



“The role of EFSA in food safety”

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Director of Risk Assessment

Euromaisiers

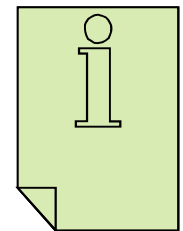
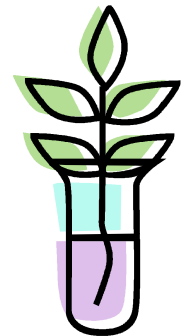
15th May 2009, Venice

Regulation 178/2002

– reasons to establish EFSA

- To improve **consumer confidence**
- Should assist in ensuring the smooth functioning of the **internal market**
- Should contribute through the provision of support on scientific matters, to the Community's and Member States' role in the development and establishment of international food safety **standards and trade agreements**

- **Provide scientific advice and support** for EU legislation/policies in all fields that impact food and feed safety, plant health, plant protection and animal health and welfare
- **Provide independent information** on all relevant matters
- **Communicate the risks**



Scientific Committee and Panels

- Plant health (PLH)
- Plant protection products (PPR)
- Genetically modified organisms (GMO)
- Feed additives (FEEDAP)
- Animal health and welfare (AHAW)
- Biological hazards (BIOHAZ)
- Contaminants (CONTAM)
- Food additives and nutrient sources (ANS)
- Food contact materials, enzymes, flavourings (CEF)
- Nutrition (NDA)

•Scientific Committee (SC)



EFSA organisation

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P. Bergman (ad interim)

BIOLOGICAL HAZARDS (BIOHAZ)
M. Ilugas

NUTRITION (NDA)
J. Kleiner

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CONTAMINANTS (CONTAM)
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PESTICIDES (PRAPeF)
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S. Pagani

