



EFSA in focus *PLANTS*

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> Key topics

EFSA publishes its first report on pesticide residues in food



The European Food Safety Authority (EFSA) has published its first Annual Report on Pesticide Residues, which provides an overview on the pesticide residues in food observed throughout the European Union (EU) during 2007 and assesses the exposure of consumers through their diets. The report showed that the majority of the samples complied with the legal maximum residue levels (MRLs) of pesticides and made a series of recommendations to further improve the collection of data required for pesticide exposure assessment.

The report, prepared by EFSA's Pesticide Risk Assessment Peer Review (PRAPeR) Unit, said that 96% of the samples analysed were compliant with the legal Maximum Residues Levels (MRLs) and 4% exceeded them, compared to 5% in 2006.

In total, more than 74,000 samples of nearly 350 different types of food were analysed for pesticide residues in 2007, representing a 13% increase in comparison with 2006. Considerable efforts were made by Member States in extending the scope of the analytical methods, which made it possible to detect up to 870 pesticides in 2007 – an increase of 13% compared to previous years.

In order to protect consumers, MRLs are set at levels which are both safe for consumers and correspond to the lowest amount of pesticide used on the crop to achieve the desired effect. EFSA specified that the presence of pesticides in foods, and even the exceedance of an MRL, does not necessarily imply a food safety concern.

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Stakeholder workshop on defining protection goal options in environmental risk assessments of plant protection products

EFSA's Panel on Plant Protection Products and their Residues (PPR) is planning to hold, in April 2010, a stakeholder workshop in Parma on defining specific protection goal options in the context of the revision of the Guidance Documents on Aquatic Ecotoxicology and on Terrestrial Ecotoxicology. Registration will open in December.

[For more information](#)

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When an MRL is exceeded, consumer exposure needs to be calculated in order to assess whether this represents a potential risk for consumers.

In assessing chronic (long-term) consumer exposure, EFSA followed a cautious approach, using conservative assumptions which overestimate exposure. For all evaluated pesticides, except one (diazinon), the chronic exposure did not raise concerns for consumer health. It is worth noting that since December 2007 all authorisations concerning this substance have been withdrawn and MRLs have been lowered.

The assessment of acute (short-term) exposure was also based on worst-case scenarios. Thus, estimates took into consideration high food consumption combined with the highest residue observed

in the 2007 EU monitoring programme. Such critical intake cases are in reality very unlikely to occur. Assuming this scenario was to occur, a potential consumer risk could not be excluded for some of the results concerning 52 pesticide/commodity combinations, many of which have already been addressed by withdrawing authorisations or by lowering MRLs.

EFSA provided a series of recommendations for future monitoring programmes on pesticide residues, such as amending the reporting format to ensure more detailed results which will allow more accurate exposure assessment. These improvements will help better inform and support risk managers in regulating the safe use of pesticides. ■

[For more information](#)

EFSA experts aim to harmonise GMO data analysis

EFSA has published a new opinion aimed at harmonising how data from field trials carried out for the risk assessment of GM plants and derived food and feed are produced and analysed. The objective of the document is to contribute to greater transparency in the risk assessment of GMOs and also to allow for a more rapid evaluation of applications.

The experts on EFSA's GMO Panel put forward some general rules on minimum requirements for the design of field trials aimed at ensuring more accurate statistical evaluation of the safety of GM plants. As with all guidance, the document may well be updated in the future in the light of experience and development of scientific knowledge.

The opinion listed a set of recommendations covering elements such as the number of sites where experiments should be carried out, growing seasons and the geographical spread. In addition, it highlighted some statistical aspects which will benefit from further research, such as the possibility of assessing simultaneously many characteristics of the GM plant.

EFSA's experts also specified that the principles proposed in the opinion may be used, in certain cases, for the evaluation of GMOs other than plants.

EFSA's risk assessment of genetically modified organisms (GMO) is based on the comparison of the GMO products with their non-GM counterparts. The equivalence between the two must be within the range of variations that would occur between two non-GMO organisms in nature.

The opinion, entitled "Statistical considerations for the safety evaluation of GMOs", is the product of over two years' work and capitalises on the experience of EFSA in the evaluation of GMO applications under EU regulations. The initial version of the document was open for public consultation during a 2-month period, from July to September 2008; this allowed the consideration of 98 submissions from various stakeholders. ■

[For more information](#)

Public health effects of increasing total aflatoxin levels for some nuts

In June 2009 the European Commission asked EFSA to rapidly assess the effect on public health of an increase of the maximum level for total aflatoxins from 4 µg/kg to 10 µg/kg allowed for tree nuts other than almonds, hazelnuts and pistachios (e.g. Brazil nuts and cashews). This would facilitate the enforcement of the maximum levels, in particular as regards mixtures of nuts. This request was triggered by discussions with Member States on aligning EU law on aflatoxins to the Codex Alimentarius decision to set the maximum level at 10 µg/kg.

EFSA's Scientific Panel on Contaminants in the Food Chain (CONTAM) concluded that public health would not be adversely affected by increasing the levels for total aflatoxins from 4 µg/kg to 8 or 10 µg/kg for all tree nuts. However, the Panel reiterated its previous conclusions regarding the importance of reducing the number of highly contaminated foods reaching the market.

In order to estimate human exposure in these two assessments, EFSA took into consideration occurrence data submitted by



20 Member States and third parties in 2006, as well as food consumption data obtained from the GEMS/Food Consumption Clusters Diets of the World Health Organisation, based on data of the Food and Agriculture Organisation. The short deadline of the Commission request for the current statement did not allow EFSA to issue a complementary call for further information, thus EFSA relied on existing information on aflatoxins in food collected in 2006.

In June 2009 EFSA also launched a call for proposals to study the potential increase in aflatoxin B1 in cereals in the EU as a result of climate change. The project will gather and analyse data on aflatoxin B1 in order to build predictive models, define scenarios and create maps highlighting potential future contamination of cereal crops (see p.9).

