



EFSA & the Panel on Contaminants in the Food Chain (CONTAM Panel)

Who is EFSA?

- European Union's **scientific risk assessment body** on food and feed safety, nutrition, animal health and welfare, and plant health and protection, tackling issues **all along the food chain**.
- Provides **science based risk assessments** supporting risk management related to food/feed safety.
- **Communicates** all scientific outputs publicly (communication task is shared with European Commission/Member States)



No responsibility for EU Food Law

No substitute for national authorities



- Formally **set up in 2002** as an independent source of scientific advice and communication on risks associated with the food chain (Regulation (EC) No 178/2002 **General Food Law**)
- Created as **part of a comprehensive programme** to:
 - improve EU food safety
 - help ensure a **high level of consumer protection**
 - **restore and maintain confidence** in the EU food supply
- Started its scientific work in 2003 in Brussels and moved to Parma in 2005
- Budget 2013 of 78 Million Euros
- Over 450 staff, 60% engaged in science
- Since 2003 about 3300 scientific outputs

EFSA Governance

**Management
Board**



**Advisory
Forum**



EFSA Staff

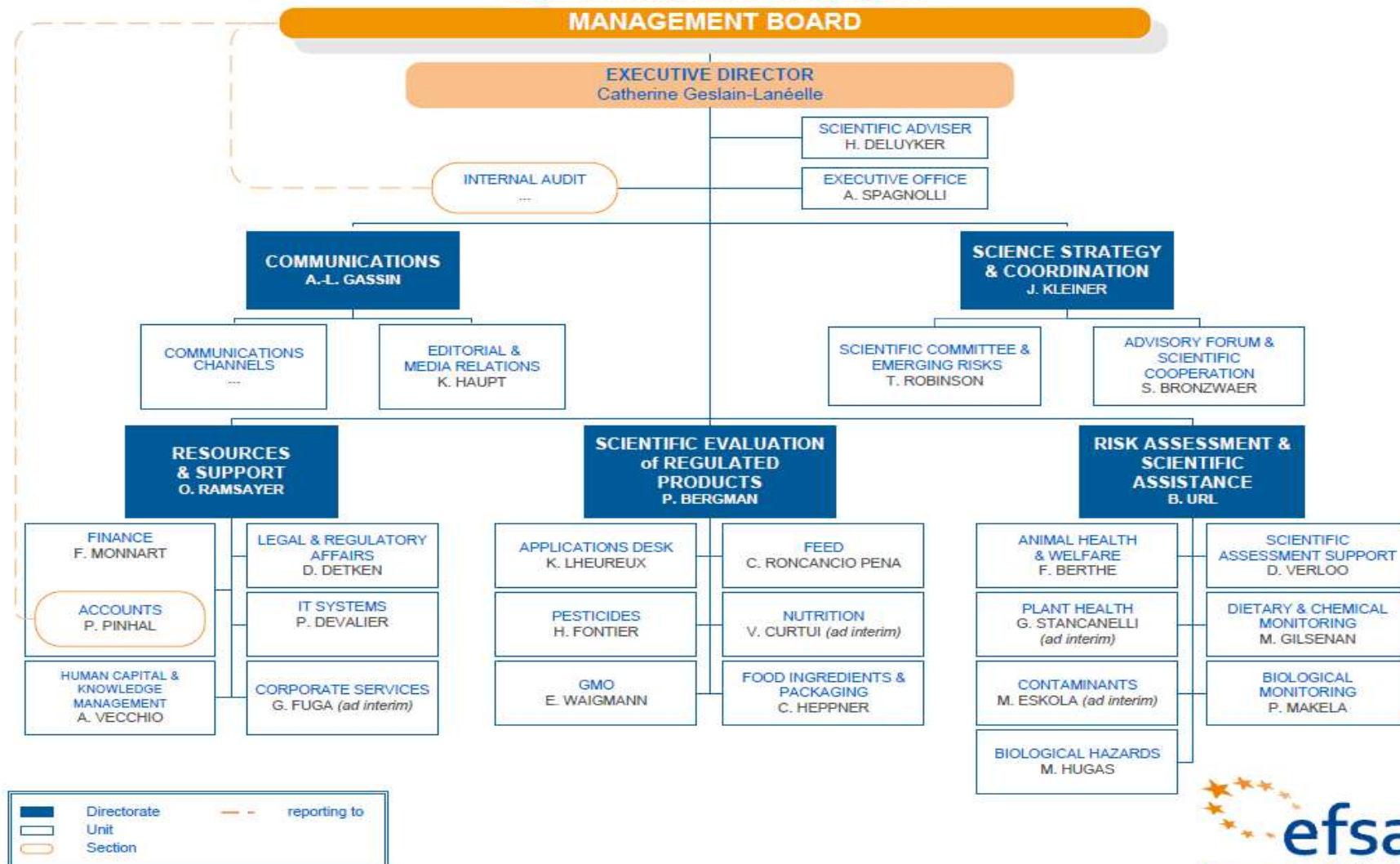