PUBLIC INFORMATION & EVENTS (PIE)
C. Buller

WEB
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Who can task EFSA



European Commission



EU Member States

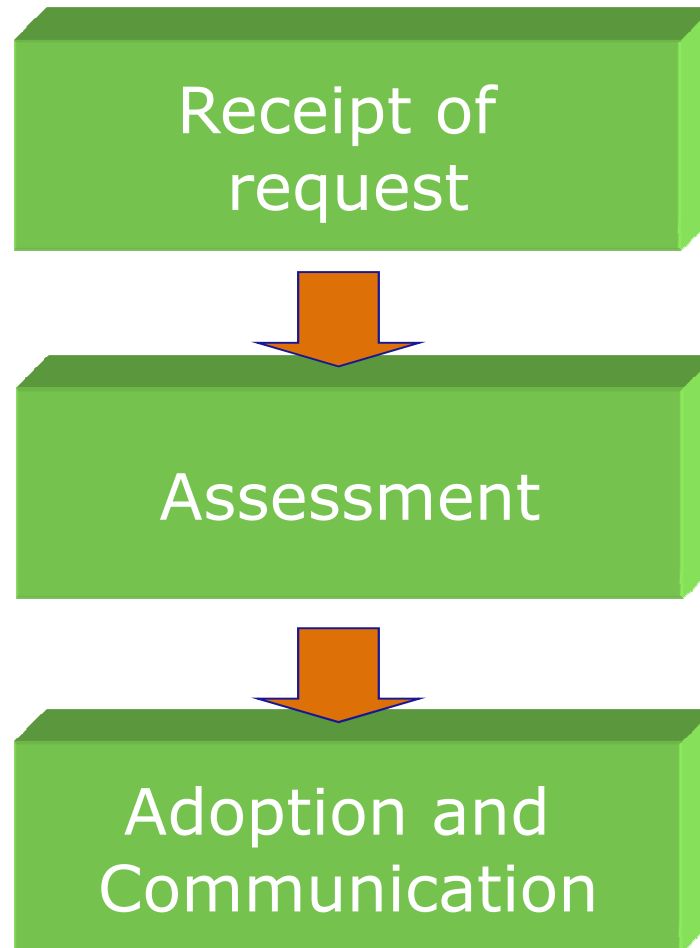


European Parliament

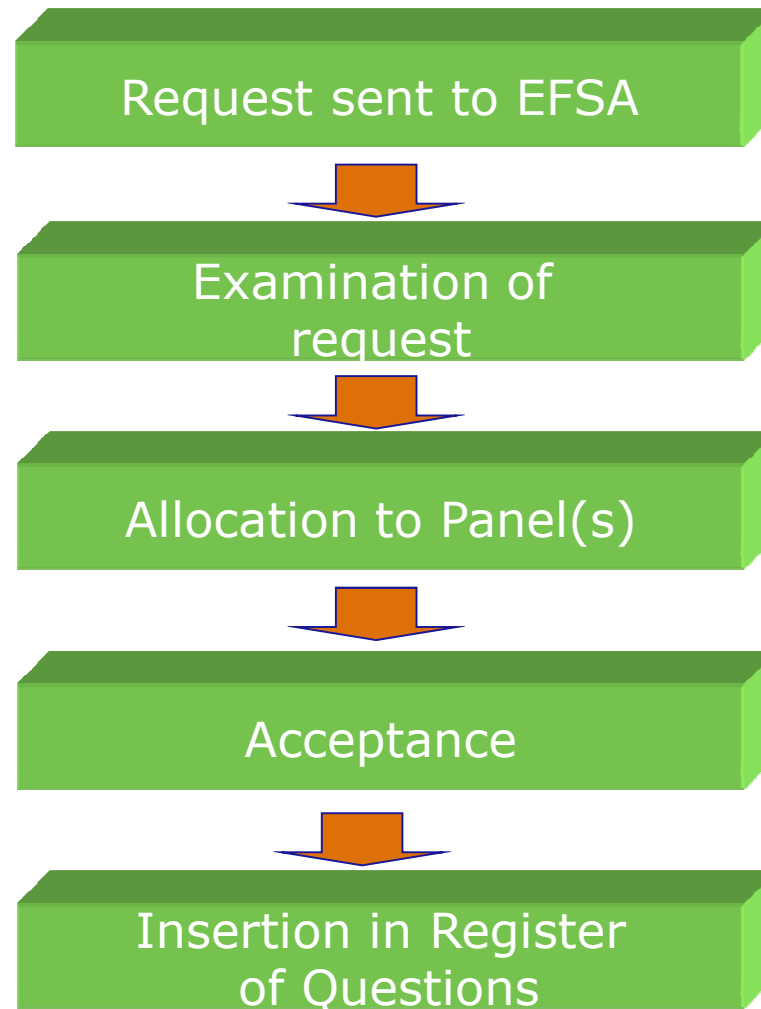


Self-tasking

Overview on workflow of scientific opinions



Receipt of request

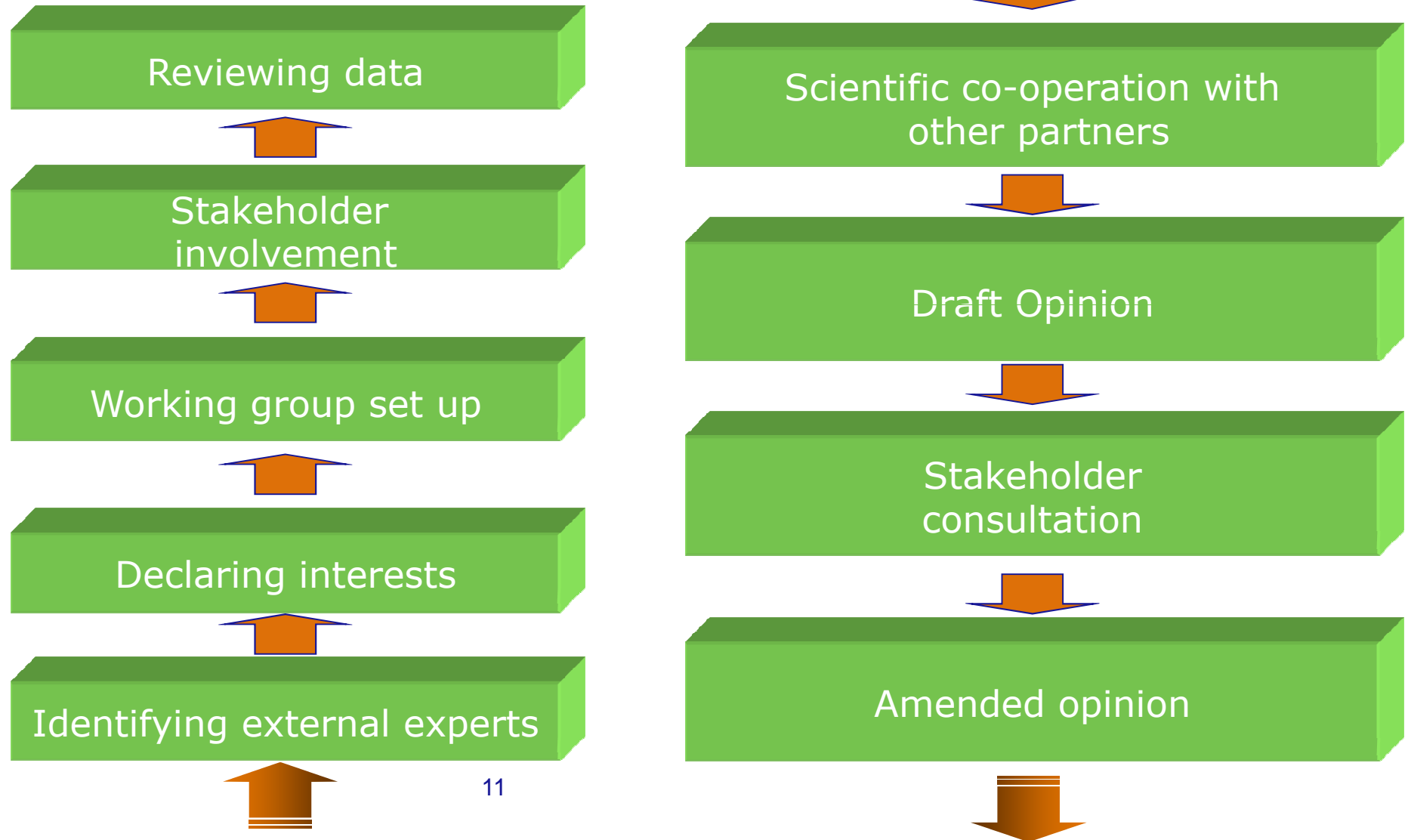


- Interests in **the 5 years** preceding the completion of the relevant DoI belonging to one of the following categories
 - Ownership or other investments
 - Membership of a Managing Body or equivalent
 - Member of a Scientific Advisory Body or equivalent
 - Employment
 - Consultancy or Advice
 - Research funding and Intellectual Property rights
 - Other memberships and affiliations
 - Other interests
- Interests of close family members should also be declared

