



EFSA in focus *PLANTS*

ISSUE 09 - MAY 2011

Contents

Key topics

- > EFSA addresses EU Council Guidelines for EC coordination of pest risk analyses process **1**
- > EFSA's outlook for 2011 **2**
- > Ensuring excellence in EFSA's scientific decision making **4**

EFSA at work

- > How prepared is EFSA for urgent requests for scientific advice? **4**

Working together

- > EFSA engages in open debate on GMOs in the European Parliament **5**
- > EFSA holds consultative workshop with stakeholders on draft guidance for GM plant comparators **6**
- > Scientific network for plant health risk assessment meets in Parma **6**

Events

- > EFSA's 16th Scientific Colloquium - Plant Health **7**

Publications

- > EFSA's 2011 Work Plan **7**
- > The challenge of describing food: scientific colloquium report available **8**
- > A compilation of EFSA scientific outputs from 2010 **8**

Consultations

- > EFSA seeks views on its updated guidance for assessing the risks of GMMs **8**

Scientific contracts and grants

9

Mandates accepted

9

Opinions and other outputs adopted

12

> Key topics

EFSA addresses EU Council Guidelines for EC coordination of pest risk analyses process



In January, EFSA outlined how it will address new EU Council guidelines for the EU's pest risk analysis process and the role of the different institutions involved.

The "Guidelines for EC coordination and handling of Pest Risk Analysis (PRA) documents and other scientific justification documents supporting the decision-making process for EC phytosanitary measures" were approved in June 2009. They were drawn up by chief officers of national plant health services across the EU in consultation with EFSA and EU institutional partners. The guidelines seek to assist the development, coordination and handling of pest risk analysis documents within the current European Union legal framework.

In the area of plant health, EFSA has a dedicated Plant Health Panel that responds to requests for advice from the European Commission. The Authority may also take the initiative to assess plant health matters. These requests lead to independent, high quality opinions on organisms posing a risk to plant health. These include plant pests which threaten crop production and species which threaten biodiversity, such as insects, bacteria, fungi, viruses, nematodes, parasitic plants and weeds.

EFSA welcomes the EU Council guidelines and its Plant Health Panel has published a guidance document detailing EFSA's role in plant health and in the implementation of these guidelines. The EFSA actions

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come in response to the guidelines and explain what EFSA does or will do to meet the risk managers' need for scientific advice related to standard procedures for handling pest risk analysis documents and fast-track procedures to produce preliminary pest risk analysis documents.

Under standard procedures, EFSA can extend the scope of national pest risk analyses to the whole of the EU or assess the EU-wide risk posed by plant pests. This can include identifying and evaluating possible risk management options. The Authority has also developed guidance to harmonise pest risk assessments and on the identification and evaluation of pest risk management options carried out by EFSA. In addition, EFSA is further developing plant health risk assessment methodologies, and has built inventories of data sources and models applicable to plant health risk assessments to ensure access to the most up-to-date information. The Authority has also established links to pan-European projects to access the latest cutting-edge research.

EFSA recognises the need to work closely with Member States to increase mutual understanding of the risk assessment process

and to further improve information exchange. The Authority has therefore created a scientific network of plant health risk assessors from EFSA and across the EU. The network will enable the sharing of best practice in pest risk assessments, the exchange of data and information, and the harmonisation of methodologies. In addition, EFSA has developed a collaborative online workspace for EFSA and Member States to electronically share information. The Authority also consults and exchanges information with the European and Mediterranean Plant Protection Organisation (EPPO).

For fast-track procedures, EFSA will work closely with the Commission to forecast the need for emergency advice. To be best prepared, EFSA will continue to work on improving the availability of data that can be shared with Member States through, for example, compiling inventories of data sources. It will also develop procedures for preparing and delivering quick advice. ■

[For more information.](#)

EFSA's outlook for 2011

EFSA expects 2011 to be another busy and productive year supporting Europe's risk managers with high quality scientific advice, according to the Authority's 2011 Management Plan.

The Authority plans to deliver some 750 scientific outputs and around 100 supporting publications in 2011. Two-thirds of these now concern applications where EFSA evaluates regulated substances and products, such as pesticides, feed additives, GMOs and enzymes, as well as the assessment of health claims. EFSA will also continue to elaborate its Science Strategy which will pull together the various strands of the Authority's scientific planning into a coherent, overarching document.

EFSA has reviewed its organisational structure and working processes to become even more efficient. This will optimise strategic planning and budgeting, establish a fully integrated performance management system, and offer a higher quality and more efficient service to applicants.

