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Committed to ensuring that Europe's food is safe

efsa
European Food Safety Authority

ANNUAL REPORT **2009**

EUROPEAN FOOD SAFETY AUTHORITY

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FOREWORD by Jo Leinen

CHAIR OF THE COMMITTEE ON THE ENVIRONMENT,
PUBLIC HEALTH AND FOOD SAFETY, EUROPEAN PARLIAMENT

As Chairman of the Committee on the Environment, Public Health and Food Safety (ENVI), one of my main priorities is to strengthen and to enhance the high level of food safety in the European Union. With the European internal market, food can be sold freely in all Member States, offering a broad variety of specialities to European consumers. It is therefore imperative that these products are assessed by an independent body, establishing compliance with the high EU safety standards.

The European Food Safety Authority (EFSA) thus plays an important role in the EU in not only assessing food and nutrition safety but also by being the watchdog for animal health and welfare, as well as for plant protection and plant health.

EFSA, although only being in existence for seven years, has become a crucial partner of the European Parliament on food safety and health issues, and a well established and recognised authority in these fields. Its work is thus not only impacting on the EU but also sets global standards.

In order to establish sound food safety legislation that protects consumers from health risks, the Parliament relies on the scientific contributions and expert opinions from EFSA. Recent debates about novel foods, products from cloned animals, genetically modified food and food additives demonstrate again the high relevance of EFSA's work of assessing risks associated with the food chain. The registration and the ongoing assessment of the so-called "health claims" has sparked high interest not only within the concerned producer community; consumers became much more aware of the issue. In the framework of the health claims regulation, ESFA is researching each claim made on food labelling, presentation or marketing in the European Union on whether it is accurate and based on evidence accepted by the scientific community. This is one of many good examples of how the agency is working in the interest of citizens, by ensuring that producers deliver on their promises.

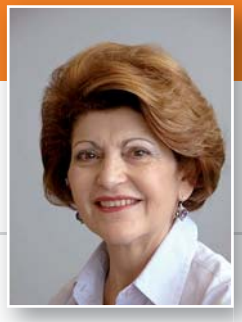
Europe faces new challenges related to climate change and sustainability. Along the entire food chain, agriculture and food production are contributing to global warming. Searching for ways to cope with these challenges, e.g. by improving crop yields or by making changes to animal feed to reduce methane emissions, new technologies will be developed. There, we also need to ensure that safety and health standards are duly taken into account.

The work of EFSA includes a huge variety of tasks and has to satisfy highest quality requirements in order to keep consumers safe. While it is therefore a very demanding occupation it is at the same time very beneficial for EU citizens. EFSA has worked successfully in the past years to establish high standards of food safety in the European Union.

Jo Leinen
Chair of the Committee on the Environment,
Public Health and Food Safety, European Parliament

FOREWORD by Androulla Vassiliou

EU COMMISSIONER FOR HEALTH (2008-2009)



We at the European Commission firmly believe that the most important ingredient in food is safety.

A series of crises in the 1990s – such as those concerning BSE and dioxins – delivered a huge blow to consumer confidence in the European Union and, in fact, worldwide. We learned our safety lesson the hard way and that led us to rethink our overall food safety approach. The end result was a comprehensive reform of the EU food safety system. It has been so successful that it allows us today to be proud of the fact that the European Union enjoys one of the finest and most comprehensive food safety systems in the world.

This significant improvement would have been impossible had it not been based on solid science. This is where the European Food Safety Authority enters the picture. EFSA has proven its capacity to deliver scientific opinions that the Union needs to underpin its legislation. To put it simply, EFSA is an essential partner in our efforts to ensure food safety.

Since its creation, seven years ago, it has gradually established itself as a scientific point of reference. It is today a well-respected authority and it is recognised for its scientific excellence.

During 2009, EFSA has successfully responded to a high number of requests from the Commission – not an easy task given the heavy workload. During the past year we had to tackle a series of challenges and risks to the food chain – melamine-contaminated milk in China is just one such example where EFSA's contribution was actually globally acknowledged. EFSA's role in providing scientific advice speedily has been pivotal in our efforts to deal with this and other similar situations.

But EFSA is not only valuable for its scientific advice. Through the gathering and analysis of scientific data, EFSA gives us a better view of the risks related to food and allows us to reassess long-term issues in the light of scientific progress and technological development.

As Commissioner for Health, I have worked hand-in-hand with EFSA to achieve a solid scientific basis for EU policies. The European Commission is committed to continue walking along the path of close cooperation with EFSA. After all, we share the same concerns and goals.

In short, the European Commission and EFSA will keep doing their utmost to ensure that the most important food ingredient is always present at our table: we will keep doing our best to keep the food we eat safe.

Androulla Vassiliou
EU Commissioner for Health (2008-2009)

MESSAGE from Diána Bánáti

CHAIR OF THE EFSA MANAGEMENT BOARD

"No one can whistle a symphony. It takes a whole orchestra to play it."

(H.E. Luccock)

EFSA's main aim is to give reliable and science-based information on all risks associated with the food chain. Our vision is to become globally recognised as the European reference body for risk assessment in food and feed safety, animal health and welfare, nutrition, plant protection and plant health. To achieve this, in 2009 EFSA has continued to grow in Europe and around the globe, reaching out further than ever before, in close cooperation with its partners in the EU Institutions and Member States.

In 2009, the Management Board adopted EFSA's international strategy, mapping the key objectives needed to consolidate existing and future initiatives with Member States, third countries and international organisations. We also encouraged the Authority's risk assessment capacity and expertise. In 2009, following the successful recruitment campaign run in 2008 until early 2009, we approved the nomination of 174 independent scientific experts to re-establish the Authority's Scientific Committee and eight of its ten Panels for a fresh three-year term. In addition, recognising the contribution of EFSA's experts, we also endorsed a proposal to strengthen compensation for experts and adopted the EUR 73 million 2010 budget required to address EFSA's ever-expanding scientific work, in particular in applications and data collection.

We already know EFSA's workload is growing because of the requests from our partners. So, last year we started negotiations to evaluate and assess the impact of EFSA's work. In 2009 one of the most important tasks in EFSA's work was to scientifically substantiate health and nutrition-based claims to help consumers make informed and meaningful dietary choices. In 2010, we will define key indicators to measure how our advice is helping shape EU law and contribute to the overall food safety system.

We believe in cooperation and dialogue, and we make great efforts each year to further reinforce and build on these networks. This does not just apply to our partners but also the wide variety of stakeholders, interested and involved in our work. Consequently in 2009, we took stock and reviewed the activities of our Stakeholder Consultative Platform. The Management Board has initiated discussion and emphasised the need to continue to further build cooperation with Member States to be more effective and efficient.

The communication landscape and EFSA itself have changed considerably since the Authority's communication strategy was first adopted in 2006. In recognition, the Board discussed a paper outlining how to best review this strategy. We look forward to continuing this discussion in 2010 to help refine the direction of EFSA's important communications work.

I would like to extend my thanks, on behalf of the Management Board, to the Executive Director, Ms Catherine Geslain-Lanéelle, to the 1 500 experts working in the Scientific Committee and Panels, and the more than 400 staff at EFSA for their continued hard work over 2009. They manage the increased workload, helping to deliver even more output for risks managers across Europe. I would also like to thank my fellow Board members, for their work during 2009. I look forward to continue to work together in guiding EFSA as it becomes increasingly recognised as an integral component of the EU's food safety system.

Professor Diána Bánáti ,
Chair of the EFSA Management Board

MESSAGE from Catherine Geslain-Lanéelle

EFSA EXECUTIVE DIRECTOR



2009 was a year of strengthened cooperation and dialogue for EFSA. We can look back on another successful year of fruitful collaboration with the European Commission, the Member States, EU agencies and international counterparts, and continued constructive dialogue with our stakeholders. EFSA's commitment to delivering high-quality outputs flourished in 2009 with 636 scientific outputs compared with 489 the year before.

One milestone in this endeavour was in EFSA's progress in the evaluation of products, substances and claims subject to authorisation. In particular, we evaluated hundreds of health claims, against quite tight deadlines, in addition to the evaluation of food additives, GMOs, flavourings, pesticides and feed additives.

Engaging with partners and stakeholders continued to be an important element of our daily work. For example, in 2009 we organised a conference to discuss, and explain, to stakeholders and scientists our role in assessing the risks of genetically modified organisms, and to clarify our position as a provider of independent scientific advice. It proved to be a valuable opportunity to listen and learn, and to engage with scientists and stakeholders through fruitful open discussions, in particular regarding strengthened guidance for environmental risk assessment.

We further worked on our responsiveness and our commitment to react rapidly and efficiently to urgent situations. In 2009, we carried out comprehensive crisis simulation exercises covering risk assessment in crisis situations and risk communications with the European Commission and Member States. As in previous years, such theory was put into practice when we provided urgent responses to immediate threats to food safety, as in the cases of nicotine in mushrooms and a printing ink in breakfast cereals.

Also in 2009, we took an important step towards realising our vision to be globally recognised as the European reference body for food and feed risk assessment through the adoption of our international strategy. This new strategy will help guide developments in our international outreach. And already in 2009 this was more than just words. We had fruitful meetings with key organisations working in the areas of food safety, animal and plant health in the United States. The cooperation with Health Canada, New Zealand Food Safety Authority and Food Standards Australia New Zealand is now supported by an exchange of letters that will facilitate the scientific cooperation on data collection and data sharing related to risk assessment. In addition, in 2009 EFSA signed a Memorandum of Cooperation with Japan.

Throughout the year, our achievements would not have been possible without the dedication and professionalism of EFSA staff, scientific experts and partners in both EU Institutions and Member States, as well as all stakeholders. Through their continuous commitment and support, EFSA continues to play a crucial role in protecting food safety and public health.

Catherine Geslain-Lanéelle,
EFSA Executive Director

I. CONSOLIDATING EFSA'S ROLE IN THE EU FOOD SAFETY SYSTEM



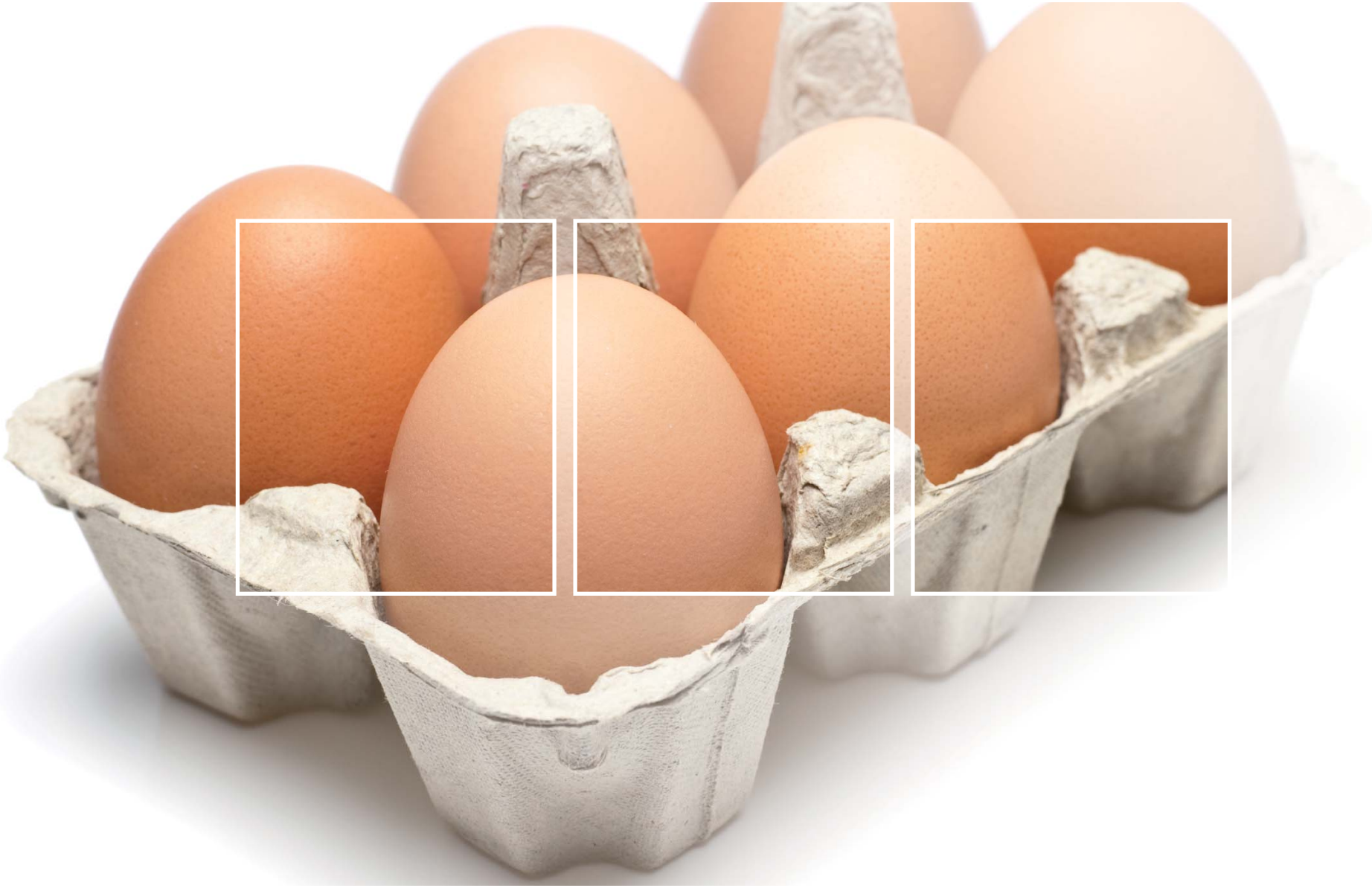
Established in 2002 in response to the food crises that undermined consumer trust in the way food safety was handled in the 1990s, EFSA enters the new decade ready to play its role in the field of food safety and risk assessment, both within the EU and increasingly internationally. EFSA invested in its early years in creating ties and building networks across Europe, while internally putting in place the processes and structures that now underpin its work. Growth over the previous years has enabled the Authority to strengthen its support for its risk management partners in the European Commission, the European Parliament and Member States, who all rely on EFSA for advice to inform their decision making.

A growing body of EU law involves EFSA in supporting the authorisation process – with respect to health claims, pesticides, GMOs, flavourings, food and feed additives, to name but a few. In addition, looking to the future and planning ahead, EFSA has strengthened its dialogue with the Commission on future medium-term activities and priorities as outlined in mutually agreed roadmaps.

2009 was the first year that EFSA's new Strategic Plan – looking forward from 2009 to 2013 – was implemented. This plan aims to shape the Authority over the coming years and to prepare it for the challenges ahead. Following the key strategic areas identified in this plan, EFSA focused on six objectives:

- A comprehensive approach to risk assessments
- Timely high-quality evaluations
- Gathering EU data
- Building international partnerships
- Communication and dialogue
- Responsiveness, efficiency and effectiveness

II. COMMITTED TO ENSURING THAT EUROPE'S FOOD IS SAFE





1. PROVIDING COMPREHENSIVE ADVICE

One of EFSA's key strengths is the breadth of its expertise in risk assessment, operating across the food chain, from field to plate. The Authority covers all areas of food and feed safety, animal health and welfare, nutrition, plant protection and plant health. This allows it to draw on a wide range of knowledge available in order to respond to the challenges presented by the evolving political environment and scientific progress, and to ensure a safe supply of food to European consumers. This means that EFSA can offer risk managers comprehensive advice, increasingly by taking a multidisciplinary and integrated approach. This is being achieved not only by incorporating the contributions of expertise from all around Europe, but also by combining forces with other EU agencies and by cooperating closely with Member States. EFSA is also internally building up a comprehensive and inclusive approach, reinforcing horizontal structures and processes, and linking together the work of its administrative and scientific units for maximum effectiveness. All told, in 2009, EFSA delivered 636 scientific outputs, a 30 % increase over 2008.

Reviewing all mandates to better address issues

Each week EFSA's Mandates Review Committee screens all requests sent to the Authority. This allows EFSA's Executive Director, the Chair of the Scientific Committee and Heads of Directorates to get a top-level view of incoming requests in order to best address the issues and allocate the work to the most appropriate panel(s) and/or unit(s). It allows the possible need for collaboration between units and communications to be considered at an early stage. As a result, EFSA can give as broad an overview as possible in its answers, ensuring that risk managers are fully informed.

Renewing EFSA's Scientific Committee and Panel members

In 2009, EFSA renewed, for a new three-year term, members of its Scientific Committee and eight of its ten Scientific Panels. This was the second renewal since the European food safety watchdog was established in 2002.

To draw up a shortlist of suitable and highly qualified candidates, a rigorous selection process was carried out. An independent external evaluation committee then reviewed the selection process. EFSA's Management Board altogether appointed 174 independent experts.

