



EFSA's Role in FEED Risk Assessment in the EU

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EFSA's tasks

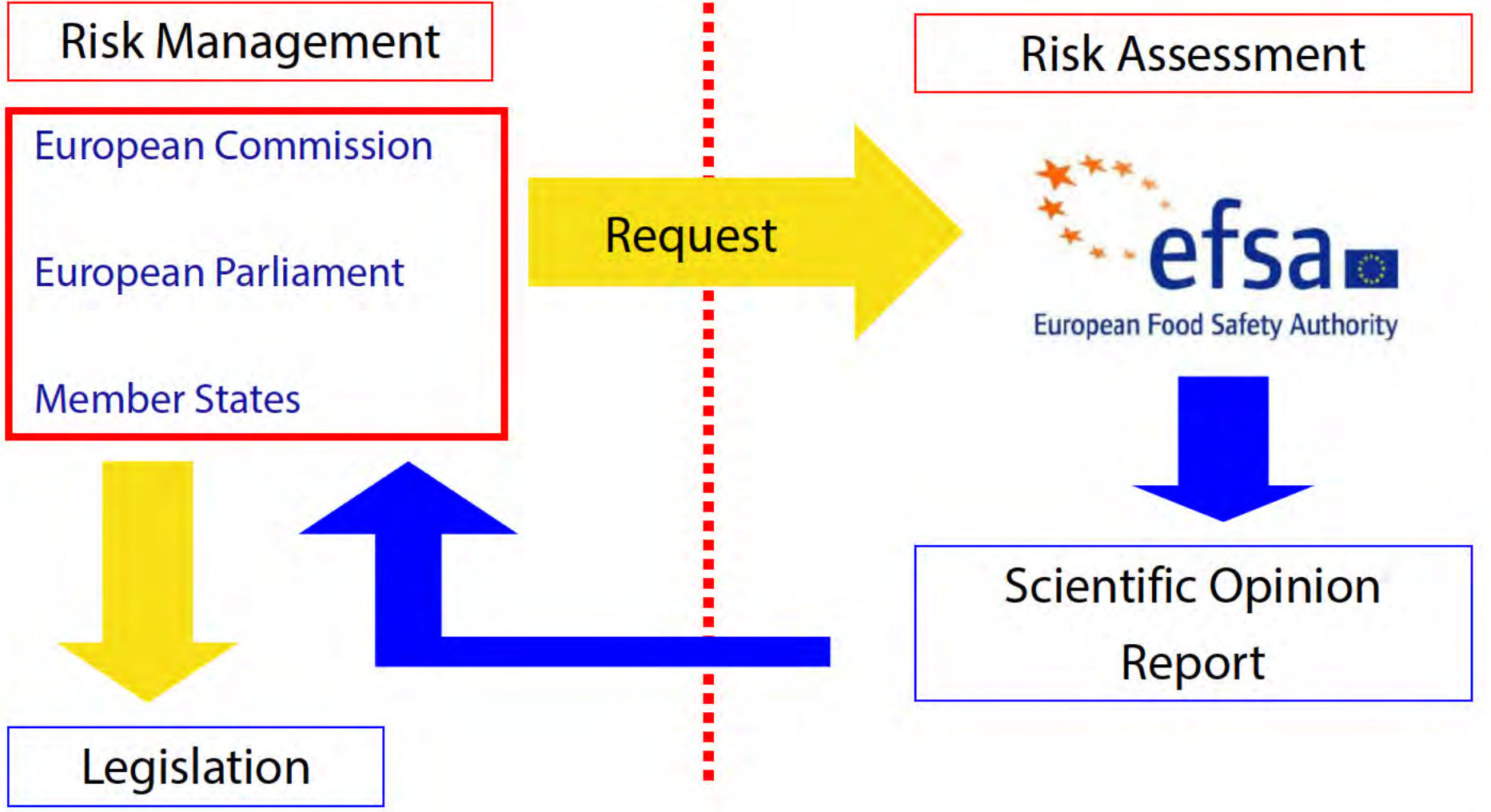
1. Provide scientific advice, opinions, information, and technical support for Community legislation and policies
2. Collect and analyse data to allow characterisation and monitoring of risks
3. Promote and coordinate development of uniform risk assessment methodologies
4. Communicate risks related to all aspects of EFSA's mandate