**Scientific Committee
and Panels**



EFSA Organisational structure

Organisational Structure on 16/05/2013



How EFSA works



EFSA receives a question

EFSA's scientists evaluate, assess, advise



Adoption and communication

EFSA JOURNAL



EFSA JOURNAL

10 Scientific Panels and Scientific Committee

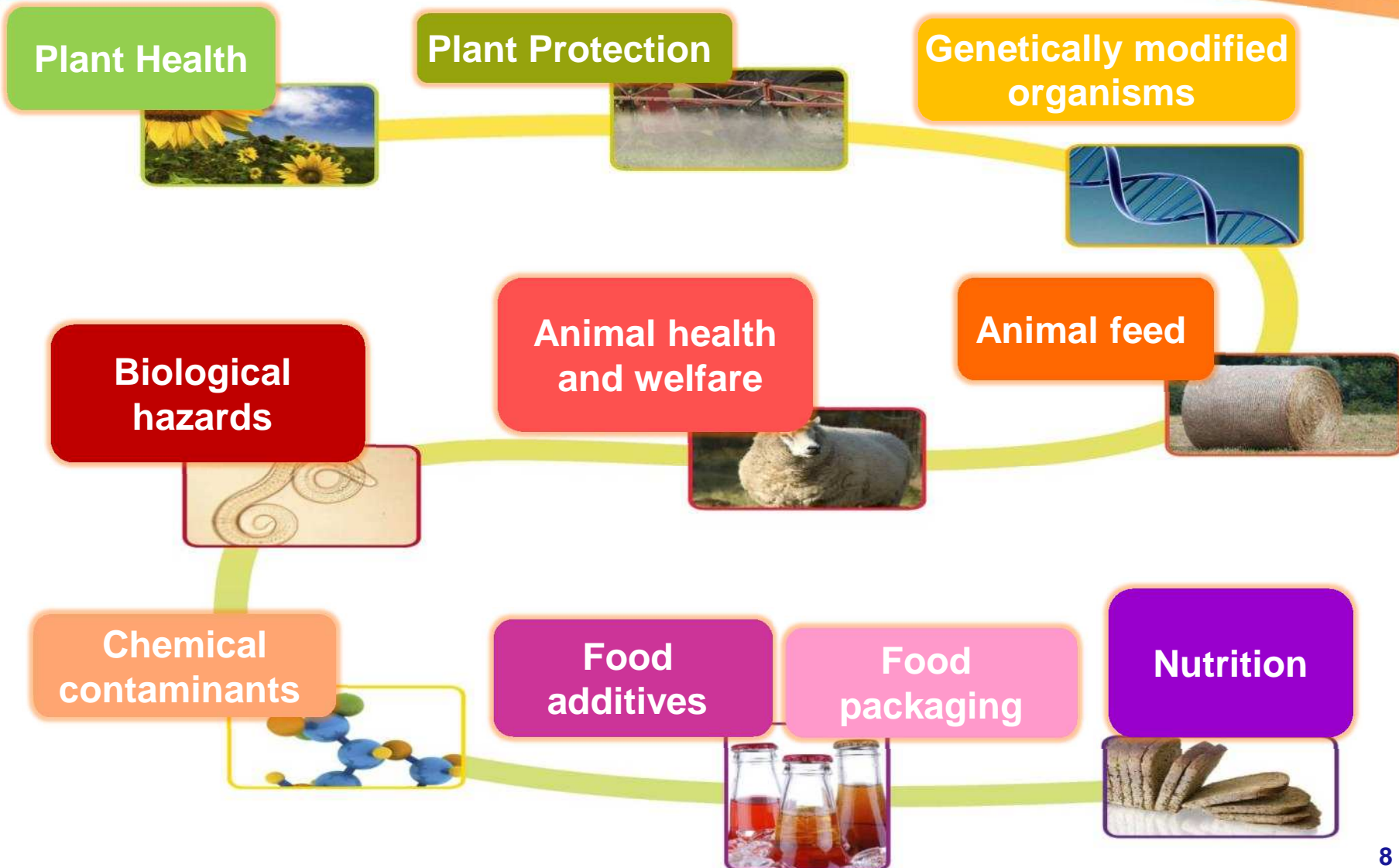
- | | |
|--|--|
| 1. Animal health and welfare | 6. Feed additives |
| 2. Food additives and nutrient sources | 7. Genetically modified organisms |
| 3. Biological hazards | 8. Nutrition |
| 4. Food contact materials, enzymes, flavourings | 9. Plant health |
| 5. Contaminants | 10. Plant protection products |



The Scientific Committee



Scientific advice from farm to fork



Independence and transparency

- Internal procedures and working processes in place to **safeguard the independence** of EFSA's scientific work
- Good risk assessment practices developed to ensure that the EFSA opinions **respect scientific standards and are transparent**
- EFSA opinions are the outcome of collective decisions; each Panel/Scientific Committee member has an equal say - minority views are recorded
- Mandates and meeting minutes of the Panels/working groups, and the scientific opinions are published on the EFSA website