Aflatoxins are genotoxic and carcinogenic. They can occur in food and feed as a result of fungal contamination by moulds, primarily by *Aspergillus flavus* and *A. parasiticus* under warm and humid conditions. They are most likely to contaminate tree nuts (e.g. almonds, hazelnuts, pistachios, Brazil nuts, cashew nuts, walnuts, pecan nuts), ground nuts (e.g. peanuts), figs and other dried fruits, spices, crude vegetable oils, cocoa beans and maize.

[For more information](#)

EFSA evaluates antibiotic resistance marker genes in GM plants

An EFSA statement was published in June 2009 that provides a consolidated overview of the use of antibiotic resistance marker genes (ARMG) in GM plants, including a joint scientific opinion of the GMO and BIOHAZ Panels. The Panels concluded that, according to information currently available, adverse effects on human health and the environment resulting from the transfer of the two antibiotic resistance marker genes, *nptII* and *aadA*, from GM plants to bacteria, associated with use of GM plants, are unlikely. Uncertainties in this opinion are due to limitations related, among others, to sampling and detection, as well as challenges in estimating exposure levels and the inability to assign transferable resistance genes to a defined source. Two members of the BIOHAZ Panel expressed minority opinions concerning the possibility of adverse effects of antibiotic resistance marker genes on human health and the environment.

In another opinion, the GMO Panel reviewed its previous assessments of individual GM plants containing ARMG taking into account the findings and conclusions of the joint opinion of the GMO and BIOHAZ Panels. The GMO Panel concluded that its previous risk assessments on the use of the *nptII* marker gene in GM plants are consistent with the risk assessment strategy described in the joint opinion and that no new scientific evidence has become available that would prompt it to change its previous opinions on these GM plants.

Following the adoption of the joint opinion of the GMO and BIOHAZ Panels, EFSA asked the panels to consider whether the minority opinions required any clarification of the joint opinion or additional scientific work. The Panel chairs responded that the minority opinions had been extensively considered during the preparation of the joint opinion and no further clarification or scientific work were needed at this time.

In their joint opinion, the GMO and BIOHAZ Panels concluded that transfers of ARMG from GM plants to bacteria have not been shown to occur either in natural conditions or in the laboratory. The key barrier to stable uptake of antibiotic resistance marker genes from GM plants to bacteria is the lack of DNA sequence identity between plants and bacteria.

The Panels concluded that the antibiotic resistance genes *nptII* and *aadA* occur at different frequencies in different bacterial

species and strains, and environments. Recent analyses of total bacterial populations using the most advanced technologies have demonstrated that resistance genes to the antibiotics kanamycin, neomycin and streptomycin are present in all environments investigated. The presence of antibiotics in the environment and antibiotic usage are key factors in driving the selection and dissemination of antibiotic resistance genes.

The Panels underlined limitations related among others to sampling, detection, challenges in estimating exposure levels and the inability to assign gene transfer to a defined source. Sampling and detection issues are technical aspects of experiments which may limit the validity of results. Furthermore, it is often not possible to find out precisely from which organism an ARM gene present in another organism may have originated nor to give a precise estimation of the extent of the phenomenon.

In collaboration with the European Medicines Agency (EMA) and the European Centre for Disease Prevention and Control (ECDC), the Panels also considered the clinical importance for human and veterinary medicine of the antibiotics to which the ARMG confer resistance. *NptII* confers resistance to the antibiotics kanamycin and neomycin. These are categorised by the World Health Organization (WHO) as 'highly important antimicrobials'. Kanamycin is used as a second-line antibiotic for the treatment of infections with multiple drug-resistant tuberculosis (MTB); increasing resistance of MTB to such antibiotics is of concern globally. However, the Panels noted that *nptII* has not been implicated in resistance to kanamycin in the treatment of MTB.

The GMO Panel also reviewed its previous opinions on the use of *nptII* in GM plants following the findings from the joint opinion of the GMO and BIOHAZ Panels. The GMO Panel concluded, in another opinion, that its previous risk assessments on the use of *nptII* in maize MON 863 and hybrids, as well as starch potato EH92-527-1, are in line with the risk assessment strategy described in the joint opinion of the GMO and BIOHAZ Panels. The GMO Panel also underlined that no new scientific evidence has become available that would prompt the Panel to change its previous opinions on these GM plants.

[For more information](#)

EFSA takes forward work on cumulative effects of pesticides

The European Food Safety Authority (EFSA) has recently published the Scientific Opinion “Risk assessment for a selected group of pesticides from the triazole group to test possible methodologies to assess cumulative effects from exposure throughout food from these pesticides on human health”. The opinion has been drafted within the framework of the on-going work to develop methodologies to assess the cumulative effects resulting from consumer exposure to pesticides. Triazoles are a group of pesticides (fungicides) that have a similar chemical structure and toxic effects. In the opinion, it was investigated if their impact on human health can be assessed collectively with the currently available methodologies.

EFSA’s Panel on Plant Protection Products and their Residues (PPR) concluded that it would be necessary to reach international consensus on which groups of pesticides could be looked at together through a cumulative risk assessment approach. The Panel specified that in order to address uncertainties, the application of new cumulative risk assessment methodologies required further work and that guidance on appropriate methodologies for exposure assessment is still needed.

In a previous opinion published within the framework on cumulative risk assessment, the PPR Panel investigated possible types of combined toxicity of pesticides including the interaction of different chemicals. The Panel concluded that only cumulative effects from concurrent exposure to substances which have a common mode of action raised concerns and merited further consideration.

In order to evaluate methodologies proposed in this previous opinion, the Panel selected pesticides from the group of triazole fungicides on the basis of their similar chemical structure and mode of action, which are considered prerequisites for the assessment of cumulative effects. It should be emphasised that this work cannot be considered as a definitive risk assessment of triazoles.

