Annual Report **2008**

ISSN 1830-3862

Committed to ensuring that Europe's food is safe

efsa

European Food Safety Authority


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FOREWORD by Miroslav Ouzký

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

EFSA plays a key role in ensuring food safety in Europe. It provides the independent scientific advice and high-quality evaluations that we, in the European Parliament, as risk managers, need in order to protect European consumers.

EFSA continued to build bridges with the European Parliament throughout 2008, keeping Members aware of the latest developments in the fields within its remit and attending relevant European Parliament committee meetings. The latter provided a good opportunity to discuss, at length, issues of interest to the Committee and to become better acquainted with the valuable work EFSA is engaged in.

In particular, EFSA representatives – both scientific experts and staff – participated in meetings of the Committee on the Environment, Public Health and Food Safety (ENVI) of the European Parliament in order to follow closely the passage through the European Parliament of dossiers, such as the food improvement agents package, the pesticides package, animal cloning, health claims and GMOs. In turn, this helped to guide EFSA in its mission to provide the independent advice that we seek when taking risk management decisions.

In April 2008, a delegation of the European Parliament led by Members of the ENVI Committee visited EFSA in Parma. The delegation met with the Chair of EFSA's Management Board, the Executive Director and EFSA staff. Among the topics discussed were EFSA's priorities in 2008, the selection of experts, independence and declarations of interest, quality review and risk assessment at EFSA, scientific cooperation and risk communication.

We see, through this Annual Report, that EFSA has grown considerably in 2008 – grown in workload, in staffing, and in its output. And now with its Strategic Plan 2009-2013 firmly in place, I look forward to seeing EFSA continuing to work alongside us, and other relevant partners, as we work hard to ensure that EU citizens can trust Europe's food safety system. Thanks to this close cooperation, Europe's consumers should feel confident that their food is safe, and that our policies are there to protect them and keep them healthy. ▮

Miroslav Ouzký
Chair of the Committee on the Environment,
Public Health and Food Safety, European Parliament

FOREWORD by Androulla Vassiliou

EU COMMISSIONER FOR HEALTH

As European Commissioner for Health, one of my main priorities is to maintain and to enhance the high level of food safety we have in the European Union, as well as to ensure appropriate responses to any threats that may arise. This is achieved thanks to the comprehensive body of EU legislation in place, but also thanks to the robust scientific advice of the European Food Safety Authority.

The establishment of EFSA responded to the need to boost the Community's capabilities to address the complex scientific issues that lie at the heart of food safety – a matter which concerns each and every one of us as EU citizens.

EFSA is only six years old, but already it is a well-established Authority, widely recognised for its scientific contribution. It is the central scientific component of European food safety policy. EFSA was created as an agency that is independent from the European Institutions, Member States and commercial or other stakeholder interests. Its independence is indispensable for the Commission as policy maker and risk manager, and strengthens consumer confidence in the European food supply. I therefore highly value the Authority's role as an essential partner in ensuring the safety of the food chain in the EU.

The division of responsibility between EFSA and the political institutions that are accountable to the European public is crucial. At the same time, close collaboration between EFSA and the Commission is needed to ensure the consistency and efficacy of the Community process for the management of risks. The Commission also relies on EFSA to contribute globally to the protection of public health. For this reason, during my mandate I have made it a priority to work closely with EFSA and its Executive Director to see how we can better ensure timely scientific advice which corresponds to the urgency of certain decisions, the Commission's priorities and the expectations of our stakeholders.

In addition, interaction between EFSA and the national bodies responsible for risk assessment is essential to ensure consistency in scientific assessment in the EU.

EFSA is not only a means for providing scientific advice. Its preventive role, including the early identification of emerging risks, is fundamental. By gathering and analysing scientific data, EFSA can give us a better view of the exposure of individuals to risks related to the consumption of foods and to reassess long-term issues in the light of scientific progress and technological development.

We all work towards the achievement of the same objective: to ensure the safety of the food chain. In doing this, we should also aim at achieving the best possible synergy. I see EFSA as an Authority of particular significance and with a strategic role in achieving the Commission's policy objectives and meeting the expectations of our citizens. It has played this role successfully over the last six years and I am confident that it will continue to do so. ▮

Androulla Vassiliou,
EU Commissioner for Health

MESSAGE from Diána Bánáti

CHAIR OF THE EFSA MANAGEMENT BOARD

"Every day you may make progress. Every step may be fruitful. Yet there will stretch out before you an ever-lengthening, ever-ascending, ever-improving path. You know you will never get to the end of the journey. But this, so far from discouraging, only adds to the joy and glory of the climb."

Sir Winston Churchill

In 2008 I had the great honour to be elected Chair of the Management Board of Europe's key food safety risk assessment organisation, the European Food Safety Authority.

The food safety system has undergone challenging times, but I remain confident that the foundations on which EFSA is built and the structures we have put in place over the years will serve all citizens of the European Union well. In 2008, we adopted the Strategic Plan 2009-2013 that will guide us for the coming years. It outlines how EFSA will maximise the benefits of the scientific expertise at its disposal across Europe while strengthening its integrated approach to risk assessment to provide Europe's decision makers with the relevant, up-to-the-minute scientific advice they need.

The Strategic Plan's six key objectives will help steer us along the right road, starting with the 2009 Management Plan, adopted in December 2008 that has, as a matter of priority, the renewal of members of 8 of EFSA's 10 Panels and its Scientific Committee. These leading members of the Scientific Committee and Panels are essential to EFSA and the sound scientific advice we continually deliver.

I am proud to be at the helm of a mature EFSA. An EFSA that has grown to almost 400 talented staff providing strong support to our dedicated scientific panels and working group experts, an EFSA that has delivered over 1000 scientific opinions and reports to date, an EFSA that now can confidently claim to be fit for purpose to meet the rigours of a food safety, ethical system increasingly confronted by change – technological, environmental, legislative and market driven.

EFSA is also making great strides in improving efficiency, productivity and responsiveness. This is helping to ensure that risk managers in the Commission, in the Member States, and elsewhere, receive the best possible scientific opinions and advice in a timely manner.

On behalf of the Management Board I would like to thank the Executive Director, Ms Catherine Geslain-Lanéelle and all the EFSA staff for their hard work over 2008 and, yet again, in breaking new ground in terms of seamlessly managing increased workload and output. Finally I would like to thank my predecessor, Prof Patrick Wall and my fellow board members, both the new and the longer-serving members, for their work during 2008. I look forward to working together with them over the coming years to help guide EFSA and help it to comply with expectations in order to be recognised as the leading food safety organisation in Europe. ▮

Professor Diána Bánáti ,
Chair of the EFSA Management Board

MESSAGE from Catherine Geslain-Lanéelle

EFSA EXECUTIVE DIRECTOR

For EFSA, 2008 was a year of significant organisational growth and consolidation. We are now a mature organisation with strong links to national food safety agencies in Member States, EU institutions and international bodies working in fields relevant to our remit. Risk assessment and risk communication form the most important part of our core tasks and the scale of these activities has doubled in just one year. Despite only a 15% increase in human resources, we produced 489 scientific outputs – opinions, reports, statements etc. – in 2008. As our Strategic Plan for 2009-2013 outlines, we have planned for our productivity to grow steadily in the coming years.