To help the Authority tackle its increasing workload, EFSA will help pool Europe's risk assessment resources more effectively by better involving Member States in its activities. For example, EFSA will outsource € 8.3m of activities to dedicated Member State organisations to assist in data collection or other such preparatory work. The Authority will also keep Member States better informed of its medium-term plans. In addition, EFSA will continue to strengthen its relationships with the European Commission, European Parliament and Council and will consult partners and stakeholders in developing its new policy on independence and scientific decision-making processes.

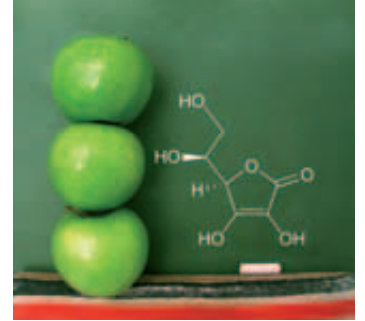
Active dialogue with stakeholders, including applicants, will continue to be vital to EFSA through, for example, technical meetings and EFSA's Stakeholder Consultative Platform.



Globally, the Authority will also continue to build bridges with international partners, in line with its 2009 international strategy and in liaison with the European Commission. This will help EFSA better position itself in relation to its work on emerging risks as well as grant it greater access to data and the shared development of risk assessment approaches.

The Authority will measure the effectiveness of its Strategic Plan 2009-2013 to see whether the planned actions are on track. EFSA will also be evaluated externally for the second time in 2011. The Authority will begin to use EFSA's newly-developed corporate impact indicators to gauge the extent to which its work is having an impact on Europe's legislative processes. In addition, EFSA will begin implementing a thematic approach to its communications as outlined in its Communications Strategy 2010-2013. ■

[For more information.](#)



Sign up and be an EFSA expert

- Want to make a difference to EU food safety?
- Contribute to EU risk assessment?
- Value high profile networking with peers?
- Driven by excellence?

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

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

Committed to ensuring that Europe's food is safe.

Ensuring excellence in EFSA's scientific decision making



Scientific excellence and independence are two closely linked core values of EFSA. The *Policy on Declaration of Interests (DOIs)* is one of the central pillars of the multifaceted system that EFSA has put in place to safeguard its independence which incorporates organisational governance, quality review, selection of experts, collegial decision-making, rules of procedure, consultation policies and transparency in risk assessment.

The *Policy on DOIs* was first adopted by EFSA's Management Board in 2007 and, as stipulated in the policy document itself, is scheduled for review this year. In light of recent questions on EFSA's independence and, more generally, global controversies related to the science underpinning public policies, it is an opportune time for reflection.

Unlike many of its international counterparts, EFSA relies heavily on external expertise, mainly drawn from academia, research organisations and national food safety agencies, for its scientific advice; for example, more than half of its scientific panel members come from the national food safety agencies. And as the European research funding model increasingly relies on public-private partnerships, it is essential that EFSA has a robust system in place to proactively identify and manage

any professional or personal conflicts of interest that might influence the objectivity of its scientific advice.

To assess the effectiveness of its independence systems, EFSA commissioned two independent reviews in 2010. The **first of these** assessed the Authority's efficiency in implementing the policy. An external consultancy analysed a sample of more than 180 DOI screenings of the 5000 that EFSA completes annually and concluded that the Authority is generally effective in implementing the policy with only minor compliance issues. EFSA also commissioned an **independent report** benchmarking its policies, structures and practices with ten peer international organisations. It found that EFSA has one of the most advanced and robust systems in place for ensuring the independence of its scientific advice.

The outcomes and recommendations of these two external reviews, together with the practical experience gained from implementing the policy and the feedback of partners and stakeholders, have helped EFSA formulate a **reflection paper** on the review of the *Policy on DOIs* which was shared with EFSA's Management Board in mid-March and later with the Scientific Committee, Advisory Forum and Stakeholder Consultative Platform. Their input will be reflected in a draft *Policy on Independence and Scientific Decision Making* which is submitted to the Management Board in June. The draft policy will integrate the existing elements of the policies, implementing procedures and systems that the Authority uses to protect its independence and will be subject to an online public consultation on EFSA's website.

The *Policy on Independence and Scientific Decision Making* will contribute to strengthening the confidence of consumers in Europe's food safety system, a key element of EFSA's mission. ■

[For more information.](#)

> EFSA at work

How prepared is EFSA for urgent requests for scientific advice?

