Committed *since 2002* to ensuring that Europe's food is safe





European Food Safety Authority

EFSA's activities with focus on the Risk Assessment and Scientific Assistance Directorate

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mitted *since 2002* Isuring that Europe's food is safe Sofia, 14-15 May 2012



Summary: EFSA: mission, priorities & how Cooperation Scope and structure of EFSA RASA Directorate Scientific output Data collections



EFSA's mission



- 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.
- Provides scientific and technical advice on all matters within these fields.
- EFSA communicates all findings publicly (task shared with EC/Member States).



- No responsibility for food safety legislation
- No task in food safety/quality controls, labelling or other such issues
- No substitute for national authorities

Priorities...



- Our objectives
 - Evaluate 700-1000 authorisation requests
 - Improve service to applicants...

EU 2020

- ...while maintaining our <u>capacity to provide scientific</u> <u>advice and develop risk assessment methodologies</u>
- Communications/ openness



Key priorities



- Boost risk assessment capacity :
 - Engage with National Agencies in routine work (financial support) to support Panels
 - Harmonise Risk Assessment methodologies
 - Consolidate International activities
 - Strengthen efficiency in processing applications
- Promote the use of the "integrated approach" for scientific advice (Science strategy 2010-2013)
- Strengthen the effectiveness of EFSA's Communication (Communication strategy 2010-2013)



Key priorities



- Assessing health and environmental impact of new products technologies: e.g. nanotechnology, active and intelligent packaging
- **Developing new risk assessment methodologies:** reduction of animal testing, novel foods
- Assess efficacy / benefit e.g. pesticides (2011), Health claims
- Sustainable innovation
 - health and environmentally friendly,
 - bringing benefits backed by science

⇒ EU 2020





In order to be successful in giving scientific advice, particularly in urgent matters, EFSA needs to work together with Member States and stakeholders to have tools available such as:



- European Food Consumption Database
- Food Composition database
- Occurrence data
- Effective network of experts

Collaboration is important !





How does EFSA work?







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How does EFSA work?



Receipt of the request



European Commission (EC)

European Parliament

Member States

(MS)





EFSA ("self mandate")

Question?



Risk Assessment Risk Communication

10 Scientific Panels 1 Scientific Committee 15 Scientific Units

Examination





Register of questions



Register of Questions (RoQ)



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<u>4-2010-0156</u> EFSA-Q-3	2010-00705	010-00705 Risk Assessment terminology in food and feed safety				Registration not yet completed		12/04/2010 10:01	
<u>4-2010-0155</u> EFSA-Q-3	2010-00704	Request for an EFSA conclusion on the active substance flutriafol according to Article 20 of Commission Regulation (EC) No. 33/2008.			PRAPER	Additional data request		12/04/2010 10:02	
<u>A-2010-0154</u> EFSA-Q-:	2010-00703	Request for an EFSA conclusion on the active substance sintofen according to Article 20 of Commission Regulation (EC) No. 33/2008.			PRAPER	In progress		12/04/2010 10:07	
1-2010-0153 EFSA-Q-		Chemically defined flavourings from Chemical Group 01 - Straight-chain primary 702 aliphatic alcohols/aldehydes/acids, acetal and esters with esters containing saturated alcohols and acetals containing saturated aldehydes: 86 substances				Under Consideration		31/03/2010 17:19	
/-2010-0152 EFSA-Q-:		Chemically defined flavourings from Chemical Group 02 - Branched-chain primary				Under Consideration		31/03/2010 17:15	

From the search result list click the **Question number** link to open the Question details page





Summary: EFSA: mission, priorities & how Cooperation Scope and structure of EFSA RASA Directorate Scientific output Data collections



Legal Basis



As defined in Article 23 (g) of Regulation (EC) No 178/2002,

EFSA shall establish networks of organisations operating in the fields within its mission and shall be responsible for their operation.

In addition, various specific sectorial legislations foresee a variety of networking activities between EFSA and the Member States' competent authorities. The main aim of the networks is to facilitate scientific cooperation through the coordination of activities; the exchange of information; the development and implementation of joint projects; and the exchange of expertise and best practice in the fields within EFSA's mission.



Legal Basis



Collection of data

1. The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission. This shall involve in particular the collection of data relating to:

(a) food consumption and the exposure of individuals to risks related to the consumption of food;

- (b) incidence and prevalence of biological risk;
- (c) contaminants in food and feed;
- (d) residues.

2. For the purposes of paragraph 1, the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from applicant countries, third countries or international bodies.

3. The Member States shall take the necessary measures to enable the data they collect in the fields referred to in paragraphs 1 and 2 to be transmitted to the Authority.

4. The Authority shall forward to the Member States and the Commission appropriate recommendations which might improve the technical comparability of the data it receives and analyses, in order to facilitate consolidation at Community level.