Overall, there was a 7 % increase in the number of application requests compared to the last call to renew panel members in 2006. There are more women in the new panels than previously and, again, there is a large spread of nationalities. 79 % of the existing panel members reapplied for the positions. Out of the 174 members proposed for nomination, 101 were re-appointed for a second or third mandate, underlining EFSA's capacity to attract and retain the scientists it relies upon.

A fully operational quality review process

Another milestone for EFSA in 2009 was the implementation of the last phase of its Internal and External Review (INEX) System for the Authority's scientific work. This entailed appointing independent experts to carry out external reviews of EFSA's scientific outputs.



The review system is now fully operational and is designed to give EFSA continuing feedback about the quality of its work. This system consists of three layers of reviews: a self-review of all scientific outputs by the unit that produced the output; an internal review of randomly sampled scientific outputs of each unit by senior scientists; and – since 2009 – an external review by independent experts. The internal and external reviews complement each other: the internal review draws on the extensive knowledge held across the units at EFSA while the external review benefits from the expertise and views of external and independent scientists.

The external review working group of 23 experts was established through a call for expression of interest in 2009 and was organised around seven scientific areas. The external review resulted in a report that was submitted to the Authority's Executive Director in December 2009.

After analysing the findings and recommendations of this report, EFSA will use the outcome to continuously improve the quality of its scientific outputs and the process of developing them.

Working closely with Member States

EFSA's Advisory Forum is a core body of the Authority that plays a central role in strengthening EFSA's cooperation with Member States. It connects EFSA with the national food safety authorities of all 27 EU Member States. One of the tasks of its members is to suggest national experts to participate in its particular meetings and EFSA networks for three years. These specific networks bring together experts, representing their Member State in a given field. Dedicated scientific networks exist in the areas of data collection (food consumption, chemical occurrence) and risk assessment (animal health and welfare, plant health, BSE). The general objectives of these scientific networks is to allow participants to share scientific information, pool resources and work towards coordinating work programmes and to facilitate harmonisation of risk assessment practises and methodologies. In addition, they hold EU Regulation-based exchange of views on EFSA's work on GMOs, feed additives and health claims.

An important example of this is the progress, spearheaded by EFSA and the Advisory Forum, in bringing together food consumption data – who is eating what and at what levels – to allow more efficient and accurate exposure assessment at EU level. Such data also help set science-based public health targets related to diet and health (see also p. 22, "*What's Europe eating?*").

In 2009, EFSA organised more frequent meetings with Member States' representatives and thus facilitated the exchange of information between the Authority and the Member States. The Advisory Forum itself met five times in 2009, with strong participation from Member States. There was increased willingness to share information and coordinate ongoing work.

In addition to Advisory Forum meetings, specialised meetings bringing together national representatives on specific topics were also held. For example, in 2009 the second meeting of national plant health representatives took place. The event focused on data collection and emerging risks to plant health, and gave EFSA's Panel on plant health (PLH Panel) an opportunity to present a review of its activities and discuss its developing role in the European plant health system, including harmonisation of pest risk assessment methodologies (see also p. 15).

EFSA Scientific Committee

During the year, EFSA also organised focused meetings to maintain a coherent approach in specific areas, and to ensure that Member States and EFSA are kept abreast of the latest developments throughout Europe. For example in September 2009, the Authority's scientists organised a special meeting with nutrition experts from Member States to exchange views on draft opinions in the area of Dietary Reference Values (DRVs) and Food-Based Dietary Guidelines. DRVs indicate the amount of an individual nutrient that people need for good health depending on their age and gender. They can be used, for instance, as a basis for reference values in food labelling. They may be also be used for the assessment and planning of diets and when making nutrient recommendations and developing Food-Based Dietary Guidelines.

The meeting also gave EFSA an opportunity to brief national experts about the comments it had received on these draft opinions during the consultation period, to clarify its scientific role in determining DRVs and to help Member State experts translate the reference values into practical food-based guidelines for their respective populations.

Focal Points are another mechanism to strengthen cooperation between and among Member States and EFSA. The Focal Points act as an interface between EFSA and national food safety authorities by supporting their Advisory Forum member. In 2009, the Focal Points experienced the second year of full operation. Their key tasks include exchanging scientific information, supporting activities under the Article 36 network, as well as promoting EFSA's expert database. For example, with the help of Focal Points, the Authority's expert database received around 2 300 applications. In addition, Focal Points raised EFSA's scientific visibility in Member States by organising in-country events and disseminating information about EFSA through Focal Point web pages and printed materials.

Encouragingly, in terms of coordination and cooperation, over 550 documents related to risk assessment were uploaded by Member States to EFSA's *Information Exchange Platform*. This tool was considered by Member States to be useful for keeping Member States and EFSA informed about upcoming and ongoing risk assessments on food and feed safety.

All told, in 2009, efforts to further strengthen Member State collaboration, as identified in the 2008 interim review of EFSA's strategy for cooperation and networking, are delivering results for the mutual benefit of EFSA and national food safety authorities (see also p. 12, "*Calling on the best of Europe*").

Making the most of pan-European scientific excellence

EFSA's Scientific Cooperation projects (ESCOs) are another effective tool through which it pooled pan-European scientific resources, and strengthened cooperation and networking between the Authority and its counterparts in Member States in 2009. In contrast to the scientific networks, ESCOs work on a specific topic for a fixed amount of time and include national experts, members of the Scientific Panels or Scientific Committee and EFSA's scientific staff. The topics covered by ESCOs are of mutual interest to the Authority and Member States.



In 2009, ESCOs delivered, for example, a report on the analysis of risks and benefits of the fortification of food with *folic acid* and advice on the EFSA guidance document for the safety assessment of *botanicals and botanical preparations* intended for use as food supplements (see also p. 13). In the case of folic acid, the ESCO working group concluded that the health benefits in relation to reducing the risk of neural tube defects are well established. However, available studies neither confirm the hypothesis that folic acid supplementation reduces the risk of, for example, cardiovascular disease risk for humans, nor provide sufficient data to allow an assessment of the possible effect of folic acid on cancer risk.

To test the methodology outlined in EFSA's guidance on how to assess botanicals, the Authority initiated an ESCO project to select a number of plant preparations and apply the methodology in the assessment of their safety. This activity ended in 2009. Through the harmonisation efforts of EFSA and due to the integration of Member States' expertise, the competent bodies of the Member States now have a comprehensive guidance document on botanicals at hand.

Calling on the best of Europe

In addition to the scientific networks and cooperation projects, EFSA also uses contracts and grants to access Member States' expertise. Using standard EU procurement procedures, contracts are put out to tender e.g. through open calls or negotiated procedures. EFSA can also award grants to organisations that have been nominated by Member States to assist the Authority in its tasks, under Article 36 of its Founding Regulation. These organisations carry out such activities as data collection, preparatory work for the development of scientific opinions and other scientific and technical support. This helps EFSA respond more effectively and flexibly to its growing workload. The Article 36 network is also an important practical tool for the Authority to leverage a wider spectrum of scientific excellence in Member States. After the list of competent organisations was enlarged and then approved by the EFSA Management Board in December 2008, in 2009 the Authority was able to access an even wider knowledge base than ever before (the list has grown from 243 organisations to 371 organisations from all but one Member State).

On grants and contracts, EFSA spent EUR 6.8 million in 2009 compared to EUR 5.5 million in 2008. Of these, EUR 2.5 million were spent on Article 36 grants (against EUR 2 million in 2008), while the remainder was spent on procurement contracts. Hence, the overall amount of money spent on outsourced projects increased by 20 % in 2009 and more than doubled compared to 2007 (EUR 2.9 million), the first operational year of the Article 36 list. There were a variety of subjects covered by the Article 36 projects launched in 2009. These included mycotoxin detoxifying feed additives; animal welfare guidelines on assessing housing and management risks; toxicology of 3-MCPD esters; modelling and mapping aflatoxins in cereals in the EU due to climate change; the identification of common assessment groups of pesticides; genetic selection and broiler chicken welfare and health; a comparative EU-wide plant health pest risk assessment using case studies; and a pilot pan-European dietary survey.

Meeting of the Heads of Agencies at EFSA in October 2009

Given the increasing importance of contracts and grants to assist EFSA, the Authority launched two new IT support tools, a *database of Article 36 organisations* and an *extranet workspace* for all members of the Article 36 network. It also surveyed units in EFSA and the organisations carrying out the work to evaluate the two schemes. The results showed that grants and contracts have contributed substantially to the scientific output of EFSA and in fostering networking among organisations. They are also perceived as effective and useful tools by both scientific units and participating organisations. Nonetheless, in 2010 the Authority will continue to analyse the survey results to identify areas where the schemes could be further improved.

Integrating interagency expertise for risk managers

In addition to leveraging the wide body of knowledge available within EFSA, in 2009 the Authority also steered and coordinated the exchange of views and experiences within the *cooperation network of EU agencies* in order to provide more comprehensive and wide reaching advice to risk managers (see also p. 30).

In November 2009, EFSA's Panel on Biological Hazards (BIOHAZ Panel) – in collaboration with the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), and the European Commission's Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) – published a *joint scientific opinion on antimicrobial resistance* (AMR). The focus was on infections transmitted to humans from animals and food (zoonoses). The agencies collaborated to produce a joint opinion, building on the already existing data and documents to answer the European Commission's request for advice. The joint opinion concluded that better surveillance is needed to fight the growing spread of antimicrobial resistance in zoonotic infections.

The agencies similarly worked together on the *joint scientific report on methicillin-resistant Staphylococcus aureus* (MRSA) in livestock, pets and foods, which was published in June 2009. Following concerns about the increase of MRSA in livestock and companion animals, both EMA and EFSA worked on the matter in a self-tasking exercise. EFSA subsequently also involved ECDC to benefit from their knowledge when touching upon issues that related to human health. The resulting umbrella document concluded that there is currently no evidence that eating or handling MRSA-contaminated food poses an increased health risk for humans.

In 2009, EFSA also collaborated with EMA and European Member States on *botanicals*. Botanical preparations are made from plants, algae, fungi or lichens and are most often marketed with a variety of claims regarding possible nutritional or health benefits. The responsibility for ensuring that these products are safe is given to the food operators and the Member States' competent authorities. As some of these products are at the frontier between foods and medicines, the Authority kept close links with EMA, and also with the European Commission and with Member States, to draw on their expertise.

This work resulted in guidance for European risk assessors with a methodology detailing how to assess the safety of botanicals. EFSA has also compiled information on botanicals that have been reported to contain substances of potential health concern; this compendium is intended to assist manufacturers and food safety authorities by highlighting possible safety issues. After EFSA's Scientific Committee published this guidance in September 2009, EFSA organised a workshop

with all parties concerned (European Commission, national food safety authorities, stakeholders and industry representatives) to present the work and to develop a common understanding of the methodology. The added-value of this inclusive approach is that EFSA's final output has already been discussed by different relevant parties, which increases its acceptance.

Furthermore in May 2009, EFSA signed a Memorandum of Understanding with ECHA. This laid the basis to further develop information exchange, cooperation and mutual understanding between both organisations, and in particular to ensure coherence in the risk assessment approach for substances that may have a bearing on food safety.

All these examples show how EFSA engages in and supports the sharing of scientific expertise. By using such a wider knowledge base, EFSA, in unison with other agencies, is better positioned to tackle bigger issues that, in their entirety, are beyond its remit but that nevertheless have the potential to affect food safety. As such, interagency cooperation can be an effective way of integrating the knowledge and the resources available within the EU's system of agencies to contribute to a high level of consumer protection.

Taking a multidisciplinary approach to food chain contaminants

An example of the broad, multidisciplinary and collaborative scientific work within EFSA was the Authority's assessment of marine biotoxins in 2009. The European Commission had asked EFSA to assess the EU limits for various different types of regulated and non-regulated toxins, known as marine biotoxins, in shellfish, as well as the testing methods established for EU legislation.

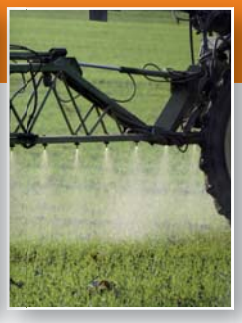
In performing this assessment a working group of the Authority's Panel on contaminants in the food chain (CONTAM Panel), supported by its Data Collection and Exposure (DATEX) and CONTAM Units, collected data and calculated the exposure to marine biotoxins. This made it possible for the CONTAM Panel to assess the potential public health risk posed by the presence of marine biotoxins in shellfish.

The work not only covered the implications of the consumption of shellfish for human health, but also incorporated animal welfare aspects. These were considered by the Panel when recommending alternative chemical methods to test for the presence of these toxins, which currently is primarily done using mouse bioassays.

In its summary opinion, EFSA brought together the conclusions of six earlier risk assessments on regulated marine biotoxins. Using available consumption data, the EFSA experts identified 400 g as a realistic estimate of a large portion of shellfish and used this in assessing current permitted levels of the toxins. The CONTAM Panel also assessed the influence of processing on the levels of marine biotoxins and started assessing non-regulated marine biotoxins.

An integrated approach to animal health

Another example of EFSA's integrated approach are the opinions that were published on dairy cow housing and husbandry systems in 2009. One, from the BIOHAZ Panel, covered the food safety aspects of dairy cow housing and husbandry systems, while five others, from the Panel on animal health and welfare (AHAW Panel), looked at the overall effects of the most relevant farming systems on the welfare of dairy cows and related diseases. They assessed the potential impacts of housing, feeding, management and genetic selection on the welfare of dairy cows.


Taking a comprehensive perspective on the topic, and after bringing together the wealth of available data, the Authority's experts first carried out risk assessments in four sub-areas (metabolic and reproductive disorders, udder disorders, leg and locomotion problems, as well as behavioural disorders, fear and pain) before adopting the five scientific opinions that provide an overall assessment of the whole topic area.

EFSA 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 and gave recommendations on housing, feeding, management and genetic selection practices that could improve the welfare of dairy cows.

Developing new risk assessment methodologies for pesticides

EFSA's work on cumulative effects of pesticides is part of the Authority's broader and all-embracing approach and, altogether, represents a new dimension of EFSA's risk assessments. For this work, EFSA proposed methodologies to assess the cumulative effects resulting from consumer exposure to pesticides, in particular those pesticides that have similar chemical structures and toxic effects.

In June 2009, the EFSA Panel on plant protection products and their residues (PPR Panel) issued an opinion on the applicability of the new methodologies by implementing them for a group of pesticides selected on the basis of their toxicological similarities. The Panel also identified the next steps and open issues that need to be addressed before cumulative risk assessments can be applied routinely for pesticides. This work is, therefore, part of EFSA's on-going commitment to be at the forefront of developing risk assessment methodologies, in particular concerning cumulative risk assessment following on from the Scientific Colloquium on this same topic organised in 2006.

Pest risk assessment to maintain plant health in Europe

EU risk managers rely on pest risk assessments to support decision-making on phytosanitary measures. This calls for a transparent evaluation procedure, based on scientific principles, to ensure an objective and consistent approach is used in evaluating assessments of the risks posed to plant life or plant health. Therefore, in October 2009, EFSA's Panel on plant health (PLH Panel) published guidance on the evaluation of documents prepared by EU Member States or third parties to justify requests for the consideration of phytosanitary measures.

In developing this guidance the Panel reviewed the 36 opinions published between 2006 and 2008, and paid particular attention to the evaluation process for 30 pest risk analysis documents prepared by France with regard to organisms considered harmful for certain French overseas departments. The Panel also verified that the criteria used by the Panel in evaluating evidence to justify claims that an organism may be considered to be harmful are in line with International Standards for Phytosanitary Measures.

The resulting guidance describes the process, criteria and main methodologies recommended by the Panel for use in pest risk assessment and for evaluating pest risk management options. Ultimately, such guidance underpins EFSA's role in harmonising assessments across Europe to better support risk managers.

In the course of 2009, the Panel also worked on guidance aimed at providing a harmonised framework for assessing the risks posed to plants and plant products by pests, and for identifying and evaluating risk management options. This additional guidance was published in February 2010.

Providing scientific support across EFSA

EFSA's Assessment Methodology Unit (AMU) provided support to most panels in EFSA in 2009. It developed new approaches to help decision making in risk assessments and also assisted various EFSA panels in managing data in their scientific opinions. This included, for example, systematic literature reviews and meta-analysis modelling activities used by the CONTAM Panel in its opinion on dose-related effects of cadmium.

AMU also provided guidance on the application of systematic review methodology to food and feed safety assessments in support of decision making. This guidance was the basis for a workshop for EFSA panel experts and staff held in February 2010.



2. TIMELY HIGH-QUALITY EVALUATIONS

Evaluating products, substances and claims that need to be authorised under EU law has steadily grown to be a large part of EFSA's workload. In this, the Authority plays an important role in the regulatory framework related to European food and feed safety. In 2009, for example, applications represented 68 % of EFSA's scientific outputs and consumed an ever-growing amount of its resources.