In January EFSA published its annual report on how prepared it was in 2009 for crises. The report looks at three elements of the Authority's crisis preparedness: the Emergency Manual, the emergency training activities that it carried out in 2009 and its emergency response assessment. The report also describes how EFSA responded to requests for urgent advice in 2009.

EFSA needs to be able to respond quickly and efficiently to provide scientific and technical support to inform Europe's risk managers and consumers on "hot issues" and to communicate about its findings. For this, EFSA aims to be fully prepared for requests for urgent advice.

In 2009, EFSA further developed its in-house procedures for use within the Authority and by its staff in case of an urgent request for scientific advice. It introduced two additional activity levels for responding to urgent requests for advice, explaining in detail the response teams' roles and responsibilities. EFSA also established additional tools that will help respond to urgent requests for scientific advice, such as a functional mailbox for storing all relevant incoming and outgoing emails.

Also in 2009, EFSA conducted one in-house training and one crisis simulation exercise with Member States and the Commission. The exercises demonstrated that EFSA has a mature

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understanding of urgent advice planning and preparedness, and is well prepared for grasping the scientific problem at hand and for dealing with it in a systematic way. It was also evident from the exercises that EFSA has a good and trusting working relationship with the Commission, the Advisory Forum, where Member States are represented, and its Advisory Forum's Communications Working Group, and the respective roles are clearly understood. However, the exercises also revealed that improvement would be beneficial in internal information management and record keeping during the response to requests for urgent scientific advice by further developing the procedures and training EFSA staff on these issues.

Last but not least, during 2009, EFSA received two urgent requests for scientific advice, one concerning the presence of packaging ink in breakfast cereals and another one on nicotine in wild mushrooms. In both cases, the Authority was able to turn the advice around quickly, achieve consistent news coverage of its messages and avoid the generation of undue public concern. ■

[For more information.](#)

> Working together

EFSA engages in open debate on GMOs in the European Parliament

The European Food Safety Authority (EFSA) welcomed the debate on the risk assessment of genetically modified plants (GMOs) organised by the ALDE (Alliance of Liberals and Democrats for Europe) group of the European Parliament on 12 January, 2011. EFSA's senior scientific officers joined the wide-ranging, open discussion, taking the opportunity to explain how EFSA's rigorous risk assessment procedures are anchored in its core values of independence, scientific excellence and transparency. EFSA's most critical commitment is to provide Europe's policy makers with objective and timely scientific advice of the highest quality to support their decision-making. EFSA is always ready to uphold the integrity and scientific independence of its experts against any prejudiced or unjustified attack.

In the European Parliament, EFSA's scientists spelled out the sound science behind EFSA's risk assessment of GMOs and outlined the extensive work that the GMO Panel's experts have carried out to date, in particular on developing the guidance document on environmental risk assessment of GM plants as well as updating the guidance document on the risk assessment of GM food and feed safety.

The European Parliament meeting was yet another chance for EFSA to listen to the views of other scientists, MEPs, industry, representatives of non-governmental organisations (NGOs) and others on GMOs, as it does on a regular basis through consultations with stakeholders across all areas of its work.

EFSA's scientists highlighted the rigour and transparency of EFSA's risk assessment practices which guide the work of EFSA's Scientific Committee and Panels to help ensure its opinions respect the highest scientific standards. This guarantees that decision-makers at European and Member State level can be confident of receiving advice free of political, economic or other influence. European Commissioner for Health and Consumer Policy, John Dalli, confirmed that EFSA has in place a whole set of procedures aiming to prevent conflicts of interests which would be further reinforced in the near future.

Around 1,700 external experts are obliged by EFSA to submit Declarations of Interests each year and before each meeting in which they take part. These procedures are among the most stringent of any public or international body in the world. By following these procedures, EFSA each day limits or excludes experts from taking part in its scientific activities.

But EFSA is not complacent. It regularly assesses the implementation of its Declarations of Interests policy through its own internal auditor and through the internal audit service of the European Commission. EFSA has commissioned external consultants to review the implementation of the Declarations of Interests policy and to benchmark it against other organisations. In 2011, independent consultants will conduct the second five-yearly assessment of the Authority, focusing in particular on the way EFSA's principles of independence, scientific excellence and transparency are applied. ■

[For more information.](#)



EFSA holds consultative workshop with stakeholders on draft guidance for GM plant comparators



The European Food Safety Authority (EFSA) held a consultative workshop in Brussels on 31 March 2011 with scientists and risk assessors from EU Member States, industry and non-governmental organisations (NGOs) to discuss its

draft guidance on the selection of comparators for the risk assessment of genetically modified plants. The outcomes from the workshop as well as a prior public consultation will be taken into consideration by EFSA's Panel on Genetically Modified Organisms (GMO) as it works to finalise the guidance document.

