

## Welcome and introduction to EFSA

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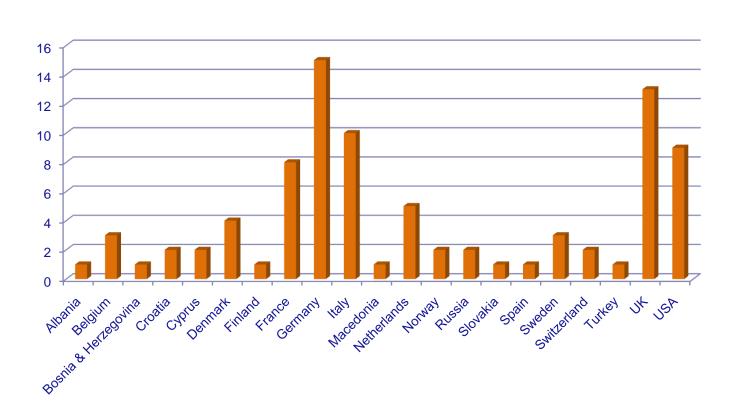
Scientific Evaluation of Regulated Products Directorate (REPRO)

EFSA's 17th Scientific Colloquium on low dose response in toxicology and risk assessment 14 -15 June 2012, Parma, Italy

# EFSA's 17th Scientific Colloquium: low dose response in toxicology & risk assessment efsa colloquium: European Food Safety Authority

## **WELCOME!**

## 87 participants from 21 countries



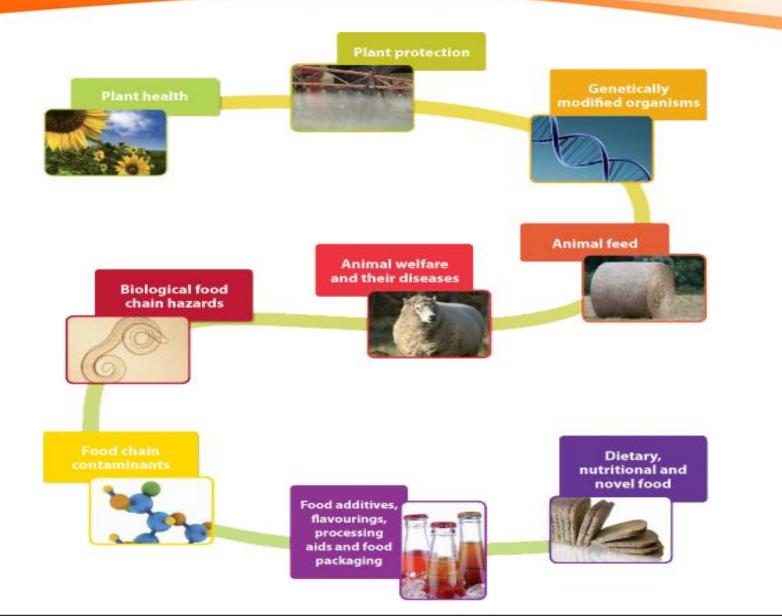
## **EFSA:** History and mission



 Set up in 2002 following a series of food crises – Reg. (EC) 178/2002

- Independent source of scientific advice responsible for risk assessment and risk communication on risks associated to food chain, animal health and plant health to support EU legislation/policies in all fields that impact food and feed safety
- Goal to be recognised as European reference body for risk assessment

# Scope: provide advice on safety of food and etsa feed throughout the food chain













**European Commission (EC)** 



**European Parliament** 



Member States (MS)



EFSA ("self mandate")

## **Question?**



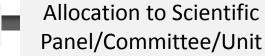
Risk Assessment
Risk Communication

10 Scientific Panels
1 Scientific Committee
16 Scientific Units

Examination



Acceptance



Register of questions



## **Scientific Committee and Panels**



## Scientific Committee (SC)

## Mainly opinions on applications

- Food additives and nutrient sources (ANS)
- Food contact materials, enzymes, flavourings (CEF)
- Feed additives (FEEDAP)
- Genetically modified organisms (GMO)
- Nutrition (NDA)
- Plant protection products (PPR) and PRAPeR unit

### Mainly generic opinions

- Biological hazards (BIOHAZ)
- Contaminants (CONTAM)
- Plant health (PLH)
- Animal health and welfare (AHAW)