Given the tight legal time constraints for EFSA to conduct these evaluations, in 2009 EFSA further strengthened internal processes supported by new IT tools to monitor and track progress of its scientific work. For instance, the risk assessment IT workflow tool helps the Authority monitor the entire risk assessment process from receipt of mandate to its eventual publication and possible communication. This helps EFSA determine publication timeframes, and to forecast and characterise future workloads. In addition, EFSA and the European Commission introduced the *"roadmap"* in 2009 to help EFSA in the planning of its resource allocation and in the managing of its scientific output, for example in the areas of flavourings and pesticides. It consists of mutually agreed prioritisations of the workload and realistic timeframes for evaluating applications, in part drawing on the information from EFSA's workflow tool. In addition, throughout the year, to further facilitate the workflow and monitor progress, EFSA and the European Commission continued to maintain close collaboration through regular dialogue on progress and prioritisation in many areas, such as pesticides, and food and feed additives.

Furthermore, in May 2009, EFSA´s Scientific Committee published further guidance in support of good risk assessment practice. The guidance focused on transparency in producing EFSA's scientific outputs. It contained general principles that should be applied to scientific risk assessments, such as evaluations, to ensure quality continues to be maintained. The principles cover the identification of data sources, criteria for including/excluding data, confidentiality of data, and assumptions and uncertainties. This follows the Scientific Committee's earlier guidance from 2006, on the procedural aspects of risk assessments.

Managing applications: the case of GMOs

Under EU law, GM food or feed or derived products must undergo a risk assessment by EFSA to help risk managers decide whether or not to authorise their use in the EU. To further improve EFSA's support in this area, the assessment of GMO applications was further streamlined in 2009. As a result, the average time between the receipt of a new application and the declaration of its validity became 21 weeks. In addition, the Panel on genetically modified organisms (GMO Panel) has more than halved the time from validation of an application until the delivery of the first letter to applicants with questions or requests for further data (in 96 % of cases, applicants are required to provide further information required for the safety assessment of GMOs). Even with these requests for further data, new efficiency gains allowed the GMO Panel to adopt three times more opinions on GMO applications in 2009 (14 opinions covering 18 applications compared to four opinions covering five applications in 2008).

Evaluating health claims

EFSA is responsible for verifying the scientific substantiation of submitted health claims, which then serve as a basis for the European Commission and Member States that decide on the authorisation of the claims.

In 2009, EFSA's Panel on dietetic products, nutrition and allergies (NDA Panel) met all legal deadlines to evaluate the numerous health claims' applications it had received. For applications on more specific health claims referring to the reduction of the risk of disease or to children's development or health, EFSA adopted 68 opinions within tight legal deadlines.

Regarding more "general function" health claims, such as "calcium is good for your bones", in 2009 the Authority published a combined list of the approximately 4 000 health claims it had received in 2008 from the Commission and Member States; it also published the literature references (approximately 40 000) it received for some 2 000 claims that had entered the scientific evaluation process. It has since adopted and published in October 2009 around 500 claims that were addressed in 94 opinions and, later in the year, adopted 400 additional health claims that are due to be published in 2010.

The new working sub-groups that were created by the Authority to support evaluations of functional health claims started their activities in 2009 and successfully relieved the standing working group on claims and the actual panel of important preparatory work.

As part of this, experts from NDA Panel also met health claims applicants and industry experts in Brussels for an exchange of views on the presentation of applications for health claim authorisations and to provide additional guidance on claim applications.



Further improving the peer review of active substances in plant protection products

By 2009, EFSA's Pesticide Risk Assessment Peer Review (PRAPeR) Unit had completed its work on the peer review of the existing active substances used in pesticides. This will enable the European Commission to decide on the list of active substances that may be included in plant protection products throughout the EU. Applicants, whose active substances were not included in the positive list, could then resubmit their applications for consideration under an accelerated procedure.

In response to the expected high workload in 2009/2010 and the challenging timelines associated with resubmissions, EFSA began to extensively review its procedures and, in close collaboration with Member States and the European Commission, further streamlined its peer review approach. Whilst active substances continue to be subject to a full risk assessment and peer review, the scientific expert consultation is now conducted in a more focused way, concentrating particularly on more important or difficult issues.

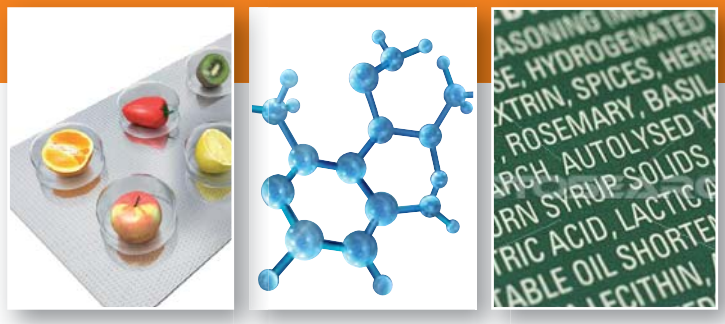
As a result of these new procedures, in 2009 EFSA was able to peer review and deliver its conclusions on the first group of nine resubmitted active substances, as well as progressing the peer review for a further 42 resubmitted substances. Alongside this work, EFSA delivered its conclusions on a further 19 active substances, including 9 new active substances, and peer reviewed the first group of existing active substances on the positive list due for renewal.

Close communication with the European Commission was also crucial in the Authority's review of Maximum Residue Levels (MRLs) for pesticide residues in or on food or feed. MRLs are the upper legal levels of pesticide residue concentrations in or on food or feed, based on good agricultural practice and the lowest consumer exposure necessary to protect vulnerable consumers. 2009 was the first full year in which the corresponding regulation on MRLs was applicable and in which EFSA (and not the Member States) was responsible for the consumer risk assessment in the MRL setting process. The Authority issued in 2009 76 opinions on 300 MRLs for 53 active substances. In this case, dialogue with the European Commission also helped in priority setting and in focusing EFSA's work on substances that are critical with regard to consumer safety and for which a full review of the MRLs established in the European legislation is planned.

Finally, in the area of plant protection products, the Pesticide Steering Committee was created to establish collaboration with the competent authorities in the Member States, with the European Commission and its Joint Research Centre (JRC), as well as with other EU agencies. In 2009, this group met five times and the committee considered ways to make the process even more efficient in the face of an ever-growing workload and an evolving regulatory environment.

Guiding and discussing with applicants: the example of feed additives

To help applicants, over the course of 2009, EFSA developed guidance so that they could better prepare for submitting dossiers. Improving understanding of the process and the information required helps speed up the process and results in better quality applications.



For example, EFSA has prepared guidance in 2009 for the re-evaluations of existing feed additives that had been previously registered. EFSA, and in particular the Panel on additives and products or substances used in animal feed (FEEDAP Panel), will be re-evaluating these products in the coming years. Therefore, the Authority not only updated the administrative guidance document for applicants, including for the first time a "completeness checklist" for applicants but also finalised the technical guidance document for sensory additives. With the latter document, in 2009 the Authority completed the set of technical guidance documents in the area of feed additives. These are chiefly aimed at operators involved in feed production, as well as stakeholders and other bodies concerned with feed safety. They also explain the Panel's approach to scientific risk assessment of feed additives. In addition, the Authority provided more support for the applicants and conducted technical hearings with specific applicants and/or industry associations.

Assessing food additives

For food additives the Authority benefited from having established two new panels to take up the work previously carried out by only one panel. The workload was divided among two panels, the Panel on food additives and nutrient sources added to food (ANS Panel) and the Panel on food contact materials, enzymes, flavourings and processing aids (CEF Panel), set up in 2008. This new organisation of the work helped EFSA to meet the deadline – in 2009 – of the evaluation programme of nutrient sources used in food supplements. This was an important achievement supporting the European Commission in drawing up a positive list of such nutrient sources by the end of 2009, as required by legislation.

In completing this first comprehensive assessment of nutritional substances proposed to be used in food supplements in the EU, EFSA examined 533 applications in total, covering 344 different substances; 186 applications were withdrawn at various stages during the evaluation process, and EFSA received insufficient scientific evidence to assess around half of the remaining applications. Possible safety concerns were identified in relation to 39 applications. With this assessment, the Authority helped ensure that food supplements sold in the EU are not only safe but also effective in providing the body with the nutrients contained in the supplement. In addition, the provision of better information for the applicants – such as the establishment of data requirements for food additive applications – accelerated EFSA's processes. The European Commission will consider the data requirements listed by EFSA when finalising legislative measures concerning applications submitted for the evaluation and authorisation of food additives. Then in 2010, the ANS Panel will start preparing a separate guidance document to indicate the scientific aspects to be considered when preparing applications for food additives.

In preparation for the re-evaluation of all permitted food additives, three public calls for data were made in November 2009, mainly directed at producers of additives, food companies, national authorities, or other involved parties. The objective was to close information gaps that could otherwise prevent the Panel from properly assessing the safety of the additives in question.



The ANS Panel was also able to finalise the re-evaluation of the six colours used in the so-called "Southampton Study" (Mc Cann *et al.*, 2008), which the European Commission had asked EFSA to consider a priority. Prior to the Authority's evaluation, a study conducted at the University of Southampton had suggested a link between mixtures of six food colours and the preservative sodium benzoate, and hyperactivity in children. In November 2009, the Panel concluded that the evidence currently available did not substantiate a causal link between any of the six individual colours and possible behavioural effects. However, for specific reasons related to the potential adverse effects of each colour, the Panel has reduced the Acceptable Daily Intake (ADI) of three of the colours (E 104, E 110 and E 124).

Evaluating and providing guidance on food contact materials and flavourings

EFSA has carried out an evaluation of about 2 600 flavouring substances that had been registered by the European Commission as existing products. The Authority was largely able to complete this task in 2009, with only a few individual issues remaining that require further coordination with other agencies, such as EMA. In addition, the Authority has outsourced the collection of the data and the preparation of summaries for the working groups and panels.

In 2009, EFSA also launched a public consultation on a draft guidance document on food flavourings that specifies which data industry should submit for the safety evaluation of new flavourings. This document reflects the experience gained by EFSA during the evaluation of the flavourings that are already on the market.

Furthermore, the Authority also published guidelines on "active" and "intelligent" substances in materials in contact with food. Active food-contact materials absorb or release substances to preserve or improve the condition of packaged food or extend its shelf life, while intelligent food-contact materials monitor the condition of packaged food or the surrounding environment and provide information on the freshness of the food.

3. GATHERING EU DATA

The quality of the risk assessment done by EFSA depends not only on the integration of the full range of expertise available. It also depends on the quality, consistency, topicality and completeness of the data that are used in the scientific analyses, monitoring of risks and deliberations on the risks being assessed. Therefore, the Authority also has an important role in data collection, coordination and harmonisation across Europe. In this role, EFSA works in particular with Member States to gather, share and analyse data at the EU level. For this, it can rely on a solid and efficient network spanning the individual countries and responsible authorities. The Authority's work in this field includes the monitoring of pesticide and veterinary drug residues, chemical contaminants, zoonoses and emerging risks, as well as the compilation of European food consumption data, on the one hand, and the use of the two data streams to calculate exposure, on the other. Collecting such data also allows EFSA to rapidly respond to urgent requests for advice with a robust evidence base, so that potential risks can be quickly assessed, enabling risk managers to act rapidly, if needed.

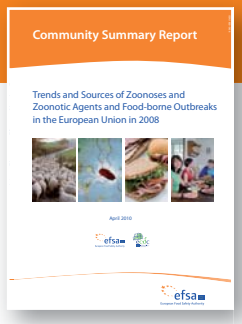
What's Europe eating?

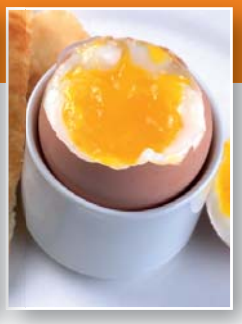
A common component of any exposure assessment is information on food consumption. EFSA's collection of food consumption data started with the development of the "Concise European Food Consumption Database", led by its Data Collection and Exposure (DATEX) Unit. This step provided a first overview of food consumption in Europe.

To be able to refine exposure assessments, the Authority, in conjunction with Member States, embarked on the collection of detailed data for a comprehensive food consumption database, which was finalised by the end of 2009. This comprehensive database represents a major step forward for exposure assessment, as the quality of available data on food consumption can have a major impact on the outcome of related risk assessments. This new comprehensive database represents the best food consumption data available at the EU level; it also marks a consolidation of the relationship between the Authority and Member States as these now share their data.

EFSA is currently in the process of extending its European food consumption database. However, Member States use different methods to collect food consumption data, which makes it difficult to carry out EU-wide analyses or country-to-country comparisons. In close cooperation with Member States, EFSA is therefore supporting further harmonisation of data collection on food consumption across Europe. Such data consistency will improve the accuracy and reliability of EU wide exposure estimates and, consequently, of the risk assessments carried out by EFSA's panels and by other risk assessors and scientific experts across Europe. In December 2009, the Authority's food consumption and exposure working group published the general principles for the collection of national food consumption data with a view to support harmonisation for data collection.

Other food consumption and exposure data are also collected by Member States and sent to EFSA to support the Authority's monitoring activities and the production of the annual data collection reports on contaminants exposure. In 2009, two target contaminants were covered by these reports, acrylamide in May and furans in June. Acrylamide can be formed in foods rich in carbohydrate during food processing at temperatures of 120 °C or higher. The compound has been shown to be genotoxic and carcinogenic in laboratory animals. Furan can also form in foods during heat treatment and is known to occur, for example,





in coffee and jarred food, including baby food containing meat. This contaminant has also been shown to be carcinogenic in animal studies.

Ad hoc reports on the occurrence of specific contaminants were also requested by the European Commission, e.g. for dioxins in food and feed. EFSA received contaminant data in food and feed products from Member States and other interested parties, and issued a draft report in 2009 for discussion with Member States and the Commission.

EFSA's first Annual Pesticide Residues Report

Another responsibility that has been handed over to EFSA from the European Commission is the publication of the Annual Report on Pesticide Residues in food, which is based on the legal framework of the new MRL legislation applicable since September 2008 and for which Member States have to provide the data. In July 2009, EFSA's Pesticide Risk Assessment Peer Review (PRAPeR) Unit published the first of these reports, providing an overview of the pesticide residues found in food samples marketed in Europe in 2007, but also providing a risk assessment of the consumer exposure to the residues. In total, more than 74 000 samples of nearly 350 different types of food were analysed; 4 % of the samples exceeded the legal MRLs. The consumer exposure assessment identified some critical results. Based on these findings, EFSA derived recommendations to be considered for future control activities.

To help draft the report, and to improve collaboration with Member States, the Authority established a networking group. The group consists of nominated experts from Member States and a European Commission representative. This group discusses all issues related to the monitoring report, in particular the necessary improvements required regarding the format of the data and the level of details reported to EFSA. Consequently, in 2009, the Authority developed a data model for the reporting of results and successfully carried out a comprehensive pilot project. After the formal adoption, the data model will be implemented for collecting data from the 2009 monitoring results. The new format will allow EFSA to perform a more accurate consumer exposure assessment.

Reporting on zoonoses and food-borne outbreaks EU-wide

As in previous years, EFSA's Zoonoses Data Collection ("Zoonoses") Unit issued in 2009 the *Community Summary Report on Zoonoses and Food-borne Outbreaks*. This report series is prepared in close collaboration with ECDC, which provides and analyses the data from the disease cases in humans, and with the Task Force on Zoonoses Data Collection. This pan-European network of national representatives and international organisations assists EFSA by gathering and sharing information on zoonoses in their respective countries. These community summary reports are used both by risk managers and assessors, as well as other stakeholders across the EU. In particular, the risk managers at EU level use the reports when considering the need for further EU control measures and when monitoring the impact of existing EU measures.

The major findings of the latest report, published in January 2010, are that in 2008 campylobacteriosis and salmonellosis continued to be the most frequently reported zoonotic diseases in humans, although salmonellosis cases decreased significantly for the fifth consecutive year. An important decline in the occurrence of *Salmonella* in laying hens was observed in 2008 due to control programmes implemented by Member States. This could be the reason for a corresponding fall in human *Salmonella* infections, typically related to the consumption of eggs that was also observed during the same year.

Other 2009 highlights were EFSA's reports on analyses of the EU-wide baseline surveys of two zoonotic bacteria, *Salmonella* and, methicillin-resistant *Staphylococcus aureus* (MRSA) in breeding pigs. Both of these bacteria were commonly found from breeding pig holdings in many Member States. The results of these surveys will help risk managers when setting *Salmonella* reduction targets for breeding pigs and when considering the need to control and monitor MRSA in pigs in view of protecting public health.