In recent years, we have concentrated on strengthening our internal organisation and building networks of excellence. These investments have produced clear results, not only in the increase in our capacity and the optimisation of its use, but also in the streamlining of our procedures and the consolidation of our internal structure. Today, we are supported in our work by the national agencies of the Member States and neighbouring countries, nearly 400 Article 36 organisations and more than 1,200 external scientific experts. In 2009, we will continue to expand our networks of experts and partners; in particular eight of EFSA's Panels and its Scientific Committee will be reconstituted in mid-year.

EFSA serves Europe's risk managers by delivering high-quality and timely risk assessments. The quality of our work is paramount: in 2008, we launched a quality review programme and started to implement the first phase: self review and internal review of our scientific outputs. We will soon issue a report from our quality manager on its conclusions. The second phase – external review – will be implemented in 2009.

Responsiveness has been an important feature of our work in 2008. On three occasions - melamine in composite foods from China, impurities in Ukrainian sunflower oil and dioxins in Irish pork – we were asked to respond to urgent food safety incidents and on each occasion we put our "fast-track" procedures into operation to provide risk managers with the scientific basis for their decision making. In doing so, we made a significant contribution to the protection of European consumers, and the speed and quality of EFSA's responses are a credit to our staff and experts.

Our achievements in 2008 were made possible by the tremendous efforts of our experts, partners and staff. In parallel, EFSA has greatly strengthened its policies and procedures in the area of human resources and support for its experts to ensure that the organisation's greatest assets have all the assistance they need.

Without doubt, EFSA has a crucial role to play in protecting food safety and public health. The ultimate result of the coordinated efforts of our staff and experts in fulfilling that role remains a source of pride. ▮

Catherine Geslain-Lanéelle,
EFSA Executive Director

I. EFSA AND ITS PLACE IN THE EUROPEAN FOOD SAFETY SYSTEM



The BSE and other crises of the late 1990s illustrated the complexity of food supply in Europe and the need to consider food safety in an integrated manner by assessing risks along the entirety of the food chain - from field to plate. As an example, the BSE crisis illustrated the principle that animal health, animal feed and primary production methods were fundamentally important to the safety of food supplied to consumers.

The European food safety system is based on the premise that safety must be guaranteed throughout the food chain if the health of consumers is to be protected. Its central goal is to ensure that European citizens have safe food to allow them to choose a healthy diet and to protect their health. Most measures aimed at protecting the safety of the food supply, including those aimed at animal health and welfare, plant health, primary production aspects, manufacturing, processing, distribution and sale, are developed at European level with their implementation being in the hands of Member States.

Europe's food safety system is governed by the Regulation on General Food Law* which established three interdependent principles of risk analysis: risk assessment - the scientific evaluation of risks; risk management - the decision making process; and risk communications. Under this system, the independent European Food Safety Authority (EFSA) has been entrusted with risk assessment and risk communications, while the responsibility for risk management decisions lies with the European Commission, the European Parliament and Member States. Therefore, EFSA is an integral part of the EU food safety system providing risk managers with scientific evidence for measures aimed at ensuring the high level of health protection chosen by the Community.

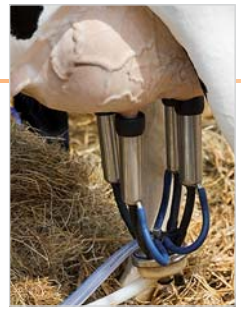
Through its 10 scientific panels and its Scientific Committee of independent scientists, EFSA is able to assess risks along the food chain from plant health, use of pesticides and GMOs, farming practices, and animal feed, animal health and welfare, through food manufacturing and processing, and eventual supply to the consumer. In 2008, EFSA produced almost 500 opinions, reports and other advice to support European legislation. By having knowledge and expertise all along the food chain from field to plate, EFSA is able to produce comprehensive risk assessments, providing insight which enables risk managers to gain a full picture and assist them in developing appropriate measures to address the risk effectively and in the most appropriate manner.

Working closely with the European Commission, European Parliament, Member States' authorities, in Europe and beyond, and with stakeholder organisations, EFSA is able to collect, analyse and provide data, and develop comprehensive advice to support its risk assessment activities. European risk managers have to be able to respond quickly and decisively to put in place appropriate measures when an emergency arises along the food chain which may have a direct or indirect impact on health. The identification of emerging risks is a core activity in EFSA. During 2008 EFSA has developed further its fast track streamlined procedures to deliver scientific advice so that risk managers were able to deal with the risk in the shortest timeframe.

EFSA has a remit to communicate widely on its findings. Working in concert with the European institutions and national food safety authorities EFSA aims in its communications to ensure that accurate, meaningful and timely information is available concerning the Authority's assessments of risks, thereby contributing to building confidence in Europe's food safety system. ▮

** Regulation (EC) No 178/2002 of the European Parliament and Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety*

II. HIGHLIGHTS AND ACHIEVEMENTS 2008



1. FOOD SAFETY – AND EFSA– AT A TURNING POINT

EFSA is now firmly established, with enhanced resources, a workforce of nearly 400, and access to a network of over 1,200 external scientific experts. It has to keep pace with increased demands and new challenges to ensure the Authority can guarantee that consumer protection and health are grounded in robust scientific evidence.

In particular, EFSA faces key challenges on several fronts. Globalisation will increase the likelihood of new or re-emerging risks to Europe's food supply. Innovative technologies and evolving risk assessment practices will make complex demands on EFSA's scientific and communications activities. Sustainability and climate change will emphasise the importance of EFSA using an integrated approach to risk assessment. Changes in socio-demographic structure and consumer behaviour will impact on EFSA's activities, particularly in the fields of nutrition, diet and health, while changes in policies and the regulatory framework will also affect EFSA's overall workload and priorities.

Expectations and demands on EFSA are growing as it operates in a fast-moving and ever-changing environment. Nonetheless, after steady growth and a strengthening of infrastructure in previous years, 2008 was a year of consolidation that will enhance EFSA's preparedness and responsiveness in the years ahead.

EFSA's strategy for the next five years

To help guide the Authority in the coming years, the Management Board adopted, in December 2008, *EFSA's Strategic Plan 2009-2013*.

Strategic objectives over the next five years

1. Providing an integrated approach to delivering scientific advice associated with the food chain from field to plate.
2. Providing timely, high-quality evaluation of products, substances and claims subject to the regulatory authorisation process.
3. Coordinating the collation, dissemination and analysis of pan-European data in the fields within EFSA's remit.
4. Positioning EFSA at the forefront of risk assessment methodologies and practices in Europe and internationally.
5. Reinforcing confidence and trust in EFSA and the EU food safety system through effective risk communication and dialogue with partners and stakeholders.
6. Assuring the responsiveness, efficiency and effectiveness of EFSA.

Commissioner Vassiliou visits EFSA in July 2008

This five-year strategic plan describes and analyses the changing context in which EFSA, and food safety in general, finds itself. It will guide EFSA in responding to those changes, and ultimately in ensuring that public health is fully protected and consumers can trust Europe's food safety system.

The plan outlines how EFSA will maximise the benefits of the scientific expertise at its disposal across Europe and will strengthen its integrated approach to risk assessment to provide Europe's decision makers with relevant, and timely scientific advice.

Six strategic objectives (see box on p. 9) were identified to enable EFSA to handle future challenges and opportunities. The plan will enable EFSA to programme its work for the coming years and serves as the basis for the development of the Authority's Annual Management Plans. However, recognising that EFSA's priorities will continue to evolve during this period, the plan is intended to be a living, dynamic document which will be revisited regularly.