The Panel evaluated different scenarios, taking into account both long and short-term toxicological effects together with different exposure conditions. The exposure evaluation was based on recent data on residues of different triazoles in food as well as data on food consumption.

EFSA’s work on cumulative risk assessment contributes to the establishment of Maximum Residue Levels (MRLs), the levels of pesticide residues allowed in food to ensure consumer protection and is part of EFSA’s on-going commitment to be at the forefront of developing risk assessment methodologies. It also follows recommendations listed in EFSA’s previous opinion and is part of EFSA’s broader work on cumulative risk assessment, following its “Scientific Colloquium on Cumulative Risk Assessment” in 2006, which helped guide further developments in the field. ■

[For more information.](#)

> EFSA at work

GM plants used for non-food or non-feed purposes – EFSA specifies requirements for safety assessment

In its opinion on “Guidance for the risk assessment of genetically modified plants used for non-food or non-feed purposes”, EFSA’s Panel on Genetically Modified Organisms (GMO) discusses risk assessment issues and defines the specific requirements that applicants need to follow to allow efficient risk assessment of GM plants used for other purposes than food or feed. This will complement EFSA’s existing “Guidance on the safety evaluation of GM plants”, initially conceived for the assessment of GM plants used for food and feed purposes.

GM plants developed for non-food or non-feed purposes are plants which may be used for a wide range of applications such as the production of: industrial enzymes; raw materials for bio-fuels, paper and starch; medicinal products (such as vaccines and antibodies); as well as other uses which can range from energy production to helping to address environmental issues (for instance the take-up of contaminants present in soil through phytoremediation).

In its opinion, the GMO Panel advocates – as for GM plants used for food and feed - a comparative approach whilst highlighting that it should be applied carefully. The Panel considered that existing guidance for environmental risk assessment is adequate but that additional emphasis should be given to issues such as gene transfer and the exposure of non-target organisms,

particularly wildlife feeding on these GM plants. When in certain cases the applicant proposes confinement strategies to reduce exposure of humans, animals or the environment, the GMO Panel has specified the information requirements needed to carry out the exposure assessment. Where new potential GM plant risks are identified, the plants are likely to require more specific risk management conditions.

The Guidance benefited from the contribution of selected experts in the field of GM plants for non-food or non-feed purposes and in the field of risk assessment of pharmaceutical products. Legal advice was also given by the European Commission and the European Medicines Agency (EMA). EFSA received comments during a 3-month public consultation which have been taken into account in finalising the opinion.

EFSA’s role is to evaluate the safety of GM plants for human and animal health and the environment. Guidance documents aim at ensuring that applications for marketing GM plants contain all information and data required to support a comprehensive risk assessment, so that applications can be efficiently evaluated by EFSA and other competent authorities in Europe. ■

[For more information.](#)

Introducing the benchmark dose approach - a more sophisticated choice for deriving health-based guidance values?

EFSA's Scientific Committee considers the benchmark dose (BMD) approach for deriving health-based guidance values, such as an Acceptable Daily Intake (ADI), to be scientifically more advanced than existing methods. This follows a comparison of the strengths and weaknesses of the different approaches.

Traditionally, when experimental animal data are used for risk assessments of non-genotoxic and non-carcinogenic food substances, the No-Observed-Adverse-Effect-Level (NOAEL) and/or the Lowest-Observed-Adverse-Effect-Level (LOAEL), are the reference points for deriving health-based guidance values. However, while these approaches may use qualitative information, they do not use all the available data quantitatively. In contrast, the BMD approach makes extended use of dose-response data from studies in experimental animals or from observational epidemiological studies to better characterise and quantify potential risks. Therefore, the Scientific Committee concludes that the BMD approach is scientifically more advanced than the NOAEL approach.

Using the BMD approach also results in a more consistent reference point, as a consequence of the specified benchmark response. In addition, health-based guidance values derived using the BMD approach can be as protective as those derived from the NOAEL approach, i.e. on average over a large number of risk assessments. Therefore the default values for uncertainty factors currently applied remain appropriate and there is no need for any additional uncertainty factor.

The BMD approach is applicable to all chemicals in food, irrespective of their category or origin, e.g. pesticides, additives or contaminants. The BMD approach is of particular value for:

- i) situations where the identification of a NOAEL is uncertain;

- ii) providing a reference point for the margin of exposure in case of substances that are both genotoxic and carcinogenic; and
- iii) dose-response assessment of observational epidemiological data. In the short term, the Scientific Committee strongly encourages EFSA's Scientific Panels and Units to adopt the BMD approach to situations such as those above.

In the longer term, the Scientific Committee anticipates that the BMD approach will be used as the method of choice for the determination of the reference points for deriving health-based guidance values and margins of exposure. Given that there are practical considerations regarding its introduction and wider use in EFSA, and that its application requires a level of expert judgement and modelling expertise, the Scientific Committee proposes that training in dose-response modelling and the use of relevant software be offered to EFSA experts. The Scientific Committee would then review the implementation, experience and acceptability of the BMD approach in EFSA's work in two years time.

EFSA has not systematically used the BMD approach so far, although some EFSA Scientific Panels have been applying the BMD approach occasionally. However, the Scientific Committee does not consider it necessary to repeat all previous evaluations using the BMD approach, because, on average, the BMD and NOAEL approaches give comparable results. Where refinement of previous risk assessments is considered necessary, for instance where the human exposure is close to the ADI, application of the BMD approach would be of particular value. ■

[For more information.](#)

> Meeting reports

Technical meeting on the risk assessment of maize MON810 for authorisation renewal

Parma, 26 May 2009

EFSA held a technical meeting with Member State experts to exchange views on the environmental risk assessment of GM maize MON810 in the context of the ongoing discussion to renew its application for cultivation.