To harmonise zoonoses-related data collection across the EU and to improve their analysis, in 2009 EFSA published two reports with specifications for harmonised surveys of the food-borne pathogens, verotoxigenic *E. coli* and *Yersinia*, as a guide to Member States. The Authority also applied improved statistical methods for analysing the trends in zoonotic agents over the years, and even better data validation by using, for the first time, a new data management system.

Helping to spot emerging risks

In 2009, EFSA's Emerging Risks (EMRISK) Unit developed new tools for efficiently monitoring and analysing data to identify new or re-emerging hazards, in particular from the Rapid Alert System for Food and Feed (RASFF). This database, maintained by the European Commission, includes detailed information on food safety events notified by the members of the RASFF-network.

Another important source of data for the identification of emerging risks is the media. EMRISK assessed the usefulness for this task of a media-monitoring tool developed by the European Commission's Joint Research Centre. These tools, together with monitoring of trade data provide a first step in the implementation of EFSA's strategy for addressing emerging risks.

One specific topic being addressed by the Authority's EMRISK Unit is the impact of climate change on aflatoxins (carcinogenic chemicals produced by certain moulds, particularly prevalent in hot and humid climates, which grow on cereals) in cereals. Based on different climate change scenarios, the aim of this project, which started in 2009, is to gather and analyse data on aflatoxin production to build predictive models, define scenarios and create maps highlighting areas where future contamination of cereal crops may occur. While this is a very prospective project that looks decades ahead, a more immediate benefit of this work is the development of methodologies and tools for anticipating the emergence of new risks in food and feed.

Visit of Japanese delegation to EFSA in December 2009

4. BUILDING INTERNATIONAL PARTNERSHIPS

Crops, animals, and food and feed products are transported around the world in an increasingly global world – as are the associated risks. Therefore, being involved internationally – in support of EU policy – is paramount for EFSA's ability to keep Europe's food supply safe and to protect consumers. To this end, EFSA seeks to build partnerships with food safety agencies in countries outside the EU and with international organisations in order to ensure access to the larger pool of international scientific data and information. This will allow the Authority to continue to provide a strong basis for risk assessment and identify emerging risks, to take part in risk assessment internationally, to support international harmonisation efforts on data collection and risk assessment, and to promote coherence in risk communications. In addition, the Authority is also building awareness of its activities internationally to build its reputation as an organisation that is globally recognised and trusted as the European reference body for risk assessment.

Going global

EFSA adopted its "strategic approach" to its international activities in January 2009. As a first step, the authority took stock of the multiplicity of existing formal and informal collaborations, and international contacts at individual levels. Then, to prioritise regions and organisations where closer collaboration and an alignment of positions are of relevance for EFSA, the Authority identified priority partners and target countries for the development of longer-term relationships. The objective of these relationships is to strengthen the Authority's capacity to perform risk assessment based on shared perceptions of the risks and to better communicate them internationally. For EFSA, strengthening its position in the international arena is also necessary given the fact that food-related risks are increasingly global: international food trade is ever-increasing and, through the global food chain, risks can easily appear in products from far-away countries.

The Authority supports the international exchange of data and risk assessments. It contributes to the development and harmonisation of methodologies and promotes a common understanding of the underlying principles. EFSA seeks to contribute to and guide international best practices – with the ultimate aim of becoming globally recognised as the European reference body for assessing the risks related to the food chain.

Forging closer ties internationally

In 2009, EFSA prepared and began implementing its international strategy – prioritising its actions on supporting EU policy – and already set new important milestones for its international activities. Foremost among these achievements was the formalisation of relationships with the Japanese risk assessor, the Food Safety Commission (FSC) of Japan, through signing in December a Memorandum of Cooperation on the collection and sharing

Visit of Chinese delegation to EFSA in January 2009

of data required for the assessment of current and emerging risks. Likewise, EFSA committed to work together and exchange data with the competent authority of New Zealand through an exchange of letters; similar activities were advanced with Canada and Australia. In addition, EFSA provided scientific support for the European Commission delegation to *Codex Alimentarius* (a joint FAO/WHO body which develops international food standards, guidelines, etc.) and contributed, in particular, to the EU position on ractopamine, a growth promoter used in animal feed.

Early in 2009, a delegation from Chinese public health authorities visited EFSA. Other international high-level visits to EFSA in 2009 included the visit of a delegation of the WHO to present their work programme in the area of food safety and to discuss scientific issues, such as animal health and welfare, pesticides, zoonoses, nutrition, food additives, contaminants, and general principles of risk assessment and risk communications. A common theme underlying all the international visits was the identification of future cooperation activities and harmonisation steps. EFSA delegations have also visited international partners; For example in July 2009 a delegation visited US Federal institutions.

Finally, in 2009 EFSA initiated a series of initiatives under the EU's pre-accession programme for candidate and potential candidate countries, i.e. Turkey, Croatia and the former Yugoslav Republic of Macedonia plus Albania, Bosnia-Herzegovina, Kosovo, Montenegro and Serbia. The objective of this programme is to help national food safety authorities in these countries in their own risk assessments and risk communications. In particular, the programme aims to help them prepare for future participation in EFSA networks; to develop communication and information exchange systems; to transfer knowledge of areas covered by EFSA; and to support the beneficiary countries in their risk communication activities.

To do this EFSA arranges training seminars and study tours for experts nominated by the respective programme coordinator in each country; four seminars were held in 2009. In the context of this programme, the candidate and potential candidate countries are also invited to participate as observers at EFSA meetings with Member States. As a result, these countries become increasingly involved in the work of EFSA, an outcome that supports international harmonisation efforts.

5. COMMUNICATION AND DIALOGUE

EFSA aims to reinforce public confidence and trust in the EU food safety system through its communications and dialogue with partners and stakeholders. It also remains committed to ensuring transparency throughout its work, ensuring visibility and accessibility for its scientific outputs, as well as raising awareness and understanding of how EFSA works.

EFSA strives to promote coherence between its own risk communications and that of its partners in the EU food safety system and beyond. This is a critical goal alongside maintaining the simplicity and accessibility of its communications, and further increasing the visibility and the understanding of its scientific work. To achieve this, and to better reach national audiences in their own languages, in 2009 EFSA also started implementing a multilingual approach to its own communications, making key corporate publications and strategy documents available in all 23 EU official languages.

In 2009, the Authority embarked on research amongst its key target audiences, acknowledging the need to measure the impact of its communications and general awareness about EFSA. Following a qualitative approach, EFSA conducted interviews with decision makers and stakeholders in politics, science and the food chain at national, European and international levels. The results of this work will support the Authority in the review of its communication strategy, which it began in 2009. This will also enable the Authority to further refine its EFSA brand guide which summarises what EFSA wants to stand for and which aims to guide communication outputs in delivering a consistent and coherent image of the Authority.

In 2009, EFSA has considerably increased its outreach. For instance, it significantly enhanced the usability and accessibility of its website attracting more than 2.4 million web visits, subscribers to the "EFSA Highlights" newsletter increased by over 20 %, media relationships were strengthened, online news expanded by nearly 30 % and publications more than doubled.

The Advisory Forum Working Group on Communication

Cooperation on communications with Member States

The Advisory Forum Communications Working Group (AFCWG) continues to be the key vehicle for strengthening the coherence of communications activities between the national authorities and EFSA, and for sharing and promoting best practice. In 2009, the AFCWG developed an overall approach and outline for risk communications guidelines to help support coherence in risk communications across the EU that will be finalised in 2010.

EFSA supported Member States in the organisation of joint events, by publishing targeted newsletters to reach stakeholders nationally and stronger collaboration through the AFCWG. Joint events were also organised by EFSA and the corresponding Member State during 2009 in Austria, Greece and Slovenia. These events addressed a variety of topics that included strengthening capacity in food safety, cooperation between EFSA and Member States, and the links between science and policy with regard to food safety and nutrition.

Dialogue with stakeholders

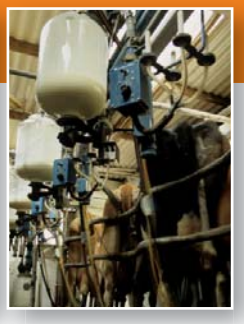
In 2009, EFSA renewed its stakeholder consultative platform, readopting 24 EU-wide organisations working in areas related to the food chain for one year. This platform meets three times a year to assist EFSA in the development of its overall relations and policy with stakeholders. The platform is an important channel for encouraging dialogue and engagement of stakeholders, and for fostering good relationships with stakeholders.

This renewal of the platform represents an important consolidation of the Authority's contacts with its stakeholders and underlines its commitment to open and transparent dialogue.

In 2009, EFSA held three plenary meetings instead of two as in previous years. At these meetings, stakeholders discussed horizontal strategic documents and submitted advice and comments on EFSA's management plan, its annual report and its communication strategy. Core EFSA processes are also discussed within the platform – for instance, in 2009 there was a working group on EFSA's approach to public consultations on scientific outputs.

As well as increasing the number of plenary meetings, EFSA also increased the frequency of the platform's technical meetings in 2009. These meetings focus more on scientific topics and covered, for example, animal welfare, pesticides, nanotechnologies and novel food. In addition, the Authority also fosters bilateral contacts with its stakeholders. In 2009, EFSA welcomed a BEUC delegation, led by its new President, on a visit to its headquarters. It enabled EFSA to explain how the Authority protects consumers through its work on risk assessment, as well as discuss its work on scientific cooperation and communications.

Another stakeholder event in 2009 was a meeting with environmental NGOs that EFSA organised in Parma at which representatives from the European Commission's Health and Consumers DG (DG SANCO) and DG Environment participated as observers. This meeting was an opportunity for the Authority to present its work in the area of GMO risk assessment and to exchange views with stakeholders. It led to a better mutual understanding of arguments and points of view between experts of the GMO Panel and members of


environmental NGOs. In the area of health claims, EFSA also met in June 2009 with stakeholders and Member States to explain EFSA's work in this area and how it evaluates claims, as well as to present the various relevant guidance documents it has produced.

Engaging in scientific dialogue

Excellence in science remains a core value for EFSA. An important element of maintaining excellence is engaging in dialogue, to listen and learn, and to share information. In doing so, EFSA also seeks to raise awareness and understanding of its work. For example, in September 2009, EFSA held a high-level conference to present its work and to exchange views on GMO risk assessments for human and animal health, and the environment. GMOs provide a good example in which the Authority provides sound scientific advice and science-based information, facilitates an exchange of views, promotes mutual understanding and learning, and communicates its risk assessment work, openly and transparently.

For the first time in Europe, this two-day conference in Brussels brought together risk managers and risk assessors from Member States, as well as representatives from stakeholders – including industry, consumer and environmental groups – to discuss the status and future challenges of risk assessment of GMOs. On the side of the European Commission, the importance of this event was acknowledged through speeches given by the Directors-General of DG SANCO and DG Environment, who gave the opening and closing speeches, respectively. In all, around 150 participants attended this conference, which was well received.

Among the scientific events organised by EFSA in 2009, its Scientific Colloquium on Novel Foods is a good example. About twice a year, EFSA organises such technical conferences to offer scientists the possibility to exchange their points of views and to foster and promote new ideas. At the time of this event, the novel foods regulation was under revision, with the new regulation foreseeing centralised risk assessment by EFSA. Therefore, the Authority convened the Colloquium to discuss the scientific information and data requirements needed for applications for authorisation of novel foods and novel food ingredients in the European Union. In this way, EFSA obtained early on valuable input from all stakeholders for the related guidance document on the safety assessment of novel foods that will be drafted in 2010. Approximately 100 international experts in safety assessment and regulatory affairs, as well as food manufacturers and others involved in novel foods, attended the colloquium, coming from 25 countries within the EU and overseas.

The EFSA Journal: Science at your fingertips

Three reasons to subscribe to the European Food Safety Authority's online scientific journal.

1. Easy access to EFSA science, past and present
2. Available free of charge
3. Comprehensive advice from field to plate:

Reaching out to the scientific community

EFSA science also reached a significant milestone in 2009, with the launch of a new, dedicated web area on the Authority's corporate website for the *EFSA Journal*. The goal of this further development of the EFSA Journal was to increase the visibility of the Authority's scientific work internationally and to acknowledge the work of the scientific experts in its panels and working groups.

The "new look" EFSA Journal now makes it easier for readers to browse and search EFSA scientific outputs. Readers can also easily subscribe to receive the latest issues of the Journal and can simply view articles using online news syndication services, such as RSS. In addition, the Journal aims to meet scholarly publishing standards and comply with requirements of bibliographic databases relevant for EFSA's work. After the EFSA Journal web area is fully implemented EFSA will apply to bibliographic databases for indexation of EFSA Journal articles, further raising the scientific visibility of the Authority's work.

A strong partnership with EU Institutions

The visit of the then European Commissioner for Health, Androulla Vassiliou, to EFSA in October 2009, was one notable example of the strong and increasing partnership between the Authority and the Institutions. In an address to staff, Commissioner Vassiliou cited EFSA's robust scientific advice as key to helping EU decision makers create a regulatory framework securing one of the highest levels of food safety in the world. The Commissioner specifically referred to improved planning and establishment of priorities as a result of the close working relationship between the Authority and the Commission – for example, agreeing on "*roadmaps*" in the areas of applications.

The Commissioner's two-day agenda included several sessions to discuss recent EFSA activities in the fields of cloning, nanotechnology, GMOs and nutrition, as well as a session addressing current and future activities in data collection. While commending the existing system of partnership between the Authority and the Commission, the Commissioner commented on "even closer co-operation" between EFSA and other institutions, particularly on issues including new technologies and GMOs. The Commissioner also identified the quality of EFSA's scientific advice, which underpins EU legislation, as being the "cornerstone" of the Authority's success.

In October, EFSA Executive Director Catherine Geslain-Lanéelle addressed the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI Committee) in Brussels. The Executive Director emphasised the importance of consultation with the Parliament on EFSA's activities and priorities.

Working alongside other EU agencies

For EFSA, another important dimension of 2009 was the Authority's role as coordinator of the network of EU agencies. The purpose of this network is to provide a forum for discussion and cooperation between the agencies at institutional level. It allows agencies to share experiences, develop common best practices, organise joint training and promote the overall image and visibility of EU agencies.

A working group between EU institutions was created to draw lessons from the deployment of EU regulatory agencies and to consider how agencies can best contribute in the context of the renewed institutional framework created by the Lisbon Treaty.

In parallel, the European Commission began a horizontal evaluation of the agencies' system. This was discussed within the network and led to reflections upon the future of the agencies, i.e. the development of a shared common vision for the agencies in terms of governance, effectiveness, management, and their relationships within the EU system.

For example, in light of this evaluation, a communication plan was developed to underline the overall role and contribution of agencies to the EU system. This led, for instance, to the development of an interagency promotional brochure. In addition, at their October 2009 meeting, the Heads of Agencies adopted the Internal Audit Services (IAS) Charter which formalises the relations between EU agencies and the IAS with respect to internal audit activities. The Heads of Agencies also endorsed the IAS Mutual Expectations Paper which outlines the working procedures between the IAS and EU agencies.

One concrete example of inter-agency cooperation is the EU Agencies Heads of Communication and Information Network, which EFSA also chaired in 2009. One of this network's 2009 milestones included a meeting with the former EU Communications Commissioner, Margot Wallström, on the agencies, work in communications. In addition, the Authority created and distributed a contact list covering web staff in all agencies, before carrying out a benchmark survey among them to determine common topics about which they need to learn. Based on this information, EFSA then organised a tailored training workshop for EU agencies' web staff, which also provided networking opportunities and a forum for professional discussions and exchanges. The workshop had 57 participants and, according to feedback, was a great success.

Forging closer ties with EFSA's local community

For EFSA, one particular aspect of local and regional outreach is communication with the community in which the Authority is located and where its staff lives. It is important that the public in Parma, as well as local and regional decision makers, understand EFSA's work. Consequently, each year EFSA tries to improve its local standing through specific events. In 2009, the Authority organised a *"Festa dell'Europa"* – in collaboration with regional and local authorities – to commemorate Schuman Day. The objective was to cultivate local understanding of EFSA and to promote awareness of the election of the European Parliament and, more generally, of the European project.



6. RESPONSIVENESS, EFFICIENCY AND EFFECTIVENESS

EFSA's ever-growing output confirms the Authority's accomplishments in effectively designing its management systems and infrastructures, in streamlining its processes optimally, in allocating its resources productively and in dealing with constraints successfully.

As in earlier years, the Authority also showed in 2009 that it can indeed react swiftly in response to urgent food safety threats. Learning its lessons from such incidents and carrying out crisis simulation exercises helps EFSA to remain prepared and alert. EFSA's effectiveness and efficiency were not only confirmed by its handling of urgent issues but by also its continuous and ever growing output.