External scientific experts, EFSA staff and independence

- External experts contributing to the EFSA work are selected based on their scientific expertise
- They are required to sign a declaration of commitment and to provide an **annual declaration of interests (ADoI)** for each EFSA group of which they are a member
- Experts declare interests annually and for each meeting
- EFSA assesses whether a declared interest poses a conflict in relation to the mandate of the EFSA group, and decides whether the expert is allowed to participate in the group
- Having an interest does not necessarily imply that there is a conflict of interest
- **ADoIs are published on the EFSA website**
- EFSA requires its professional staff to provide DoIs annually
- ADoIs of the EFSA Management Team are published on the EFSA website

CONTAM Panel

Where from the CONTAM Panel receives the requests?



European Commission (EC)



European Parliament



Member States (MS)



EFSA (*"self mandate"*)

Question?

Terms of reference (TOR)



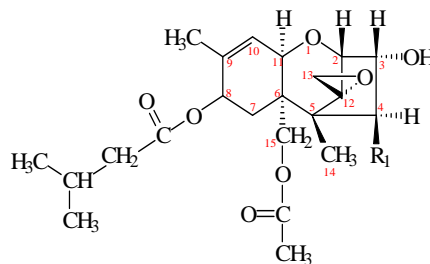
Risk Assessment
Risk Communication

10 Scientific Panels
1 Scientific Committee
13 Scientific Units



Mandate of the CONTAM Panel

To deliver scientific opinions on **contaminants in food and feed**, associated areas and undesirable substances *i.e.* natural toxicants, mycotoxins and residues of non authorised substances not covered by another Panel



The CONTAM Panel (2012-2015)

- Chair: Dr. Diane Benford (UK)
- Vice-chairs: Prof. Dr. Peter Fürst (DE)
Prof. Dieter Schrenk (DE)
- 20 Panel members
- More information about the CONTAM experts
<http://www.efsa.europa.eu/en/contam/contammembers.htm>



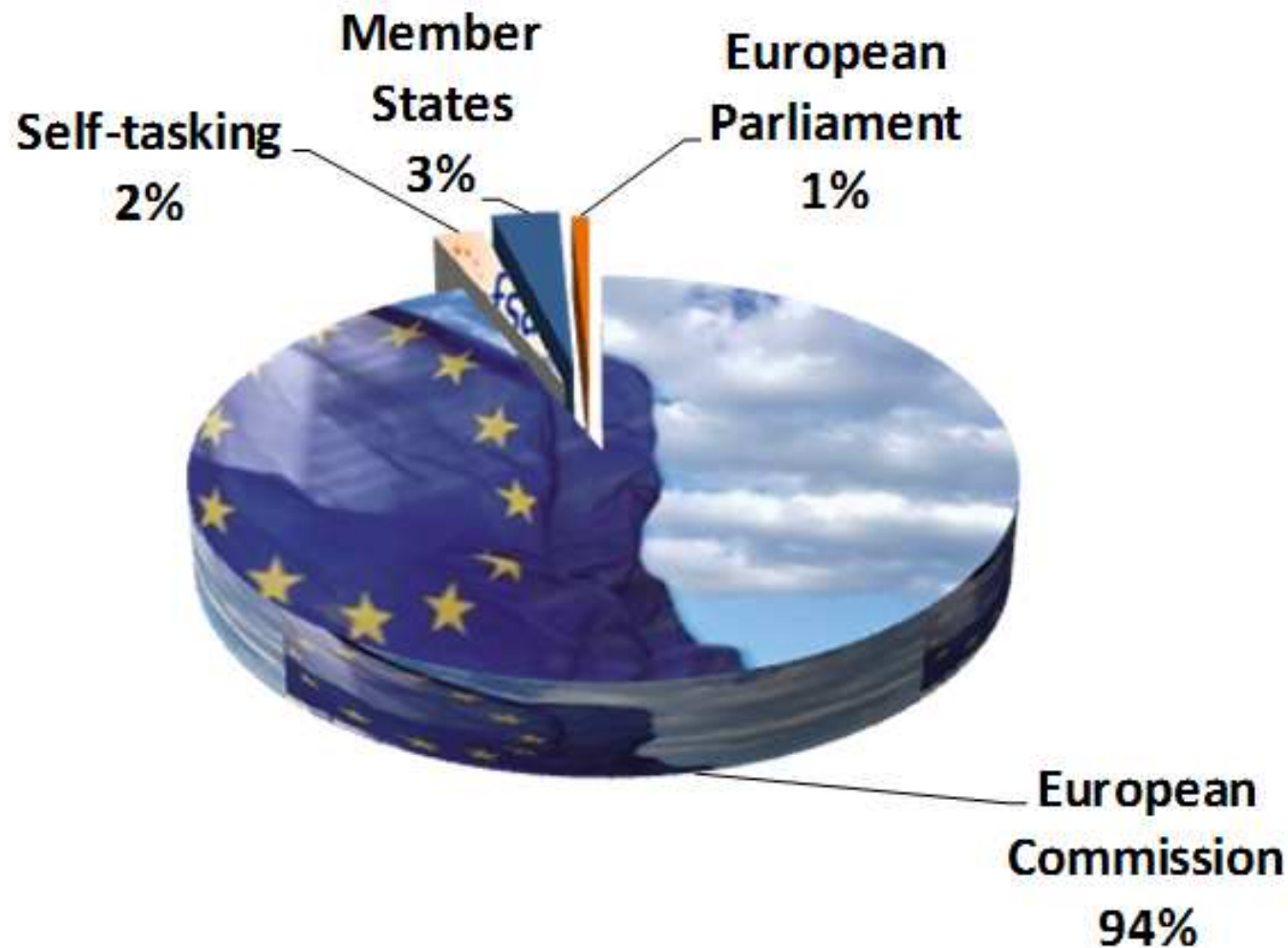
How does the CONTAM Panel work?



