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European Food Safety Authority

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Contents

In focus

EU Commissioner returns to EFSA

The European Commissioner for Health, Androulla Vassiliou, returned to Parma on 16 October 2009 for her second visit to EFSA.

She was welcomed by EFSA's Executive Director, Catherine Geslain-Lanéelle, and by Bart Sangster, Vice-Chair of the Management Board. The Chair of the Scientific Committee, Professor Vittorio Silano, the Chair of the Panel on Dietetic Products, Nutrition and Allergies, Dr Albert Flynn, and George Gaskell, a member of EFSA 's Advisory Group on Risk Communications, together with EFSA Directors also took part in the meetings.

During the visit, the Authority's activities on new technologies, in particular animal cloning and nanotechnology, as well as EFSA's recent GMO work were discussed. How consumers perceive the risk of new technologies, and the subsequent need for social dialogue, were also touched upon.

STOP PRESS

Better surveillance needed to fight spread of antimicrobial resistance in zoonotic infections

The European Centre for Disease Prevention and Control (ECDC), the European Food Safety Authority (EFSA), the European Medicines Agency (EMEA) and the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) have published on 16 November a joint scientific opinion on antimicrobial resistance (AMR) focused on infections transmitted to humans from animals and food (zoonoses).

For more information

Latest publications

2007 report on foodborne outbreaks in the EU now available

The recently-published 2007 report on foodborne outbreaks in the EU reveals that *Salmonella* was, as in previous years, the most commonly reported cause of outbreaks. Eggs and egg products were the most common source of outbreaks.

Foodborne outbreaks are infections or intoxications in humans caused by the consumption of contaminated food. In total, in 2007, 5,609 foodborne outbreaks were reported by Member States, a slight fall compared to 2006. Of these outbreaks, 36% were verified by laboratory detection of the pathogen or by epidemiological evidence showing a link between human infection and the food source. These verified outbreaks affected almost 40,000 people resulting in 3,291 hospitalisations and 19 deaths.

Salmonella was again the most commonly reported cause of foodborne outbreaks in the EU. *S. enteritidis* was the most common serovar involved and eggs or egg products were the most frequently involved in these outbreaks. Foodborne viruses, mainly calicivirus (including norovirus), were reported as the second most common known cause of outbreaks, most frequently from crustaceans, shellfish, molluscs and buffet meals. *Campylobacter* also remained a common cause of outbreaks.

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In focus

Contd. from page 1

There was also an exchange of views about the Authority's current and future activities on nutrition. This was then followed by a further exchange on EFSA's data collection and exposure assessment work, and its impact on the quality of risk assessments.

During the Commissioner's public address to EFSA, she reminded staff of her first visit to EFSA in July 2008, soon after being appointed Commissioner for Health in April 2008: *"During my first visit here last year, I emphasised how highly I value the role of EFSA as a vital partner to ensure the safety of the food chain. I would like to reiterate this point today."* She later added: *"EFSA has now established itself as a well-respected authority, recognised both inside and outside the EU for the quality of its scientific work,"* and personally thanked staff for their commitment, motivation and professionalism.

During the visit, the Commissioner also met with representatives from Parma's European school and laid the first foundation stone of the Authority's new building.

EFSA's Management Board backs cooperation plans with Member States, renews Stakeholder Platform

EFSA's Management Board has given its backing to proposals to boost risk assessment capacity and expertise in Europe for the benefit of both national and European risk assessment activities. A more strategic, longer term view on future joint cooperation initiatives will allow better leverage and strengthening of expertise in Member States for the benefit of the EU food safety system. The Board also reviewed the activities of the Stakeholder Consultative Platform and approved its renewal for the next three years.

In line with its Strategic Plan for 2009-2013, EFSA aims to further develop cooperation with national food safety agencies and other national scientific organisations. Longer term planning was seen as important for Member States to participate more actively in EFSA's work.

Board members encouraged the further development of these initiatives with the Scientific Committee and the Advisory Forum and to keep the Management Board updated on progress.

Board members also renewed EFSA's **Stakeholder Consultative Platform**, following the positive review of EFSA's Stakeholder Consultative Platform, which highlighted the valuable contribution of the Platform to many general issues related to the work of the Authority. All 24 original organisations were reconfirmed as full members and 21 other groups were approved as associated members for one year. The stakeholder organisations work in areas related to the food chain, representing consumers, food and feed operators, food industry, food trade and NGOs.

For more information.

EFSA offers guidance on assessing the safety of botanicals

To help improve the basis on which the safety of widely-marketed plant-based products can be assessed EFSA has published advice for food authorities on botanical materials and preparations used in food supplements. The advice will also help food manufacturers consider the safety of ingredients used in their products.