In case of crisis…

The *crisis simulations* in 2009, which comprised of two separate exercises, were part of a systemic approach to be ready and prepared for urgent food safety threats. The objective of the first exercise was to test EFSA's internal processes, to hone its capacity to provide rapid risk assessment and to support the publication of advice with adequate communications measures. The second exercise tested the Authority's ability to communicate and collaborate with the European Commission and Member States in an emergency.

Together these two simulations covered all operations and the full course of action that the Authority has to complete – to be as fast as possible while delivering high quality results – in order to manage a crisis successfully. These simulations were also used to test EFSA's emergency manual that had been updated in early 2009. Overall, the simulations were a valuable exercise for Authority staff to learn and test the procedures and infrastructure, as well as to feel more comfortable when a real situation arises.

From theory to practice

In addition to simulated crises, EFSA had to deal with real life scenarios, in particular the need to provide urgent scientific advice regarding the presence of nicotine in wild mushrooms and of packaging ink in breakfast cereals.

In February 2009, a laboratory in Germany found high levels of 4-methylbenzophenone (a substance used in printing inks for food packaging) in breakfast cereals. As a result EFSA received a request for rapid advice from the European Commission. In a first assessment, and building on data from Member States, the Authority concluded that short-term consumption of contaminated breakfast cereals should not pose a risk to most people, but that more data would be needed to carry out a full risk assessment if the contamination of food through 4-methylbenzophenone



were to continue. Following this incident, EFSA continued to look into this matter, and gave further advice building on the rapid response provided earlier. The Authority also established a working group for non-plastic food-contact materials and compiled a list of contacts of experts for scientific support.

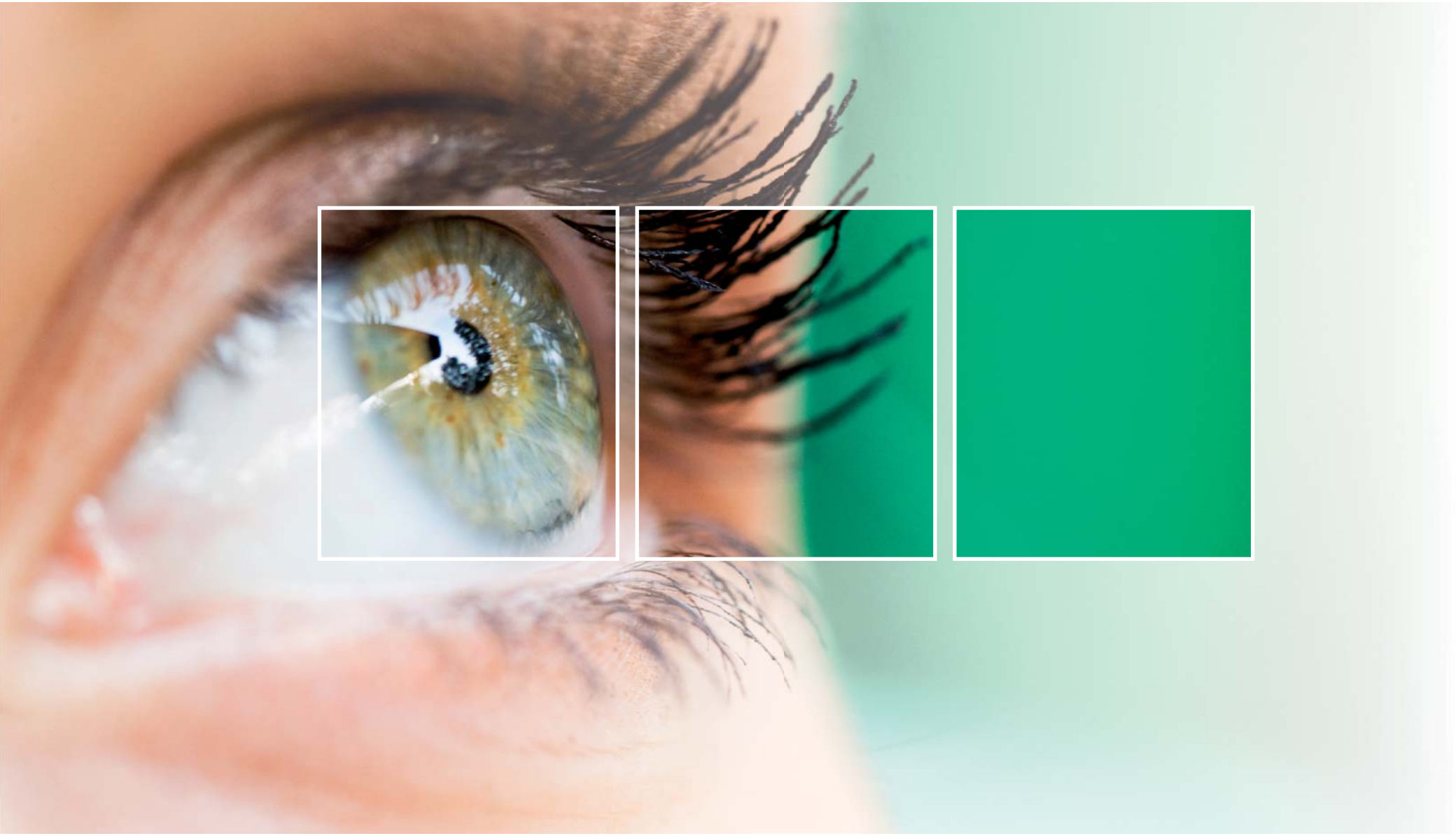
Also in Germany in 2009, nicotine was detected in samples of boletus mushrooms. Again, the European Commission contacted EFSA to request an opinion on whether the nicotine represented a safety concern. The request was received on 27 April and the deadline for the statement was set ten days later, on 7 May. The Authority concluded that the residues found indeed represented a potential consumer health risk. Based on the EFSA statement, the European Commission and Member States established guidelines ensuring a high level of consumer protection in the EU. In particular, a monitoring programme and temporary guideline values for residues in fresh and dried mushrooms were established.

For both these urgent cases, the Authority was able to turn the advice around quickly and avoid the generation of undue public concern.

Being efficient and effective

EFSA's scientific workload also continued to grow in 2009, with the number of mandates for scientific advice, mainly from the European Commission, increasing from around 285 in 2008 to 317 in 2009. Correspondingly, the scientific outputs also increased significantly: a total of 636 in 2009 compared with 489 in 2008, an increase of 30 %. In particular, efficiency gains coupled with the increase in resources devoted to the units dealing with applications (ANS, CEF, FEEDAP, GMO, NDA and PRAPeR Units) in recent years have been accompanied by a significant increase in their productivity, from 165 adopted opinions in 2008 to 435 in 2009. Furthermore, to support panels and to increase their throughput further, more activities were outsourced through contracts and grants (see also p. 12, "*Calling on the best of Europe*"), and the number of external experts assisting the panels in working groups increased. In addition, the Authority continued to raise awareness of EFSA scientific work through proactive media relations: 34 % of EFSA's opinions were supported by media activities in 2009; through publications in all EU languages, 19 events across Europe, and continual improvements to the EFSA website to further enhance its usability and accessibility.

III. LOOKING AHEAD TO 2010



In 2009, the European Food Safety Authority continued to be tightly woven into the fabric of the EU food safety system and was increasingly visible internationally. In 2010, EFSA aims to continue to build on these achievements by boosting risk assessment capacity in Europe, strengthening the effectiveness of its communications and consolidating its attractiveness for staff and experts.

In 2010, EFSA will continue to see its workload increase, particularly in the area of authorisations. As it continues to streamline its workflows, EFSA productivity will lead to an anticipated output of around 900 scientific outputs. Boosting risk assessment capacity in Europe means sharing EFSA's work programmes with national agencies at an early stage to facilitate their medium-term planning and the setting of priorities in tandem with the Commission.

Another important project for the Authority in 2010 is to continue to build its data collection activities across the EU. The aim will be to further improve consistency of data across Member States so that data becomes more comparable. An example of this is the "*EU Menu*" project – "*What's on the Menu in Europe?*" – aiming to harmonise data collection on food consumption across Europe.

Putting all this work in perspective, EFSA will release its first Science Strategy in 2010.

Strong EFSA cooperation will continue with Member States, stakeholders and other actors in the food chain to ensure that consumer protection and health policy are supported by the most robust scientific evidence available and that EFSA remains influential in the development of risk assessment methodologies in Europe and beyond. To this end, EFSA will continue to implement its strategic approach to international activities.

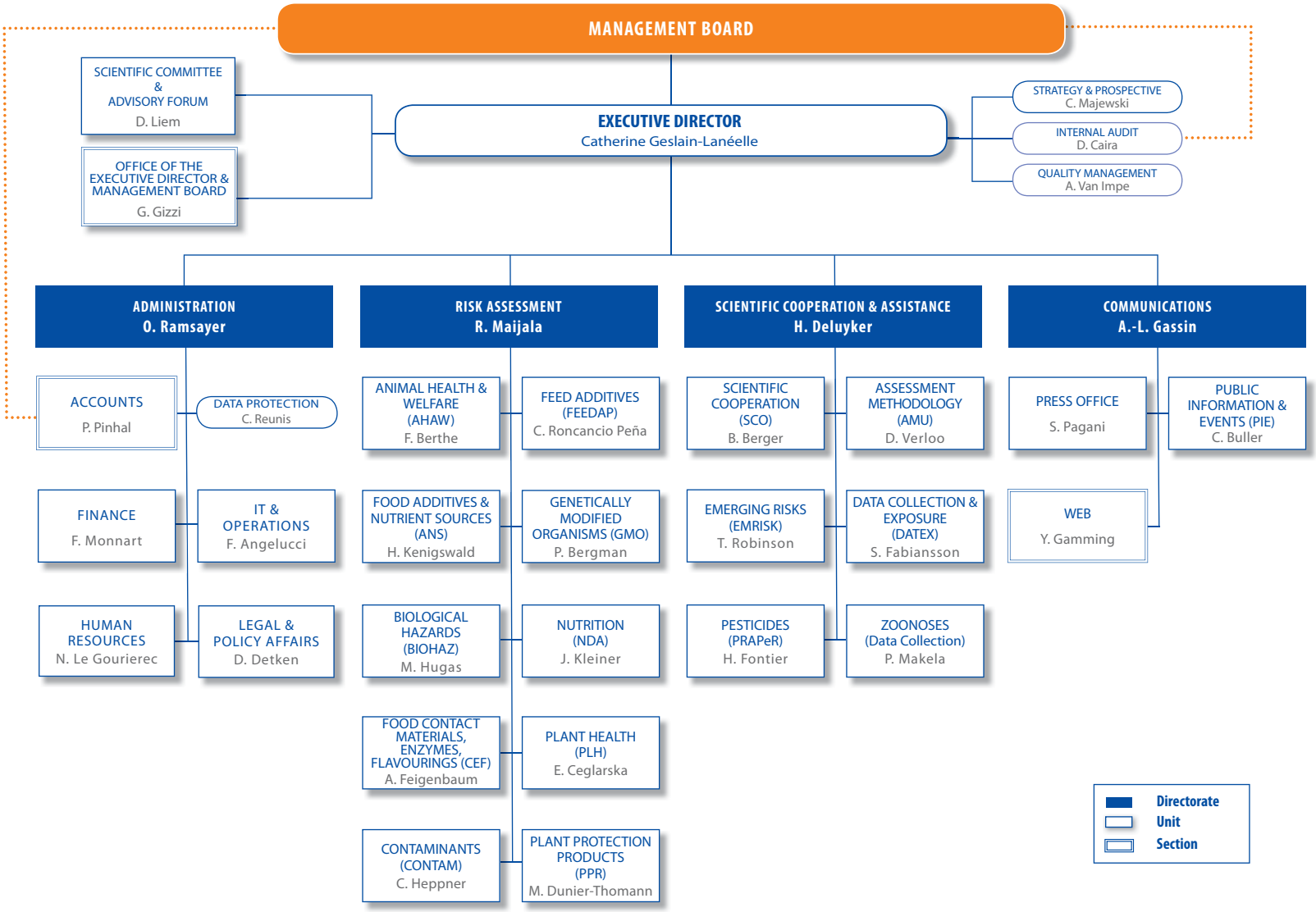
With a newly-designated European Commission and the European Parliament, EFSA will forge even stronger links with EU Institutions. A fundamental goal of the Authority remains the reinforcement of confidence and trust in EFSA and the EU food safety system through effective risk communication and through dialogue with partners and stakeholders.

EFSA will also review its communications strategy, first adopted in 2006, to take account of changes in the communications landscape, as well as the growth and evolution of the organisation. The overall approach aims to continue the close working relationships with national food safety agencies and stakeholder networks while further improving the simplicity of its communications and further expanding public outreach. The revised communications strategy will be submitted for public consultation and is expected to be submitted to the Management Board for final validation by the end of 2010.

In 2010, EFSA will also continue to strengthen relations with stakeholders. For this, it will develop a rolling work plan that will be constantly updated. This plan will provide an overview of all activities and events organised for and with its stakeholders. Examples include: even more technical meetings with stakeholders in 2010; a new working group to propose ways to further engage and reinforce stakeholders' involvement in EFSA's activities, in addition to participating in public consultations and EFSA's scientific events; and the formation of consultative groups.

In conclusion, EFSA will further build on the progress made in recent years to address the ever-growing workload while further engaging with partners and stakeholders at national, European and international levels. This will ensure that EFSA continues to be ready and able to play its part in protecting food safety and public health in Europe.

ANNEX I – ORGANISATIONAL CHART


MANAGEMENT BOARD
SCIENTIFIC COMMITTEE & ADVISORY FORUM
D. Liem
OFFICE OF THE EXECUTIVE DIRECTOR & MANAGEMENT BOARD
G. Gizzi
EXECUTIVE DIRECTOR
Catherine Geslain-Lanéelle
STRATEGY & PROSPECTIVE
C. Majewski
INTERNAL AUDIT
D. Caira
QUALITY MANAGEMENT
A. Van Impe
ADMINISTRATION
O. Ramsayer
RISK ASSESSMENT
R. Maijala
SCIENTIFIC COOPERATION & ASSISTANCE
H. Deluyker
COMMUNICATIONS
A.-L. Gassin
ACCOUNTS
P. Pinhal
DATA PROTECTION
C. Reunis
FINANCE
F. Monnart
IT & OPERATIONS
F. Angelucci
HUMAN RESOURCES
N. Le Gourierec
LEGAL & POLICY AFFAIRS
D. Detken
ANIMAL HEALTH & WELFARE (AHAW)
F. Berthe
FEED ADDITIVES (FEEDAP)
C. Roncancio Peña
FOOD ADDITIVES & NUTRIENT SOURCES (ANS)
H. Kenigswald
GENETICALLY MODIFIED ORGANISMS (GMO)
P. Bergman
BIOLOGICAL HAZARDS (BIOHAZ)
M. Hugas
NUTRITION (NDA)
J. Kleiner
FOOD CONTACT MATERIALS, ENZYMES, FLAVOURINGS (CEF)
A. Feigenbaum
PLANT HEALTH (PLH)
E. Ceglarska
CONTAMINANTS (CONTAM)
C. Heppner
PLANT PROTECTION PRODUCTS (PPR)
M. Dunier-Thomann
SCIENTIFIC COOPERATION (SCO)
B. Berger
ASSESSMENT METHODOLOGY (AMU)
D. Verloo
EMERGING RISKS (EMRISK)
T. Robinson
DATA COLLECTION & EXPOSURE (DATEX)
S. Fabiansson
PESTICIDES (PRAPeR)
H. Fontier
ZOONOSES (Data Collection)
P. Makela
PRESS OFFICE
S. Pagani
PUBLIC INFORMATION & EVENTS (PIE)
C. Buller
WEB
Y. Gamming
Directorate
Unit
Section