- Set up of a **CONTAM Working Group (WG)** with:
 - **Member of the CONTAM Panel as chair of WG**
 - **Scientific experts** having expertise to address the mandate (external experts and CONTAM Panel members)
- The **WG** develops a **draft opinion**, supported by **EFSA's CONTAM Unit staff** and other staff e.g. (Dietary and Chemical monitoring (**DCM**) unit)
- Once **adopted by the CONTAM Panel** the opinion is **provided to the requesting body and published on the EFSA website in the EFSA journal**



128 requests for the CONTAM Panel since 2003



- In addition 8 urgent requests with CONTAM involvement

The CONTAM Panel issued 114 scientific outputs since 2003



Food



Feed



Food&Feed

FOOD	61
Metals	7
Mycotoxins	5
Persistent organic pollutants	11
Plant toxicants	1
Marine biotoxins	13
Food processing	3
Other	21
FEED	42
Metals	4
Mycotoxins	5
Persistent organic pollutants	10
Plant toxicants	9
Coccidiostats	11
Others	3
FOOD&FEED	11
Mycotoxins	6
Plant toxicants	2
Other	2
Persistent organic pollutants	1

Current work programme of the CONTAM Panel

- **Meat inspection (just finished)**
- **Reference Point of Action (just published)**
- **Chromium in food**
- **Nickel in food**
- **Tropane alkaloids in food and feed**
- **Beauvericin and enniatins in food and feed**
- **Moniliformin in food and feed**
- **Diacetoxyscirpenol in food and feed**
- **Acrylamide in food**



Risk assessment on contaminants

Risk assessment on contaminants in food and feed

(1) HAZARD IDENTIFICATION



(2) HAZARD CHARACTERISATION

Toxicokinetic variability (ADME),
acute/sub/chronic toxicity, human data,
genotoxicity, mode/mechanism of action, dose-
response for critical effect, derivation of a health
based guidance value

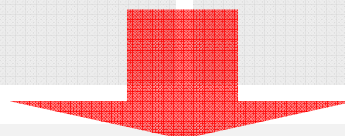


(3) EXPOSURE ASSESSMENT

Occurrence data x Food consumption

EXPOSURE

Relevant food groups, adults and specific
groups of the population, time trends



(4) RISK CHARACTERIZATION

Relates exposure to a chemical in a given population with toxicological effects (health based guidance value/margin of exposure), and concludes with the likelihood of adverse effects.

Types of toxicity data used:

Experimental and farm animals

- Toxicokinetics
 - absorption, distribution, metabolism and excretion

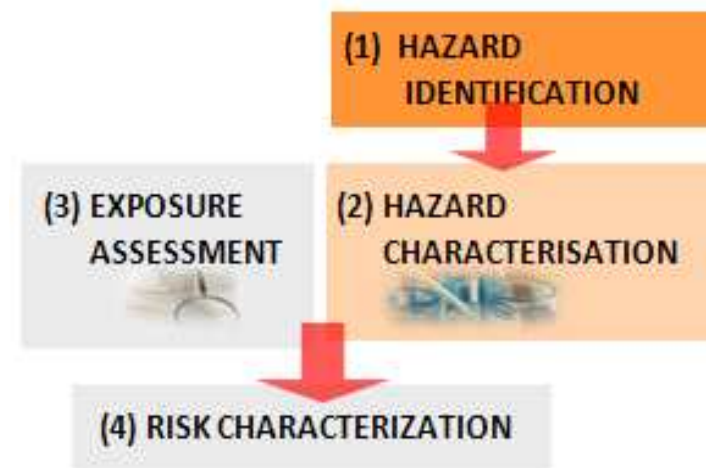
Experimental animals

- Tissue lesions
- Neurotoxicity
- Immunotoxicity
- Reproductive effects (e.g. impaired fertility, developmental changes)
- Mutagenicity/genotoxicity
- Carcinogenicity
- Modes/mechanisms of action