What we cannot do

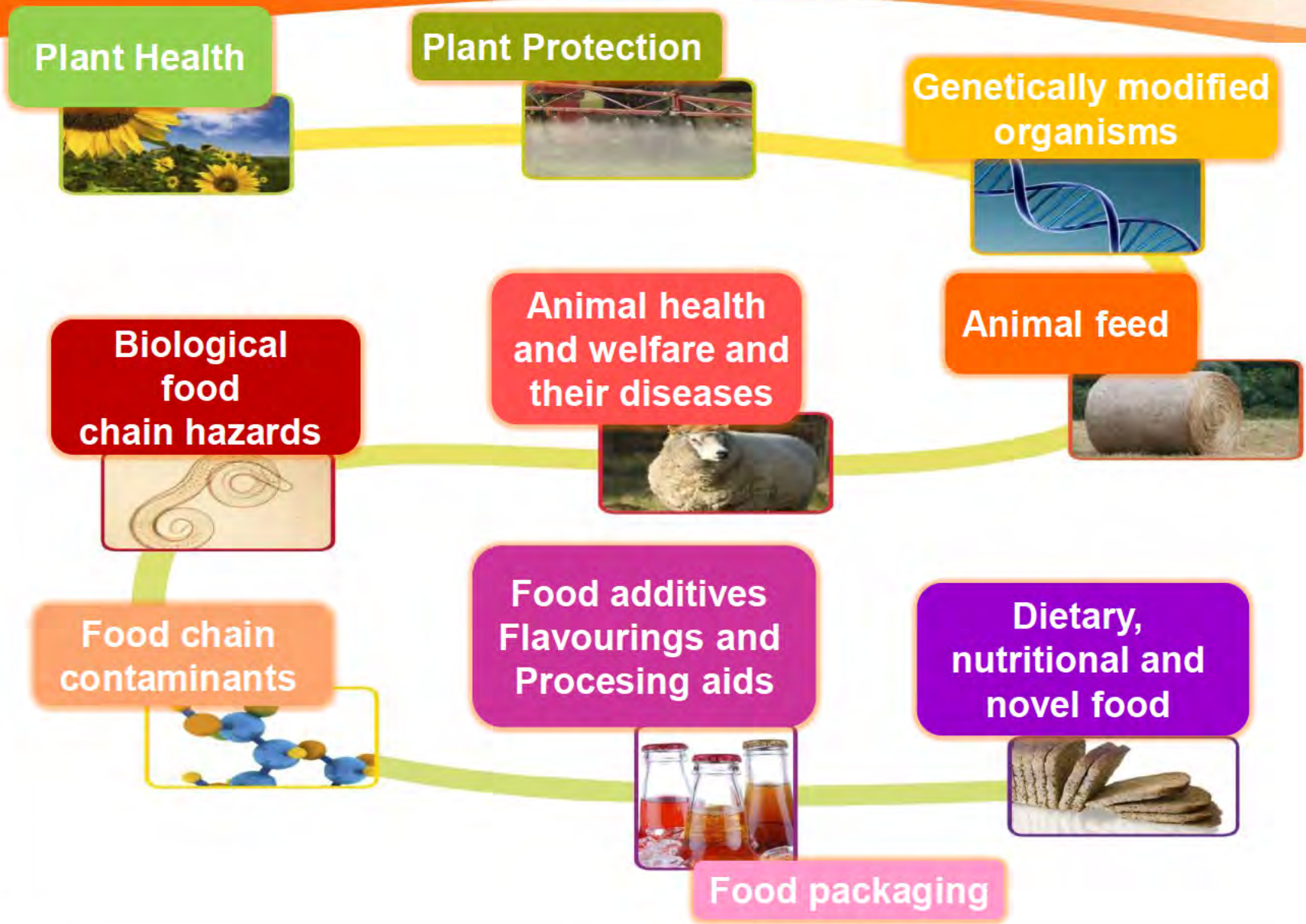


- ◉ Enforce food safety legislation
- ◉ Take charge of food safety/quality controls, labelling or other such issues
- ◉ Substitute for national authorities

How the process works



Scientific advice from farm to fork



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

+

The Scientific Committee





Feed Risk Assessment

FEED – a “complex” mixture ...