EFSA decided to call this meeting to address the scientific comments received in a letter signed by 18 Ministers from 12 Member States on the renewal application for MON810. Scientific experts from all Member States were invited to the meeting with environmental experts of EFSA's GMO Panel. In total, 18 experts from 13 Member States attended, plus observers from Norway and the European Commission.

During the meeting, EFSA outlined the Panel's work on GMOs, detailing its activities and regularly updated guidelines. EFSA also underlined that it was aware of the concerns raised in the joint letter and explained how these issues had been >>>



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addressed in the environmental risk assessment of maize MON810. Nonetheless, the Authority welcomed further discussion, which would be considered in the finalisation of the scientific opinion.

The scientific arguments from Member States centred on the evolution of resistance in target pests and the effects on non-target organisms, in particular *Lepidoptera* species. Delaying the evolution of resistance by the use of refuges was discussed. There were concerns that the minimum area threshold of five hectares to implement refuges, as proposed by the applicant, might not be appropriate for the European agricultural landscape, as most farmers grow less than five hectares of maize. After discussing the matter, it was agreed that this was an issue more for risk managers than risk assessors. The panel also agreed that if the risk of resistance not was adequately managed then Bt resistance would be likely to emerge eventually. Moreover, it was agreed that more specific refuge management measures might be required, if Bt-maize is adopted on a large scale in a region.

As for the effects on non-target species, despite concerns over the studies and the expression data submitted by the applicant, the Panel assured attendees that the assessment also took into account the latest scientific studies and that effects on non-target species will be addressed in the opinion. Concerning comparative baselines, the Panel explained that common agricultural practices for conventional maize are a baseline for risk assessment. The Panel is responsible for assessing whether the impacts of GM maize are expected to be worse than those of conventional maize. The Panel emphasised that it must assess likely areas across all of Europe. Regarding monitoring, the Panel pointed out that post market monitoring is a requirement in the approval process for the renewal of MON810.

The outcomes of the meeting were taken into account by the GMO Panel in finalising its scientific opinion on the renewal application for maize MON 810. ■

[For more information.](#)

EFSA and NGOs meet in Parma to discuss GMOs

EFSA has held a meeting in Parma with environmental NGOs on the subject of genetically modified organisms as part of its commitment to regular open dialogue with organisations with a legitimate interest in its work.

EFSA Executive Director, Catherine Geslain-Lanéelle, welcomed all participants to the meeting. Five members of EFSA's GMO Panel, including its chair Harry Kuiper, held a day of discussions with Helen Holder and Werner Mueller of Global 2000/Friends of the Earth, Austria and Janet Cotter of Greenpeace.

EFSA scientific officers from the GMO unit also took part in the meeting which was chaired by the head of EFSA's Risk Assessment Directorate, Riitta Maijala, and the Head of the GMO unit, Per Bergman. Representatives from the Commission's DG SANCO and DG Environment were also present as observers.

Per Bergman also presented EFSA's work in the area of GMO risk assessment including actions arising from the conclusions from the Environmental Council in December last year.

Discussions focused on recent issues linked to the GM maize MON810 and the GM rice LLRice62. The meeting included an exchange of views on the scientific comments received on the Commission's public consultation on the risk assessment of MON810 and the scientific questions raised during the risk assessment of LLRice62.

Additional topics discussed were EFSA's review of long-term environmental risk assessment and its review of the environmental impacts of herbicide tolerant GM crops. ■

The European Consumers' Association (BEUC) visits EFSA

The European Food Safety Authority (EFSA) welcomed Paolo Martinello, the new President of the European Consumers' Organisation (BEUC), who led a BEUC delegation on a visit to EFSA headquarters on 9 July 2009. EFSA presented its core activities in risk assessment, scientific cooperation and communications and reiterated the importance of dialogue with stakeholders in fulfilling its mandate of protecting consumers.

EFSA explained how scientific opinions are finalised, from the initial mandate given to the European food safety watchdog to the final publication of the opinion. The BEUC delegation received an update on the work of the Panel dealing with dietetic products, nutrition and allergies (NDA), with a focus on EFSA's opinion on reference intakes and nutrient profiles, and on the guidelines produced by EFSA's Panel on food contact materials, enzymes and flavourings for the safety assessment of substances used in active and intelligent materials. In addition, EFSA also discussed with BEUC its approach to risk communication and provided an update on its activities in this area.



BEUC is a member of EFSA's Stakeholder Consultative Platform where it contributes its views on a wide variety of issues related to the work of the Authority. The Platform is composed of 24 EU-wide stakeholder organisations working in areas related to the food chain, representing consumers, food and feed operations, the food industry, food trade and NGOs. The Platform meets twice a year to assist EFSA in developing its overall relations and policy with stakeholders. ■

Dutch Minister of Agriculture, Nature and Food Quality visits EFSA

The Dutch Minister of Agriculture, Mrs Gerda Verburg, visited EFSA on 8 June 2009, accompanied by a delegation of government officials and representatives from the Dutch food safety agency, VWA.

Minister Verburg was welcomed by EFSA's Chair of Management Board, Prof. Diána Bánáti and EFSA's Executive Director, Catherine Geslain-Lanéelle. During the visit the delegation discussed how EFSA works, its scientific cooperation with Member States and its risk communication activities. Particular attention was paid to EFSA's work on nutrition, GMOs, animal health and welfare, and new technologies. ■



EFSA holds two-day conference to debate GMO risk assessment

The European Food Safety Authority (EFSA) held a two-day conference on GMO risk assessment for human and animal health and the environment in Brussels on 14-15 September 2009, bringing together risk assessors from EU Member States, risk managers, and representatives from stakeholders including industry, consumer and environmental groups from the EU and beyond.