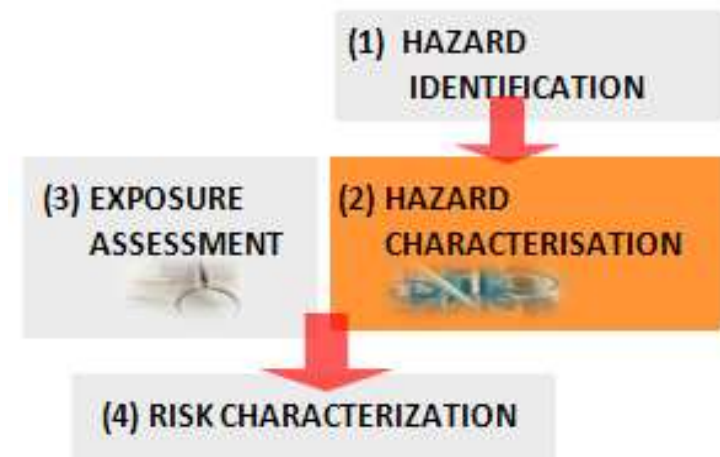
Adverse effects in farm animals, fish and pets

(e.g. reproductive effects, immunotoxic effects)

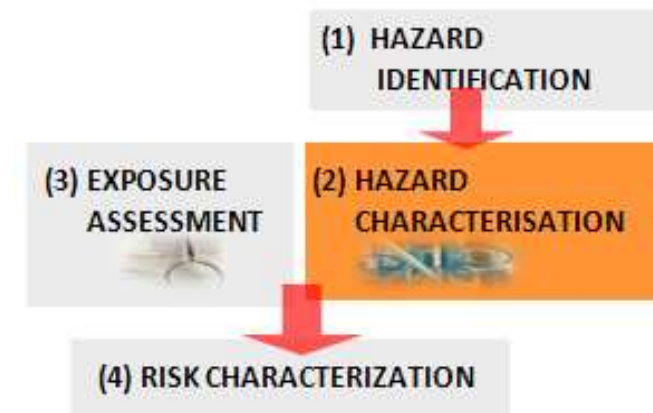
Human data



- Critical effect
 - the **relevant** adverse effect seen at the lowest dose level
- NO(A)EL – No-Observed-(Adverse)-Effect Level
 - maximum dose that produced no observable effect (usually adverse) in the study identifying the **critical effect** in the most sensitive species (animals, human)
 - **human data preferred**, if available in human risk assessment



Health-based guidance values e.g.



Chronic toxicity:

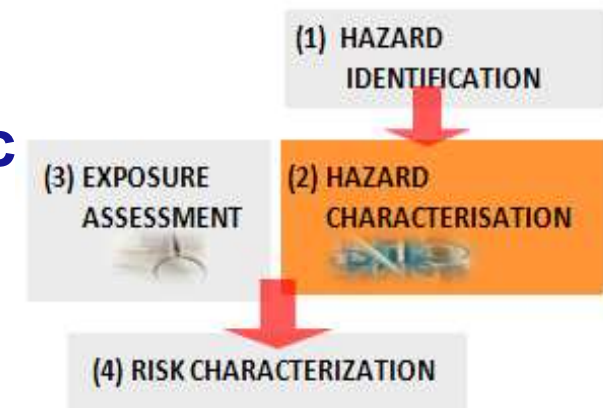
- Tolerable Daily Intake (TDI)
 - *“The amount, expressed on a body weight basis, that can be ingested daily over a lifetime without appreciable health risk”*

Acute toxicity:

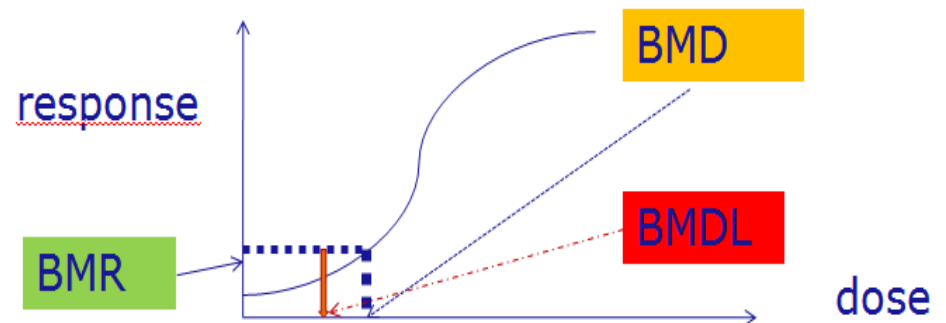
- Acute Reference Dose (ARfD)
 - *“Estimate of the amount of a substance in food or drink, expressed on a body weight basis, that can be ingested in a period of 24 hours or less without appreciable health risk”*

Benchmark dose (BMD)

- Used also for **genotoxic carcinogenic** compounds (**non-thresholded toxicity, chronic toxicity**)



- Modelling benchmark dose (BMD) for 10% extra risk of the critical effect
- $BMDL_{10}$ = 95% lower confidence limit of the BMD of 10 % extra risk of the critical effect