The choice of an appropriate comparator is the cornerstone of the risk assessment of GMOs. The current approach followed by risks assessors worldwide is to carry out comparative assessments of the GM crop plant and its conventional crop counterpart to determine if the GM plant, such as for example GM maize, is as safe as its conventional non-GM counterpart. EFSA's GMO Panel took the initiative to strengthen the guidance to be followed by applicants when selecting appropriate comparators to be used in the risk assessment of GM plants.

The workshop began with a wide-ranging debate on the concept of substantial equivalence, giving context to the regulatory environment in which EFSA operates when carrying out risk assessment of GMOs. In the second session, a series of four discussions was held to explore comments made during the written public consultation on the draft guidance document. Each discussion focussed on different areas, including the risk assessment of single events, stacked events, stacked events from methods other than conventional crossing of plants and risk assessment when no comparator is available.

The GMO Panel regularly reviews its guidance taking into account scientific developments and experience gained through its risk assessments. EFSA always carries out a public consultation on its draft guidance documents. ■

[For more information.](#)

Scientific network for plant health risk assessment meets in Parma

EFSA's Scientific Network for Risk Assessment in Plant Health met for the first time in October in Salsomaggiore Terme near Parma to discuss pertinent issues in pest risk assessment on a national and European level. The aim of the network, a new platform for cooperation between EFSA and national plant health authorities, is to exchange views on improving data collection and harmonising pest risk assessment across the European Union. The participants discussed possible areas for cooperation, including sharing on-going pest risk assessment activities, identifying emerging risks and other priorities in the area of plant health.

The meeting brought together plant health experts from EU Member States and Norway, observers from Turkey, Croatia, Macedonia, Albania, Bosnia and Herzegovina, Montenegro and Serbia and representatives of the European Commission, Plant Health Panel members and EFSA staff. It gave EFSA an



opportunity to give an overview of its activities, including an update on current risk assessment work. The European Commission also presented the outcome of the recent evaluation study of the EU plant health legislation.

Network members agreed that environmental threats posed by exotic plants and plant pests were among the most pertinent issues in plant health and they welcomed EFSA's initiative to create a plant health guidance document for environmental risk assessment. EFSA is developing new guidance which will help evaluate the impact of plant pests on biodiversity. The draft guidance will be published for public consultation in mid-2011 with the final document available by the end of 2011.

The Chair of the EFSA Plant Health Panel, Mike Jeger, and the Head of EFSA's Emerging Risks Unit, Tobin Robinson told the network that EFSA would begin regular screening

for emerging issues in the area of plant health next year. An emerging issue to plant health is a risk resulting from a newly identified pest or a known plant pest that might spread in new areas. The screening process will include monitoring changes in exposure to known plant pests, changes in agricultural practices, spread of known pests to new countries or the introduction of new routes for movement of plants and plant products.

To explore this issue further EFSA is holding a scientific colloquium on emerging issues in plant health in June 2011 focusing on such factors as international trade in commodities and genetic variation in plants and plant pests. ■

[For more information.](#)

> Events

EFSA's 16th Scientific Colloquium - Plant Health

Parma, 9-10 June 2011

EFSA is organising its Scientific Colloquium XVI on emerging issues in plant health on 9 – 10 June 2011. International experts are gathering for an open scientific debate on key issues related to the identification of emerging risks in plant health in order to provide input for the development of EFSA's methodological framework for emerging risks identification in plant health.

The Colloquium is structured in a way to provide for in-depth discussion in discussion groups, alternated by plenary sessions. ■

[For more information.](#)

> Publications

EFSA's 2011 Work Plan

EFSA has published its 2011 Work Plan outlining its activities over the year. It predicts that 2011 will again be a busy and productive year, resulting in some 900 scientific outputs and supporting publications. Two-thirds of these will involve the evaluation of regulated substances, an area to which EFSA is devoting more and more of its resources.

In 2011, EFSA will review its organisational structure and working processes. This will enable it to: optimise strategic planning and budgeting; establish a fully integrated performance management system; and offer higher quality and more efficient service to applicants.

EFSA will help pool Europe's risk assessment resources more effectively by better involving Member States. It will continue to strengthen its relationships with the European Commission, European Parliament and Council and further engage in active dialogue with stakeholders.