In June 2006, EFSA's Management Board recommended the development of greater cooperation and networking between EFSA and its counterparts in the Member States as a key priority over the next five years. They envisage this network of EFSA with the national authorities to be in a position to mobilise pan-European scientific resources towards the establishment of a network of scientific excellence, enabling all partners to maintain/further strengthen their system, both in terms of national activities and their contribution to European activities.



Cooperation?













Definition of Networks



Article 1: Definition and role of networks

- 1. The aim of the networks is to support the European Food Safety Authority (EFSA) and the Member States in carrying out its mission in accordance with the established standards of scientific excellence, transparency and responsiveness foreseen in Regulation No 178/2002/EC of the European Parliament and the Council of 28 January 2002 laying down the general principles of food law, establishing the European Food Safety Authority and laying down procedures in relation to food safety (hereinafter referred to as 'the Regulation'). These include *inter alia* facilitating the development of a scientific cooperation framework by the coordination of activities, the exchange of information, the development and implementation of joint projects and the exchange of expertise and best practices in the fields within the Authority's mission.
- 2. The activities laid down in Paragraph 1 of this Article are reported to the Executive Director of EFSA.
- 3. EFSA informs the Advisory Forum and the Scientific Committee of the activities of the network through regular reports.



Constitution of a Network



Article 2: Creation and composition of networks

1. Networks are created by EFSA in consultation with the Advisory Forum and Scientific Committee to work on specific areas within EFSA's remit.

SPECIFIC REM

- 2. A network shall be set up on the basis of a specific remit and shall be dissolved as soon as the remit has been completed.
- 3 A network shall be composed of organisations of EU Member States with expertise in the fields covered by the network. MEMBER - ALTERNATE

ADVISORY FORUM

Article 3: Appointment of members of the networks

- EFSA shall ask the Advisory Forum, which is responsible for ensuring close cooperation between EFSA and the 1. competent bodies in the Member States, to designate the members of the networks.
- 2. EFSA will provide all necessary information to the Advisory Forum in order to allow it to identify if organisations in European countries can contribute to the tasks of the network.
- 3. On this basis, the Advisory Forum may designate or not designate an organisation as member of a network and inform EFSA of the name of its representative and his/her alternate.
- 4 In the case where sectoral EU legislation specifies the competent organisations for a specific networking, these organisations are members of the network.



Network meetings



MINUTES / DOCUMEN

Article 6: Documentation of the outcome of the discussions

- 1. Networks shall endorse their contributions at their meetings or by the procedure set out in paragraph 2 of this Article.
- In the event that the nature, urgency or circumstances do not require or allow discussion at a meeting, a consultation may take place by written procedure.

Article 8: Minutes

- 1. The Secretariat shall prepare draft minutes of meetings.
- 2. The draft minutes shall be circulated for comments and agreed on either at the next meeting or in writing.
- 3. The minutes shall be placed on EFSA's website after adoption.

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Article 9: Mission expenses of representatives of the organisational members of the networks or of their alternates

 Unless already covered by reimbursements from the relevant organisation, travel and subsistence expenses incurred by representatives of the organisational members of the networks or their alternates in connection with meetings relating to networks shall be reimbursed by the Authority in accordance with the scales laid down in the Authority's expert compensation guide.





Summary: EFSA: mission, priorities & how Cooperation Scope and structure of EFSA RASA Directorate Scientific output Data collections



SCOPE: scientific advice on safety of food and feed throughout the food chain





Scientific Committee and Panels



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)
- Scientific Committee (SC)

Mainly generic opinions

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







Evaluation of **regulated products** takes up a major share of EFSA work:

- Steadily increasing applications in number (900 new dossiers in 2010 - of which 450 on health claims) and complexity
- 2. Applications typically come in bulk within large product reviews (PPP, food and feed additives, health claims, etc.)
- 3. Very complex legal environment (39 workflow stemming from 34 EU regulations and directives) evolving over time.
- 4. More than 40% of EFSA budget spent on applications in 2011



EFSA organigramme









 Reporting to
 Including coordination with the 2 Scientific Directorates



- Scientific Committee, Advisory Forum & 10 Panels
- Three scientific directorates:
 - Science Strategy & Coordination (SCISTRAT)
 - Scientific Committee, Emerging Risks, Advisory Forum & Scientific Cooperation

Mission: to develop general advice on matters of strategic and scientific nature , to foster scientific cooperation with Member States, preparation for responding to urgent requests, manages the Scientific Committee and networks , and maintains EFSA's capability in the area of identification and evaluation of emerging risks



Enhancing EFSA science – cont.