Occurrence data collection for food and feed

EFSA calls for occurrence data on the EFSA web site

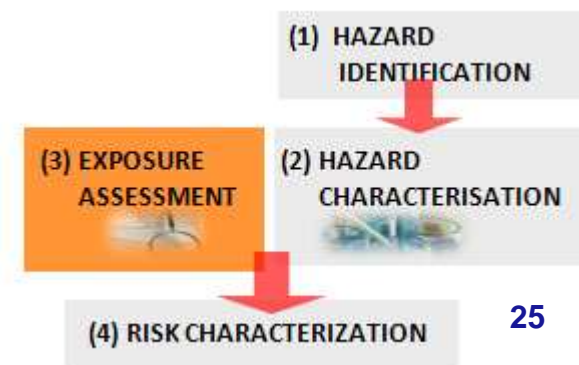


<http://www.efsa.europa.eu/en/calls/data.htm>

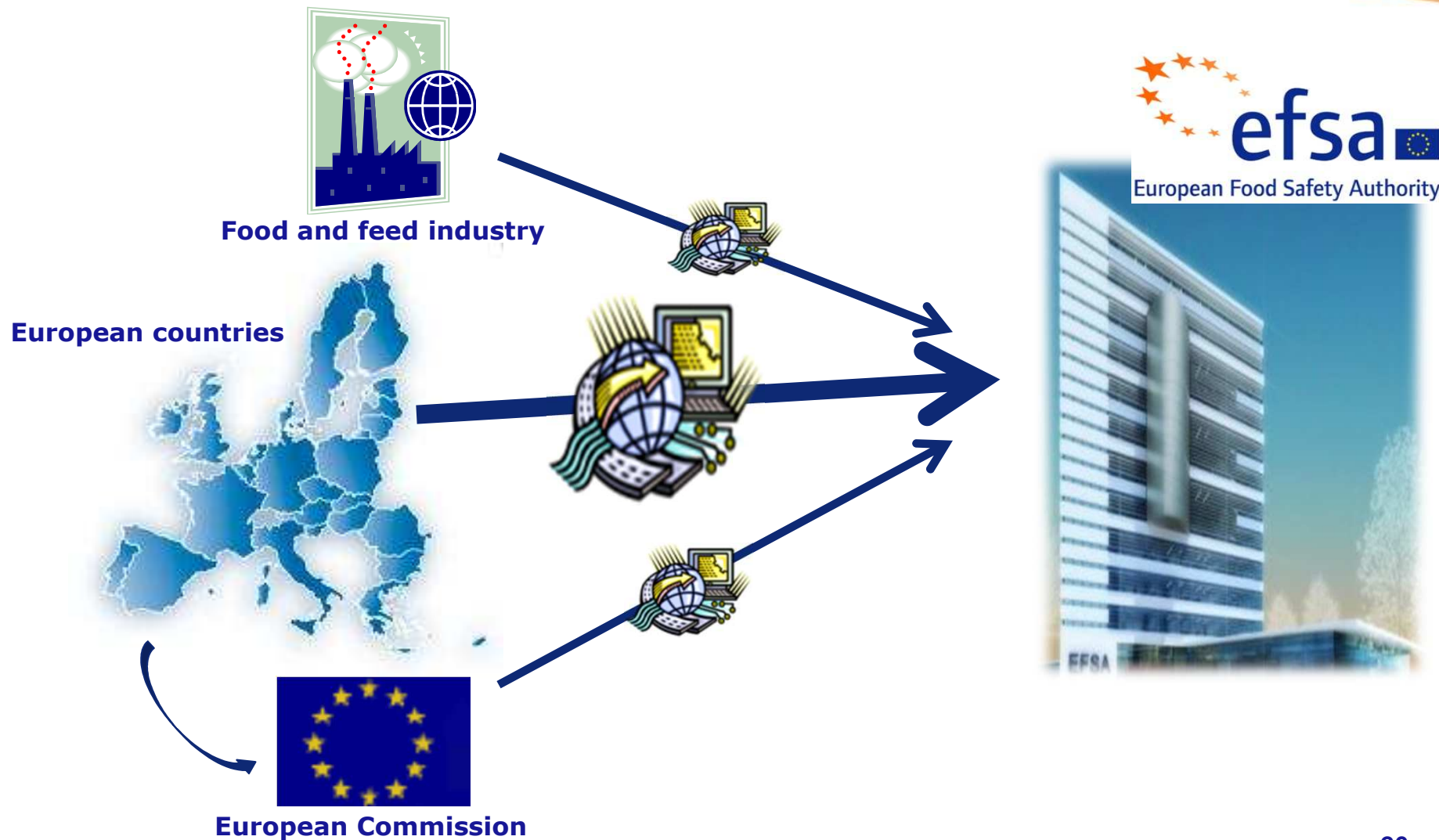
Occurrence data to be submitted to EFSA in **standardised format**:

- electronic format (XML)
- Excel reporting format

Prepared by the EFSA CONTAM Unit 2013



Occurrence data sources in Europe



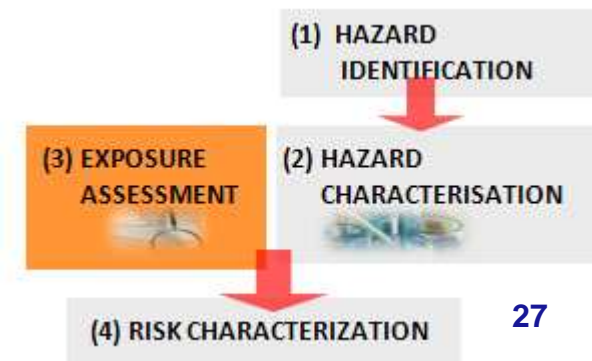
EFSA Comprehensive European Food Consumption Database:

- Data for adults from 22 EU Member States
- Data for children from 13 EU Member States
- The most recent data within the country
- The most complete and detailed data currently available in EU

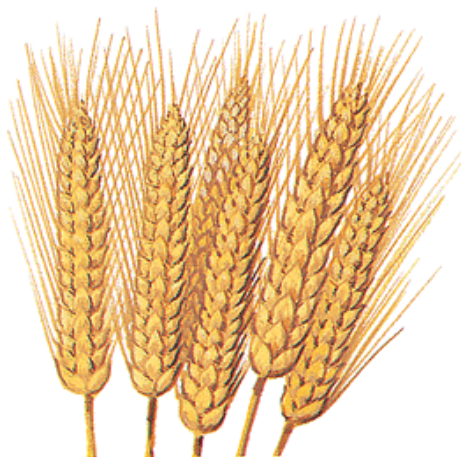


FEED consumption:

- External databases
- Literature data



Human exposure assessment



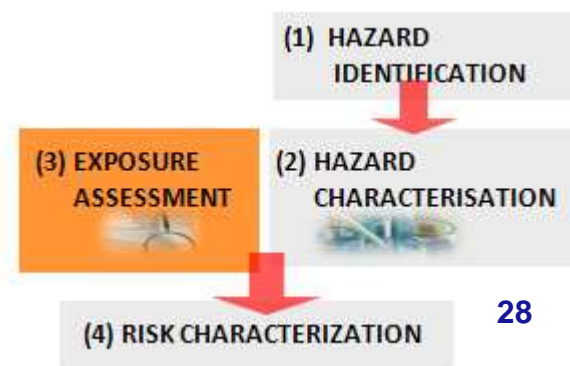
**Chemical
Occurrence**



**Exposure
Assessment**



**Food
consumption**



Exposure assessment for different population groups



Mean consumers



High consumers



Small children



Infants

Pregnant women

Vegetarians, diabetics, ...