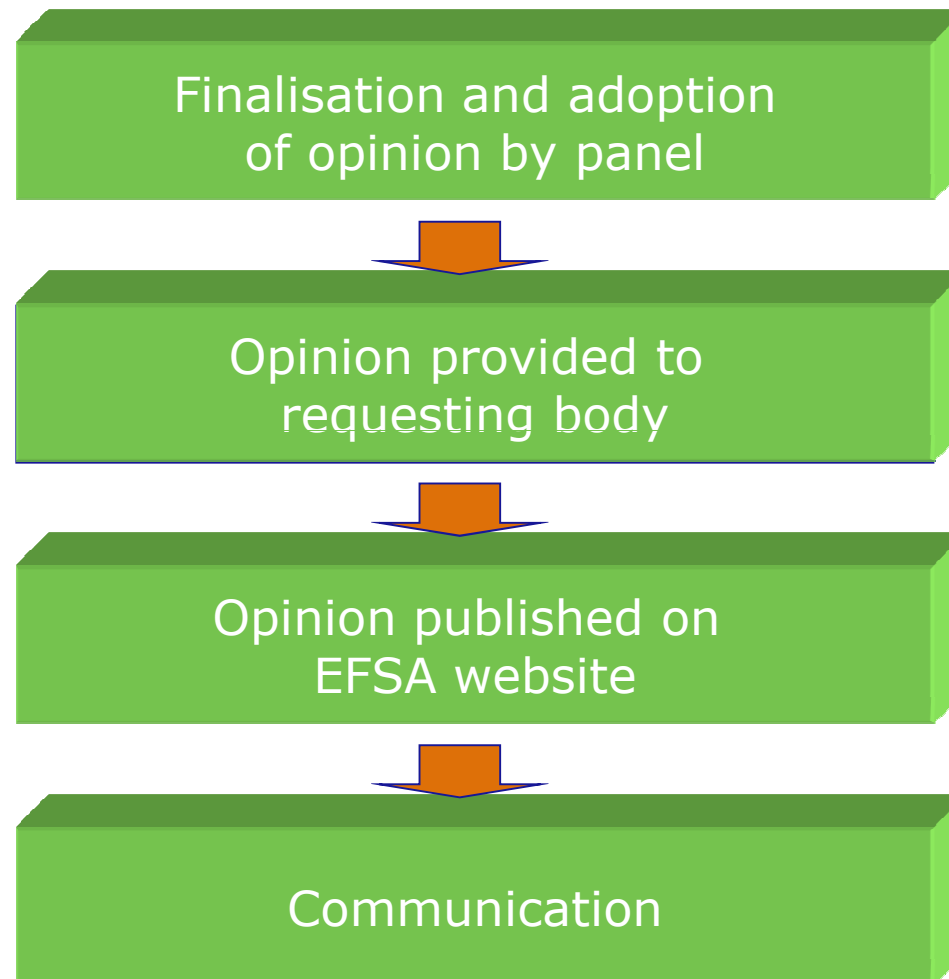
Declared interests vs conflict of interest

- Interests are **part of expertise**
- Having an interest does **not imply there is a conflict**
- Potential conflicts of interests can only be established through a **case by case** assessment in relation to
 - the relevant EFSA activity
 - interest declared by the expert.
- The conflict may occur for one activity but not necessarily for all activities an expert has been invited to

Risk assessment



Adoption and publication



Transparent workflow on the web

Receipt of request

- Accepted mandates (Register of Questions)
- Names of panel and working group members
- Declaration of interest of experts