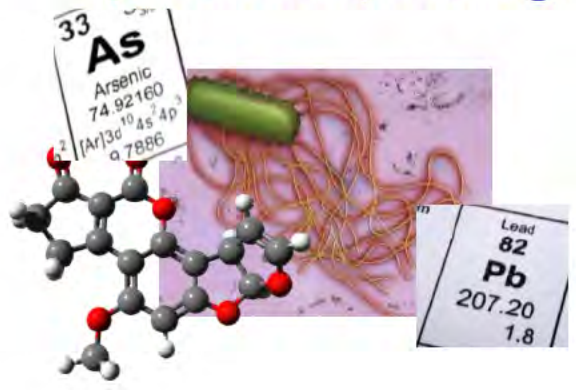
Feed materials



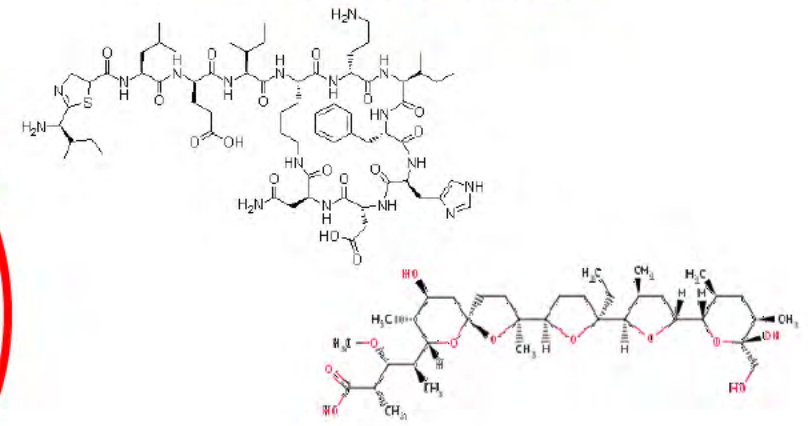
Feed additives (Chemical/Biological)



Contaminants (Chemical/Biological)



Medicines



... with multiple players



- BIOHAZ Panel:** The BIOHAZ Panel deals with **biological hazards** in relations to food safety and food-borne diseases.
- CONTAM Panel:** The CONTAM Panel deals with **contaminants** in the food chain.
- GMO Panel:** The GMO Panel deals with **genetically modified organisms** and genetically modified food and feed.
- FEEDAP Panel:** The FEEDAP Panel deals with **additives and products or substances used in animal feed.**



Regulatory Framework

General Food Law Regulation (EC) 178/2002

Feed Materials
Reg. (EC) 767/2009

Feed Hygiene
Reg. (EC) 183/2005

Feed Additives
Reg. (EC) 1831/2003

Undesirable substances
Dir. 2002/32/EC

GMO Feed
Reg. (EC) 1829/2003

REGULATION (EU) No 767/2009 on placing on the market and use of feed

- “Feed may only be placed on the market and used if it is safe and does not have a direct adverse effect on the environment or animal welfare.”
- No pre-market authorisation process
- EU Register of feed materials
- EU Catalogue of feed materials
- “Claims”

REGULATION (EC) No 1831/2003 on additives for use in animal nutrition

- Pre-market authorisation
- Definition of feed additive and categories/ functional groups
- Conditions for the authorisation
- EFSA evaluation
- Re-evaluation of all feed additives
- Time-limited authorisations

- **Regulation (EC) No 429/2008 – “Guidelines”**
- **EFSA Guidance documents (~20)**
 - Categories of additives
 - Safety aspects: target species, consumer, user, environment
 - Food additives
 - Minor species, pets and non food-producing animals
 - Antimicrobial resistance, *Bacillus* spp, *Enterococcus faecium*
 - ...

RE-EVALUATION of **ALL** feed additives

- **2004: Notification:**
 - 10 000 notifications – 2 500 additives
- **2010: Re-evaluation**
 - 400 dossiers covering ~ 1 200 additives
 - ~150 opinions adopted dealing with approx. 500 substances
- **Work to be finalised in the next 2-3 years**

Things we learned (I)

Flavourings

- High use levels
- All animal species
- Use in water
- Very little toxicological data
- Inconsistent use
 - Methyl anthranilate.
Bird aversion agent
 - Iso-eugenol
Fish anaesthetic

Colourings

Allura red

- Colouring agent for petfood
- Used also in food for humans
- Potential genotoxicity concerns

Trace elements

- **Cobalt:** setting of maximum levels, species restriction
- **Copper:** development of antimicrobial resistance
- **Iodine:** consumer safety concerns, setting of lower maximum feed levels
- **Zinc:** environmental concerns, reduction of feed levels
- **Selenium:** reduction of Se levels and limitation of organic Se

Vitamins

- **Beta carotene:** Maximum limit of in milk replacer
- **Vitamin A:** reduction levels in feed for consumer safety