The opinion from EFSA's Scientific Committee specifies what data are needed to carry out such safety assessments. It also suggests a two-tiered scientific approach depending on the existing level of knowledge on a given botanical and the substance(s) it contains.

"Although many botanicals have a long history of use in Europe, for some of them safety concerns cannot be excluded," said Vittorio Silano, Chair of the Scientific Committee. *"Risk assessors from the EU Member States have recognised the public health significance of this issue and worked together with EFSA experts to develop this scientific framework which makes it possible to systematically and effectively assess the safety of botanical ingredients."*

The guidance also provides criteria to help prioritise the safety assessment of botanical ingredients which are in use. A related report - produced by a working group of experts identified by EFSA and by national authorities - gives examples explaining how the proposed approach could be applied in different circumstances.

Working together with Member States, EFSA has also compiled available information on a large number of botanicals which have been reported to contain substances that may be of health concern when used in food or food supplements. This compendium, which will be regularly updated, is intended to assist manufacturers and food safety authorities by highlighting possible safety issues which may require further consideration.

At a workshop in Athens, on 24 November, EFSA presented its work on botanicals and discussed possible future developments with Member States and other stakeholders.

For more information.

>>> Latest publications

Foodborne outbreaks report contd.

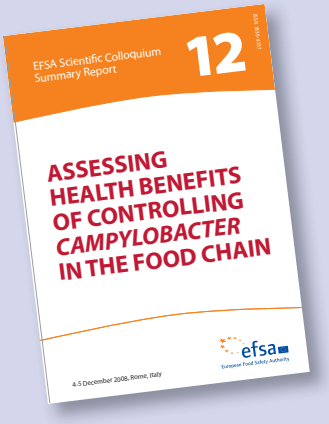
The majority of foodborne outbreaks in 2007 were outbreaks affecting more than one household. The contaminated foodstuffs were most commonly consumed in homes or in restaurants, cafés, hotels or other caterers. Other places where outbreaks occurred included schools, canteens, and hospitals or medical care facilities.

Member States varied considerably in the numbers and proportions of verified outbreaks reported. However, this may be due to differences in the sensitivity and efficiency of the national systems for investigating and reporting outbreaks. The report was based on information submitted by 22 Member States, as well as Norway and Switzerland. The report was jointly produced by EFSA, and the European Centre for Disease Prevention and Control (ECDC).

For more information.

>>> Latest publications

Controlling *Campylobacter* in the food chain: scientific colloquium report available



The latest in EFSA's series of scientific colloquium reports has been published. It assesses the health benefits of controlling *Campylobacter* in the food chain.

The colloquium was organised to discuss openly the current issues and future challenges concerning the risk assessment of *Campylobacter* in the food chain in the EU. In particular, the debate focused on the best approaches for data collection and quantitative risk assessment to determine the human health impact, resistance to fluoroquinolone antibiotics, and what are the most effective control measures.

Even though *Campylobacter* is recognised as the leading cause of acute bacterial enteritis in Europe, the true incidence of campylobacteriosis is considerably higher than reported, and underestimation is likely to vary considerably between countries. Therefore, at the meeting, colloquia delegates recommended that public health surveillance systems be further strengthened. Also experts should increase their collaboration to improve and standardise data collection so as to provide baseline information on campylobacteriosis, and to monitor the effectiveness of interventions. In addition, given that contaminated poultry meat is a major source of human exposure, relevant quantitative risk assessment models need to be further developed to support EU-wide risk management strategies.

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In focus

EFSA's first report on pesticide residues in food finds most samples legally compliant

EFSA first Annual Report on Pesticide Residues showed that 96% of food samples complied with the legal Maximum Residue Levels (MRLs) of pesticides.

The report, prepared by EFSA's Pesticide Risk Assessment Peer Review Unit, provides an overview on the pesticide residues in food observed throughout the European Union during 2007 and assesses consumers' dietary exposure.

In total, over 74,000 samples of nearly 350 different types of food were analysed for pesticide residues in 2007, 13% more than in 2006. It was possible to detect 870 pesticides in 2007, a 13% rise compared to the previous year.

To protect consumers, MRLs are set at levels which are 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 - even at concentration levels which exceed MRLs - does not necessarily imply a food safety concern, as consumer exposure needs to be calculated to assess whether consumers are potentially at risk.

In assessing long-term consumer exposure, EFSA followed a cautious approach, using assumptions which overestimate exposure. The chronic exposure of all evaluated pesticides, except diazinon, was not a concern for consumers. Since December 2007 all diazinon authorisations have been withdrawn and the corresponding MRLs lowered.