Opening the conference, EFSA Executive Director Catherine Geslain-Lanéelle reaffirmed EFSA's role as a provider of independent scientific advice on GMOs. "EFSA is neither pro-GMO nor anti-GMO," she said. She acknowledged that there exists a significant divergence of opinion among various actors in the field of GMOs in the EU and low social acceptability. It was important that the conference clarified EFSA's role in the risk assessment of GMOs. "We are here not only to inform but also to listen and learn. We want to get as wide a range of views and experiences as possible," she said. The Commission's Director-General for Health and Consumers DG Robert Madelin welcomed the conference and said scientists can help regulators make better decisions. He said the EU needed to continue to open up the risk assessment process to integrate public concerns and imbed it in a global context.

Day 1: Assessing the risks for human and animal health and the environment

On the first day, experts from EFSA's GMO Panel and the GMO Unit presented the EU legal framework for GMOs and some of EFSA's updated guidelines on the risk assessment of GM plants, which are developed in the context of mandates from the European Commission and to reflect the latest scientific state of the art. Specific and detailed guidelines ensure greater clarity for applicants regarding data requirements.

Howard Davies from the GMO Panel, presenting EFSA guidance related to food and feed safety, stressed that this was defined in close consultation with Member States and stakeholders. EFSA participated in several consultation meetings and held a public consultation on the guidance before adoption. The

updated guidance is currently being discussed by the European Commission (EC) and Member States in view of adoption as an annex to an EC regulation. It has been developed to include more detailed data requirements from applicants, for example, concerning field trials, as highlighted by Claudia Paoletti from the GMO Unit.

The environmental risk assessment (ERA) of GM plants is a complex area where science is evolving and EFSA's guidelines in this field are currently being updated to take into account latest scientific developments. GMO Panel experts Salvatore Arpaia and Jeremy Sweet presented two of the main topics related to the new ERA guidelines: the assessment of effects on non-target organisms and the assessment of long-term environmental impacts. Andreas Heissenberger of Austria's Environment Agency presented Austria's scientific view on environmental risk assessment. He concluded that while Austria endorses EFSA's case-by-case approach, it believes the ERA is based on insufficient data and he provided a detailed view on how it could be improved. EFSA will consider inputs from the EC, Member States and stakeholders when finalising its updated guidelines.

The aim of the new guidelines is to strengthen and streamline GMO risk assessment processes, contributing to increase their efficiency and transparency. EFSA's risk assessment is only one part of the EU regulatory framework on GMOs, as highlighted by Chantal Bruetschy, Head of the Commission's Unit of Biotechnology, Pesticides and Health, who explained the legal provisions on Post Market Environmental Monitoring, as well as its relation with the risk assessment carried out by EFSA and also with the initial environmental risk assessment carried out by Member States.

Day 2: The impact of GM crop cultivation on the environment

The second day began with presentations from the Organisation for Economic Cooperation and Development (OECD) and the Joint Research Centre of the European Commission (JRC). EFSA works in close liaison with the scientific community >>>



and international bodies in the field of GMO risk assessment. Peter Kearns from the OECD illustrated risk assessment from a global perspective and presented the work of the OECD Working Group on Biosafety.

Emilio Rodriguez Cerezo from the JRC focused on the impact of GM crops presenting an analysis of the experiences in the cultivation of Bt maize during the past 10 years in Spain and showed figures from various Spanish regions on reduced use of insecticides and yield increase. Similar experiences of farmers on GM cultivation were shared by Esther Esteban Rodrigo of Spain's Ministry of Environment, Rural and Marine Affairs. Spain has practical experience in GM crop cultivation and is a Member State working closely with EFSA in environmental risk assessment of GMO applications.

Representatives from stakeholder organisations were also invited to the conference to present their views. Helen Holder from Friends of the Earth recognised that there had been improvements in EFSA's risk assessment work, but reported

some outstanding concerns of her organisation regarding environmental risk assessment and expressed criticism of some of EFSA's scientific opinions on GMOs. EFSA held one of its regular meetings with NGOs on October 2 this year for further dialogue on a number of specific GMO issues, (see p.6).

Presenting the views of EU farmers, Copa-Cogeca's Director of Commodities and Trade, Arnaud Petit, said farmers wanted to keep the option of choosing between GM, conventional or organic farming. The biotechnology industry, represented by Willy De Greef of Europabio, European Association for Bioindustries, asked for the existing experiences of the safe use of GM crops to be better taken into consideration in EU risk assessment and called for a clearer distinction between risk research and risk assessment.

Closing the conference, the Commission's Director-General for the Environment, Karl Falkenberg, said the Commission valued the work that EFSA carries out as the body providing scientific advice to support its decision making. ■

> Calls

Call for proposals to compare pest risk assessment approaches in Europe

EFSA launched a call to further develop the scientific basis for assessing the risks of organisms considered harmful to plant and plant products. The objective of the call is to ensure reproducible and comparable scientific outputs, and to identify suitable methodologies for EU pest risk assessment and for the evaluation of management options.

The call requested consideration of a number of elements. It asked for a review of pest risk assessment approaches including the methods used for the assessment of pest entry, establishment and spread; the potential consequences of pest introduction and spread; the overall risk characterisation and the uncertainty analysis. In addition, a review of the methodologies

for evaluating the effectiveness of management options in reducing the risk of pest introduction and/or spread was sought. In order to compare the different methodologies, pilot studies using 10 pest organisms selected after discussions with Member States and the European Plant Protection Organisation, should be undertaken.

The project should identify the most suitable methods for conducting pest risk assessments and for evaluating the effectiveness of management options. In this way it shall assist EFSA's Plant Health Panel with its work.

The call closed on 30 September 2009. ■

EFSA launches project to predict the effect of climate change on aflatoxin B1 in cereals

The European Food Safety Authority has launched a call for proposals to study the potential increase in aflatoxin B1 in cereals in the EU as a result of climate change. Aflatoxin B1 is a mycotoxin produced by moulds which grow on certain cereals including maize, wheat and rice. It is particularly prevalent in hot and humid climates, and is carcinogenic.