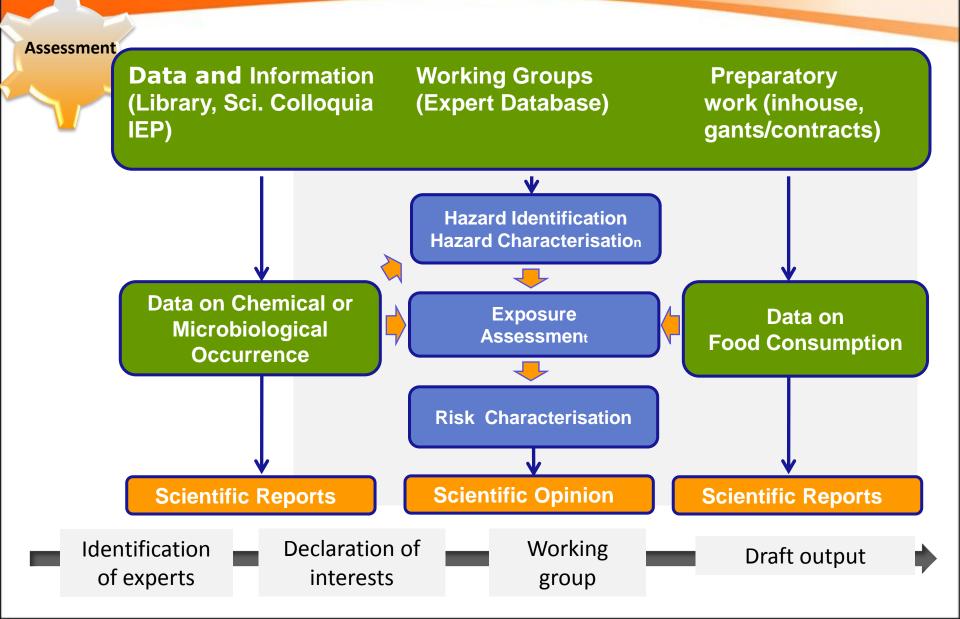
















- The Working Group submits its draft opinion for adoption to the Panel or Scientific Committee.
   Scientific reports (inhouse) follow approval procedure
- Adopted (Panel) or approved (EFSA) output is provided to the requesting body.
- Publication on the EFSA website
- Development of a suitable communication approach, e.g. media activities, profiling the issue on the EFSA website.
- Regular updates on the latest opinion: EFSA highlight

Adoption by the Panel/SC

Output to the requesting body

Publication of output on EFSA website

Communications



## Expert Database – Sign up today



## Sign up as an Expert





## Sign up and be an EFSA expert

- Want to make a difference to
   Value high profile networking EU food safety?
- Contribute to EU risk assessment?

EFSA invites leading scientists to sign up to its new expert database.

EFSA is the European Union's scientific risk assessment body on food and feed safety, nutrition, animal health and welfare, plant health and protection.

EFSA, in cooperation with Member States, has decided to set up a database of external scientific experts able to assist its Scientific Committee, Scientific Panels, EFSA networks

- with peers?
- Driven by excellence?

and respective working groups. EFSA will draw on this database to find experts to help deliver high-quality, independent and timely scientific advice.

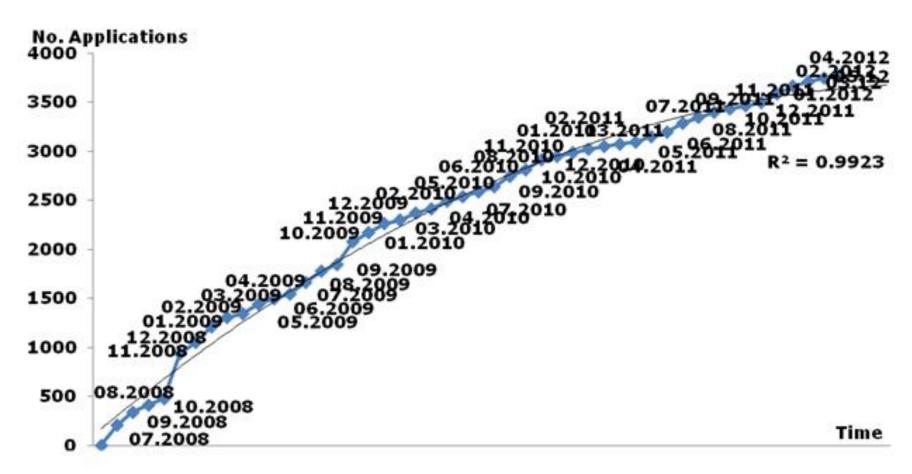
You can be part of that team of top scientists helping EFSA support Europe's decision makers in ensuring that Europe's food is safe.

#### How can I apply?

Simply visit the EFSA website and fill in the form at www.efsa.europa.eu

## Expert Database: current state-of-play efsa

## Application forms received as of 5 May 2012: 3.772



The four steps in the risk assessment paradigm



#### **Hazard identification**

- identification of adverse health effects
  - Human studies:
  - Animal-based toxicological studies
  - in vitro toxicology studies;
  - Structure-activity considerations;

#### Occurrence data

EFSA: E.U. Member States, Island, Norway, Switzerland and Liechtenstein

## Food consumption

Concise European Food Consumption Database

#### **Exposure assessment**

Deterministic vs. probabilistic approach

Adults, subgroups of population (e.g. children, infants, vegetarians, pregnant women etc

#### **Hazard characterisation**

- Selection of critical data set:
- Mode/mechanism of action;
- Kinetic variability
- Dynamic variability;
- Dose-response for critical effect
- Identification of starting point
- establishment of a health based guidance value (e.g. ARfD, TDI)