ANNEX II - GLOSSARY

ADI	Acceptable Daily Intake
AFC	(Former) Panel/Unit on food additives, flavourings, processing aids and materials in contact with foods
AFCWG	Advisory Forum Communications Working Group
AHAW	Panel/Unit on animal health and welfare
AMR	Antimicrobial resistance
AMU	Assessment Methodology Unit
ANS	Panel/Unit on food additives and nutrient sources added to food
ARfD	Acute reference dose
BIOHAZ	Panel/Unit on biological hazards
BMD	Benchmark dose
BPA	Bisphenol A
BSE	Bovine Spongiform Encephalopathy
CEF	Panel/Unit on food contact materials, enzymes, flavourings and processing aids
CIBUS	International food fair in Parma
CONTAM	Panel/Unit on contaminants in the food chain
DATEX	Data Collection and Exposure (Unit)
DG	Directorate General (European Commission)
DG SANCO	Health and Consumers DG, Directorate-General for Health and Consumers
DRV(s)	Dietary Reference Value(s)
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMRISK	Emerging Risks (Unit)
ENVI	European Parliament Committee on the Environment, Public Health and Food Safety
EP	European Parliament
ESCO	EFSA Scientific Cooperation
EU	European Union
FAO	United Nations Food and Agriculture Organisation
FEEDAP	Panel/Unit on additives and products or substances used in animal feed
FSANZ	Food Standards Australia New Zealand
GM	Genetically modified
GMO(s)	Genetically modified organism(s)
HC	Health Canada
IAS	Internal Audit Services (European Commission)
INEX	EFSA internal and external review system
JRC	Joint Research Centre
MRL(s)	Maximum residue level(s)
MRSA	Methicillin-Resistant *Staphylococcus aureus*
NZFSA	New Zealand Food Safety Authority
NDA	Scientific Panel/Unit on dietetic products, nutrition and allergies
OIE	World Organisation for Animal Health
PLH	Panel/Unit on plant health
PPR	Panel/Unit on plant protection products and their residues
PRA	Pest Risk Analysis
PRAPeR	Pesticide Risk Assessment Peer Review Unit
RA	Risk Assessment Directorate
RASFF	Rapid Alert System for Food and Feed (European Union)
SC	Scientific Committee
SCA	Scientific Cooperation and Assistance Directorate
SCENIHR	Scientific Committee on Emerging and Newly Identified Health Risks (European Commission)
SCO	Scientific Cooperation Unit
TDI	Tolerable Daily Intake
TSE	Transmissible Spongiform Encephalopathy
UK	United Kingdom
US	United States
WHO	World Health Organisation

ANNEX III - EFSA'S OPINIONS AND SCIENTIFIC DOCUMENTS 2009

Overview of EFSA's scientific outputs 2009:

Panel / Unit	Application Opinions of the Scientific Committee / Panels	Generic Opinions of the Scientific Committee / Panels	Statements of the Scientific Committee / Panels	Guidance of the Scientific Committee / Panels	Statements of EFSA	Guidance of EFSA	Conclusions on Pesticides Peer Review	Reasoned Opinions	Scientific or Technical Reports of EFSA	External reports*
Scientific Committee (SC)	-	2	-	3	1	-	-	-	7	-
Animal health and welfare (AHAW)	-	15	1	1	-	-	-	-	2	7
Food additives and nutrient sources (ANS)	33	2	37	1	-	-	-	-	-	-
Biological hazards (BIOHAZ)	-	16	2	-	2	-	-	-	-	-
Food contact materials, enzymes, flavourings (CEF)	78	3	-	2	1	-	-	-	2	-
Contaminants (CONTAM)	-	12	2	-	1	-	-	-	-	2
Feed additives (FEEDAP)	36	3	-	1	-	1	-	-	-	1
Genetically modified organisms (GMO)	17	9	1	-	1	-	-	-	16	-
Nutrition (NDA)	165	9	-	-	1	2	-	-	-	-
Plant health (PLH)	-	2	1	1	-	-	-	-	-	10
Plant protection products (PPR)	4	8	-	-	-	1	-	-	5	1
Assessment Methodology (AMU)	-	-	-	-	-	-	-	-	1	2
Data Collection and Exposure (DATEX)	-	-	-	-	-	1	-	-	4	2
Emerging Risks (EMRISK)	-	-	-	-	-	-	-	-	2	1
Pesticides (PRAPeR)	-	-	-	-	1	-	28	76	1	-
Scientific Cooperation (SCO)	-	-	-	-	-	-	-	-	-	2
Zoonoses – Data Collection (Zoonoses)	-	-	-	-	-		-	-	14	5
Total	***331***	***81***	***44***	***9***	***8***	***5***	***28***	***76***	***54***	***33***
Total scientific outputs of EFSA	**636**									

**Reports produced for EFSA by external parties under specific EFSA procedures*

Scientific Committee

The main task of the Scientific Committee is the preparation of scientific advice in the area of new and harmonised approaches for risk assessment of food and feed. It also provides strategic advice to EFSA's Executive Director.

Scientific outputs 2009	Quantity
Generic Opinions of the Scientific Committee	2
Guidance of the Scientific Committee	3
Statements of EFSA	1
Scientific or Technical Reports of EFSA	7

Further advice on the implications of animal cloning were sought from the Scientific Committee, in particular to provide further details on the recommendations included in the animal cloning opinion published in 2008. An EFSA statement was published in June 2009. The Scientific Committee was also requested to prepare a guidance document for the safety assessment of applications involving the application of nanoscience and nanotechnologies to food and feed. Work was started on providing practical recommendations for the risk assessment of food-related applications of nanotechnologies to the extent possible with current knowledge. The guidance will be finalised by summer 2010. Antimicrobial resistance approaches, a cross-cutting activity for EFSA, were addressed by both the GMO and BIOHAZ Panels with the support of the Chair of the Scientific Committee who chaired a joint working group on this topic. The Scientific Committee adopted a document focusing on transparency in the scientific outputs produced by EFSA. This document deals with general principles to be applied in the identification of data sources, criteria for inclusion/exclusion of data, confidentiality of data, assumptions and uncertainties.

The Scientific Committee and its working groups contributed to the development, promotion and application of new and harmonised approaches and methodologies for risk assessment in the area of food and feed safety. In particular, the guidance document on transparency in risk assessment was finalised after public consultation. Another guidance document on the use of benchmark dose approach (BMD) in risk assessment was finalised; a workshop will be organised in 2010 to build EFSA's expertise in this area and to ensure the implementation of a harmonised approach across panels. The opinion on the existing approaches for the replacement, reduction and refinement of animal testing in food and feed risk assessment was also published. The guidance on the safety assessment of botanicals and botanical preparations was finalised, taking into consideration the recommendations made by an ESCO (EFSA Scientific Cooperation) working group on selected cases. A workshop was organised in November 2009 to present the work done by EFSA to stakeholders and Member States, and to discuss the possible way forward on this issue. Work is in progress on the wider applicability of the threshold of toxicological concern concept in EFSA's risk assessment. The opinion on risk-benefit assessment of foods will be finalised in 2010 after public consultation. A new working group was established to provide a commentary and recommendations on genotoxicity testing strategies in the field of EFSA's activities.

For further details please refer to the attached CD-ROM.

Animal health and welfare

The Panel on Animal health and welfare (AHAW Panel) provides independent scientific advice on all aspects of animal diseases and animal welfare. Its work chiefly concerns food producing animals, including fish.

Scientific outputs 2009	Quantity
Generic Opinions	15
Statements of the AHAW Panel	1
Guidance of the AHAW Panel	1
Scientific or Technical Reports of EFSA	2
External reports*	7

**Reports produced for EFSA by external parties under specific EFSA procedures*

The AHAW Panel adopted 13 scientific opinions on animal welfare issues covering the welfare of dairy cows, stunning and killing of fish species, general approaches to fish welfare and the concept of sentience in fish. In addition, a statement on research needs for the welfare of farmed fish was adopted. Scientific opinions on *Brucella suis* in swine and epizootic hemorrhagic disease were adopted. An internal scientific report on the new pandemic influenza (H1N1) was completed as a first preparedness response in collaboration with several other units. Under Article 36, external reports on tuberculosis in wildlife in the EU, Crimean Congo haemorrhagic fever, epizootic haemorrhagic disease, viral haemorrhagic septicaemia virus, *Bonamia* spp. and animal welfare risk assessment guidelines in relation to transport were finalised. Two Article 36 calls were launched on animal welfare risk assessment guidelines (husbandry and management) and the impact on animal health and welfare of genetic selection in livestock species, respectively. A technical meeting on genetic selection in broiler breeding was held with stakeholders (NGOs, industry, farmer associations and Member State experts) to discuss data sources and availability and risk assessment approaches to support the mandate on health and welfare aspects of genetic selection in broilers. In addition, a public call for data was launched for this mandate.

A guidance document on good practice in conducting scientific assessment in animal health using modelling was adopted. A special Advisory Forum meeting on animal health and welfare was held in May to discuss topics of common interest and it is proposed to repeat this exercise to promote closer collaboration between Member States and EFSA. A technical report presenting the outcome of a survey undertaken by the AHAW Unit on the organisation, approach and procedures applied in risk assessments on animal health and welfare in Member States was published. Work on the development of risk assessment methodologies will continue, including an Article 36 project on commodity-based import risk assessments.

For further details please refer to the attached CD-ROM.

Food additives and nutrient sources added to food

The Panel on food additives and nutrient sources added to food (ANS Panel) deals with questions of safety in the use of food additives, nutrient sources and other substances deliberately added to food (for flavourings and enzymes, see p. 46).

Scientific outputs 2009	Quantity
Application Opinions of the ANS Panel	33
Generic Opinions of the ANS Panel	2
Statements of the ANS Panel	37
Guidance of the ANS Panel	1

A total of 72 scientific opinions and statements were adopted by the ANS Panel corresponding to 157 application dossiers. To finalise the evaluation of nutrient sources, 23 scientific opinions and 36 scientific statements corresponding to 144 application dossiers were adopted. The risk assessment of other food additives (e.g. evaluation of new food additives and re-evaluation of food colours) continued and the Panel adopted 12 scientific opinions (ten application opinions and two generic opinions) and one statement in this area. Two contracts issued in 2008 for the preparation of pre-evaluation documents for the evaluation of nutrient sources for food supplements were finalised in May 2009. Four new contracts were signed to support ongoing and future mandates on food additive re-evaluation. A meeting was held with the Joint FAO/WHO Expert Committee on Food Additives (JECFA) secretariat to discuss co-operation.

Three public calls for data were published in order to collect data for the re-evaluation of various food additives belonging to the functional classes of preservatives, antioxidants, emulsifiers, stabilisers, gelling agents and waxes.

The ANS Panel adopted a statement on data requirements for food additive applications with the aim of providing a basis for the future preparation of guidance on food additive applications. A procurement contract to obtain comments on the existing guidance for food additive applications and proposals for further development of an updated guidance was finalised in May. Stakeholders were also consulted in writing on the existing guidance. New guidance for food additive applications is planned.

For further details please refer to the attached CD-ROM.

Biological hazards including TSEs

EFSA's Panel on biological hazards (BIOHAZ Panel) deals with biological hazards related to food safety, foodborne diseases, transmissible spongiform encephalopathies (TSEs), food microbiology, food hygiene and associated waste management issues.

Scientific outputs 2009	Quantity
Application Opinions of the BIOHAZ Panel	2
Generic Opinions of the BIOHAZ Panel	16
Statements of the BIOHAZ Panel	2
Statements of EFSA	2

The BIOHAZ Panel adopted a total of 24 scientific opinions and reports in 2009. A joint opinion on AMR was issued in collaboration with EMA, ECDC and SCENIHR and a joint scientific report on meticillin-resistant *Staphylococcus aureus* (MRSA) in collaboration with ECDC and EMA. In addition, BIOHAZ adopted an opinion on MRSA in animals and food and with the GMO Panel issued a joint opinion on the use of AMR genes as markers in GM plants. Other opinions covered: the use of bacteriophages in food production; food safety aspects of dairy cow welfare; *Campylobacter*; BSE resistance in goats; BSE in bovine intestinal casings; risk to human and animal health related to the revision of the BSE monitoring regime in some Member States; and three opinions on animal by-products (ABP). The first EU-wide full quantitative microbiological risk assessment (QMRA) model of *Salmonella* in pigs, funded by Article 36, was concluded in 2009.

A workshop was held with experts and stakeholders and the BIOHAZ Panel will deliver its opinion based on the report in 2010. Stakeholder meetings were also held with the European Livestock and Meat Trading Union (UECBV) and the European Fat Processors and Renderers Association (EFPRA). The outsourced project on the fate of *Salmonella* spp. on broiler carcasses was completed.

Meetings of the Microbiological Risk Assessment and the BSE-TSE networks were held in June and October 2009, respectively. The opinion on the maintenance of the list of Qualified Presumption of Safety (QPS) microorganisms was adopted.

For further details please refer to the attached CD-ROM.

Food contact materials, enzymes, flavourings and processing aids

The Panel on food contact materials, enzymes, flavourings and processing aids (CEF Panel) deals with questions on the safety of use of materials in contact with food, enzymes, flavourings and processing aids, and also with questions related to the safety of processes.

Scientific outputs 2009	Quantity
Application Opinions of the CEF Panel	78
Generic Opinions of the CEF Panel	3
Guidance of the CEF Panel	2
Statements of EFSA	1
Scientific or Technical Reports of EFSA	2

A total of 78 opinions were adopted by the CEF Panel of which 38 covered 300 flavouring substances and 29 covered substances used to manufacture materials in contact with foodstuffs. A total of 11 opinions on smoke flavourings were adopted. Urgent advice was given in the form of an EFSA statement on possible risks associated with 4-benzophenone and hydroxybenzophenone originating from food contact materials. A total of eight meetings with stakeholders (industry, consumer organisations and the Commission) were organised. The ongoing evaluation of 2600 flavouring substances on the market was supported by two contracts and two new contracts were assigned for preparatory work in the area of food contact materials.

The CEF Panel adopted guidelines for the evaluation of active and intelligent packaging and the evaluation of food enzymes. Public consultations were held for three guidance documents on enzymes, active and intelligent packaging, and flavourings. Eight meetings with industry were organised to discuss and clarify the requirements laid down in the guidance document for the evaluation of enzymes. In addition, opinions on the clarification of the margin of safety applied for smoke flavouring evaluations and dietary exposure assessment of smoke flavourings were adopted. A safety assessment of the extraction solvent dimethylether was completed.

For further details please refer to the attached CD-ROM.

Contaminants in the food chain

The Panel on contaminants in the food chain (CONTAM Panel) is responsible for questions on contaminants in the food and feed chain, and undesirable substances such as natural toxicants, mycotoxins and residues of unauthorised substances not covered by other panels.

Scientific outputs 2009	Quantity
Generic Opinions of the CONTAM Panel	12
Statements of the CONTAM Panel	2
Statements of EFSA	1
External reports*	2

**Reports produced for EFSA by external parties under specific EFSA procedures*

The CONTAM Panel adopted 14 scientific outputs (12 opinions and two statements). Three opinions covered the impact of metals such as cadmium, arsenic and uranium. In addition, five opinions on regulated shellfish toxins were finalised. The Panel issued a statement addressing the influence of processing on shellfish toxins and a statement on the public health effects of aflatoxins in tree nuts other than almonds, hazelnuts and pistachios. The evaluation of risks to animal health of natural plant toxicants present in animal feed was finalised (two opinions). Following a request from the Commission, the CONTAM Panel evaluated the criteria and safety of substances that are transported as cargoes in ship containers that are then used to ship edible fats and oils into the EU (two opinions).

In addition, the CONTAM Panel in collaboration with the DATEX and PRAPeR Units provided fast track advice on nicotine in wild mushrooms which enabled the Commission to implement timely measures to safeguard public health. A database on veterinary medicinal products used in third countries was successfully developed within the framework of an Article 36 project; the database facilitates a proactive approach to preparation for future requests on residue limits of pharmacologically active substances in foodstuffs of animal origin. A background document summarising information related to the analysis, occurrence, and toxicology of eight mycotoxins and natural plant products was prepared via an Article 36 project to facilitate future risk assessments.

For further details please refer to the attached CD-ROM.

Additives and products or substances used in animal feed

EFSA's Panel on additives and products or substances used in animal feed (FEEDAP Panel) provides independent scientific advice on the safety and/or efficacy of additives and products or substances used in animal feed.

Scientific outputs 2009	Quantity
Application Opinions of the FEEDAP Panel	36
Generic Opinions of the FEEDAP Panel	3
Guidance of the FEEDAP Panel	1
Guidance of EFSA	1
External reports*	1

**Reports produced for EFSA by external parties under specific EFSA procedures*

A total of 36 opinions in the framework of Regulation (EC) No 1831/2003 were adopted by the FEEDAP Panel, including 22 opinions for new products or extension of use of authorised products, one for a re-evaluation, three combining a new use and re-evaluation, two for a modification of the terms of authorisation of an authorised product, one for an urgent authorisation and seven requests for the evaluation of supplementary information submitted by the applicants after inconclusive opinions. Other adoptions included: part III of the opinion on carotenoids relating to yellow carotenoids; an opinion on ractopamine; and an opinion on the use of cobalt compounds as additives in animal nutrition. Nine technical hearings were held with industry associations/applicants to discuss issues related to applications. In order to prepare the work for the re-evaluation of all existing feed additives in accordance with Article 10 of Regulation (EC) No 1831/2003, five meetings were organised with Member States, the Commission and the Community Reference Laboratory. In addition, administrative guidance for applicants for the presentation of applications for authorisation of feed additives was updated in 2009. With the aim of improving the management, distribution, archiving and assessment of data included in applications, a procurement procedure was initiated in collaboration with EFSA's "IT & Operations" (ITOP) Unit for the review of systems for the electronic submission of dossiers. An Article 36 grant was awarded for the preparation of a series of monographs on the biological role, content in feed and requirements in animal nutrition of 27 trace and ultra-trace elements.