EFSA's 2009 priorities include the renewal of eight of its 10 panels and its Scientific Committee. The Authority also plans to boost its *Strategy on Cooperation and Networking* by, for example, working with Member States to expand the list of Article 36 organisations that can help the Authority with work such as data collection. A review of this strategy was presented to the Management Board in December 2008.

The Strategic Plan took into consideration comments from a wide range of sources: the European Commission, the European Parliament, the Council of Ministers, EFSA's Scientific Committee and Advisory Forum, other European agencies, and the Stakeholder Consultative Platform, as well as comments received during EFSA's online public consultation in autumn 2008.

Progress in implementing this Strategic Plan will be monitored, evaluated and revised regularly to allow adjustments to be made to changing circumstances.

EU Commissioner for Health welcomed by EFSA

European Commissioner for Health, Androulla Vassiliou, visited EFSA in July for the first time since her appointment as Commissioner in April 2008. Her visit provided the opportunity for an exchange of views on EFSA's activities, on how EFSA works and on its role in the EU food safety system. Special emphasis was given to the Authority's close cooperation with Member States.

The Commissioner's visit was of prime importance in strengthening a mutual understanding of the relationship between EFSA as an independent risk assessor and the European Commission as a risk manager. During the visit she met with members of EFSA's Scientific Committee, members of EFSA's Management Board and EFSA staff.

Commissioner Vassiliou expressed her appreciation of the priorities that have been identified together with the European Commission's Health and Consumers

EFSA Management Board, December 2008

Directorate-General (DG SANCO). It was agreed to put more emphasis on the alignment of priorities, work programmes, and on strengthening the coordination of communications between DG SANCO and EFSA. The Commissioner stressed the essential independence of EFSA which is making a major contribution towards bolstering the confidence of consumers in the European food safety system.

New appointments to EFSA's Management Board

The Council of the European Union appointed seven members to the Management Board of EFSA in July 2008. They join the seven existing Board members appointed in June 2006 and the current European Commission representative. All have proven expertise and long-standing experience in a wide range of areas related to EFSA's mission, including relations with institutions and stakeholders as well as consumer organisations. The Council's decision, taking into consideration the opinion of the European Parliament, was based on a list of candidates proposed by the European Commission.

The independent Board ensures that EFSA carries out its mandate as defined in its Founding Regulation, that it functions effectively and efficiently, and that it meets the expectations of European and national institutions, stakeholders and the public.

The new members, appointed for a period of four years, replace seven of the 14 members from the first EFSA Management Board established in 2002 whose term of office ended on 30 June 2008. Two of the new members were re-appointed.

The inaugural meeting of the new Board was held in October 2008 in Paris, presided by new Chair Diána Bánáti, Director General of the Hungarian Central Food Research Institute (CFRI). The new Vice-Chairs are Marianne Elvander and Bart Sangster.

Newly-appointed members of the Management Board

Sue Davies, Chief Policy Advisor of the UK consumer organisation "Which?"

Piergiuseppe Facelli, Director Office for International Affairs in Food and Veterinary of the Italian Ministry of Health

Matthias Horst, Director-General of the Federation of the German Food and Drink Industry (BVE)

Milan Pogačnik, Minister of Agriculture, Forestry and Food of the Republic of Slovenia

Jiri Ruprich, Director, Czech National Institute of Public Health

Sinikka Turunen, Secretary General of the Finnish Consumers' Association

Url Bernhard, Managing Director of the Austrian Agency for Health and Food Safety (AGES)



EFSA's wider scientific community

In 2008 EFSA's workforce grew to 395. Of these, 63% were engaged in scientific activities. They support EFSA's Scientific Committee and Panels which are composed of highly qualified experts in scientific risk assessment and evaluations in their respective fields. The Authority's scientists also assist EFSA's risk assessment activities through data collection, reporting and analysis of trends in zoonoses, pesticide peer review, scientific cooperation, emerging risks, and assessment methodologies. All members are appointed through an open selection procedure on the basis of proven scientific excellence – including experience in risk assessment and peer-reviewing scientific work and publications – and independence. To assist EFSA in the assessments and evaluations, the Authority calls on the expertise available in Member States. To this end, EFSA has built networks of over 1200 scientific experts, 30 national food safety agencies and nearly 400 national scientific organisations.

Moving together with Member States and beyond

Today, EFSA is an important partner in the risk assessment community among Member States and internationally, recognised by key institutions and stakeholders as a trusted authority in food safety matters.

In 2008, the Authority continued to forge even closer links with Member States by actively working with Member States on a number of fronts, such as EFSA's Advisory Forum, the network of national Focal Points, EFSA's Scientific Cooperation Projects, as well as by contracting preparatory scientific work to organisations throughout Europe. In addition, in 2008 EFSA's Executive Director went on bilateral visits to several Member States to meet national risk assessors, risk managers and stakeholders to build an even better mutual understanding.

By the end of 2008, EFSA had created networks that, included more than 1,200 experts, national agencies from the 27 Member States and neighbouring countries and nearly 400 Article 36 organisations (see p. 39) supporting the scientific work of EFSA.

Cooperation with EU agencies and other bodies

EFSA also enhanced its relationship with other EU agencies active in related fields to foster information exchange and cooperation on matters of mutual interest. In April 2008, EFSA and the European Centre for Disease Prevention and Control (ECDC) signed a Memorandum of Understanding. The agreement serves to increase cooperation and the sharing of scientific information, specifically in the areas of food safety, control of communicable diseases, the prevention of infectious diseases and in emergency responses. The two organisations also worked together on zoonoses and avian influenza.

EFSA also signed a cooperation agreement with the European Commission's Joint Research Centre (JRC) in November to advance scientific cooperation and to contribute to the development of international standards in food and feed safety. The aim is to ensure that additional data are provided for risk assessments, that harmonised standards are

applied to data generation and that analytical best practices are shared. EFSA and the JRC will also continue to work closely in identifying problem areas impacting European consumers and in developing innovative scientific solutions.

EFSA also continued to forge closer alliances with other agencies in 2008, through a visit of EFSA's Executive Director to the European Medicines Agency (EMEA) and a visit of representatives of the European Chemicals Agency (ECHA) to EFSA. EFSA has joint mandates on antimicrobial resistance with ECDC and EMEA with whom the Annual Community Summary Report on zoonoses is also produced every year.

Assistance in food safety for pre-accession countries

EFSA continued working with food safety authorities from Croatia and Turkey as part of the EU's Pre-Accession Programme and started to cooperate with the Former Yugoslav Republic of Macedonia. Seminars, workshops, and study tours related to food safety and risk assessment, communication and management, were held thanks to the Commission-funded Pre-Accession Programme. Together with participation in EFSA meetings, the programme helps prepare candidate country experts for possible future cooperation with EFSA as their countries become full members of the EU.

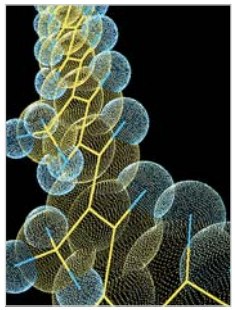
Additionally, EFSA organised the third European agencies meeting on network building with a focus on the EU's Pre-Accession Programme and its Neighbourhood Policy. Nine EU agencies and two representatives from the European Commission came to Parma to exchange information and best practices.