Based on different climate change scenarios, the aim of the project is to gather and analyse data on aflatoxin B1 in order to build predictive models, define scenarios and create maps highlighting potential future contamination of cereal crops. The results will help to inform any future work in this area by EFSA and

give an indication of potential emerging food contamination by mycotoxins in the EU due to climate change.

The project is being coordinated by EFSA's Emerging Risks Unit, which has identified this issue as a potential area of concern. Scientific organisations designated by the EU Member States had until 7 September 2009 to submit proposals. The selected applicant(s) will receive a grant of up to €250,000 from EFSA. ■

[For more information.](#)

> Consultations

EFSA consults on its guidance document to perform pest risk assessments and to evaluate pest risk management options

EFSA has launched a public consultation on its draft guidance document that prescribes the procedures to be followed when EFSA's Panel on Plant Health (PLH) conducts pest risk assessments and evaluates pest risk management options.

The draft document, developed by the PLH Panel, addresses the risks presented by non-indigenous living organisms associated with the movement of plants or plant products. These organisms may enter, establish, spread and cause harmful effects on plants

and/or plant products and may harm plants in their natural or semi natural environments.

The guidance document describes the process, criteria and main methodologies recommended by the Panel for use in pest risk assessment and for evaluating pest risk management options.

The consultation closed on 2 October 2009. ■

[For more information.](#)

EFSA proposes new acute risk assessment for pesticides

EFSA ran a public consultation on its draft guidance for assessing the risks from exposure to pesticides for workers, operators, bystanders and residents. The draft guidance aims at harmonising exposure assessments and at more precise estimates of the actual exposure to pesticides.

EFSA's Panel on Plant protection products and their residues (PPR) proposed a series of changes to current practices in the evaluation of exposure to pesticides through skin contact and inhalation. In particular, it introduced an additional risk assessment for those plant protection products (PPPs) where toxicity could arise from acute exposure (exposure over a single day). The Panel stated that such an assessment will require the specification of a new toxicological reference value: the Acute Acceptable Operator Exposure Level (AAOEL) which can be employed as a reference value for realistic estimates of exposure in a single day for operators, workers and bystanders. A separate acute risk assessment for residents will not be necessary as this is already covered by the acute risk assessment for bystanders.

EFSA's PPR Panel specified that through the improvement of the current methods of risk assessment and applied statistical models, the level of protection for these exposed groups will improve. The availability of harmonised exposure models will ensure consistency between the approaches employed by



regulatory authorities and other stakeholders at EU level. In addition, the Panel listed a series of options corresponding to various levels of protection that risk managers may take into consideration when regulating the safe use of PPPs. The draft document also gives recommendations for further research to reduce current uncertainties for those scenarios where exposure estimates are least reliable. For some scenarios, the >>>

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available data on exposure are particularly limited, and there would be value in further research to improve the knowledge base (e.g. worker exposure studies for crop inspection scenarios, especially for cereals, and for post-harvest activities such as packing vegetables).

This draft opinion of the PPR Panel on "Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Bystanders and Residents" was available on EFSA's website for public consultation and comment until

15 September 2009. All interested parties were invited to submit their comments which will be taken into account to finalize the opinion by spring 2010. The opinion will be part of the first guidance document of this kind for use in regulatory risk assessment of plant protection products in the European Union, which will be finalised by the European Commission and Member States.

[For more information.](#)



Introducing EFSA's family of newsletters

EFSA has a wide range of newsletters, suited to different readers' needs. Available in English, French, German and Italian, they include :

- **EFSA news** – our regular round up of recent EFSA developments
- **Moving Together** – for twice-yearly news on food safety cooperation between EFSA and EU Member States
- **EFSA in focus** – our regular easy-to-read thematic newsletters bringing together related topics to allow readers to choose whether they are most interested in information related to plants, animals or food.

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> Latest mandates received

Mandates accepted: June-September 2009

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

Assessment Methodology (AMU)

Production-To-Retail Microbiological Modelling

Deadline: 31-Mar-10 Mandate Number: M-2009-0166

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

Deadline: 31-May-10 Mandate Number: M-2009-0243

Genetically Modified Organisms (GMO)

Application for authorisation of genetically modified maize MON89034 x MON88017 for cultivation submitted under Regulation (EC) No. 1829/2003 by Monsanto

Mandate Number: M-2009-0146

Application for authorisation of genetically modified maize MON89034 x NK603 for cultivation submitted under Regulation (EC) No. 1829/2003 by Monsanto

Mandate Number: M-2009-0147

Application for authorisation of genetically modified soybean MON87701 x MON89788 for food and feed uses, import and processing submitted under Regulation (EC) No 1829/2003 by Monsanto

Mandate Number: M-2009-0198

Plant health (PLH)

***Dryocosmus kuriphilus* Yasumatsu, the Oriental chestnut gall wasp**

Deadline: 15-Mar-10 Mandate Number: M-2009-0155

***Gibberella circinata* Nirenberg & O'Donnell for the EU territory**

Deadline: 15-Mar-10 Mandate Number: M-2009-0156

Quantitative pathway analysis on US wheat – April 2008 for the EU territory

Deadline: 16-May-10 Mandate Number: M-2009-0197

Pesticide Risk Assessment and Peer Review Unit (PRAPeR)

EFSA has received requests to:

Assess MRL applications: EFSA received 25 requests to give a reasoned opinion on the modification of around 160 MRLs.