In addition, EFSA will develop its science strategy and implement the actions resulting from its Communications Strategy 2010-2013. The overarching approach will be more thematic, demonstrating and illustrating the impact of EFSA's work. ■

[For more information.](#)

The challenge of describing food: scientific colloquium report available



The latest in EFSA's series of scientific colloquium reports has been published. It reports on discussions held among European and international experts on key issues related to the development of a harmonised food description and classification system.

EFSA scientists organised the colloquium to have an open scientific debate on the requirements of such a food description and classification system and to

build on experiences gained from the development of existing systems. Consideration was given to different approaches to classify foods and the diversity of needs for the various areas of food safety.

EFSA has a role in promoting and co-ordinating the development of harmonised risk assessment methodologies. Exposure assessment is a crucial and integral part of risk assessment and the quality of available data both on food consumption and on occurrence levels may have a major impact on the outcome of risk assessment.

Implementation of a common food description and classification system would improve the consistency and reliability of exposure assessment carried out by EFSA and its various panels and by other experts in Europe. ■

[For more information.](#)

A compilation of EFSA scientific outputs from 2010

EFSA has compiled the scientific outputs from its Scientific Committee, Panels and units from 2010 into one easy-to-use portable DVD.

Users can quickly and simply browse the DVD contents to find the documents they want. These can be opinions, guidance, statements, pesticide conclusions or reasoned opinions, or scientific and technical reports of EFSA. The outputs are also divided by Scientific Committee, Panel or unit for ease of use. ■



[For more information.](#)

> Consultations

EFSA seeks views on its updated guidance for assessing the risks of GMMs

EFSA's Panel on Genetically Modified Organisms (GMO) launched a public consultation on its updated guidance for assessing the risks of Genetically Modified Micro-Organisms (GMMs), and their food and feed products.

The update is aimed at those who are required by law to prepare and present applications involving genetically modified micro-organisms and their food and feed products that they would like to bring to market. The guidance covers products that consist of, contain, or are derived from genetically modified



micro-organisms. Substances such as additives, vitamins and enzymes produced with genetically modified micro-organisms are also covered.

The guidance which was sent for public consultation is an update of the previous guidance from 2006. It describes the steps to be taken and the issues to be considered when carrying

out a comprehensive risk characterisation. The guidance clarifies some issues and goes into greater depth in others, based on experience gained and input received since the 2006 document was made available. The consultation has since closed.

[For more information.](#)

> Scientific contracts and grants

External reports published

Defining Environmental Risk Assessment Criteria for Genetically Modified (GM) Mammals and Birds to be placed on the EU market

<http://www.efsa.europa.eu/en/supporting/pub/107e.htm>

Collection and evaluation of relevant information for the development of a new Guidance document on Emissions of Plant Protection Products from Protected Crops (e.g. greenhouses and crops grown under cover)

Central zone: <http://www.efsa.europa.eu/en/supporting/pub/76e.htm>

Southern Europe: <http://www.efsa.europa.eu/en/supporting/pub/106e.htm>

Collection and evaluation of relevant information on crop interception for the revision of the Guidance Document on Persistence in Soil

(lot 1): <http://www.efsa.europa.eu/en/supporting/pub/84e.htm>

(lot 2): <http://www.efsa.europa.eu/en/supporting/pub/73e.htm>

Emissions of PPP from protected crops

<http://www.efsa.europa.eu/en/supporting/pub/151e.htm>

Data entry of pesticide ecotoxicology Tier 1 study endpoints in a XML schema – database

<http://www.efsa.europa.eu/en/supporting/pub/155e.htm>

QSAR Analysis of Developmental Toxicity and Neurotoxicity

<http://www.efsa.europa.eu/en/supporting/pub/169e.htm>

> Mandates accepted

Mandates accepted: January-April 2011

Information on all other on-going requests is available in EFSA's [register of questions](#).