#### Risk characterisation

Relate exposure to Health Based Guidance Value or Margin of exposure (MOE)

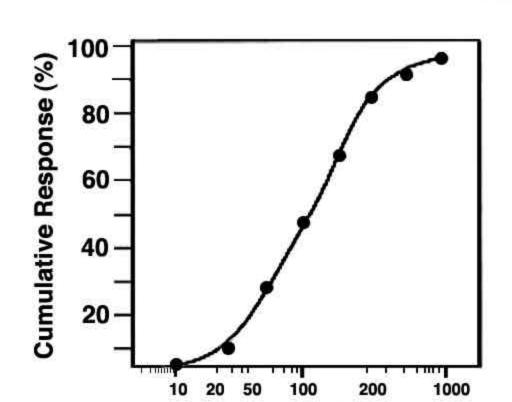
## Principles of toxicology



- "All substances are poisons: there is none which is not a poison. The right dose differentiates a poison and a remedy."

  Paracelsus (1493-1541)
- An understanding of the dose response relationship is important as a given substance could be at very low doses non-toxic, at intermediate doses toxic and at high doses lethal.

## Classical dose-response (monotonic) efsa

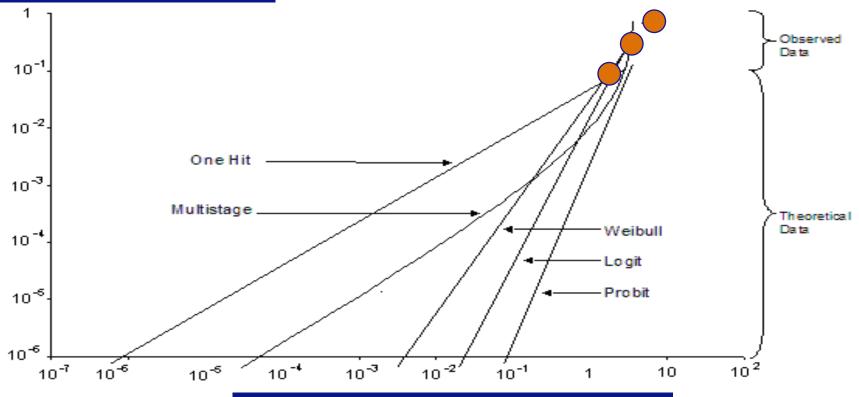


Dose (mg/kg)

# Extrapolation from observable range to low-dose exposure





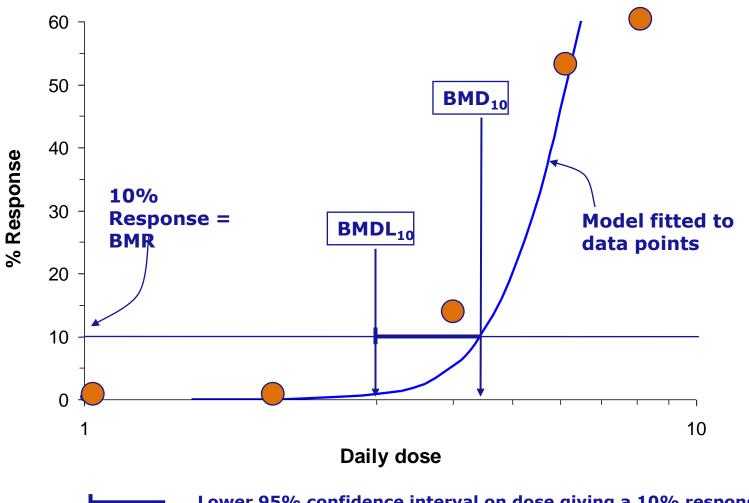


Dose (mg/kg bw per day)

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## Benchmark dose modelling

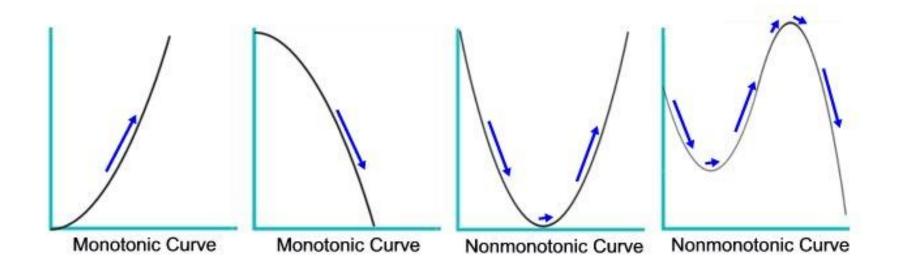




Lower 95% confidence interval on dose giving a 10% response

# Endocrine active substances: low dose effects (non-monotonic)





Challenge!











Thank you for sharing your expertise, and wishing you a fruitful and open debate!

## Safety



- If you hear the emergency alarm you must go immediately to the closest security exit (there are doors on both sides of the room).
- Once you are out of the room <u>please go</u> to the <u>meeting point in the courtyard</u> in front of the EFSA building and wait for instructions from EFSA's fire pickets.