Elderly

Animal exposure assessment



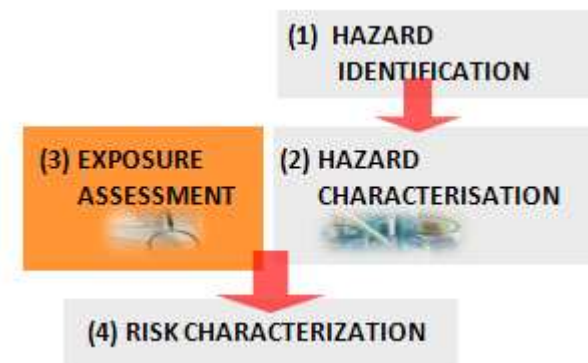
**Chemical
Occurrence**



**Exposure
Assessment**



**Feed
consumption**



Exposure assessment for different animal species



Farm
animals



Fish

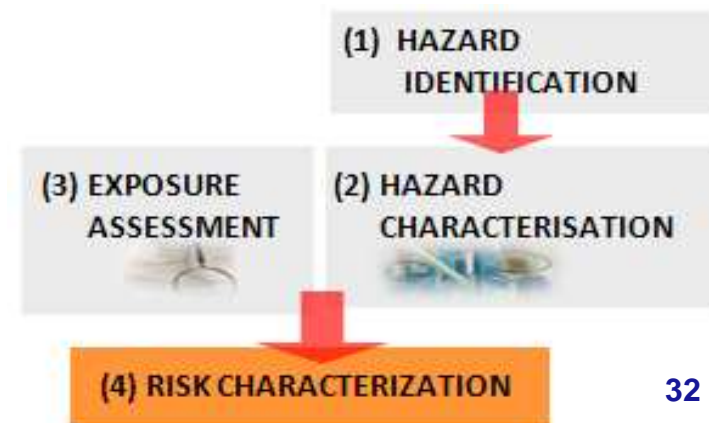
Pets
and
horses



Comparison of TDI and dietary exposure

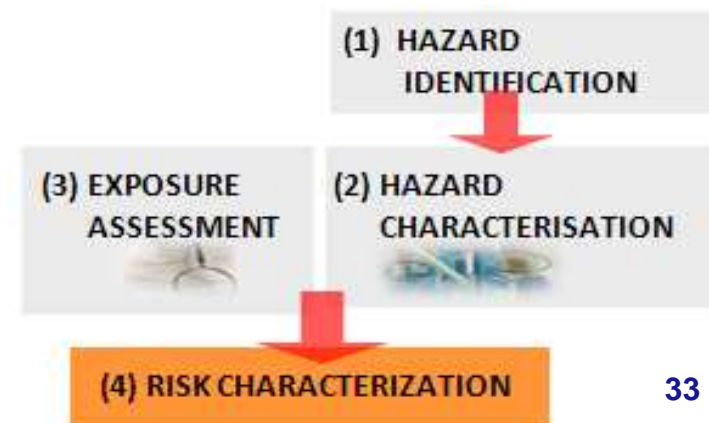
Comparison of ARfD and dietary exposure

Calculation of margin of exposure (MOE)
= comparison of $BMDL_{10}$ and dietary exposure



Comparison of NOAEL and exposure

Comparison of BMDL and exposure



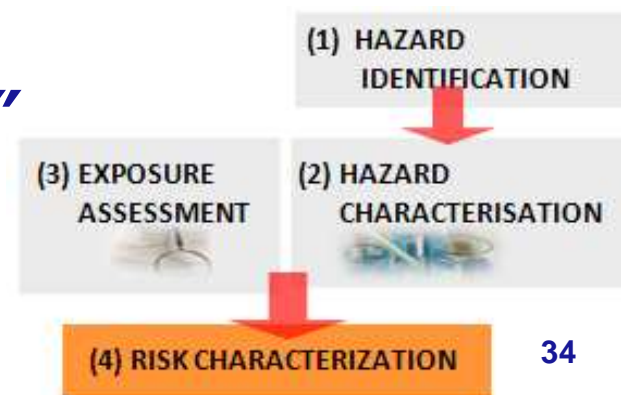
The CONTAM Panel may conclude on health risk e.g.

"Estimates of dietary exposure to "mycotoxin" based on the available occurrence data are below TDI for all age groups and not a health concern"

"For high consumers the MOE is close to 10 000 for genotoxic carcinogenic compound, which as proposed by EFSA, indicates a potential concern for consumer health"

"The estimated exposures to "mycotoxin" are well below doses causing toxicity and are therefore not expected to pose a risk to livestock and fish"

"Not possible to comment on health risk"



- **Uncertainties are described in the scientific opinions of the CONTAM Panel**
- The CONTAM Panel risk assessments rely on scientific information in the public domain or being provided to EFSA
- Incomplete toxicological databases
- Limited occurrence data (e.g. feed)
- Limitations in the animal consumption data



And then – what then ? ? ? ? ?

CONTAM Panel's scientific opinions will advise and help the risk managers such as **EC to decide the need for possible revisions of the current legislation and/or any other possible follow-up actions** required in relation to the presence of contaminants in food and feed.



Urgent advice within CONTAM remit



- **Melamine in food and feed**

- July 2007 (Statement in 10 days)



- **Mineral oil in sunflower oil**

- April 2008 (Initial view in 1 day & update in 4 weeks)



- **Melamine in food**

- September 2008 (Statement in 6 days)



- **Dioxin in Irish pork**

- December 2008 (Statement in 2 days)



- **Nicotine in wild mushrooms**

- April 2009 (Statement in 10 days)



- **Icelandic volcanic ash fall**

- April 2010 (Statement in 3 days)



- **Ammonium in water filters**

- October 2012 (Statement in 15 days)



- **Phenylbutazone in horse meat**

- April 2013 (Joint EFSA and EMA Statement in 6 weeks)

EFSA CONTAM Unit



Natalie THATCHER

Scientific officer, toxicologist

Silvia Inés NICOLAU SOLANO

Scientific officer, veterinarian

Katleen BAERT

Scientific officer, food engineer

Luisa RAMOS BORDAJANDI

Scientific officer, pharmacologist

Bistra BENKOVA

trainee



Mari ESKOLA

Acting Head of Unit,
food chemist



Valentina MOTA

Administration

Doina STOICA

Administration



Gina CIOACATA

Administration



Marco BINAGLIA

Deputy Acting Head of
Unit, toxicologist

Provides support to the CONTAM Panel and its WGs groups in carrying out risk assessments:

- organises & plans the work and meetings of the Panel and WGs
- assesses declarations of interest (DOIs)
- collects literature, drafts scientific opinions on request, finalises opinions for publication in the EFSA Journal
- assists with communication activities and disseminates outcomes of opinions

Prepares scientific advice on contaminants, e.g. urgent advice

Co-ordinates EFSA grants and procurements awarded to the EU Member State organisations



Thank you for your attention !

EFSA: <http://www.efsa.europa.eu/>

CONTAM Panel: <http://www.efsa.europa.eu/en/panels/contam.htm>

EFSA Journal: <http://www.efsa.europa.eu/en/publications/efsajournal.htm>

Prepared by the EFSA CONTAM Unit 2013