Closer ties with similar authorities and international organisations

International cooperation is essential for sharing information, data and best practice. Global partnerships are also of major importance for the early identification of emerging risks and for the development of coherent communication activities on the risks in the food and feed chain. Therefore, again in 2008, the Authority has continued to develop new partnerships and strengthen existing alliances.

Throughout 2008, EFSA welcomed visiting delegations, representatives and officials from food safety authorities from the US, China, New Zealand and Japan who came to learn more about how EFSA operates and to explore possibilities for further cooperation. The Authority also began preparations for its visit in March 2009 to US Food and Drug Administration (FDA), and other organisations such as the Center for Disease Control and Prevention (CDC), and the US Department of Agriculture (USDA).

For the first time, EFSA joined forces with the World Health Organisation (WHO) and the Food and Agriculture Organisation (FAO) to organise a seminar addressing an issue of common concern: the health impacts of climate change on food and water safety, as well as nutrition. This event took place in Rome in October within the framework of World Food Day.



2. RISK ASSESSMENT AND SCIENTIFIC ADVICE DOUBLES

In 2008 the scientific workload continued to grow. Requests for scientific advice, mainly from the European Commission, grew from around one in 2007 to two per day in 2008. Scientific output also increased significantly. A total of 489 scientific outputs were finalised in 2008. Data collection tasks also expanded considerably reaching 129. To meet with the ever increasing workload regarding substances found in food and food packaging, two new panels began work, replacing the former AFC Panel (see p.17).

Several initiatives increased support to the panels: staffing levels were greatly increased, especially for units working on applications, and more activities were outsourced through signed contracts and grants worth €5.5 m in 2008, compared to €2.9 m in 2007. Additionally, the number of external experts assisting the panels in working groups increased and support from the Scientific Cooperation & Assistance (SCA) Directorate was enhanced, especially in the area of data collection and statistics.

The quality of scientific output received special attention in 2008. The implementation of EFSA's self, internal and external review quality assurance system (see p.38) began, starting with the self-evaluation of all scientific outputs and an internal evaluation of randomly selected outputs. Quality assurance was also strengthened through increased documentation of workflows and the development and implementation of more precise Standard Operating Procedures.

Monitoring and planning tools were also developed to support work prioritisation. Coordination of priorities with the Commission similarly helped EFSA to focus on the most important requests. A weekly Mandates Review Committee, including the Executive Director and EFSA Directors, was also established to analyse all requests to EFSA, and address them in an integrated manner.

With all these procedures in place, the organisation of EFSA's scientific work has matured. This ensures that high quality and timely risk assessments are delivered by EFSA to Europe's risk managers, for them to ensure, in turn, that Europe's citizens are protected, and food and feed in Europe are safe.

Defining EFSA's scientific outputs

In 2008, EFSA redefined how it classifies its scientific outputs. There are two main families of scientific outputs – opinions of the Scientific Committee and panels, and other scientific outputs. The first brings together the outputs of the Scientific Committee and panels, such as generic opinions and opinions on applications, statements and guidance. The second unites all scientific outputs including those not adopted by a panel or the Scientific Committee. These can be EFSA statements or guidance, a conclusion resulting from pesticide peer review, a reasoned opinion (a term used for the peer review of Maximum Residue Levels), or a scientific or technical report from EFSA.

In addition, 2008 saw a change in the classification of questions. In 2008, as in 2007, EFSA received many mandates from the European Parliament, the European Commission, Member States or from itself, in other words, a self-task request. Whereas before there may have been one mandate leading to one or more scientific outputs, now the individual components of the mandates are divided in separate questions which can result in one or several scientific outputs.

EFSA's scientific outputs

Panel	Scientific Committee/ Panel opinions*	Other scientific outputs	Public consultations
Scientific Committee (SC)	3	4	4
Food additives and packaging (AFC)	56	0	2
Animal health and welfare (AHAW)	13	0	0
Food additives and nutrient sources (ANS)	12	0	0
Biological hazards (BIOHAZ)	12	3	1
Food contact materials, enzymes, flavourings (CEF)	21	0	0
Contaminants (CONTAM)	15	4	0
Feed additives (FEEDAP)	41	0	0
Genetically modified organisms (GMO)	18*	0	3
Nutrition (NDA)	53	0	3
Plant protection products (PPR)	4	34	6
Plant health (PLH)	32	0	1
Assessment methodology (AMU)	-	15	0
Data collection exposure (DATEX)	-	17	0
Emerging risks (EMRISK)	-	2	0
Scientific cooperation (SCO)	-	27	0
Zoonoses (Data collection)	-	17	0
Pesticides (PRAPeR)	-	86	18
Total	***280***	***209***	***38***
Total scientific outputs	**489**		

5 are co-adoptions

EFSA's Scientific Committee, December 2008

2.1 EFSA's scientific panels and units: a productive 2008

Scientific Committee: A broad remit - from harmonising assessments to nanotechnology

Tasked with delivering opinions and advice for risk managers on scientific matters of a multidisciplinary nature, the Scientific Committee is also responsible for the general coordination of EFSA's scientific work and for ensuring consistency in the scientific approaches used by the Scientific Panels. It focuses on developing and promoting new and harmonised scientific approaches for hazard and risk assessment of food and feed in fields where EU-wide methodologies are not already defined. The Scientific Committee also provides strategic advice to EFSA's Executive Director.

Throughout 2008, the Scientific Committee was involved in the development of new and harmonised approaches for risk assessment. In particular, a guidance document on transparency in risk assessment was endorsed for public consultation. This document aims to show more clearly and comprehensively the approaches used to ensure transparency of the scientific aspects of risk assessments. It is planned to be adopted in early 2009.

The Scientific Committee also worked on assessments of food safety issues, ranging from cloning and nanotechnology to botanicals.

Botanicals and derived preparations (supplements from plants, algae, fungi or lichens) are widely available throughout the EU in the form of food supplements. Most of these products have been in use for years. As there is currently no EU legislation providing guidance on how to assess the safety of these products, EFSA has developed a science-based approach for evaluating the food safety aspects of botanicals. In June 2008, EFSA published a draft guidance document on the safety assessment of botanicals and botanical preparations which is currently being tested. A final version is expected to be published by summer 2009.

The Scientific Committee also prepared an opinion on the potential risks arising from nanoscience and nanotechnologies in food and feed safety and the environment. This followed a question from the European Commission as to whether existing risk assessment approaches can be appropriately applied to this new technology. EFSA's opinion addresses possible risks from the use of engineered nanomaterials that could be deliberately introduced into the food chain and provides guidance on risk assessment, recommending a case-by-case approach. It also calls for further data and research to address existing uncertainties in this area. The draft opinion was presented to EFSA's stakeholders in October and to EU Member States through the Advisory Forum. A public consultation was launched on EFSA's website mid-October to December. The Scientific Committee finalised the opinion in early 2009, taking into account the comments received. The final opinion will help the Commission investigate appropriate measures in this field.



AFC: The safety of flavourings, nutrient sources, food additives and packaging

Since EFSA was created, the Panel on food additives, flavourings, processing aids and materials in contact with food (AFC Panel) contributed significantly to European Union risk assessment on substances added to food. The areas of activity were related to the safety of flavourings, food contact materials, nutrient sources and food additives, including food colours.