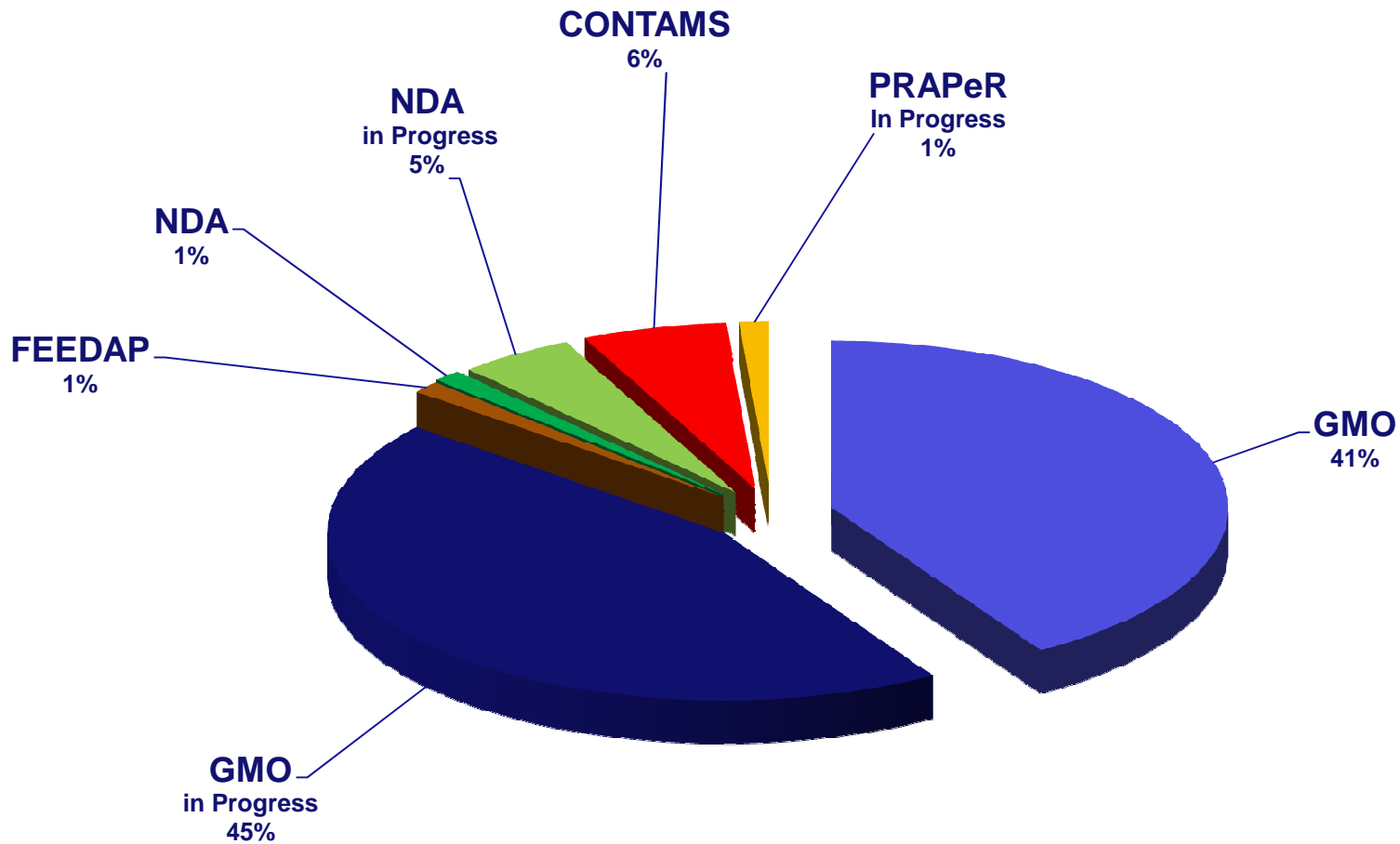
Assessment

- Agendas of the panel's plenary meetings
- Minutes of the panel's plenary
- Minutes of working group meetings

Adoption and Communication

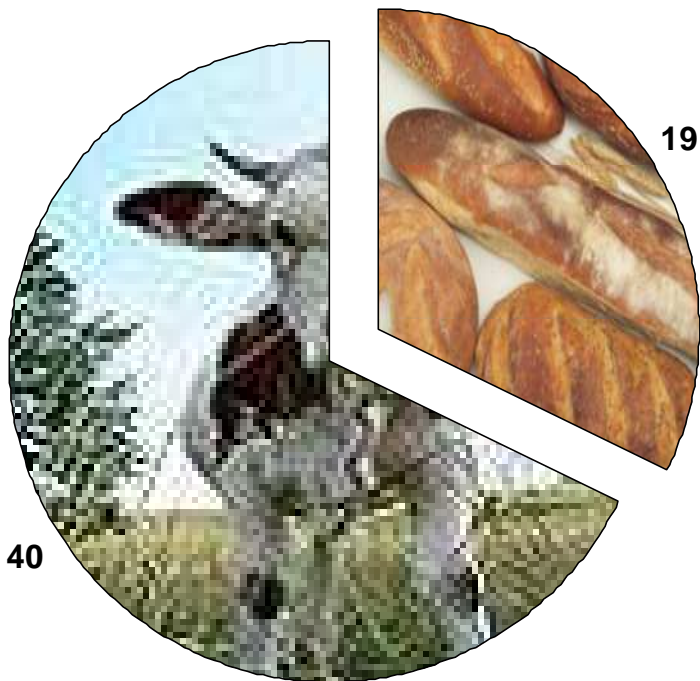
- Adopted opinions
- Press releases and web stories
- Key-topics on the web
- EFSA newsletters (plant, animal and food)
- EFSA news