- Scientific Committee, Advisory Forum & 10 Panels
- Three scientific directorates:
 - Scientific Evaluation of Regulated Products (REPRO)
 - Applications desk, FEED, Pesticides, Nutrition, GMO, Food Ingredients & Packaging

Mission: to provide independent scientific advice to e.g. European Commission related to risk assessment of substances, products and processes intended to be used in the food chain and substantiation of claims made on foods in order to support the protection of public as well as the environment. REPRO is also responsible for developing guidance and providing advice on emerging safety issues related to products already authorised within the European Union.



Enhancing EFSA science - cont.



- Scientific Committee, Advisory Forum & 10 Panels
- Three scientific directorates:
 - <u>Risk Assessment & Scientific Assistance (RASA)</u>
 - Animal health & welfare, Plant health, Contaminants, Biological Hazards, Scientific Assessment support, Dietary & Chemical monitoring, biological monitoring





Summary: EFSA: mission, priorities & how Cooperation Scope and structure of EFSA RASA Directorate Scientific output Data collections





MISSION

To support the conduct of risk assessment and monitoring on general health and safety priorities in areas such as biological hazards, chemical contaminants and residues, plant health and animal health and welfare.







Four units supporting directly one of the following Scientific Panels which mainly address generic questions:

- the Panel on Animal Health and Welfare (AHAW),
- the Panel on Biological Hazard (BIOHAZ),
- the Panel on Contaminants in the Food Chain (CONTAM)
- the Panel on Plant Health (PLH)





RASA UNITS



Three units giving horizontal support across the three science directorates :

- Unit on Dietary and Chemical monitoring (**DCM**)
 - Coordination of data collection on food consumption and chemical compounds, and residues and veterinary drugs in the food chain
- Unit on Biological monitoring (**BIOMO**)
 - Coordination of data collection for zoonoses, food-borne outbreaks and antimicrobial resistance
- Unit on Scientific Assessment Support (SAS)
 - Supports quantitative modelling and systematic retrieval and analysis of scientific information, including library support



RASA Directorate



Three units giving horizontal support:

- Unit on Dietary and Chemical monitoring (DCM)
- Unit on Biological monitoring (BIOMO)

 Unit on Scientific Assessment support (SAS)

- Collection and analysis of data on food consumption, food composition, chemical contaminants in food and feed, residues and nutrient composition
- Data collection and reporting of data on biological hazards, zoonoses, foodborne outbreaks, animal populations and antimicrobial resistance
- Supports quantitative modelling as well as systematic retrieval and analysis of scientific information, including library support



Main ongoing activities in RASA 2011-2012

DIETARY AND CHEMICAL MONITORING

- Dietary exposure to hazardous compounds using contaminant data submitted by Member States and food consumption data from the Comprehensive Food Consumption Database;
- Harmonisation and standardisation of data collection;
- Residue monitoring reports on pesticides and veterinary drugs.





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Main ongoing activities in RASA 2011-2012 *

BIOLOGICAL MONITORING

- Annual data collection and reporting on zoonoses, antimicrobial resistance and food-borne outbreaks in EU and preparation of annual Community Summary Reports;
- Analyses of EU-wide baseline surveys on zoonotic agents in animals and food and preparation of baseline survey schemes;
- Definition of epidemiological criteria for adaptation in meat inspections.



efsa

s and Sources of Zoonoses and

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Main ongoing activities in RASA 2011-2012 🛫



SCIENTIFIC ASSESSMENT SUPPORT

- Statistical modelling support/review following good statistical and epidemiological practices to all units in EFSA.
- Development of framework to elicit expert knowledge to inform a risk assessment.
- Harmonisation and quality assurance of environmental monitoring.



Main ongoing activities in RASA 2011-2012

CONTAMINANTS

- Risk assessments for consumers in Europe from chemical and microbiological compounds in food
- Risk assessment for animals contaminants in feed and impact on human health
 - Mycotoxins (Fusarium toxins, Aspergillus) in food and feed,
 - plant toxicants (alkaloids) in food and feed,
 - metals (mercury) in food,
 - persistant organic pollutants (dioxins in food for children).





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Main ongoing activities in RASA 2011-2012 *

BIOLOGICAL HAZARDS

- Meat inspection mandate
 - Addressing biological and chemical hazards, as well as the potential impact on animal health and welfare of any changes to meat inspection;
 - Considering: domestic swine, poultry, bovine, domestic sheep and goats, farmed game and domestic solipeds;
 - BIOHAZ, CONTAM and AHAW Panels are involved.