The AFC Panel also assessed a study from the UK, known as the "Southampton Study". The study, by McCann *et al,* suggested a link between children's behaviour and their intake of two mixtures of certain food colourings and the preservative sodium benzoate. EFSA concluded that, due to limited evidence and considerable uncertainties, the study could not be used as a basis to reassess the Acceptable Daily Intakes of the substances used in this study.

The panel also examined all recent and new scientific information available on bisphenol A (BPA), a chemical permitted for use in food contact materials in the European Union. People are exposed to BPA in food through its presence in, for example, polycarbonate plastics. Infants may be more exposed to BPA, especially if they are fed with baby bottles from polycarbonate plastics. A Tolerable Daily Intake (TDI) of BPA was set by EFSA in its risk assessment published in January 2007. The panel concluded that this TDI provides a sufficient margin of safety for infants and adults. Following new evidence from the US and Canada, among others, the AFC Panel conducted a further assessment of BPA in 2008, addressing the difference between infants and adults in eliminating BPA from the body. The panel concluded that infants should be able to eliminate BPA from the body and the conclusions of its previous risk assessment remain valid.

In July 2008, the AFC Panel also published guidelines for applicants on the safety evaluation of recycling processes used to produce recycled plastics for food packaging. This follows the new European regulation on plastics requiring recycled plastics to be used in contact with food only when obtained from processes that have been assessed for safety by EFSA.

The AFC Panel ceased to exist in 2008. It was replaced by the Panel on food additives and nutrient sources added to food (ANS) and the Panel on food contact materials, enzymes, flavourings and processing aids (CEF). The new arrangement enables EFSA to better fulfil mid- and long-term needs in these areas of its remit, as well as to respond to the high volume of requests for scientific advice within tight deadlines.

Before handing over its work to these two new panels, the AFC Panel mainly worked, in 2008, on the safety assessment of flavourings, nutrient sources, food additives and food contact materials.

ANS: The safety of food additives and nutrient sources for food supplements

The Panel on food additives and nutrient sources added to food (ANS) handles questions of safety in the use of food additives, nutrient sources and other substances deliberately added to food but not flavourings and enzymes. The new ANS Panel began work in July 2008, after the former AFC Panel was replaced by the ANS and CEF Panels.

The first meeting of the ANS Panel, July 2008

Food supplements are concentrated sources of nutrients or other substances with a nutritional physiological effect that act as a supplement to normal diets. These are marketed as pills, tablets, capsules, or liquids in measured doses.

As part of the Europe-wide process to harmonise food supplements across the EU, a list of permitted sources of vitamins or minerals that may be added for specific nutritional purposes in food supplements is being created.

The Commission asked EFSA for scientific opinions on the safety and bioavailability of these nutrient sources prior to any approval of their continued use for nutritional purposes in food supplements. EFSA endorsed guidelines to assist companies in understanding the kind of scientific data needed on their products in order to perform a risk assessment.

Hundreds of dossiers have since been reviewed, and in the interest of protecting consumers, EFSA has had to return some of them for lack of information.

In accordance with the priorities defined with the European Commission, the ANS Panel has concentrated its work on the evaluation of the nutrient sources for food supplements and issued 12 opinions in 2008.

CEF Panel at its first meting, July 2008

CEF: Evaluating the safety of flavourings

The CEF Panel deals with questions related to the safety of the use of food contact materials, of enzymes, of flavourings and of processing aids (CEF). The Panel started work in July 2008 alongside the ANS Panel, after the former AFC Panel ceased to exist.

The European regulatory framework for flavourings is being harmonised. Around 2,800 substances authorised nationally must additionally be submitted to a uniform EU safety evaluation programme. Flavourings that successfully pass will enter a positive list of flavourings that may be added to food. The approval procedure for these substances is based on scientific evaluation by EFSA.

EFSA has divided the 2,800 substances currently in use in the EU into Flavouring Groups based on chemical structure similarities and on metabolism. Each group is being evaluated to ensure the safety of compounds for human health. EFSA scientists consider intake levels, absorption, metabolism and toxicity data for the Flavouring Groups Evaluations (FGE).

When gaps are identified in the data needed for risk assessment (e.g. on specifications, toxicity, exposure), EFSA notifies the applicants and the European Commission.

In its work, EFSA has identified 360 substances which, based on their chemical structure, could be genotoxic. As long as the issue on genotoxicity has not been cleared, these substances are not further evaluated. The genotoxicity dataset available on these compounds was evaluated and gaps were identified. The relevant studies needed are outlined in a Genotoxicity Test Strategy developed for this group of flavourings.

By the end of 2008, about 85% of nationally authorised flavourings had passed the evaluation at EFSA. In 2008, the AFC Panel adopted 41 opinions on flavourings, and the CEF Panel adopted a further seven opinions and two statements on flavourings. The deadline for finalising the evaluation programme is 31 December 2009.



AHAW: The welfare of farmed fish

The Panel on animal health and welfare (AHAW) provides opinions and advice primarily related to food-producing animals, including fish. It covers all aspects of animal diseases and animal welfare. In 2008, the panel undertook an in-depth study to identify welfare hazards in aquaculture and published five opinions on fish welfare.

About half of the fish eaten in Europe now comes from farmed fish. With the growth in large-scale farming of fish and other aquatic species, policy makers, scientists and consumers are focusing on how fish are actually being farmed today and how this affects their welfare.

Therefore, the European Commission asked EFSA to assess how the different farming systems affect the welfare of the main fish species farmed in the EU. In its assessments EFSA took note of the EU directive on minimum standards for the protection of animals bred or kept for farming, including fish, and other international recommendations and guidelines, amongst which the work being developed by the World Organisation for Animal Health (OIE) and the Council of Europe.

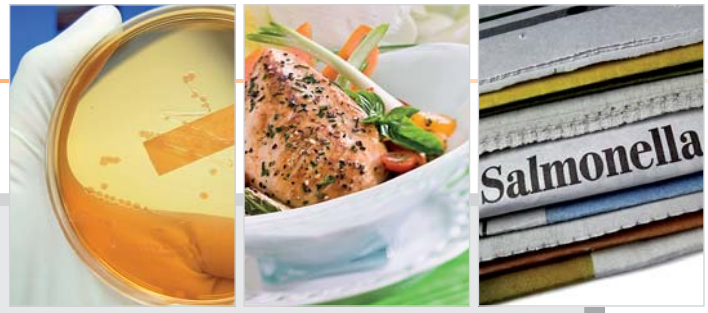
In 2008, the AHAW Panel adopted five opinions on the welfare of main species of farmed fish in Europe: Atlantic salmon, trout, European eel, European sea bass, gilthead sea bream, and carp.

In its risk assessments, the panel ranked potential welfare hazards. These present a sound basis for risk managers to evaluate and improve husbandry systems in order to avoid unnecessary pain, distress and suffering for animals and to increase welfare where possible. Examples of potential hazards include:

- Poor water quality with its damaging effects on fish health;
- Limited availability of veterinary medical products;
- Commercial feed not delivering basic nutritional requirements of the various species and problems arising from changes in formulations or poor storage.

Since the various farming practices affect the welfare of fish differently, EFSA recommends constant monitoring. Further research is also needed on feeding, stocking density, and the development of veterinary therapeutics and vaccines.

Further to the five opinions on the welfare of individual fish species, the panel adopted an opinion in January 2009 on the general approach to fish welfare, taking into account the biology and physiology of fish.