A cautious approach was similarly taken for short-term exposure assessments. Based on this, a potential consumer risk could not be ruled out for some 52 pesticide/commodity combinations, many of which have already been addressed by withdrawing authorisations or by lowering MRLs.

The report also recommended further improvements to the collection of data required for consumer exposure assessments. In particular, amending the data reporting format to include more details 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.

Building bridges

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 produced, 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 dietary 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.

For more information.

EFSA meets Swedish risk managers and assessors

As part of EFSA's regular dialogue with EU Presidency holders, a delegation from the Authority met Swedish risk managers and assessors on 24 September 2009 in Stockholm.

During the meeting, attendees discussed the priorities of the Swedish Presidency that fall within EFSA's remit. These included the novel food regulation, animal cloning, animal and plant health, pesticides and antimicrobial resistance. In addition, both sides talked about how to further strengthen Member State cooperation, such as new EFSA initiatives to boost risk assessment capacity in Member States.

>>> Latest publications

Controlling *Campylobacter* report contd.

Concerning fluoroquinolone resistance, delegates recommended monitoring the use of antimicrobials overall in animals, in particular, when planning any intervention. However, experts noted that it is unlikely that there will be a single effective measure applicable across all Member States. Current interventions show limited effectiveness or are difficult to sustain. Therefore, the recommendations included running well-designed field trials, informed by quantitative risk assessments, to test the most promising strategies. Novel control strategies are also required but will need advanced planning to evaluate their efficacy and safety.

The report contains the presentations given at EFSA's 12th scientific colloquium, which took place in Rome, Italy, on 4 December 2008. It also contains reports from discussion groups, as well as an overall summary and full recommendations.

For more information.

Events

Meeting with national experts on Dietary Reference Values

Barcelona, 7 September 2009

European Food Safety Authority (EFSA) scientists organised a special meeting with nutrition experts from Member States to exchange views on draft opinions published in the area of Dietary Reference Values (DRVs) covering fats, carbohydrates, fibres and water as well as Food-Based Dietary Guidelines.

The meeting, held on 7-8 September 2009 in Barcelona, was an opportunity to: discuss with Member States the issues surrounding the draft opinions; brief the national experts about the comments received during the consultation period; and to clarify EFSA's scientific role in determining the DRVs.

Professor Albert Flynn, Chair of EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) said: *"Following a successful public consultation, a further valuable contribution was received from national experts that enables EFSA to finalise its draft opinions on DRVs."*

The Barcelona meeting also addressed EFSA's continuing work on DRVs and any possible cooperation with Member States on the remaining assessment of DRVs for micronutrients. EFSA expressed interest in receiving the most recent scientific data available at national level, necessary for finalisation of the scientific opinions.

For more information.

Building bridges

EFSA in Slovenia explains its role in assessing risks from farm to fork

Experts gathered at the 47th Gornja Radgona Agricultural Fair in Slovenia on 29 August, to attend the joint EFSA-Slovenian Ministry of Agriculture, Forestry and Food conference that was opened by the Slovenian Minister of Agriculture, Prof. Pogačnik and followed up by a keynote speech by EFSA's Executive Director, Catherine Geslain-Lanéelle. The event, entitled 'EFSA: Assessing risks from the field to the plate', was an opportunity to discuss how risk assessments ensure food safety and consumer protection in Slovenia and the European Union.

EFSA presented issues such as the Authority's role in plant pesticide and pesticide residues risk assessments, in collection and analysis of zoonoses data, and its activities in food consumption data. The event allowed food authorities and industry representatives, consumer representatives, and scientists, to meet and exchange views on risk assessment, food safety, animal and plant health, and consumer protection. It was also an opportunity for EFSA to meet government representatives from countries neighbouring Slovenia, such as the former Yugoslav Republic of Macedonia, Kosovo and Bosnia.

For more information.

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EFSA and Austrian food safety

Austrian risk management and risk assessment institutions, and EFSA came together in Vienna, on 5 June 2009, to discuss the importance of the Authority's work for Austria.

The Austrian Agency for Health and Food Safety (AGES) together with the European Food Safety Authority, hosted the conference entitled, 'Relevance of EFSA for Austrian Food Safety'. It covered issues such as scientific exchange and networks, including practical examples of how EFSA and national agencies already interact. During the event attendees discussed what food safety research can or should provide, and future food safety challenges.