Advise on certain MRLs: Between June and September 2009 EFSA issued 24 reasoned opinions on 56 MRLs.

http://www.efsa.europa.eu/EFSA/ScientificPanels/PRAPER/efsa_locale-1178620753812_1178713248967.htm

Request for an EFSA peer review and conclusion on the active substance haloxyfop-P

Deadline: 11-Oct-09 Mandate Number: M-2009-0176

Request for an EFSA peer review and conclusion on the active substance 1,3-dichloropropene

Deadline: 30-Sep-09 Mandate Number: M-2009-0177

Request for an EFSA peer review and conclusion on the active substance carbosulfan

Deadline: 18-Oct-09 Mandate Number: M-2009-0184

Request for an EFSA peer review and conclusion on the active substance quinmerac

Deadline: 01-Mar-10 Mandate Number: M-2009-0217

Request for EFSA to draft a conclusion on the active substances imazalil and prohexadione-calcium, and where appropriate to arrange for an expert consultation

Deadline: 05-Dec-09 Mandate Number: M-2009-0218

Request for an EFSA peer review and conclusion on the active substance pyridaben

Mandate Number: M-2009-0219

Request for EFSA to draft a conclusion on the active substance azimsulfuron, and where appropriate to arrange for an expert consultation

Deadline: 01-Dec-09 Mandate Number: M-2009-0227

Request for EFSA to draft a conclusion on the active substance azoxystrobin, and where appropriate to arrange for an expert consultation

Deadline: 11-Dec-09 Mandate Number: M-2009-0228

Request for an EFSA peer review and conclusion on the active substance napropamide

Deadline: 29-Mar-10 Mandate Number: M-2009-0267

> Opinions and other documents

List of adopted opinions and other documents per unit: June-Sept. 2009

Disclaimer: This is not the full list of all EFSA opinions but only those considered relevant to this newsletter. [For the full list](#)

Genetically Modified Organisms (GMO)

EFSA overall opinion on an application for authorisation of genetically modified NK603 Maize and derived food and feed including Cultivation (EFSA-GMO-NL-2005-22)

Adoption date: 11-Jun-09 Question number: EFSA-Q-2009-00626

EFSA overall opinion on an application for renewal of authorisation for continued marketing of food additives, feed materials and feed additives produced from NK603 maize submitted under Articles 8(1)(b) and 20(1)(b) of Regulation (EC) 1829/2003 (EFSA-GMO-RX-NK603)

Adoption date: 11-Jun-09 Question number: EFSA-Q-2009-00625

EFSA overall opinion on an application for renewal of authorisation for continued marketing of feed materials and feed additives produced from 1507 Maize (EFSA-GMO-RX-1507)

Adoption date: 11-Jun-09 Question number: EFSA-Q-2009-00624

Request from the European Commission related to the safeguard clause invoked by Austria on oilseed rape MS8, RF3 and MS8xRF3

Adoption date: 15-Jun-09 Question number: EFSA-Q-2008-743
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902599714.htm

Request from the European Commission related to the safeguard clause invoked by Austria on maize lines MON863

Adoption date: 15-Jun-09 Question number: EFSA-Q-2008-742
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902599701.htm

Request from the European Commission related to the safeguard clause invoked by Austria on oilseed rape GT73

Adoption date: 15-Jun-09 Question number: EFSA-Q-2008-315
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902598000.htm

Applications for renewal of authorisation for the continued marketing of (1) existing food and food ingredients produced from genetically modified insect resistant maize MON810; (2) feed consisting of and/or containing maize MON810, including the use of seed for cultivation; and of (3) food and feed additives, and feed materials produced from maize MON810 Application for renewal of authorisation for continued marketing of feed consisting and/or containing MON810 Maize and MON810 Maize for feed uses (including cultivation)

Adoption date: 15-Jun-09
 Question numbers: EFSA-Q-2007-150, EFSA-Q-2007-153, EFSA-Q-2007-164
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902628240.htm

EFSA overall opinion on the application for renewal of authorisation for continued marketing of existing food and food ingredients produced from maize MON810 (EFSA-GMO-RX-MON810_8-1a).

Adoption date: 22-Jun-09 Question number: EFSA-Q-2009-00658

EFSA overall opinion on the application for renewal of authorisation for continued marketing of feed consisting and/or containing MON810 Maize and MON810 Maize for feed uses (including CULTIVATION) (EFSA-GMO-RX-MON810_20-1a)

Adoption date: 22-Jun-09 Question number: EFSA-Q-2009-00657

EFSA overall opinion on the application for renewal of authorisation for continued marketing of food additives and feed materials produced from MON810 maize (EFSA-GMO-RX-MON810_8-1b/20-1b)

Adoption date: 22-Jun-09 Question number: EFSA-Q-2009-00656

Application application for authorisation of genetically modified maize MON88017 x MON810 for food and feed uses, import and processing under Reg. (EC) No 1829/2003 submitted by Monsanto

Adoption date: 02-Jul-09 Question number: EFSA-Q-2006-020
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902691146.htm

Application for authorisation of genetically modified maize MIR604 for food and feed uses, import and processing under Reg. (EC) No 1829/2003

Adoption date: 02-Jul-09 Question number: EFSA-Q-2005-046
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902691168.htm

Opinion on a request from the European Commission related to the enzyme preparation of trade name "Danisco Xylanase G/L (endo-1,4-beta-xylanase)" as a feed additive for laying hens and chickens and ducks for fattening

Adoption date: 02-Jul-09 Question number: EFSA-Q-2009-00498
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902672420.htm

Safety and efficacy of Ronozyme® ProAct (serine protease) for use as feed additive for chickens for fattening

Adoption date: 02-Jul-09 Question number: EFSA-Q-2008-431b
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902706995.htm

EFSA overall opinion on the application for authorisation of genetically modified maize MON88017 x MON810 for food and feed uses, import and processing under Reg. (EC) No 1829/2003 (EFSA-GMO-CZ-2006-33)

Adoption date: 21-Jul-09 Question number: EFSA-Q-2009-00660

EFSA overall opinion on the application for authorisation of genetically modified maize MIR604 for food and feed uses, import and processing under Reg. (EC) No 1829/2003 (EFSA-GMO-UK-2005-11)