BIOHAZ: The role of food in conferring antimicrobial resistance to humans

EFSA's Panel on biological hazards (BIOHAZ) deals with biological hazards related to food safety, foodborne diseases, transmissible spongiform encephalopathies (TSEs), food microbiology, food hygiene and associated waste management issues. Antimicrobial resistance figured prominently in the panel's work in 2008.

Exposure to antimicrobial resistant (AMR) bacteria is an emerging biological hazard that each year kills thousands of Europeans. This is a major concern as antimicrobials become less effective in fighting human infections. In 2008, the BIOHAZ Panel decided to thoroughly analyse the role of food consumption and food processing in exposing humans to antimicrobial resistant bacteria. The final opinion was published in August 2008 after public consultation. EFSA received comments and additional data from EMEA, ECDC, national food safety authorities and the food industry.

The main conclusion is that the current use of antimicrobial agents throughout the food chain significantly contributes to a growing and diverse range of resistant bacteria particularly through:

- Food contaminated by bacteria present in live animals;
- Fresh produce from land recently irrigated with contaminated water;
- Food contaminated during handling and preparation.

Resistant *Salmonella* and *Campylobacter* are mostly spread through food: *Salmonella,* particularly through contaminated poultry meat, eggs, pork and beef; and *Campylobacter*, through poultry meat. Animal-derived products are also a potential source of methicillin-resistant *Staphylococcus aureus* (MRSA) and may be an emerging food-related risk. Poultry also appears to be a major source of human exposure to fluoroquinolone resistance and cephalosporin-resistant bacteria have been found in poultry, pork and beef.

The opinion made recommendations for preventing and controlling transmission, highlighting good hygiene practices at all stages of the food chain as critical. For example, controlling and limiting antimicrobial usage may have the most impact in reducing the occurrence of AMR bacteria in food. The panel concluded that these findings require all stakeholders to respond in order to prevent the development and spread of antimicrobial resistance.

CONTAM: Assessing the risks and benefits of nitrates in a vegetable-rich diet

The Panel on Contaminants in the Food Chain (CONTAM) 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. In 2008, the Panel's work included a risk-benefit analysis of nitrates in a diet high in vegetables, the first opinion of its kind for EFSA.



Nitrate occurs naturally in foods and is an approved food additive. It is found in fruit, vegetables, preserved meat and drinking water. Concentrations are higher in leaves than in seeds or tubers, and also vary according to the extent of fertiliser use or exposure to sunlight. While nitrate itself is relatively non-toxic, when humans convert it to nitrite or nitric oxide in their body, it can be harmful to health. While eating more vegetables is widely recommended because of their health benefits, are consumers at risk?

The European Commission asked EFSA to weigh up the health risks and benefits to consumers from nitrate in vegetables, as it plans to revise related EU legislation.

The CONTAM Panel analysed data on nitrate levels in vegetables. Some 42,000 results came from 20 Member States and Norway, which were used together with EFSA's concise European food consumption database to estimate dietary exposure to nitrate in Europe.

In a balanced diet, vegetables and fruit can represent over half or even two-thirds of all nitrate intake. The panel explored a variety of dietary scenarios based on a vegetable and fruit intake of 400 g/person/day, recommended by the WHO. Nitrate exposure estimates were compared with the Acceptable Daily Intake (ADI) for nitrate; for most Europeans, daily levels of nitrate intake are well within the ADI.

The critical driver for dietary exposure to nitrates is not the amount of vegetables, but the type of vegetables consumed. Only 2.5% of the population in some Member States eat large amounts of only leafy vegetables, which could lead to the ADI being exceeded. Vegetarians and vegans are not considered likely to exceed the ADI. However, those who eat more than 47g of rocket a day might exceed the ADI. Overall, it was concluded after assessing the risks and benefits to consumers from nitrates in vegetables, that the benefits outweigh the potential risks.



FEEDAP: Guidance for feed additive applicants

EFSA's Panel on additives and products or substances used in animal feed (FEEDAP) evaluates each new additive and/or new use of a feed additive submitted for authorisation. In 2008, it adopted several technical and administrative guidance documents for applicants.

In May 2008, the European Commission issued new rules for the preparation of feed additive applications, their assessment and authorisation. These rules set out the scientific data that should be submitted for identifying and characterising the additive concerned. They also defined the studies needed to demonstrate its efficacy and safety for humans, animals and the environment.

With the deadline approaching for submitting applications for re-evaluation, and aware of the situation faced by applicants, EFSA took action. The FEEDAP Panel worked on drafting detailed and user-friendly guidance to assist applicants in preparing and presenting their applications. The resulting guidance documents published in the second half of 2008 are meant to help applicants understand the requirements in the Commission's guidelines, thus increasing the consistency and quality of the dossiers submitted.

Fifteen new guidance documents have been published. They can be divided into three sets of documents on:

- The specific categories of feed additives (e.g. nutritional, technological additives);
- Horizontal issues, including, for instance, guidance on tolerance and efficacy studies in target animals, microbial additives, consumer safety, user safety and environmental risk assessment;
- The re-evaluation of certain additives already authorised.

With such user-friendly guidance, EFSA also presents, transparently, how the FEEDAP Panel evaluates submitted applications. The documents contain a series of hyperlinks to regulatory texts and other relevant documents to provide the needed background information. Flow charts within the guidance documents ('Quick checks') support applicants in the selection of required safety studies. Finally, templates assist reporting on required safety and efficacy studies, as well as on the experimental design of the studies.

FEEDAP has also prepared an administrative guidance document to help applicants fulfil all the different administrative procedures, foreseen in the legislative acts, when preparing and presenting the dossiers and the applications.

GMO: Updated guidance on GM plants

The Panel on genetically modified organisms (GMO) 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. As part of its remit, the GMO Panel produces Guidance Documents to clarify its approach to risk assessment and to ensure transparency in its work. These documents also provide companies with guidance for preparing and presenting applications.

The panel regularly reviews its guidance taking into account scientific developments and experience gained through its risk assessments. In June 2008, the panel published its updated guidance document for the risk assessment of genetically modified plants, and derived food and feed.

The revised document includes updated guidance on the role of animal feeding trials with whole plant material for toxicity testing, based on the report adopted in September 2007, and on the experimental design of field trials. It also includes advice on the proper statistical analysis of collected data and incorporates guidance on risk assessment for GM plants containing stacked events.

A public consultation on the draft guidance document was conducted in summer 2008. The updated Guidance Document has been presented to the European Commission and Member States. This will be used by the Commission to draft a Commission Regulation including guidance for assessing the risks of genetically modified plants, and derived food and feed as an annex.

NDA: Contributing to a healthy diet

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 (i.e. foods or ingredients which have not been consumed in the EU to a significant degree before 15 May 1997). In 2008, much of its work concerned updating dietary recommendations for nutrients and energy, and the EU's regulation on Nutrition and Health Claims.

The main objective of nutrition recommendations is to ensure that consumers can enjoy a diet that provides energy and nutrients for optimal growth, development, function and health throughout their life. The European Commission asked EFSA to review, and if necessary, to update the earlier recommendations of the Scientific Committee on Food that provided reference intakes for energy and certain nutrients. EFSA's work will ensure that EU action in this area of nutrition is underpinned by the latest scientific advice.