The FEEDAP Panel finalised the technical guidance document for sensory additives, which completes a set of guidance documents for applicants in the preparation and presentation of applications. The external report of an Article 36 project on mycotoxin-detoxifying agents used as feed additives was received and will be used by the FEEDAP Panel in the preparation of the guidance document. An Article 36 grant was awarded for the preparation of a report to collect and synthesise scientific data and information on the potential of microorganisms and enzymes used in food and feed to induce respiratory sensitisation. The final report on a procurement project for the pre-assessment of the environmental impact of zinc and copper used in animal nutrition is expected in January 2010.

For further details please refer to the attached CD-ROM.

Genetically modified organisms

The Panel on genetically modified organisms (GMO Panel) conducts risk assessments of GM food and feed applications, provides scientific advice in response to ad-hoc requests from risk managers, and identifies scientific issues which require further attention.

Scientific outputs 2009	Quantity
Application Opinions of the GMO Panel	17
Generic Opinions of the GMO Panel	9
Statements of the GMO Panel	1
Statements of EFSA	1
Scientific or Technical Reports of EFSA	16

The GMO Panel adopted 17 scientific opinions covering 21 application dossiers. EFSA published 12 technical reports connected to application dossiers ("overall opinions"), which in addition to the scientific opinion also contain Member State comments and other documents stipulated in the regulation. A total of 14 of the scientific opinions adopted covered applications for placing GM plants on the market under Regulation (EC) No 1829/2003, while three were co-adoptions with the FEEDAP Panel (under Regulation (EC) No 1831/2003). A total of eight generic opinions were adopted, three in relation to the evaluation of information submitted in support of Safeguard Clauses invoked by Member States (Article 23 of Directive 2001/18/EC), two in relation to a request from the European Commission on the safety assessment of antibiotic resistance marker genes, and three on requests for scientific advice related to previously adopted application opinions.

In 2009, EFSA organised four meetings with Member State experts, three with applicants and one with NGOs to discuss applications.

The GMO Panel adopted draft scientific opinions on guidance for the statistical analysis of data generated for comparative food safety evaluation and guidance on the risk assessment of GM plants for non-food or non-feed purposes. Both were subject to public consultation, comments from which were incorporated in the adopted versions. The GMO Panel adopted one draft guidance document for applicants concerning the allergenicity of GM plants and GM microorganisms; a public consultation was launched in December 2009 and adoption of the final document is scheduled for 2010. In the process of developing guidance, meetings were held with Member State experts (2), applicants (1) and third parties (2). In addition, a conference on the risk assessment of GMOs for human and animal health and the environment was held in September 2009 in Brussels bringing together 150 key actors from Europe and beyond. In order to support the work of the GMO Panel in developing guidance for the risk assessment of GM animals, three outsourcing projects were signed.

For further details please refer to the attached CD-ROM.

Dietetic products, nutrition and allergies

The NDA Panel deals with questions related to human nutrition, dietetic products and food allergies. It also advises on associated subjects such as novel foods, dietary recommendations for nutrients and energy, and the EU's regulation on Nutrition and Health Claims.

Scientific outputs 2009	Quantity
Application Opinions of the NDA Panel	165
Generic Opinions of the NDA Panel	9
Statements of EFSA	1
Guidance of EFSA	2

In 2009, the NDA Panel adopted 174 opinions, most (125 opinions) relating to Article 13(1) functional claims covering 937 claims. On children and risk reduction claims, 24 opinions were adopted and ten opinions were adopted on claims based on newly developed science and/or proprietary data. In the context of the procedure for the authorisation of health claims, the NDA Panel also adopted two opinions on the conditions for the use of health claims on essential fatty acids and on plant sterols and stanols. In the area of the safety assessment of novel foods, the NDA Panel adopted five opinions corresponding to five applications. In addition, the Panel adopted opinions on the appropriate age for the introduction of complementary feeding in infants and the possible exemption from labelling for beta-amylase from barley. In relation to Dietary Reference Values, the NDA Panel launched public consultations on its draft opinions on fats and carbohydrates and organised an expert meeting with Member States to discuss these opinions along with draft opinions on food-based dietary guidelines, general principles of deriving and applying Dietary Reference Values and Dietary Reference Values for water. Revised versions of these documents incorporating the feedback received were adopted. Advice on labelling reference intake values for selected nutritional elements was also adopted. In light of the experience gained from the health claim applications, EFSA provided additional advice to applicants in the form of a frequently asked questions document (FAQ). The draft FAQ was subject to public consultation and discussed at a meeting with applicants before finalisation as a technical report of EFSA. Comments received from both the public consultation and meeting were published along with a summary of how comments had been taken into consideration. EFSA also held a meeting with Member States and the Commission to update them on the evaluation of Article 13(1) health claims and, to this end, a draft briefing document was prepared which was updated and published after the meeting as a technical report of EFSA. A project on the characterisation of probiotics in the framework of health claims evaluation was outsourced.

In the light of the upcoming revision of the novel foods regulation, a Scientific Colloquium was organised to receive early input from stakeholders for the preparation of revised scientific and technical guidance for applicants for the preparation of novel food applications.

For further details please refer to the attached CD-ROM.

Plant health

The EFSA Panel on plant health (PLH Panel) provides scientific advice on risks posed by pests which can harm plants, plant products or biodiversity in the EU.

Scientific outputs 2009	Quantity
Generic Opinions of the PLH Panel	2
Statements of the PLH Panel	1
Guidance of the PLH Panel	1
External reports*	10

**Reports produced for EFSA by external parties under specific EFSA procedures*

The PLH Panel adopted four outputs in 2009, including opinions on the reliability and the effectiveness of a proposed method to treat wood shavings infested by the pinewood nematode *Bursaphelenchus xylophilus* and an evaluation of a pest risk analysis (PRA) made by the United Kingdom on the oak processionary moth, *Thaumetopoea processionea*. The Panel also produced a statement as an urgent reply on a proposal for cold treatment of strawberry plants to eliminate *Bemisia tabaci* from consignments to be shipped to the EU from the USA. Guidance on the evaluation of pest risk assessments for phytosanitary measures made by third parties was also issued.

The PLH Panel adopted a guidance document for evaluating PRAs made by third parties to justify phytosanitary measures under Council Directive 2000/29/EC. The second Special Advisory Forum on Plant Health meeting took place in October and the agenda included data requirements, emerging risks and pest surveillance. Collaboration with the JRC on modelling used for predicting establishment and spread of harmful organisms resulted in the launch of ClimPest, a framework for modelling pest climatic suitability. An Article 36 project on an inventory of data sources for PRAs (PRASSIS) was completed and an Article 36 call for a comparative approach to case studies for PRAs was signed. A renewed collaborative project with Agricast and JRC (Ispra) was agreed and signed at the end of 2009. The guidance document on a harmonised framework for the assessment of risks of organisms harmful to plants and plant products was endorsed by the panel and the comments received from public consultation incorporated into the document for adoption and publication in 2010.

For further details please refer to the attached CD-ROM.

Plant protection products and their residues

The PPR Panel provides independent scientific advice on the risk assessment of plant protection products (commonly known as pesticides) and their residues, looking at risks for the user/worker, the consumer and the environment.

Scientific outputs 2009	Quantity
Generic Opinions of the PPR Panel	8
Guidance of EFSA	1
Scientific or Technical Reports of EFSA	5
External reports*	1

**Reports produced for EFSA by external parties under specific EFSA procedures*

The PPR Panel adopted one opinion on cumulative exposure assessment of triazole fungicides and six opinions on the update of the Annexes II and III of Directive 91/414 EEC. Opinions on protection goal options and on the development of eco-regions are scheduled to be published in first half of 2010.

The PPR Panel adopted an opinion on the assessment of exposure in soil – this is related to the guidance document on persistence of pesticides in soil that is under development. The guidance document on risk assessment for birds and mammals was published in December by a joint working group, comprising Member State representatives, the European Commission and EFSA.

Reports produced via Article 36 grants were used in the preparatory work for the production of guidance documents on emissions from protected crop systems (e.g. greenhouses) scheduled for adoption in 2010, exposure of workers, operators, bystanders and residents and for an opinion on the establishment of common assessment groups of active substances for cumulative risk assessment and the evaluation of the toxicological relevance of pesticide metabolites.

An outsourcing contract was signed for preparatory work for guidance on dermal absorption. Guidance documents for the evaluation principles of the toxicological burden of metabolites, degradation and reaction products of pesticides in food commodities and on persistence in soil (to be published in the first half of 2010) were completed via contracts with JRC. Two stakeholder workshops on the "fate" of pesticides were organized by the PPR unit in May in JRC (Ispra) and in November in Parma, with 70 and 60 participants, respectively. In 2010, work on updating the two existing guidance documents on ecotoxicology (terrestrial and aquatic) will continue.

For further details please refer to the attached CD-ROM.

Assessment methodology

The Assessment Methodology Unit (AMU) provides technical support in the field of statistics, modelling, data management and risk assessment. It contributes in particular to the development and application of new or refined risk assessment approaches in the field of food and feed safety.

Scientific outputs 2009	Quantity
Scientific or Technical Reports of EFSA	1
External reports*	2

**Reports produced for EFSA by external parties under specific EFSA procedures*

The AMU Unit provided scientific support for opinions of the CONTAM, PLH, AHAW, BIOHAZ and GMO Panels and the Scientific Committee. This included: data management support for BIOHAZ opinions; epidemiological and statistical analysis for BIOHAZ, CONTAM and PLH; and systematic literature reviews with meta-analyses. An example of the latter was the technical report *"Meta-analysis of Dose-Effect Relationship of Cadmium for Benchmark Dose Evaluation"* which was integrated into the CONTAM opinion on cadmium.

In December, AMU Unit, supported by a working group of external experts, issued a guidance document on the application of systematic review methodology to food and feed safety assessments. It will be tested during a workshop for EFSA experts and staff in February 2010. Since 2003, there have been reports in Europe and the USA of serious mortality of bees in beehives. In 2006 the term Colony Collapse Disorder (CCD) was first used to describe this phenomenon which is characterised by the rapid loss from a colony of its adult bee population. While the cause of CCD has not been determined, several aetiologies have been proposed. To investigate further possible risk factors, AMU launched a call for a project open to competent organisations under Article 36 of Regulation (EC) No 178/2002. The outcome of this project was published in December 2009.

AMU also published a report on quantitative models describing the spread, establishment or development of plant pests on crops in Europe including geographical and climatic data and/or plant phenology as input factors. The output of this project, which was supported by an Article 36 grant, also includes a structured, electronic inventory of selected and analysed models which will be valuable for future plant pest predictive modelling work.

While foods rich in isoflavones are considered to be part of a healthy diet, questions remain with regard to their impact on health, reduction of disease risk and improvement of quality of life. Following consultation with the Advisory Forum, it was determined that this topic is of interest to several Member States. Consequently, AMU was requested to establish an ESCO working group that will deliver a report in 2010 providing a literature overview of the potential hazards and health benefits associated with isoflavone consumption. AMU also provided epidemiological and modelling support to the DATEX Unit (β-casomorphin-7) and to the Zoonoses Unit baseline studies as well as data management support for the Annual Report on Pesticide Residues.

For further details please refer to the attached CD-ROM.

Data collection and exposure

The Data Collection and Exposure (DATEX) Unit deals with the collection, collation and analysis of data on food consumption and chemical occurrence in food and feed for exposure assessments at European level.

Scientific outputs 2009	Quantity
Guidance of EFSA	1
Scientific or Technical Reports of EFSA	4
External reports*	2

**Reports produced for EFSA by external parties under specific EFSA procedures*

A major undertaking for the DATEX Unit was the formation of a working group to review available scientific evidence of possible health effects of β-casomorphins and related peptides, and in particular β-casomorphin-7 (BCM7), a peptide sequence present in the milk protein β-casein. A few studies had suggested that BCM7 might contribute to increased risk of certain non-communicable diseases, such as autism, cardiovascular diseases and type I diabetes. EFSA undertook this work as part of its regular monitoring and assessment of possible emerging risks associated with the food chain. The working group concluded that a cause and effect relationship could not be established between the dietary intake of BCM7, related peptides or their possible protein precursors and non-communicable diseases.

A comprehensive food consumption database is being populated with information at the most detailed level available in each collaborating Member State for children and adults. It is expected that the database will be operational from 2010 to enable more precise exposure calculations in relation to beneficial or harmful substances or agents in food. Guidelines to further harmonise food consumption data collection were issued during the year. In a cooperative effort with Member States, EFSA took a major step to further improve the quality of European food safety exposure assessments. A draft guidance document on how to best handle left-censored data (data below the detection limit) was developed by a working group coordinated by the DATEX Unit. The unit investigated default assumptions used across EFSA for estimating risk with the aim of harmonising such use across disciplines. The document will be published during 2010.

On request of the European Commission, the DATEX Unit analysed data collected by Member States for acrylamide and furan, and issued two reports. The acrylamide report reviewed the impact of voluntary measures taken by industry to reduce acrylamide levels. Although there seemed to be a trend towards

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lower exposure, it is not yet clear if the measures have had the desired effect. The furan report was an interim step in better understanding levels of furan in food and was complemented by two projects granted under Article 36 covering the influence of food preparation methods on furan formation and exposure to furan by inhalation during cooking. The resulting data sets will enable EFSA to produce a more robust assessment of exposure through different routes including inhalation. A report on the presence of dioxins in food and feed was drafted. The unit also assisted the Commission for the first time in preparing the statistics for the annual veterinary medicine residue report.

The DATEX Unit contributed to several opinions by assessing dietary exposure to a range of substances, in particular contaminants. Information on levels of marine biotoxins in seafood was collected and exposure levels compared with health-based guidance values by the CONTAM Panel. The collection of data on arsenic proved difficult in that little information was available for inorganic arsenic, the major toxic component. Algorithms were produced based on literature information to relate levels of total arsenic to estimates of inorganic arsenic in the respective food groups. Exposure was calculated for adults and for the first time it was possible to provide detailed exposure calculations for different age groups of children covering several Member States. Support was provided to the CEF Panel in selecting a method suitable for assessing exposure to smoke flavourings.

For further details please refer to the attached CD-ROM.

Emerging risks

The Emerging Risks (EMRISK) Unit is responsible for establishing procedures to monitor, collect and analyse information and data in order to identify emerging risks in the field of food and feed safety with a view to their prevention.

Scientific outputs 2009	Quantity
Scientific or Technical Reports of EFSA	2
External reports*	1

**Reports produced for EFSA by external parties under specific EFSA procedures*

The ESCO Working Group on Emerging Risks published a technical report on emerging risks which, along with previous reports from the Scientific Committee, forms the basis of EFSA's first Annual Report on Emerging Risks due in 2010. A technical report describing the evaluation of different web monitoring systems for the identification of emerging risks was published. This report describes the evaluation of a media monitoring tool, MedISys, developed by the Joint Research Centre, and its comparison with ProMED-mail for its usefulness in identifying emerging risks. A database on bioactive compounds from plants was delivered through an outsourced project and a call was launched and awarded on modelling, predicting and mapping the emergence of mycotoxins in cereals in the EU due to climate change.

EMRISK is also responsible for coordinating EFSA's preparedness for responding to urgent issues. To this end, the procedures put in place by EFSA for dealing with such urgent requests (the Emergency Manual) have been updated, building on the experience gained in handling urgent issues and internal training exercises. An exercise held with Member States and DG SANCO was coordinated by EMRISK with the specific aim of simulating communication in "crisis" situations. The exercises were planned and executed in collaboration with an external consultant (funded through procurement) and an expert working group.

For further details please refer to the attached CD-ROM.

Pesticide risk assessment peer review

The Pesticide Risk Assessment Peer Review (PRAPeR) Unit is responsible for the peer review of active substances used in plant protection products. The assessments, including the peer review, are sent to the European Commission to decide whether the substance should be included on the EU's positive list of permitted substances that may be used in products across Europe. The Unit is also involved in the risk assessment of consumers exposed to pesticide residues in food, which forms the basis for the setting of maximum residue levels (MRLs) under EU law. The unit is also responsible for preparing the annual report on pesticide residues.