In the afternoon a meeting with risk managers was also organised by AGES. At this meeting, representatives from EFSA and from the various Austrian ministries exchanged views on topics such as GMOs, pesticides, scientific cooperation and risk communication. This meeting provided a good opportunity for all involved to better understand each others' areas of work and competences.

For more information.

New Zealand Food Safety Authority comes to EFSA

The Chief Executive of New Zealand's Food Safety Authority, Dr Andrew McKenzie, and its Director of Science, Dr Steve Hathaway, visited EFSA on 26 June 2009. During the visit, both parties discussed areas of common interest and cooperation. Both sides also talked about their work on biological food chain hazards and zoonoses.

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Events

EFSA and NGOs meet in Parma to discuss GMOs

Parma, 2 October 2009

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 an 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.

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.

For more on EFSA's work on GMOs, see also p11.

Events

Scientific Colloquium on what's new in novel foods

Amsterdam, 19-20 November 2009

EFSA held its 13th Scientific Colloquium on 19 November in Amsterdam. The focus of the meeting was novel foods, foods and food ingredients that were not eaten to a significant degree in the EU before 15 May 1997.

Since 2003, EFSA has been responsible for assessing the safety of novel food applications. The European Commission is likely to ask the Authority to provide scientific and technical guidance for applicants on novel food and novel food ingredients. This is due to the forthcoming revision of the EU's novel food regulation, the impact of emerging sciences and the proposed introduction of assessments of traditional foods from non-EU countries on the basis of a history of safe use.

The objective of the colloquium is to gather international experts and interested parties from different sectors for an open scientific debate on key issues related to the revision of the novel foods regulation that will serve as input for the preparation of an EFSA guidance for applicants. Discussions focussed on various aspects in the safety assessment of novel foods such as history of (safe) use, traditional foods from countries outside the EU, intake assessment, how to set maximum levels, toxicological data requirements, and emerging sciences such as nanotechnology.

Scientists from different disciplines, experts in regulation and safety assessment, food manufacturers and others involved in novel foods were invited to participate and contribute to the colloquium.

For more information.

Building bridges

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 and the European Commission initiated closer cooperation with European Neighbourhood Policy countries

The European Food Safety Authority hosted a seminar on food safety for the European Neighbourhood Policy (ENP) countries on 1-2 July, together with the European Commission. The two-day meeting, held in Brussels, was a first step in building closer cooperation in this area with Mediterranean and Eastern European countries bordering the European Union.

The seminar provided a valuable platform to outline EFSA's role in the EU food system and to gain insight into the priorities of the ENP countries. EFSA was represented by Prof. Diána Bánáti, Chair of the Management Board, and Hubert Deluyker, Director of Scientific Cooperation and Assistance.

As increasingly globalised food trade exposes European consumers to global food safety challenges EFSA considers international cooperation programmes to be particularly important. In addition to close cooperation with the EU Member States EFSA is already working with the pre-accession countries. Through the EU's pre-accession programmes EFSA has gained experience in supporting building risk assessment capacity in candidate (Turkey, Croatia, the former Yugoslav Republic of Macedonia) and pre-candidate countries (Albania, Bosnia and Herzegovina, Montenegro, Kosovo UNSCR 1244 and Serbia).

EFSA hopes to establish a similar level of cooperation with ENP countries. The Brussels seminar was the first event EFSA has arranged in cooperation with DG SANCO and EFSA. DG SANCO plans to arrange two follow-up events in 2010, one for the Eastern and the other for the Mediterranean countries bordering the European Union.

For more information.

Scientific highlights

EFSA issues advice on marine biotoxins

Scientists at the European Food Safety Authority (EFSA) have concluded that eating shellfish contaminated with marine biotoxins from the yessotoxin or pectenotoxin groups, at levels permitted in the European Union, was not considered to pose any health risk. However, experts on the Panel on contaminants in the food chain (CONTAM) said in an opinion that people consuming shellfish contaminated with toxins from the okadaic acid, azaspiracid, saxitoxin or domoic acid groups could be at risk of ill health.

The European Commission asked EFSA to assess the current EU limits which exist for six different types of toxins in shellfish, known as marine biotoxins and the testing methods established in EU legislation. Marine biotoxins are poisonous substances produced by different algae that can accumulate in shellfish.

This EFSA opinion brings together the conclusions of six earlier risk assessments on marine biotoxins. For each type of toxin, the Panel established the amount which can be consumed within a 24-hour period without any appreciable health risk (the acute reference dose). These were then compared with shellfish consumption and occurrence data from a number of EU countries in order to assess the EU limits.