Assessment Methodology (AMU)

Request to provide a scientific opinion on the request from the USA regarding export of Florida citrus to the EU

Deadline: 31-Dec-11

Mandate number: M-2010-0449

Assistance request for EFSA-Q-2010-01343 guidance on methodology for evaluation of the effectiveness of options to reduce the risk of introduction and spread of organisms harmful to plants in the EU territory

Deadline: 31-Dec-11

Mandate number: M-2010-0510

AMU Assistance to GMO M-2010-0445, EFSA-Q-2010-01253 Mandate to update the 2006 Opinion of the GMO Panel on the Post-Market Environmental Monitoring (PMEM) of GM plants

Deadline: 30-Jun-11

Mandate number: M-2010-0445

Mandates accepted

4080 - Melatonin (including from plant sources e.g. Graminaceae, such as Festuca arundinacea) - Sleep patterns

Deadline: 30-Jun-11 Mandate number: M-2008-1061

AMU Methodological Consultation (systematic review and extensive literature search) / Support to PLH Unit - WG Citrus Cancer / Quantitative Risk Assessment EFSA-Q-2010-01262 Review of the supporting literature to support US request on export of citrus fruits to Europe

Deadline: 16-Sep-11 Mandate number: M-2010-0449

Internal Mandate proposed by EFSA to the AMU Unit for an Article 36 on "Feasibility study on the use of farmer/producer associations/federations to form sentinel surveillance networks for adverse events in primary production"

Deadline: 31-Jan-13 Mandate number: M-2011-0130

AMU assistance to M-2010-0281 Request for an EFSA opinion on the risks for public health related to the presence of opium alkaloids in poppy seeds

Deadline: 31-Jul-11 Mandate number: M-2010-0281

Emerging Risks (EMRISK)

Assistance request for EFSA-Q-2010-00794: Development of Guidance for the Assessment of Environmental Risks by EFSA Panel on Plant Health

Deadline: 30-Sep-11 Mandate number: M-2010-0182

Genetically Modified Organisms (GMO)

EC request on complementary environmental risk assessment of GM maize Bt11

Deadline: Additional data request Mandate number: M-2011-0001

Application for authorisation of genetically modified potato AV43-6-G7 for food and feed uses and cultivation submitted in accordance with Regulation (EC) No. 1829/2003 by BASF (EFSA-GMO-NL-2009-69)

Deadline: Additional data request Mandate number: M-2009-0113

Request to assess MON810 PMEM report for the 2009 cultivation season

Deadline: 15-Sep-11 Mandate number: M-2010-0445

Application for authorisation of genetically modified maize MIR604 for cultivation submitted under Regulation (EC) No 1829/2003 by Syngenta (EFSA-GMO-UK-2010-83)

Deadline: Additional data request Mandate number: M-2010-0357

Application for authorisation of genetically modified cotton GHB614 x LLCotton25 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2010-77)

Deadline: Additional data request Mandate number: M-2010-0085

Internal mandate for the preparation of a Scientific Report of EFSA on trial descriptions of strains of *Bacillus licheniformis* and *Aspergillus niger* modified with additional alpha-amylase gene(s)

Deadline: 30-Jun-11 Mandate number: M-2011-0025

EFSA approaches to risk assessment in the area of antimicrobial resistance, with an emphasis in commensal microorganisms

Deadline: 30-Jun-11 Mandate number: M-2011-0032

Application for authorisation of genetically modified cotton 281-24-236 x 3006-210-23 x MON88913 for food and feed uses, import and processing submitted in accordance with Regulation (EC) No. 1829/2003 by Mycogen Seeds c/o Dow Agroscience LLC (EFSA-GMO-NL-2009-68)

Deadline: Additional data request Mandate number: M-2009-0076

Application for authorisation of genetically modified maize DAS-40278-9 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Dow AgroSciences (EFSA-GMO-NL-2010-89)

Deadline: Additional data request Mandate number: M-2010-0505

Request for an opinion on the adequacy of EFSA guidelines to perform a risk assessment of plants developed through a number of new techniques

Deadline: 07-Jul-11 Mandate number: M-2011-0062

Application for authorisation of genetically modified amylopectin potato AM04-1020 for food and feed uses, import and processing and cultivation submitted under Regulation (EC) No 1829/2003 by BASF (EFSA-GMO-SE-2010-88)

Deadline: Additional data request Mandate number: M-2010-0379

EFSA scientific network for risk assessment of GMOs

Deadline: 22-Oct-13 Mandate number: M-2010-0409

Consultative workshop on the draft guidance on the selection of comparators for the Risk Assessment of GM plants

Deadline: 13-May-11 Mandate number: M-2010-0446

EFSA administrative guidance to applicants on the preparation and presentation of applications for authorisation on genetically modified plants and derived food and feed under Regulation (EC) No 1829/2003 complementing EFSA GMO Panel Food and Feed Guidance and EFSA GMO Panel ERA Guidance

Deadline: 18-Jul-11 Mandate number: M-2011-0147

Plant Protection Products and their Residues (PPR)**Guidance from EFSA for evaluating laboratory and field dissipation studies to obtain DegT50 values of Plant Protection Products in Soil containing the guidance for PRAPeR, Member State evaluators and applicants**