EFSA's work on setting updated Dietary Reference Values (DRVs) for energy, water, carbohydrates, fats and proteins began in 2008. Dietary Reference Values include nutrient recommendations and reference values, such as the average requirement, adequate intake level and the lower threshold intake.

To ensure a consistent approach, the panel first worked on sound scientific principles for establishing DRVs. The Panel also drafted an opinion on DRVs for water, because adequate hydration of the body is essential for ensuring nutritional balance.

For public understanding, it is generally better to express recommendations for the intake of individual nutrients or substances in food-based terms. In this context the Commission asked EFSA to provide guidance for Member States on the translation of nutrient-based recommendations into practical Food-Based Dietary Guidelines. Such guidelines are specific food consumption recommendations for healthy eating based on nutritional recommendations and on scientific evidence on the relationship between diet and chronic disease.

Consequently, the panel gave its draft opinion on the scientific process underlying the development, monitoring and evaluation of dietary guidelines in the EU. It concluded that it is not feasible to establish detailed and effective guidelines which could be used across the EU. Diet-related public health priorities and consumption patterns may differ between countries. EU Member States were therefore advised to adapt guidelines to their citizens' needs.

Both the draft opinion on Food-Based Dietary Guidelines and its general approach to establish DRVs were subject to a public consultation in 2008.

PLH: Guiding scientific advice on the risks posed by plant pests

The EFSA Panel on Plant Health (PLH) provides scientific advice on the risks posed by pests which can harm plants, plant products or biodiversity in the EU. The panel evaluates those risks to ensure the safety and security of the food chain.

In 2008, EFSA asked the PLH Panel to develop a guidance document on the evaluation of pest risk assessments made by Member States or other parties. Pest risk assessments can be used to justify phytosanitary measures required by EU law. This work represents an innovation in this field as previously no such guidance existed.

The guidance document describes the process and criteria to be used for a science-based evaluation of a pest risk assessment. A public consultation on the document began in early 2009.

Following requests from the European Commission, the PLH panel produced 30 scientific opinions on plant pests in 2008. The panel assessed the risks posed by various banana and citrus plant pests to the French overseas departments of Guadeloupe, French Guiana, Martinique and Réunion. The Panel looked into documentation provided by French authorities, and identified and evaluated additional scientific and technical data. It concluded that most of the pests studied could threaten food production in these overseas departments and thus should be considered candidates for the EU list of harmful organisms.



PPR: The impact of pesticides on birds and mammals

The PPR Panel deals with plant protection products, commonly known as pesticides, and their residues, looking at risks for the user/worker, bystander, the consumer and the environment. It works closely with EFSA's Pesticide Risk Assessment Peer Review Unit (PRAPeR) giving scientific advice on issues that cannot be resolved by peer review or when further scientific guidance is needed, mostly in toxicology, ecotoxicology, and the fate and behaviour of pesticides and residues. In 2006, the Panel started to revise and update existing European Guidance Documents and to develop new ones.

According to EU law, industry seeking authorisation to market pesticides must provide appropriate information to enable Member States to assess their direct impact on human and animal health, and on the environment. For this, many guidance documents exist to help Member States and industry fulfil these obligations. The PPR Panel is responsible for updating these guidance documents in light of scientific advances, and for proposing new ones.

In revising the Guidance Document on risk assessment for birds and mammals, the Panel recognised that the task embraced several risk management issues, such as deciding on the required level of protection, which it not within EFSA's remit. Therefore, it decided to follow a two-stage approach.

In 2008, the PPR Panel adopted an opinion, following extensive stakeholder and public consultation, on appropriate approaches for assessing the direct impact of pesticides on birds and mammals. It provides a sound scientific basis for carrying out an improved risk assessment, and will help industry and Member States safeguard birds and mammals from any potential negative effects.

The panel evaluated the impact of pesticides to birds and mammals according to various scenarios, including different crops and different types of pesticide uses (e.g. granules, seed treatment, sprays). A tiered approach was used to assess the risk of mortality and the reproductive effects in birds and mammals. In a tiered approach, risk assessment of the pesticide first begins by using fundamental, conservative data (e.g. from acute laboratory studies). If the risk from this assessment is not acceptable according to EU law, then data from more complex studies are accessed in a higher tier to add more realism and to reduce uncertainty.

In a second stage, a joint working group with EFSA representatives, and with risk managers from the Commission and Member States, will use the opinion and focus on risk management aspects.



AMU: Colony Collapse Disorder in European bees

The Assessment Methodology Unit (AMU) provides technical and methodological support on risk assessment and quantitative decision support to the different units of all EFSA Directorates. The unit also carries out projects through the application and harmonisation of quantitative or qualitative scientific risk assessment methods, and through the development of new decision support approaches.

Since 2003 there have been reports in Europe and America of serious losses of the adult bee population from beehives. Beekeepers have reported that the hive contains a live queen but no attendant adult bees. This phenomenon has been termed Colony Collapse Disorder (CCD). While the cause of the disappearance of the adult bees cannot be determined yet, it is thought to be multifactorial. Pathogens, parasites, pesticide exposure, starvation, management practices and environmental stresses have all been postulated as possible causes. A decline in honey bee populations could have a serious impact on agricultural production as bees play an important role in the pollination of crops.

The "Mortality, collapse and weakening in bee hives" working group of the Agence Française de Securité des Aliments (Afssa) contacted EFSA in March 2008 seeking information on the existence of monitoring programmes for chemical residues in honey surveillance programmes for the collapse, weakening and mortality of bees, as well as data on honey production levels in the EU. Using its network of National Focal Points (see p.40), EFSA distributed a questionnaire to national authorities requesting such data. Responses from 22 Member States, as well as Norway and Switzerland, provided the basis for the report on Bee Mortality and Bee Surveillance in Europe published in August 2008 by the Assessment Methodology Unit.

The report identified 17 bee surveillance programmes in 16 countries. Reported mortality rates were in the range of 7% to 50%. Italy reported the highest mortality rate (40-50%) in 2007. The different methodologies employed in the surveillance programmes and the different outcomes recorded make reported mortality rates difficult to compare at a European level.

Therefore, EFSA subsequently launched a call for proposals for an EU-wide collective study in the area of CCD under Article 36 (see p.43) of its Founding Regulation and awarded a grant of €100,000 in 2008 to a consortium of European scientific institutes. The 9-month project began in January 2009. The study comprises an EU-wide review of literature on the topic, a description of active surveillance programmes and a collation of historical mortality data to facilitate an objective assessment of all possible causes of CCD. The resulting work from the study will prepare the ground and orientate research towards identified gaps in scientific knowledge.

DATEX: Understanding who eats what in Europe

EFSA's data collection and exposure Unit (DATEX) collects and analyses data on food consumption and chemical occurrence in food and feed for Europe-wide exposure assessments. The unit also contributes to the scientific development and application of new exposure assessment methods. In 2008, it also created Europe's first database of EU-wide dietary information.

Knowing what consumers eat is essential for assessing their exposure to risks, related, for instance, to contaminated food. Therefore, food consumption data feed risk assessments. The quality of the data can also impact risk assessments. Although food consumption data from dietary surveys are available in most European countries, no uniform survey methodology is currently applied in Member States and the availability of data was restricted.

To overcome this, the DATEX Unit developed the 'Concise European Food Consumption Database', launched in spring 2008. It is the first database in Europe containing dietary information from most EU Member States.