Using available consumption data, the experts identified 400g as a realistic estimate of a large portion of shellfish and used this in assessing current permitted levels of the toxins. Based on these calculations, however, people eating a smaller portion of shellfish contaminated with toxins from the okadaic acid, azaspiracid, saxitoxin or domoic acid groups could also experience ill effects, such as diarrhoea and vomiting.

The Panel concluded that the mouse bioassay, an official test used for analysis of most of these toxins in shellfish, could not be sufficiently sensitive to detect specific toxins or to determine whether the levels of some of the toxins are at or below current EU limits. The Panel made recommendations for future work on alternative methods.

EFSA's scientific advice on this issue will help inform any appropriate follow-up action to be taken by the Commission. Later this year, EFSA is due to publish a further series of opinions on marine biotoxins for which no EU limits have so far been set.

For more information.

Calls

Call for data for further advice on animal cloning

EFSA published a call for new scientific evidence following the European Commission's request for further advice on the implications on animal cloning. This call follows EFSA's previous opinion on animal cloning, published in July 2008.

Specifically EFSA sought information which has become available since January 2008. Such data could include new scientific publications, as well as scientific information which was not as yet published.

EFSA was particularly interested in the health and welfare of animal clones throughout their life, and information on the causes of pathologies and mortality in clones. EFSA also sought information on the cloning of sheep, goats and chicken, especially concerning the:

- Health and welfare of the surrogate mother and clone;
- Extent epigenetic dysregulation occurring in clones is transmitted to their off spring;
- Genetic make-up of animal clones;
- Comparative physiology of clones and conventional animals, including their reproductive capacity;
- Safety of consuming animal clones and their products (meat, milk products, eggs).

The call closed on 30 April 2009. EFSA then published a statement on further advice on the implications of animal cloning in June 2009.

For more information.

Consultations

EFSA launched public consultation on Dietary Reference Values

Following a request from the European Commission, EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) is currently preparing advice on Dietary Reference Values (DRVs) for Europeans for carbohydrates (including sugars), dietary fibre, and fats.

EFSA reviewed existing population reference intakes in the light of new scientific evidence and took into account more recent national recommendations. As part of this review, EFSA launched a public consultation on its draft opinions on DRVs for carbohydrates, dietary fibre, and on fat. And held a meeting with Member States nutrition experts on 7-8 September 2009.

Revised versions of the draft opinions, taking into account comments made during the public consultation and at the meeting with Member States, are due for adoption by the NDA Panel in December 2009.

Scientific highlights

EFSA offers guidance on food contact materials and food enzymes

EFSA has published guidance for industry supplying information for food safety assessments. The guidance specifies the type of information that industry should provide for EFSA to assess the safety of food enzymes. Another set of guidelines explains how to submit applications covering active and intelligent substances in food contact materials.

Enzymes may be used to help the manufacturing, processing, preparation, treatment, packaging, transport or storage of food. Making cheese or brewing beer are two examples. Enzymes can also improve the texture, appearance or nutritional value of food.

The guidance on food enzymes explains how industry should describe the food enzyme's characteristics and which toxicological tests were used. EFSA will then use the information provided to address the safety of the source materials from which the food enzyme is produced (including the presence of possible impurities), the manufacturing process and dietary exposure.

As part of the common EU authorisation procedure for food additives, enzymes and flavourings, EFSA will evaluate food enzymes currently on the market in the EU. Once complete, an EU list of authorised substances will be established by the European Commission. EFSA will then begin evaluating new food enzymes.

Active food contact materials absorb or release substances to preserve or improve the condition of packaged food or extend its shelf life. Intelligent food contact materials monitor the condition of packaged food or the surrounding environment, providing information on the freshness of the food.

For the authorisation of active or intelligent substances in food contact materials, under EU law, manufacturers must first submit an application for a safety assessment of the relevant substance(s) to EFSA. All substances for which a valid application will be received by EFSA until 13 February 2011 will be placed in a register published by the Commission. A list of authorised substances will be published by the Commission once the EFSA has delivered its opinion on all substances in the register.

EFSA's food materials' guidelines specify what the Authority will take into account when assessing the safety of active or intelligent substances - for example, their toxicological properties and the extent to which they, or their breakdown products, may transfer into foods. They also set out the types of data that EFSA needs to conduct its safety assessments, such as information on the physical or chemical characteristics of the relevant substances, how they are manufactured and their intended uses.

For more information on food contact materials and food enzymes.

EFSA and GMOs: advice and open dialogue

EFSA has developed a range of guidance surrounding its work on GMOs. Recently the Authority has published advice on harmonising GMO data analysis and on assessing GM plants used for non-food or non-feed purposes.