EFSA opinions on maize in 2003-2009



Panel on contaminants

- 59 scientific outputs since 2003



FOOD	19
Metals	2
Mycotoxins	2
Persistent organic pollutants	4
Marine biotoxins	3
Food processing	3
Other	5
FEED	40
Metals	5
Mycotoxins	5
Persistent organic pollutants	10
Plant toxicants	7
Coccidiostats	11
Others	2

Mycotoxins **in food**: none of the opinions relate to maize

Mycotoxins **in feed**: the following opinions touch on maize:

aflatoxin B1, deoxynivalenol, zearalenone, fumonisins

CONTAM aflatoxin B1 - feed

- **Main outcome of the opinion:**

- The current maximum levels of aflatoxin B1 in animal feeds provide adequate protection from adverse health effects in target animal species
- Also successfully prevent undesirable concentrations of aflatoxin M1 in milk

Within the opinion it was mentioned that in 2003 Italy had for the first time an increase in numbers of milk samples exceeding the statutory limit of aflatoxin M1 (metabolite of aflatoxin B1 occurring in dairy milk) indicating that this was caused due to the presences of high contamination rates of locally grown maize with aflatoxin B1.

- **Risk management follow up:**

EU legislation. No need to change current maximum level (ML) in Com. Directive 2002/32/EC

In addition,

- Monitoring of aflatoxin B1 in feed materials continued and intensified
- Aflatoxin M1 to be monitored on milk at farm level

CONTAM – deoxynivalenol feed

- **Main outcome of the opinion:**
 - Foods of animal origin contribute only to a minor extent to total human exposure
 - Pigs most sensitive
 - Poultry also sensitive

- **Risk management follow up:**

No EU legislation. Recommended guidance values e.g. for cereals, maize products and compound feed (Com. Recommendation 2006/576/EC)

Recommended guidance values

Cereals and cereal products	8 ppm
Maize by-products	12 ppm
Complementary and complete feed:	5 ppm
Except for pigs	0.9 ppm
Except for calves, lambs and kids	2 ppm

CONTAM – zearalenone feed

- **Main outcome of the opinion:**
 - Foods of animal origin contribute only marginally to total human ZEA exposure
 - Female pigs most sensitive
 - Sheep also quite sensitive
 - Cattle less sensitive
 - Poultry: not sensitive
- **Risk management follow up:**

No EU legislation. Recommended guidance values e.g. for cereals, maize products and compound feed (Com. Recommendation 2006/576/EC)

Recommended guidance values

Cereals and cereal products	2 ppm
Maize by-products	3 ppm
Complementary and complete feed:	
For piglets and gilts (young sows)	0.1 ppm
For sows and fattening pigs	0.25 ppm
For calves, dairy cattle, sheep and goats	0.5 ppm

CONTAM – fumonisins feed

Main outcome of the opinion

- Carry-over of fumonisins from animal feeds into edible tissues, including milk and eggs limited and consequently products of animal origin do not contribute substantially to human exposure
- Fumonisins exhibit toxic effects in all animal species
- Pigs and horses the most sensitive animal species
- Also rabbits sensitive
- Broilers - NOAEL of 2 mg/kg bw/day
- Adult ruminants not sensitive

Risk management follow up:

No EU legislation. Recommended guidance values e.g. for cereals, maize products and compound feed (Com. Recommendation 2006/576/EC)

Recommended guidance values for Fumonisin B1 + B2

Maize and maize products	60 ppm
Complementary and complete feed:	
For pigs, horses, rabbits and pet animals	5 ppm
For fish	10 ppm
For poultry, calves, lambs and kids	20 ppm
For adult ruminants and mink	50 ppm

GMO panel has adopted scientific opinions

- 15 maize applications (including on 8 stacked events)
- 4 applicants

Ongoing work

- 29 applications currently in progress
- including 17 opinions on stacked maize events
- including 8 applications for cultivation purposes

- Insect-resistant maize producing a substance toxic to certain Lepidoptera (= butterflies & moths)
- Maize MON810 is authorized for cultivation in Europe since 1998
- In 2008, maize MON810 was grown
 - mainly in Spain
 - to a lesser extent, the Czech Republic, Germany, Slovakia, Portugal, Romania and Poland

Maize MON810, almost everywhere in the pipeline of environmental risk assessment in EFSA...

(1) Application for renewal of the EU authorization of maize MON810

Art 23 of Regulation (EC) 1829/2003 on GM Food & Feed

(2) Several national safeguard clauses (GR, HU, FR, AU)

Art 23 of Directive 2001/18/EC on deliberate release of GMOs into the environment

(1) Renewal of MON810 consent in EU after 10-year authorisation

- First Environmental Risk Assessment (ERA) by the Spanish Competent authority in November 2008
- Ongoing Environmental Risk Assessment (ERA) by the EFSA GMO Panel
- Opinion will be tabled for discussion and possible adoption by the EFSA GMO Panel in May 2009



Comprehensive ERA considering all data from applicants, recent scientific data and relevant peer-reviewed publications

(2) National safeguard clauses on maize MON810

- Article 23 of Directive 2001/18/EC
 - ↳ possibility to invoke a provisional ban of use of a specific GMO on a national territory based on a scientific argumentation specific to the MS invoking the clause
- The EFSA GMO Panel was requested to assess the scientific argumentation and supporting documents provided by invoking MS (i.e. GR, HU, FR, AU) in support of their national measures,
- The EFSA GMO Panel met each invoking MS

(2) National safeguard clauses on maize MON810

- The EFSA GMO Panel has issued a scientific opinion on the past safeguard clauses on maize MON810 on
 - 2nd July 2008 for Greek national measure
 - 3rd July 2008 for the Hungarian national measure
 - 29th October 2008 for the French national measure
 - 4th December 2008 for the Austrian national measure

(2) National safeguard clauses on maize MON810

- The EFSA GMO Panel investigated the claims and documents provided by each invoking MS
- The EFSA GMO Panel did not identify any new data subject to scientific scrutiny or scientific information that would change previous risk assessments conducted on maize MON810
- More information
<http://registerofquestions.efsa.europa.eu/roqFrontend/questionsListLoader?panel=GMO>

In near future for maize - PRAPeR pesticide residues

- Today, the maximum residue levels (MRLs) are fully harmonised within the EU
- The PRAPeR Unit is performing an independent risk assessment for all new MRLs to be set in the EU, and is thus contributing to the safety of the consumers
- MRLs are set for food of plant and animal origin and will in the near future also be set for feed, as for instance maize silage

In near future for maize - NDA panel health claims

- ***Opinion adopted***

Opinion of the Scientific Panel on Dietetic products, nutrition and allergies [NDA] related to maize-germ oil high in unsaponifiable matter as a novel food ingredient **Adopted 6 December 2005**

- ***Ongoing evaluation of Health Claims***

- **Zea mays(Maize)- Kidney health**
- **Zea mays(Maize)- Liver health**
- **Resistant starch-type 2 (RS) fom high amylose maize- Digestive health benefits**
- **Resistant starch-type 2 (RS) fom high amylose maize- Healthy blood glucose/sugar levels**

Thank you for your attention!