Terms of reference:

- Identify and rank the main risks for public health that should be addressed by meat inspection at EU level.
- Assess the strengths and weaknesses of current meat inspection
- Recommend changes in inspection methods
- Taking into account implications of these changes for animal health and welfare



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Main ongoing activities in RASA 2011-2012

PLANT HEALTH

- Pest risk assessment:
 - Potato cyst nematodes (G. rostochiensis and G. pallida)
 - Cotton whitefly (Bemisia tabaci)
 - Support revision of the EU PLH Directive Annex IIAII (e.g. Lyriomyza leafminers)
- Peer-review:
 - Pine wood nematode (Bursaphelenchus xylophilus) a)
 - Golden apple snail (Pomacea insularum) a)
- Guidance documents:
 - Environmental risk assessment of plant pests ^{a)}
 - Identification and evaluation of risk reduction options
 - *a)* Potential significant environmental impact





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Main ongoing activities in RASA 2011-2012 🛫

ANIMAL HEALTH AND WELFARE

- Welfare of Animals during transport (published in Jan 11);
- Implementation of risk assessment for animal welfare (Guidance);
- Health and Welfare aspects of genetically modified animals (Guidance);
- Use of animal based indicators for animal welfare (dairy cows, pigs, and broilers);
- Meat inspection mandates;
- Various mandates on bovine tuberculosis, foot and mouth disease, swine vesicular disease and vesicular stomatitis.



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For animal welfare, the AHAW management plan aims at:

- Fine tuning the existing EU legislation to protect animal welfare (e.g. electrical requirements for water bath stunning equipment in Regulation 1099/2009, or 2005 Regulation on transport).
- Contributing to the EU Strategy for Animal Protection and Welfare (e.g. move towards a more flexible legislation based on welfare parameters to be measured on the animals).
- Developing Scientific Opinions on animal-based welfare indicators



Score o



Score 1



Score 2





Summary: EFSA: mission, priorities & how Cooperation Scope and structure of EFSA RASA Directorate Scientific output Data collections



EFSA Scientific Outputs



1² Scientific Opinions

of the Scientific Panels/Scientific Committee

- a. Opinion
- b. Statement
- c. Guidance







EFSA Scientific Outputs



Other Scientific outputs of EFSA

not adopted by the Scientific Panels/Scientific Committee

- a. Statement of EFSA
- b. Guidance of EFSA
- c. Conclusion on Pesticides Peer Review
- d. Reasoned opinion
- e. Scientific or Technical Report









- EFSA's Scientific Panels are responsible for EFSA's risk assessment work and cover whole food chain
- Members appointed by Management Board (MB) following open call for applications for three years renewable
- Selected on basis of proven scientific excellence, experience in relevant fields of risk assessment, specialised expertise coming from universities, research institutions and national food safety authorities
- Geographical balance and gender also taken into account
- Call for members of the Scientific Committee and 8 Scientific Panels for 2012-2015 was launched in 2011, and MB will nominate experts in March 2012



Overview of workflow on scientific opinions







Expert Database – Sign up today





EFSA Expert











Sign up and be an EFSA expert

- 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

- Want to make a difference to
 Value high profile networking with peers?
 - Driven by excellence?

and respective working groups. EFSA will draw on this database to find experts to help deliver high-guality, 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



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Identification of Working Group (WG) members





WG composition + ADOIs published on EFSA's Website



Risk assessment steps



HAZARD IDENTIFICATION

EXPOSURE ASSESSMENT

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



HAZARD CHARACTERISATION

ADME, acute/sub-chronic/chronic toxicity, human data, genotox, reprotox, mode/mechanism of action, mathematical modelling (BMD), derivation of a health based guidance value(*e.g.* TDI, ARfD)

RISK CHARACTERIZATION

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



Scientific Support: workflow







Scope: Monitoring of Risks and Exposure Compliance (pesticides case)





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Summary: EFSA: mission, priorities & how Cooperation Scope and structure of EFSA RASA Directorate Scientific output Data collections





- Commission Tasks: Art. 33 Reg. 178/2002
 - publish inventory Community data collection systems
- EFSA Tasks: Art. 33 Reg. 178/2002
 - set up networks with current and applicant MS, 3rd countries, international organisations
 - recommendations for improvement of data comparability and consolidation
 - collect, analyse, and summarise data
 - provide the results to Eur. Parliament, Comm, MS





• Objective data collections: Art. 22 Reg. 178/2002

- monitoring risks exposure compliance
- risk assessment exposure assessments

• Scope: Art. 33 Reg. 178/2002

- food consumption
- occurrence micro-organisms
- contaminants & residues and
- all data in EFSA's remit: food composition, animal health and welfare, plant health, and GMOs





- Data collection on zoonoses
 2007 report issued in Jan 2009
- Data collection on food consumption
- Data collection on chemical occurence
- Data collection on pesticide residues
 1st report in March 2009
- Emerging risks
 - RASFF analysis
 - Revision of Crisis Management Plan





Thank you very much for your attention!