Deadline: 07-Feb-12 Mandate number: M-2011-0041

Scientific Opinion on the science behind the guidance for scenario selection and scenario parameterisation for predicting environmental concentrations in soil

Deadline: 07-Feb-12 Mandate number: M-2011-0041

Tier-1 and Tier-2 Scenario Parameterisation and Example Calculations. In Support of Revision of the Guidance Document on Persistence in Soil

Deadline: 07-Feb-12 Mandate number: M-2011-0041

Public consultation on the Guidance document on tiered risk assessment for aquatic organisms in edge-of-field surface waters

Deadline: 31-Jul-12 Mandate number: M-2009-0001

Guidance document on aquatic risk assessment procedures for individual and multiple plant protection products at the edge-of-field and catchment scale

Deadline: 31-Dec-14 Mandate number: M-2011-0128

Guidance document on tiered risk assessment procedure for sediment organisms and exposure via the sediment compartment in edge-of-field surface waters

Deadline: 31-Dec-13 Mandate number: M-2011-0128

Guidance document on ERA modelling approaches for aquatic organisms

Deadline: 31-Dec-13 Mandate number: M-2011-0128

Request of the European Commission to the European Food Safety Authority (EFSA) for providing opinions on the report of the FOCUS Groundwater working group (FOCUS, 2009): assessment of higher tiers

Deadline: 31-Dec-11 Mandate number: M-2011-0193

Mandates accepted

Request of the European Commission to the European Food Safety Authority (EFSA) for providing opinions on the report of the FOCUS Groundwater working group (FOCUS, 2009): assessment of lower tiers

Deadline: 27-Apr-12 Mandate number: M-2011-0193

State of the art on identification of appropriate reference points for the derivation of health-based guidance values for pesticides and on the derivation of uncertainty factors to be used for human risk assessment

Deadline: 31-Jan-13 Mandate number: M-2011-0154

Pesticide Risk Assessment and Peer Review (PRAPeR)

Mandates related to residues

Between January and April 2011, EFSA has received 9 requests to assess MRL applications under Article 10 of Regulation (EC) No 396/2005 and give reasoned opinions on modifying MRLs, 3 requests under Article 12.1 of Regulation (EC) No 396/2005 for review of existing MRLs, and 25 requests under Article 43 of Regulation (EC) No 396/2005 concerning scientific advice on certain MRLs.

Pesticide Risk Assessment and Peer Review of BAS 700 F (fluxapyroxad) under the programme of work referred to in Art. 6 of Council Directive 91/414/EEC

Deadline: Additional data request Mandate number: M-2009-0032

Request for EFSA to organise a peer review and to deliver its conclusions on the new ADI for phosmet proposed by the rapporteur Member State

Deadline: 30-Apr-11 Mandate number: M-2011-0056

Request for an EFSA conclusion on the active substance diphenylamine according to Article 20 of Commission Regulation (EC) No. 33/2008

Deadline: Additional data request Mandate number: M-2011-0108

Updating of the EFSA Pesticide Residue Intake Model (PRIMo) – Revision 3

Deadline: 30-Jun-11 Mandate number: M-2011-0123

> Opinions and other outputs adopted

Opinions and other outputs adopted: January-April 2011

Disclaimer: This is **not the full list** of all EFSA opinions but only those considered relevant to this newsletter.

Assessment Methodology (AMU)

Internal Mandate proposed by EFSA to the Assessment Methodology Unit for a Working Group on the submission of scientific peer-reviewed open literature in view of the approval of pesticide active substances under the new Regulation concerning the placing of plant protection products on the market

Adopted on: 24-Feb-11 Question number: EFSA-Q-2009-00827
<http://www.efsa.europa.eu/en/efsajournal/pub/2092.htm>

Genetically Modified Organisms (GMO)

Application for authorisation of genetically modified soybean A5547-127 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Bayer CropScience (EFSA-GMO-NL-2008-52)

Adopted on: 13-Apr-11 Question number: EFSA-Q-2008-290
<http://www.efsa.europa.eu/en/efsajournal/pub/2147.htm>

Selection of comparators for the Risk Assessment of GM Plants

Adopted on: 14-Apr-11 Question number: EFSA-Q-2009-00550
<http://www.efsa.europa.eu/en/efsajournal/pub/2149.htm>

Update of the Guidance document for the risk assessment of food and feed from genetically modified plants