Scientific outputs 2009	Quantity
Statements of EFSA	1
Conclusions on Pesticides Peer Review	28
Reasoned Opinions	76
Scientific or Technical Reports of EFSA	1

On 1 September 2008, Regulation (EC) No 396/2005 came into effect. As a result, the PRAPeR Unit was involved in procedures for setting and amending maximum residue levels (MRLs) for which Member States intend to authorise new uses of pesticides and in the framework of establishing import tolerances (Article 10 of Regulation 396/2005). In 2009, 101 MRL applications were submitted by the European Commission pertaining to the amendment of approximately 400 MRLs. In response to these requests, EFSA issued 70 reasoned opinions (addressing 76 requests). In addition, EFSA provided three reasoned opinions concerning specific requests of the European Commission for active substances for which consumer health risks were presumed. In the MRL review programme (Article 12 of Regulation 396/2005), EFSA received background information from Member States for 137 active substances which are now assessed by EFSA. In collaboration with Member States and the European Commission, a work plan for prioritisation and finalisation of the reasoned opinions was established. It was not possible to finalise the expected numbers of Article 12(1) and Article 12(2) reasoned opinions as outlined in Management Plan 2009 for the following reasons:

- delayed submission of documents by Member States;
- higher priority given to routine MRL applications (Article 10 of Regulation 396/2005) and prioritised allocation of available resources in the PRAPeR Unit to this task;
- the number of routine MRL applications and the reasoned opinions issued by EFSA in response to these applications (Article 10 of Regulation 396/2005) was higher than expected, further limiting the capacity available for Article 12 applications.

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Pesticide risk assessment peer review

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The PRAPeR Unit updated the database on toxicological reference values of pesticides, taking into account new or amended values established in the EU or by international bodies. The database comprises more than 1100 acceptable daily intake (ADI) values and 900 acute reference dose (ARfD) values. A call for tender was launched aimed at enhancing the scientific database on MRLs recommended by *Codex Alimentarius*. This information is necessary for performing a comprehensive risk assessment as required in the MRL review programme under Article 12, and to provide risk managers the information whether the MRLs established by *Codex Alimentarius* are safe for European consumers. In collaboration with the CONTAM, DATEX and EMRISK Units, the PRAPeR Unit prepared a statement in response to the request for an urgent scientific opinion on the risk for public health due to the presence of nicotine in wild mushrooms.

In 2009, EFSA published the first Annual Report on Pesticide Residues for 2007. The report summarises the results of approximately 74 000 samples analysed in 2007 by Member States to ensure compliance with the legal provisions. In brief, the report found that 96 % of the samples analysed were compliant with the legal maximum residue levels (MRLs) and 4 % exceeded them, compared to 5 % in 2006. These data were used to estimate the actual consumer exposure to pesticide residues via food; the results of this assessment are also included in the report. Due to deficiencies identified in the current reporting format, EFSA developed a new data model to submit the results of monitoring activities. This new data format was tested in a pilot project with six Member States that submitted the results of the monitoring results derived in 2008 for approximately 6 million determinations of pesticides in 27 000 samples. The Unit launched a call for tender regarding scientific and technical assistance for the drafting of the next annual report on pesticide residues.

Activities in pesticide peer review in 2009 included: new active substances; substances resubmitted for inclusion in Annex I of Directive 91/414/EEC following an initial non-inclusion decision; substances already included in Annex I with inclusion periods expiring; substances included in Annex I for which EFSA conclusions are due to be delivered by 31 December 2010 (the so-called "green track", i.e. substances complying with the criteria of clear indications of no harmful effects); and substances for which confirmatory data have been submitted after inclusion. A series of scientific meetings was held with Member State experts in relation to new and existing active substances and microorganisms used as active substances. EFSA received assessment reports for 50 resubmitted substances and six substances for Annex I renewal, and opened consultation with Member States, applicants and the general public to provide feedback to the European Commission. For a large proportion of the resubmitted substances the consultation period extends into 2010. EFSA has also received a request from the European Commission to organise a peer review with Member State experts and provide conclusions on 20 resubmitted substances and six substances for Annex I renewal. In response to the challenging timelines associated with the resubmission and renewal programmes, the PRAPeR Unit increased the use of tele-conferences, organising 23 tele-conferences with Member State experts, for example. EFSA was also invited to provide comments to the European Commission on the assessment of confirmatory data submitted by the rapporteur Member States for nine substances.

In total, the PRAPeR Unit delivered conclusions on 28 substances in 2009, including nine new active substances, nine resubmitted substances and seven existing active substances included in Annex I but for which the peer review had been postponed. This number is lower than expected because: EFSA has not been asked by the Commission to draft conclusions on confirmatory data; unforeseen delays in both the Annex I renewal and the resubmission programmes; and, by agreement with the Commission, extension of the deadline for the majority of "green track" substances to 2012. As a result, the number of public consultations launched in 2009 was also lower than expected.

For further details please refer to the attached CD-ROM.

Scientific cooperation

The objective of the Scientific Cooperation (SCO) Unit is to foster scientific cooperation, projects and exchange of scientific information between EFSA and national food safety agencies in EU Member States.

Scientific outputs 2009	Quantity
External reports*	2

**Reports produced for EFSA by external parties under specific EFSA procedures*

The Focal Point network, which started in 2007, continued its work in supporting the Advisory Forum Members. To this end, multi-annual Focal Point agreements were signed with all 27 Member States to consolidate the existing network. In September 2009, the three EU-candidate countries joined the Focal Point network. Many Focal Points, in particular in Central European countries, organised events to raise awareness of the work of Member States and EFSA. The SCO Unit prepared a report on Focal Point activities in 2009. The priorities of the Focal Point network included the exchange of information on training activities and on projects such as data collection and research funding.

The extended list of Article 36 organisations that support EFSA now comprises 370 organisations and the 2010 work programme was adopted by the EFSA's Management Board in 2009 to ensure an early start to its implementation. Training was provided to Focal Points in 2009 to enable them to enhance support for the Article 36 organisations in their countries and IT tools are under development to improve networking. An assessment report, based on a survey of activities covered by EFSA's grant and procurement schemes, was prepared. EFSA's expert database has continued to grow and now includes around 2000 experts from over 60 countries. This growth results from cooperation activities initiated this year with Member States and international organisations to enhance the use of this database. Five regular activity reports on the expert database project were issued during 2009.

The ESCO Working Group on the "Analysis of Risks and Benefits of Fortification of Food with Folic Acid" completed its work. Its report, incorporating the outcomes of a scientific event in Uppsala, was issued and submitted by the Executive Director to the Scientific Committee for consideration by the NDA Panel. The Information Exchange Platform (IEP) provides a tool for Member States and EFSA to exchange information on risk assessment activities undertaken by Member State organisations with a mandate similar to EFSA's. To date, the IEP has published over 400 scientific documents. In addition, it provides work plans and other country specific information. Starting in April, nine monthly reports have been provided to users.

A new web area for the EFSA Journal was launched in December to facilitate the inclusion of the Journal in bibliographic databases. The enhancement of the Journal is aimed at providing an outlet of EFSA's scientific work that is visible and influential in the scientific community and at the same time complies with best practice in academic publishing. The Summary Report on Colloquium No 12 (*Campylobacter*) was published in March. On 19–20 November, approximately 100 scientists and stakeholders from 25 countries attended EFSA's 13th Scientific Colloquium: "*What's new on Novel Foods*" in Amsterdam.

For further details please refer to the attached CD-ROM.

Zoonoses data collection

The Zoonoses Unit analyses and reports data of zoonoses, antimicrobial resistance, microbiological contaminants and food-borne outbreaks. The data is submitted by Member States and other reporting countries in accordance with Directive 2003/99/EC.

Scientific outputs 2009	Quantity
Scientific or Technical Reports of EFSA	14
External reports*	5

**Reports produced for EFSA by external parties under specific EFSA procedures*

The harmonisation of monitoring and reporting of zoonoses in EU was continued in 2009 with the aim of improving the quality of the data received and analysed at the Community level. In particular, four reports on specifications for harmonised monitoring and reporting of zoonotic parasites *(Trichinella, Echinococcus, Cysticercus* and *Sarcocystis)* in animals by EU Member States were published as outcomes of an Article 36 grant project. In addition, the unit coordinated two other Article 36 grant projects aiming to harmonise the monitoring and reporting of rabies and Q fever in animals as well as the survey methods for zoonotic agents in food among the Member States. Furthermore, the unit itself, supported by the Task Force of Zoonoses Data Collection and external working groups, issued specifications for harmonised surveys on two zoonotic pathogens, verotoxigenic *E.coli* and *Yersinia enterocolitica*, in animals and food. These specifications are intended to guide Member States in their national monitoring activities highlighting the importance of good survey design. On the request of the Commission, technical specifications for an EU-wide survey on *Listeria monocytogenes*, an important foodborne pathogen, in ready-to eat foods were also prepared for a survey that will take place in 2010.

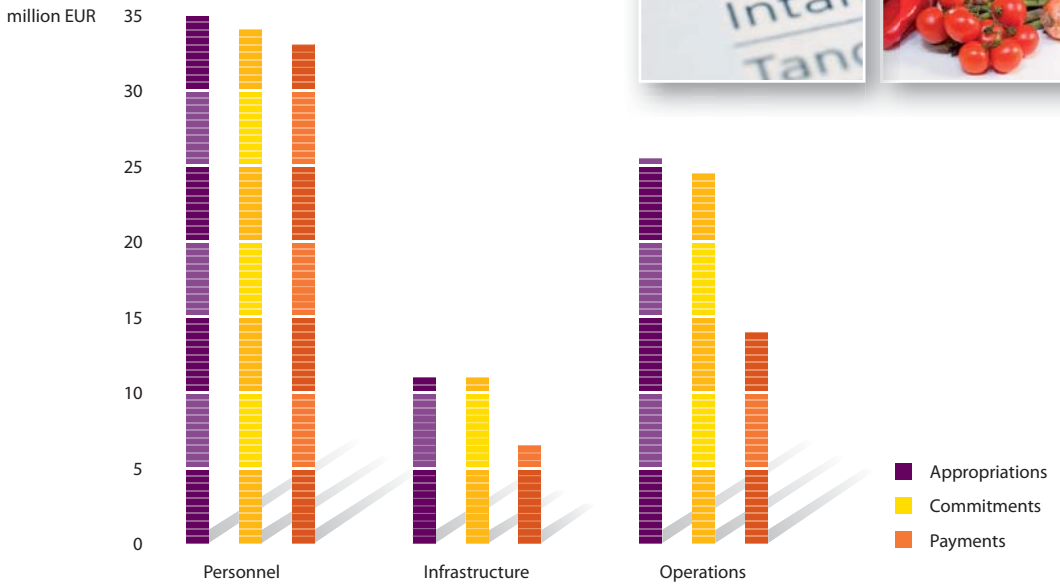
Data from the annual zoonoses reporting by the Member States and from the three EU-wide baseline surveys carried out in 2008 were successfully validated using a new SAS-based data management system with automatic validation criteria. Special efforts were made to improve the analyses of the annual zoonoses and baseline survey data from both the IT and methodological aspects. To this end, web-based data warehouse and GIS (geographic information) systems were developed to facilitate easier data handling and access. Furthermore, the development of statistical and spatial analyses of zoonoses data as well as analyses of temporal trends were further addressed by two expert working groups that provided recommendations for the most appropriate methods to be applied in future development. The improved analytical methodology was previously used in the Community Summary Report on Zoonoses in 2008 and in the Summary Report on Foodborne Outbreaks in 2007 which were prepared in collaboration with the European Centre for Disease Prevention and Control (ECDC). Once again *Salmonella* and *Campylobacter* were found to be the most frequently reported zoonotic pathogens in the EU. Two reports on the EU-wide baseline surveys on methicillin-resistant *Staphylococcus aureus* (MRSA) and *Salmonella* in breeding pigs were published. In all reports, special emphasis was placed on clear communication of findings and analyses.

For further details please refer to the attached CD-ROM.

ANNEX IV - FINANCIAL REPORT

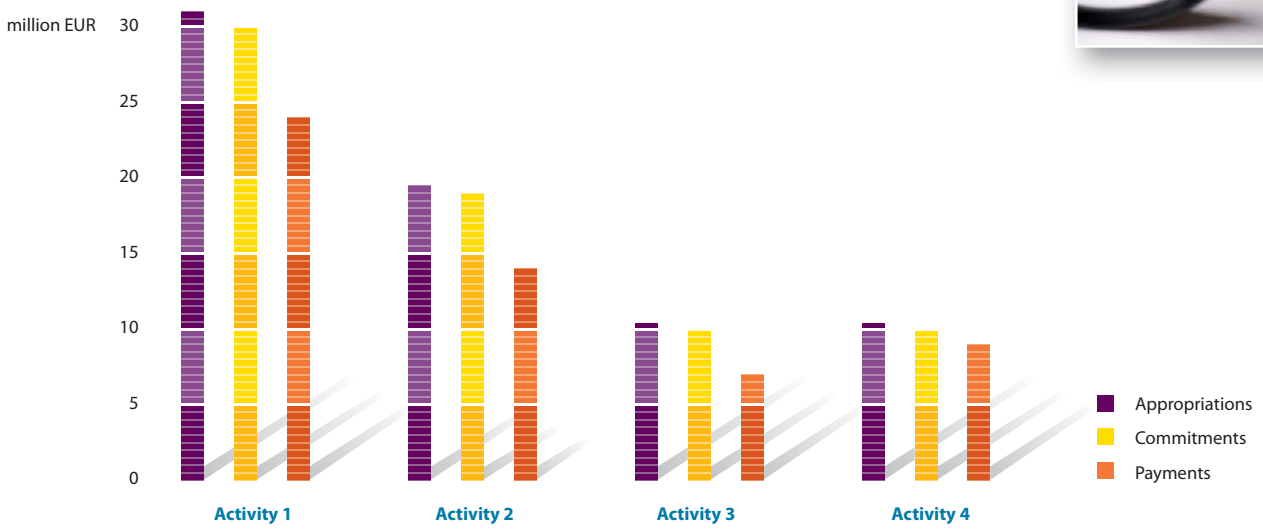
Budget Execution 2009

- EUR 68.92 million or **97.1 %** of the EUR 70.96 million budget including the Pre-accession programme was committed. The commitment level was 1 % below the target set for the year, i.e. 98 %.
- EUR 53.47 million or **75.4 %** of the total appropriations were paid. This payment level stands 3 % below the target of EUR 55.6 million.
- EUR 9.5 million of payment appropriations were carried forward to 2010 or **13 %** of the executed budget (24.4 % in 2008).



Title	Appropriations (million EUR)	Commitments (million EUR)	Percentage committed	Payments (million EUR)	Percentage paid	RAL (million EUR)
Personnel	34.77	33.81	97 %	33.12	95 %	0.69
Infrastructure	10.75	10.69	99 %	6.30	59 %	4.40
Operations	25.44	24.42	96 %	14.05	55 %	10.37
of which Pre-accession	0.51	0.35	69 %	0.23	46 %	0.11
TOTAL	70.96	68.92	97 %	53.47	75 %	15.45

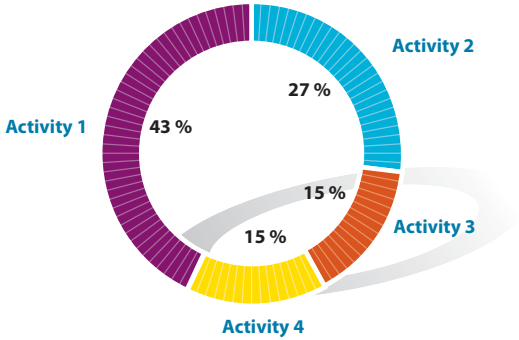
Activity Based Budgeting (ABB) Execution 2009



Activity	Appropriations (million EUR)	Commitments (million EUR)	Percentage committed	Payments (million EUR)	Percentage paid	RAL (million EUR)
Activity 1	30.72	29.84	97 %	24.05	78 %	5.79
Activity 2	19.52	19.04	98 %	13.58	70 %	5.46
Activity 3	10.42	9.96	96 %	7.18	69 %	2.78
Activity 4	10.30	10.09	98 %	8.67	84 %	1.42
TOTAL	70.96	68.92	97 %	53.47	75 %	15.45

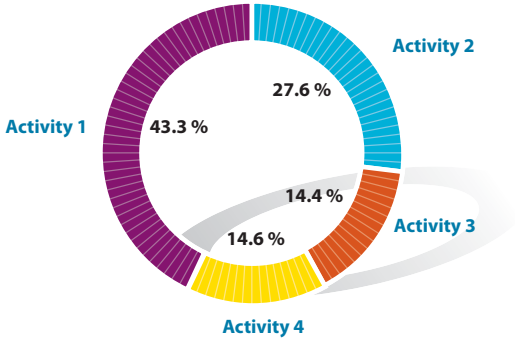
Activity 1: Scientific advice and opinions
Activity 2: Risk assessment methodologies
Activity 3: Communication and dialogue
Activity 4: Management and administration

ABB Appropriations 2009



Activity 1: Scientific advice and opinions
Activity 2: Risk assessment methodologies
Activity 3: Communication and dialogue
Activity 4: Management and administration

ABB Execution 2009



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