Adoption date: 21-Jul-09 Question number: EFSA-Q-2009-00659

Application for renewal of authorisation for continued marketing of food and food ingredients and feed materials produced from Ms8/Rf3 oilseed rape submitted by Bayer CropScience

Adoption date: 09-Sep-09 Question number: EFSA-Q-2007-159
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902900464.htm

Application for authorisation of genetically modified maize MON89034 x NK603 for food and feed uses, import and processing

Adoption date: 09-Sep-09 Question number: EFSA-Q-2007-046
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902910348.htm

Application for authorisation of genetically modified maize Bt11 x GA21 for food and feed uses, import and processing submitted under Regulation (EC) No. 1829/2003 by Syngenta

Adoption date: 15-Sep-09 Question number: EFSA-Q-2007-195
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902900450.htm

EFSA overall opinion on the application for renewal of authorisation for continued marketing of food and food ingredients and feed materials produced from Ms8/Rf3 oilseed rape

Adoption date: 22-Sep-09 Question number: EFSA-Q-2009-00748

EFSA overall opinion on the application for authorisation of genetically modified maize Bt11 x GA21 for food and feed uses, import and processing

Adoption date: 22-Sep-09 Question number: EFSA-Q-2009-00747

EFSA overall opinion on the application for authorisation of genetically modified maize MON89034 x NK603 for food and feed uses, import and processing

Adoption date: 29-Sep-09 Question number: EFSA-Q-2009-00759

Plant Protection Products and their Residues (PPR)

Updating the opinion related to the revision of Annexes II & III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Physical and chemical properties

Adoption date: 18-Jun-09 Question number: EFSA-Q-2009-00619
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902694154.htm

Updating the opinion related to the revision of Annexes II & III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Analytical methods

Adoption date: 18-Jun-09 Question number: EFSA-Q-2009-00618
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902694404.htm

Updating the opinion related to the revision of Annexes II & III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Residues

Adoption date: 18-Jun-09 Question number: EFSA-Q-2009-00617
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902695300.htm

Updating the opinion related to the revision of Annexes II & III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Fate and behaviour

Adoption date: 18-Jun-09 Question number: EFSA-Q-2009-00616
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902694264.htm

Updating the opinion related to the revision of Annexes II & III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Toxicological and metabolism studies

Adoption date: 18-Jun-09 Question number: EFSA-Q-2009-00615
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902660462.htm

Updating the opinion related to the revision of Annexes II & III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: Ecotoxicological studies

Adoption date: 18-Jun-09 Question number: EFSA-Q-2009-00556
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902684485.htm

Risk assessment for a selected group of pesticides from the triazole group to test possible methodologies to assess cumulative effects from exposure through food from these pesticides on human health

Adoption date: 19-Jun-09 Question number: EFSA-Q-2007-183
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902879573.htm

Report on the PPR Stakeholder Workshop - Improved Realism In Soil Risk Assessment (IRIS)- How will pesticide risk assessment in soil be tackled tomorrow?

Adoption date: 23-Jul-09 Question number: EFSA-Q-2009-00690
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902706552.htm

Pesticide Risk Assessment and Peer Review Unit (PRAPeR)

EFSA has issued 23 reasoned opinions between June and September 2009 regarding routine MRL applications for the following active substances:

Aminopyralid	Glyphosate	Spinetoram
Azoxystrobin	Indoxacarb	Spirotetramat
Boscalid	Isoxaflutole	Tebuconazole
Cyprodinil	Lambda-cyhalothrin	Tebufenpyrad
Difenoconazole	Mandipropamid	Thiacloprid
Difenoconazole	Metazachlor	Thiamethoxam
Fenamiphos	Propyzamide	Trifloxystrobin
Fosetyl	Pyraclostrobin	

In addition, 2 reasoned opinions were adopted regarding a comprehensive MRL review for the following active substances:

Fenamiphos
 Ethepon

http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_Opinions498.htm

Pesticide Risk Assessment and Peer Review of:**Captan**

Adopted: **04-Jun-09** Question number: **EFSA-Q-2009-00604**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620763379.htm

Carbofuran

Adopted: **16-Jun-09** Question number: **EFSA-Q-2009-00496**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902673261.htm

Clofentezine

Adopted: **04-Jun-09** Question number: **EFSA-Q-2009-00238**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902693468.htm

Diflubenzuron

Adopted: **16-Jul-09** Question number: **EFSA-Q-2009-00240**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902719821.htm

Folpet

Adopted: **04-Jun-09** Question number: **EFSA-Q-2009-00605**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1178620763306.htm Fluopicolide

Fluopicolide

Adopted: **04-Jun-09** Question number: **EFSA-Q-2009-00309**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902663089.htm

Heptamaloxyloglucan

Adopted: **17-Jul-09** Question number: **EFSA-Q-2009-00322**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902782469.htm

Lenacil

Adopted: **25-Sep-09** Question number: **EFSA-Q-2009-00242**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902929463.htm

Malathion

Adopted: **17-Jul-09** Question number: **EFSA-Q-2009-00587**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902719994.htm

Myclobutanil

Adopted: **04-Jun-09** Question number: **EFSA-Q-2009-00606**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902666045.htm

Penoxsulam

Adopted: **31-Aug-09** Question number: **EFSA-Q-2009-00312**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902899056.htm

Pyriproxyfen

Adopted: **21-Jul-09** Question number: **EFSA-Q-2009-00239**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902782446.htm

Spirodiclofen

Adopted: **27-Jul-09** Question number: **EFSA-Q-2009-00669**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902782643.htm

Trifluralin

Adopted: **14-Jul-09** Question number: **EFSA-Q-2009-00588**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902779519.htm

2007 Annual Report on pesticide residues

Adoption date: **10-Jun-09** Question number: **EFSA-Q-2008-714**
http://www.efsa.europa.eu/EFSA/efsa_locale-1178620753812_1211902667778.htm

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