Guiding applicants on statistical requirements of GM plant field trials

This guidance is aimed at harmonising how the data from field trials, used to assess the risks of GM plants, and derived food and feed, are produced and analysed. Experts from EFSA's GMO Panel put forward detailed rules on minimum requirements for designing field trials to ensure that the statistical evaluation of the safety of GM plants is more accurate.

The guidance lists recommendations covering the number of sites where experiments should be carried out, growing seasons and the geographical spread etc. 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.

Guiding applicants on non-food/ non-feed GM plants

The Panel also published guidance defining the specific requirements that applicants seeking authorisation need to follow to allow efficient risk assessment of GM plants used for other purposes than food or feed. These include plants which may be used for producing industrial enzymes, medicinal products, such as vaccines and antibodies, and other uses ranging from energy production to helping to address environmental issues.

As for GM plants used for food and feed, the Panel advised that applicants should adopt a comparative approach. The Panel also felt that, in addition to issues raised in the existing guidance for environmental risk assessment, special 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.

In drawing up this guidance, EFSA called on experts in assessing the risks of GM plants used for non-food or non-feed purposes and in assessing the risks of GM-pharmaceutical products. Legal advice was also given by the European Commission and the European Medicines Agency.

Open dialogue

As part of EFSA's policy of openness and transparency, partners and stakeholders also had the chance to comment on both these pieces of guidance during public consultations, which helped shape them. The guidance aims to further increase transparency in assessing GMO risks and also to allow for a more rapid evaluation of applications.

EFSA also engaged in further dialogue with partners and stakeholders, on 14-15 September 2009 in Brussels, during its two-day conference on GMO risk assessments (see EFSAnews20, p.7). In addition, the Authority met with non-governmental organisations on GMOs in October 2009 (see also p.7).

For more information on EFSA's opinion on GMO data analysis and on its guidance for assessing GM plants used for non-food/feed.

Consultations

EFSA proposes new acute risk assessment for pesticides

EFSA launched a public consultation on its draft guidance for assessing the risks of exposure to pesticides for workers, operators, bystanders and residents. This will lead to more harmonised evaluations and more precise estimates of the risk of exposure to pesticides.

EFSA's Panel on Plant Protection Products and their Residues (PPR) proposed a series of changes to current practices in evaluating exposure to pesticides through skin contact and inhalation. In particular, it introduced an additional risk assessment for those plant protection products where toxicity could arise from acute exposure over one day.

The PPR Panel specified that these changes will allow better protection through improved risk assessment methods and statistical estimates of exposure scenarios. The availability of a harmonised model will ensure consistency between the approaches adopted by EU regulatory authorities. The Panel also listed a series of options corresponding to various levels of protection that risk managers may take into consideration when regulating the safe use of plant protection products.

All interested parties were invited to submit their comments which will be taken into account to finalise the opinion by spring 2010. The consultation closed on 15 September 2009.

For more information.

Profile

Per Bergman

In October 2009 Per Bergman was appointed Head of the Genetically Modified Organisms (GMO) unit of EFSA. Since April 2008, he has worked as acting head of this unit. The GMO Unit supports the GMO Panel which carries out risk assessments in order to provide scientific opinions and advice for risk managers on the safety of GMOs.

He completed both his BSc in biology and his PhD in Medical Genetics at Uppsala University, Sweden after which he worked at the Swedish University of Agricultural Sciences (SLU) were he is an associate professor in genetics and plant breeding. At SLU he performed research in molecular genetics of floral organ development and mitochondrial-nuclear communication, and was engaged in teaching in gene technology and in science communication in the context of the GMO debate.

During his last five years at SLU he was chairman of the department and held a chair as a member of the Swedish Gene Technology Advisory Board. He subsequently worked as Senior Advisor on GMO issues at the Ministry of Agriculture in Stockholm before transferring to EFSA in Parma.

Scientific highlights

EFSA advises on the welfare of dairy cows

In a major review of dairy cow welfare, EFSA's Panel on Animal Health and Welfare (AHAW) concluded that the nature of the farming systems and long term genetic selection for higher milk yields are important factors affecting the health and welfare of dairy cows. To improve dairy cow welfare, the Panel made recommendations to risk managers on housing, feeding, management and genetic selection.

The European Commission asked EFSA whether current farming and husbandry systems meet the welfare needs of dairy cows. As part of this, EFSA should also consider the impact of genetic selection aimed at increasing milk yield on the incidence of the most common disorders of dairy cows.