Directive 2002/32/EC on undesirable substances in animal feed

- **Inorganic contaminants and nitrogenous compounds:** As, Cd, F, Pb, Hg, Nitrite, melamine
- **Mycotoxins:** aflatoxin B1, Rye ergot
- **Inherent plant toxins:** free gossypol, hydrocyanic acid, theobromine, ...
- **Organochlorine compounds:** aldrin, dieldrin, ...
- **Dioxins and PCBs**
- **Harmful botanical impurities:** weeds, seeds, ...
- **Authorised feed additives in non target feed:** diclazuril, decoquinate

Commission Recommendation 2006/576/EC on the presence of deoxynivalenol, zearalenone, ochratoxin A, T-2 and HT-2 and fumonisins in products intended for animal feeding

- Sets guidance values for deoxynivalenol, zearalenone, ochratoxin A and fumonisins

- **T-2 and HT-2 toxins** in food and feed
- **Nivalenol** in food and feed
- **Ergot alkaloids** in food and feed
- **Pyrrolizidine alkaloids** in food and feed
- ***Alternaria* toxins** in food and feed
- **Citrinin** in food and feed
- **Sterigmatocystin** in food and feed
- **Phomopsins** in feed and food

Previous opinions on feed contaminants (2004-2010)

- **Metals** in feed, e.g. cadmium, mercury, lead, arsenic
- **Mycotoxins** in feed, e.g. aflatoxin B₁, deoxynivalenol, zearalenone, ochratoxin A, ergot alkaloids
- **Persistent organic pollutants** in feed, e.g. gamma-HCH and other hexachlorocyclohexanes, endrin, aldrin and dieldrin, hexachlorobenzene, chlordane, heptachlor
- **Plant toxicants** in feed, e.g. ricin, gossypol, cyanogenic compounds, pyrrolizidine alkaloids
- **Cross contamination with coccidiostats** used as feed additive, e.g. narasin, lasalocid, salinomycin, monensin, etc.
- **Other feed contaminants**, e.g. fluorine, nitrites

Current work in feed contaminants:

- deoxynivalenol, metabolites of deoxynivalenol and masked deoxynivalenol
- the risks for animal and public health related to the presence of metabolites and masked or bound forms of certain mycotoxins in food and feed



Harmonising & developing risk assessment methodologies

- **Data collection**
 - Harmonised food consumption data
 - Continuous collection of chemical contaminants occurrence data in food and feed
 - Zoonoses, antimicrobial resistance and food-borne outbreaks
 - Pesticides
- **Databases**
 - EU Food consumption database
 - Chemical hazards database

Default values of EU food consumption for high consuming adults and toddlers (g/day)



	Chronic intake ¹		Acute intake ²	
	Toddlers ³	Adults ⁴	Toddlers	Adults
Meat	90	290	135	390
Liver	-	60	-	170
Kidney	-	15	-	100
Animal fat	-	30	-	40
Milk	1050	1500	1500	2000
Eggs	35	70	50	130
Honey	-	30	-	50
Fish	65	125	130	280
Seafood	-	75	-	200
Fish + seafood	-	165	-	360

¹: Chronic intake is the 95th percentile of the distribution of average individual consumption levels (over the survey period) for consumers only from all available EU national surveys

²: Acute intake is the 95th percentile of the distribution of daily consumption levels (all days considered as independent) for consuming days only from all available EU national surveys

³: Toddlers: 1-3 years of age, 12 kg body weight

⁴: Adults: 18-65 years of age, 60 kg body weight

Developing RA methodologies

- Benchmark dose
- Genotoxicity testing
- Threshold of toxicological concern (TTC)
- Default values
- Exposure assessment, uncertainty, transparency
- Combined exposure to multiple chemicals
- QPS for microorganisms
- QPS for botanicals (?)

- Risk assessment of complex mixtures (e.g., botanicals)
- Low dose effects
- Characterisation of uncertainties in risk assessment
- Implementing new technologies in risk assessment
- SC opinion on cross cutting issues:
 - interpretation of epidemiological studies
 - weight of evidence approach
 - biological relevance in toxicology
 - import risk assessment

Working with partners

In the EU

- National food safety agencies
- 400 research institutes
- 1500 experts annually

EU Agencies



EUROPEAN MEDICINES AGENCY
SCIENCE MEDICINES HEALTH



National FSO

- US FDA, USDA APHIS, USDA FSIS, ARS, EPA
- Health Canada
- Food Safety Commission of Japan
- Food Standards Australia
- New Zealand Food Safety Authority

International organisations





European Food Safety Authority

Thanks for your attention