Adopted on: **14-Apr-11** Question number: **EFSA-Q-2008-05020**
<http://www.efsa.europa.eu/en/efsajournal/pub/2150.htm>

Plant Health (PLH)**Request to provide a scientific opinion on the risk to plant health of *Monilinia fructicola* for the EU territory**

Adopted on: **23-Mar-11** Question number: **EFSA-Q-2010-00912**

Request to provide a scientific opinion on a technical file submitted by the US authorities to support a request to list a new option among the EU import requirements for wood of *Agrilus planipennis* host plants

Adopted on: **20-Apr-11** Question number: **EFSA-Q-2010-01097**

Pesticide Risk Assessment and Peer Review (PRAPeR)**Reasoned opinions**

Between January and April 2011, EFSA issued 22 reasoned opinions (under Article 10 of Regulation (EC) No 396/2005) on the modification of MRLs, responding to 25 requests. In addition, EFSA provided one reasoned opinion (under Article 43 of Regulation (EC) No 396/2005) on specific questions regarding the risk assessment of MRLs.

<http://www.efsa.europa.eu/en/pesticides/mrls.htm>

Conclusions on the peer review of the pesticide risk assessment on active substances:**1-naphthylacetamide**

Adopted on: **15-Feb-11** Question number: **EFSA-Q-2010-00871**
<http://www.efsa.europa.eu/en/efsajournal/pub/2020.htm>

1-naphthylacetic acid

Adopted on: **15-Feb-11** Question number: **EFSA-Q-2010-00870**
<http://www.efsa.europa.eu/en/efsajournal/pub/2019.htm>

2-naphthyloxyacetic acid

Adopted on: **27-Apr-11** Question number: **EFSA-Q-2010-01021**
<http://www.efsa.europa.eu/en/efsajournal/pub/2152.htm>

acetochlor

Adopted on: **15-Apr-11** Question number: **EFSA-Q-2010-01022**
<http://www.efsa.europa.eu/en/efsajournal/pub/2143.htm>

aluminium sulfate

Adopted on: **02-Mar-11** Question number: **EFSA-Q-2011-00140**
<http://www.efsa.europa.eu/en/efsajournal/pub/1889.htm>

carbetamide

Adopted on: **02-Mar-11** Question number: **EFSA-Q-2011-00142**
<http://www.efsa.europa.eu/en/efsajournal/pub/1913.htm>

chloropicrin

Adopted on: **23-Feb-11** Question number: **EFSA-Q-2010-00861**
<http://www.efsa.europa.eu/en/efsajournal/pub/2084.htm>

flufenoxuron

Adopted on: **23-Feb-11** Question number: **EFSA-Q-2010-00853**
<http://www.efsa.europa.eu/en/efsajournal/pub/2088.htm>

fluquinconazole

Adopted on: **25-Feb-11** Question number: **EFSA-Q-2010-01020**
<http://www.efsa.europa.eu/en/efsajournal/pub/2096.htm>

fluroxypyr

Adopted on: **24-Feb-11** Question number: **EFSA-Q-2010-01215**
<http://www.efsa.europa.eu/en/efsajournal/pub/2091.htm>

Opinions and other outputs adopted

metaldehyde

Adopted on: **02-Mar-11** Question number: **EFSA-Q-2011-00144**
<http://www.efsa.europa.eu/en/efsajournal/pub/1856.htm>

oxyfluorfen

Adopted on: **02-Mar-11** Question number: **EFSA-Q-2011-00141**
<http://www.efsa.europa.eu/en/efsajournal/pub/1906.htm>

propanil

Adopted on: **23-Feb-11** Question number: **EFSA-Q-2010-00851**
<http://www.efsa.europa.eu/en/efsajournal/pub/2085.htm>

propargite

Adopted on: **23-Feb-11** Question number: **EFSA-Q-2010-00852**
<http://www.efsa.europa.eu/en/efsajournal/pub/2087.htm>

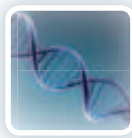
triazoxide

Adopted on: **15-Feb-11** Question number: **EFSA-Q-2010-01058**
<http://www.efsa.europa.eu/en/efsajournal/pub/2018.htm>

Scientific Committee & Advisory Forum (SC&AF)

Guidance on risk assessment concerning potential risks arising from applications of nanoscience and nanotechnologies to food, feed, and pesticides

Adopted on: **06-Apr-11** Question number: **EFSA-Q-2009-00942**
<http://www.efsa.europa.eu/en/efsajournal/pub/2140.htm>



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