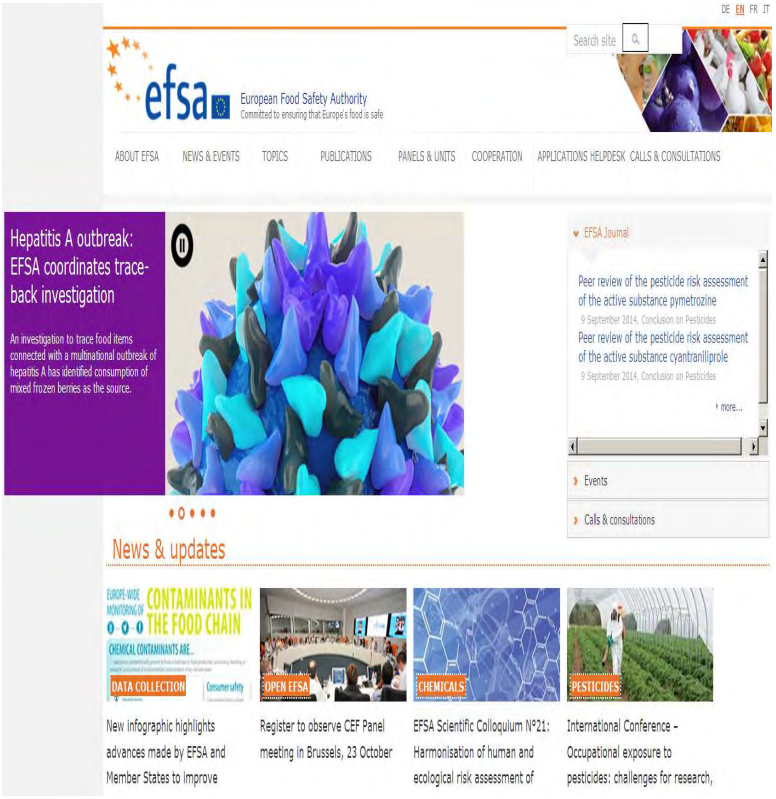


OUTLINE

1. Chemical RA in EFSA
2. General principles
3. Challenges 2017-2020

THE NATURE OF EFSA WORK IS CHANGING…

- More work on regulated products
- Not always predictable
- Increased calls for responsiveness, more efficiency
- Direct interest by industry, close scrutiny by other stakeholders
- More guidance, better services



… AND DIVERSIFYING INTO NEW AREAS

- Evaluation of the safety and environmental impact of new products
  - e.g. novel food, additives
- Development of new risk evaluation methods
  - e.g. nanotechnology, active and intelligent packaging
  - e.g. 'omics', less animal testing
- Evaluation of efficacy/ benefits
  - e.g. pesticides, claims

Sustainable innovation
=
safe, environmentally-friendly, backed by science

EU 2020

… AND NEW RISKS AND CHALLENGES ARISING

- Chemical mixtures/combined toxicity
- Emerging antimicrobial resistance
- Hazards linked to globalisation (plant pests, animal diseases, food-borne diseases outbreaks…)

CHALLENGES FOR ASSESSMENT PROCESS

Problem formulation

Which methods?
Clarity of the question?
Impartiality

Exposure Assessment

Hazard Identification
Hazard characterisation

Relevance
Reliability
of the data?

Risk Characterisation

Conclusions balanced?
Uncertainties?
Knowledge gaps?
Answer clear?
Timeliness?
Transparency?
Open data access?

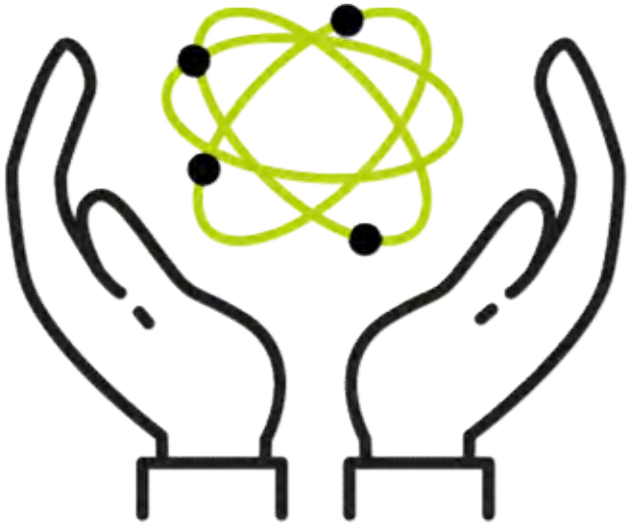
Risk Communication

GUIDANCE DEVELOPMENT

- Systematic review
- Transparency guidance (update)
- Guidance on handling of uncertainties
- Guidance on weight of evidence
- Guidance on biological relevance
- Guidance on RA of chemical mixtures
- Guidance on Environmental RA
- Guidance on BMD Approach (update)
- Guidance on Exposure Assessment (update)
- Implementing new RA methods

FUTURE CHALLENGES FOR RISK ASSESSMENT

FUTURE CHALLENGES FOR RISK ASSESSMENT



SCIENTIFIC EXCELLENCE

INNOVATION

FUTURE CHALLENGES FOR RISK ASSESSMENT

OPENNESS

INDEPENDENCE

MUCHAS GRACIAS POR SU ATENCIÓN