This led to the AHAW Panel's five scientific opinions and a scientific report on the overall effects of the most relevant farming systems on dairy cow welfare and diseases. The Panel also evaluated the impact of genetic selection and highlighted the correlation between genetics and the incidence of lameness, mastitis, reproductive and metabolic disorders.

Over the last 30 years genetic selection has changed the body shape and increased the size of dairy cows. Scientific experts highlighted the importance of allocating enough space for cattle movement when designing resting, feeding and walking areas. The Panel recommended that the genetic selection of dairy cows should address their resistance to diseases such as lameness and mastitis, as well as improve their fertility, health and longevity.

The Panel concluded that mastitis can be reduced not only by treating the disease and preventing its transmission, but also by improving the animals' immune systems. This can be achieved by minimising stress factors, and through controlled and nutritionally-balanced feeding (e.g. by providing the most appropriate type of dietary fibre for the digestive system of dairy cows).

The Panel also concluded that farms with a prevalence of lameness in dairy cows of over 10% do not have an adequate prevention programme and should improve housing conditions, genetic selection and management practices. Moreover, farmers who are well trained in recognising the early signs of disease and in knowing when to seek veterinary advice can contribute to reducing the prevalence of lameness.

For more information.

European public health agencies evaluate MRSA in livestock, pets and foods

Currently there is no evidence that eating or handling meticillin resistant *Staphylococcus aureus* (MRSA) contaminated food poses an increased health risk for humans, according to a recent scientific report produced by European public health agencies.

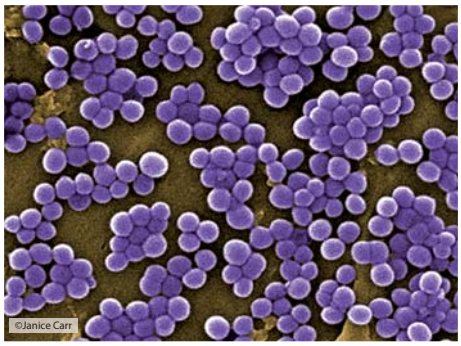
Following a request from the European Commission, EFSA and the European Centre for Disease Control and Prevention (ECDC) concluded that food-producing animals such as pigs, veal calves and broiler chickens often carry without symptoms, a specific strain of MRSA called CC398. In addition, in a recent, but separate, EU-wide EFSA survey of MRSA in breeding pigs, 17 out of 24 Member States surveyed, found some type of MRSA in their holdings with breeding pigs.

While food may be contaminated by MRSA there is currently no evidence that eating or handling contaminated food can lead to an increased health risk for humans. The report also noted that people in contact with live animals that carry the CC398 strain of MRSA could be at risk of infection. This specific strain of MRSA has been associated, albeit rarely, with serious skin and soft tissue infections, pneumonia and blood poisoning in humans.

Pets can also be infected with MRSA, where the bacteria first pass from humans to pets, and then back to humans. The document noted the importance of basic hygiene measures, especially hand washing before and after contact with animals, and if possible, avoiding direct contact with nasal secretions, saliva and wounds.

The report concluded that as animal movement and contact between live animals and humans are likely to be important factors in the transmission of MRSA, the most effective control measures will be at farm level.

In a parallel review, the European Medicines Agency (EMEA) looked at the risk of colonisation or infection of livestock and pets with MRSA in the context of the authorisation and the use of antimicrobial veterinary medicines. EMEA's Committee



for Medicinal Products for Veterinary Use (CVMP) found that MRSA is resistant to virtually all antibiotics from the beta-lactam group, and very often to other antimicrobials. Prudent use of antimicrobials in animals should remain a key measure. The CVMP recommended monitoring of animal consumption of antimicrobials to identify any sources of unnecessary use. The Committee also recommended that medicines of last resort for MRSA treatment in humans should be avoided in animals, so as to ensure their continued efficacy in humans.

MRSA infections are widespread in hospitals in many EU Member States and are a major cause of hospital-acquired infections, which can lead to severe illness and in some cases fatalities. In recent years, a link has also been established between MRSA in animals and human MRSA infections. Where MRSA is found amongst food-producing animals, people in contact with these animals, such as farmers, veterinarians and their families, are at risk of acquiring an MRSA infection. To raise awareness of the issue, the ECDC promotes the prudent use of antibiotics in food-producing animals.

EFSA, ECDC, EMEA and the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) have also recently published a joint scientific opinion on antimicrobial resistance (AMR) in general focused on infections transmitted to humans from animals and food (zoonoses). It concluded that better surveillance is needed to fight the growing spread of antimicrobial resistance in zoonotic infections.

For more information

Profile

Dirk Detken

Dirk Detken is Head of the Legal and Policy Affairs Unit (LPA) at EFSA. The LPA Unit comprises two main pillars of activities. The legal expertise supports EFSA's mission by ensuring that its operations remain in line with the legal framework. The policy activities provide the coordination of EFSA's cooperative approach to its institutional, international and interested partners.

His previous assignments include the European Medicines Agency in London, the European Parliament and the German Federal Bar. He has been involved in the regulatory framework of regulated substances since 1999.

He studied law at the Friedrich-Wilhelms University in Bonn and the Université de Lausanne in Switzerland. He concluded his legal training at the presidential Office of the Court of Appeal in Berlin.

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For more information

EFSA promotes alternatives to animal testing

In a recent review of the use of experimental animals in risk assessments, EFSA's Scientific Committee outlines strategies which can reduce the number of animal studies needed and may also lead towards their replacement in some areas.

"This opinion is a thorough review of the guiding principles on the use of animals for experimental purposes. It summarises possibilities for replacement, reduction and refinement of animal testing within the diff erent areas of EFSA's activities," said Professor Vittorio Silano, Chair of EFSA's Scientific Committee that worked on this opinion. *"We hope it will help EFSA in further developing a proactive approach to animal welfare in its risk assessment activities based on sound scientific principles."*

Most of EFSA's risk assessments require experimental data. It is currently not possible to obtain all the necessary data and information required to ensure a high level of consumer protection without some animal experiments.

This opinion lists the type of internationally recognised alternative methods to animal testing which are available for different types of studies used in risk assessment – e.g. acute toxicity, skin irritation and eye irritation testing – and says that these should be used in line with existing EU laws. For areas where alternative methods cannot provide all of the necessary information, such as reproductive and developmental toxicity, the opinion describes integrated testing and risk assessment strategies which can help reduce the need for animal experiments.

The opinion also proposes ways to better implement animal welfare practices within EFSA's work. For example, in line with existing EU legislation, applicants submitting dossiers to EFSA should use accepted alternative methods to animal testing whenever possible. Moreover, EFSA should fully reflect on the use of such methods when developing guidelines for applicants. In addition, EFSA, when carrying out risk assessments, should review all existing data before requesting any additional animal studies.

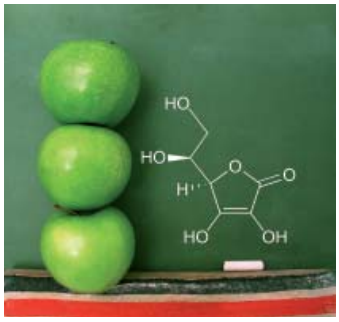
The opinion stresses that animal testing should be conducted in line with guidelines endorsed by the European Commission, EU agencies or other international bodies, such as the OECD. It also recommends a dialogue between EFSA and the Commission on the best ways to address the inclusion of new, validated testing methods in existing guidelines. Furthermore, it stresses the importance of good communication in this area between the different agencies dealing with chemical risk assessments.

This opinion is in line with EFSA's commitment to continue to improve animal welfare when conducting risk assessments. The Scientific Committee also recommended that EFSA should review progress on alternative methods to animal testing in three years.

For more information







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Scientific outputs

Number of scientific opinions, statements and other scientific documents per panel/ unit from May to September 2009.

Scientific area of expertise	Scientific Opinions of Scientific Committee/ Panel	Other scientific outputs of EFSA
Animal health and welfare (AHAW)	7	1
Assessment methodology (AMU)	-	0
Food additives and nutrient sources (ANS)	48	0
Biological hazards (BIOHAZ)	4	2
Food contact materials, enzymes, flavourings (CEF)	37	1
Contaminants (CONTAM)	5	1
Data collection & exposure (DATEX)	-	1
Emerging Risks (EMRISK)	-	0
Feed additives (FEEDAP)	14	0
Genetically modified organisms (GMO)	13	13
Nutrition (NDA)	108	2
Plant health (PLH)	2	0
Plant protection products (PPR)	7	1
Pesticides (PRAPeR)	-	49
Scientific Committee (SC)	4	4
Scientific cooperation (SCO)	-	0
Zoonoses (Data collection)	-	1

The aim of this table is to provide an overview of the latest scientific opinions, statements and other working documents adopted by EFSA's Scientific Panels and Units. These numbers vary according to the nature of the question raised, and the type of risk assessment required. Hence, the number of opinions, statements and other working documents issued by a Panel is not in itself an indicator of productivity. The list of all opinions adopted can be found in the Register of Questions. Summaries and texts of the opinions by Panel are available online.

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