By the end of 2008, the concise database had data from 19 European countries on the daily consumption of food for adults, including both average intakes and high intake percentiles. It comprises 15 broad categories (e.g. milk and dairy-based products) and 21 subcategories (e.g. cheese). The data was harmonised as far as possible. This data, available on the EFSA website, will help scientists at EFSA, and potentially beyond, to carry out preliminary exposure assessments and to set priorities when assessing the risks associated with food. For example, in the case of dioxin contamination in Irish pork in December 2008, the database supported EFSA's assessment of the risks to European consumers.

More detailed information on food consumption in Europe is required to undertake full exposure assessments. The current database will serve as a starting point for EFSA to develop a more comprehensive database with information on more refined food categories and specific population groups (e.g. children).

Work has started in 2008 to harmonise survey methods at European level. A harmonised database containing reliable consumption data will also be an important component of EFSA's work on assessing nutrition and health claims made about certain types of food, and will be used by risk managers in defining nutrient profile schemes.

EMRISK: Identifying emerging food safety risks

EFSA's Emerging Risks Unit (EMRISK) is responsible for establishing procedures for the systematic collection of up-to-date information to identify and analyse emerging risks in food and feed safety. Climate change, which may affect various areas of food and feed safety, is an important issue for the Unit.

The Emerging Risks Unit was established to contribute to the safety of food and feed in Europe through the timely identification of emerging risks based on defined automated procedures for monitoring, collecting and analysing information and data.

EFSA, Member States, and other stakeholders involved in food and feed safety are committed to building and developing an integrated approach to monitor and control such emerging risks. The development of such an approach should enable risk managers to respond quickly to lower the risks' potential impacts.

The identification of early signals of emerging hazards and risks represents a great challenge. The unit is developing specific monitoring tools for this task. Among these tools, the Europe Media Monitor (EMM) system, and the European Commission's Rapid Alert System for Food and Feed (RASFF) are being assessed.

New challenges for food safety and food security, and thus possible sources of emerging risks may be induced by worldwide climate change. While the entire food chain is likely to be affected, particular problems are expected to arise in relation to plant health, crop yields, soil quality, biohazards, food contaminants, animal health and pesticides' use. For example, as extreme weather events become more frequent, toxins from fungi contaminating moist grains are expected to increase. Other possible effects include the new geographical distribution of diseases and the emergence of new diseases.

Recently, in cooperation with Member States, EFSA launched a systematic review of existing data and data gaps in the field of climatic data and the periodic stages of plant growth. During the World Food Day that was held in Rome in October 2008, EFSA organised, in cooperation with WHO and FAO, a seminar on the possible effects of climate change on food and water safety, nutrition and health. From 2009, and as a first step, EMRISK will organise the collection of data on defined emerging risks that may be caused by climate change and that will be further analysed in the near future.

PRAPeR: Safety assessment of active substances in pesticides

The Pesticide Risk Assessment Peer Review Unit (PRAPeR) 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. In addition, the unit is also involved in the risk assessment of consumers exposed to pesticide residues in food. This risk assessment is the basis for setting of the maximum residue levels (MRLs) under EU law.

In 1993, there were around 900 active substances used in plant protection products in Member States. To protect Europe's consumers, workers and the environment, a harmonised risk assessment approach was called for. Thus, Europe's pesticide peer review programme was created, tasked with evaluating all active substances that were on the market in the EU in 1993 ('existing active substances'). 'New substances' that have been on the market since 1993 are also assessed.

Member States perform an initial assessment. The peer review of this initial assessment is the responsibility of the PRAPeR Unit and results in the adoption of a conclusion on each active substance. In 2008 it published three times as many reports as in the previous year. With streamlined peer review procedures in place, the Unit delivered conclusions on 62 active substances. These conclusions are given to the European Commission for it to decide whether the active substance may be used in a product in the EU. If so, the active substance is included on the EU's positive list.

The unit is also involved in the risk assessment of pesticide residues in food. EFSA provided the basis for the setting of MRLs for about 200 active substances which was a precondition for the entry into force of the EU's MRL Regulation. Since 1 September 2008, the Unit assesses the risk of setting or amending MRLs. In 2008, the unit issued 7 reasoned opinions on setting new MRLs and 12, in response to a specific request from the Commission, about MRLs of concern for certain active substances.

The risk assessments provided by the Unit support risk managers in setting, amending or deleting of MRLs under EU law. In the next years one of the Unit's major tasks will be the review of MRLs for more than 300 active substances. The preparatory work for this project began in 2008.




SCO: An expert database to boost EFSA's pool of scientific expertise

The Scientific Cooperation Unit (SCO) fosters scientific collaboration and exchange of scientific information between EFSA and national food safety agencies in EU Member States. In 2008, among its many activities, SCO has set up EFSA's database of external scientific experts.

EFSA aims to deliver timely high quality scientific advice to support the policies and decisions of Europe's risk managers. This can only be achieved through effective pooling of scientific excellence across Europe and beyond. To this end, EFSA, in cooperation with Members States, officially launched a database of external scientific experts on 5 June 2008.

By creating such an online database EFSA enhances its capacity to conduct risk assessments, and the transparency of the process through which experts are selected. Ultimately this assists EFSA's Scientific Committee and Panels in performing their scientific tasks. The database is also available to all EU Member States for selecting experts for their own scientific activities. It thereby enables both EFSA and national authorities to respond more effectively, and flexibly, to the growing workload, particularly in cases where very specialised, unexpected and urgent work may be required.

Scientists with relevant expertise in all fields of EFSA's remit, such as food and feed safety, nutrition, toxicology, chemistry, animal health and welfare, plant protection and plant health are invited to apply. Over 1,000 experts had applied to the expert database by the end of 2008. Applications received are being validated by EFSA on a regular basis.

The search tool allowing EFSA and Member States, through Advisory Forum members, to identify experts has been available since the end of November 2008. The database will be kept permanently open for experts to apply.

ZOONOSES: The latest trends in pathogens causing foodborne diseases

EFSA's Zoonoses Data Collection Unit is responsible for monitoring and examining EU-wide data on zoonoses, antimicrobial resistance and foodborne outbreaks. The data is submitted by Member States and other reporting countries.

Zoonoses are diseases or infections that are transmissible from animals to humans. Infections can be acquired directly from animals, or by eating contaminated food. These diseases can lead to mild symptoms or life-threatening conditions.

Every year the Zoonoses Data Collection Unit publishes the Community Summary Report to highlight the latest trends, and to provide scientific support and advice to European risk managers. The report, the only such systematic international survey, is jointly produced with ECDC.

The Zoonoses Task Force, a Europe-wide network of national representatives, assists EFSA by gathering and sharing information on zoonoses in animals and food in their countries. In 2008, information was received from 27 Member States and four non-EU Member States. The most common foodborne infections in humans in the European Union are caused by *Campylobacter*, *Salmonella*, and *Listeria* bacteria. Highlights from the 2007 report include:

- Campylobacteriosis was again the most frequently reported zoonotic disease in humans with cases increasing in most Member States. The highest proportion of *Campylobacter* positive samples in food was reported in fresh poultry meat, where, on average, 24% of the samples tested positive.
- For the fourth year, salmonellosis cases in humans continue to decline. It remains the second most commonly reported zoonotic disease in the EU. Major sources of the human infections are from eggs, and meat from pigs and poultry.
- 2007 was the first year that new *Salmonella* control programmes in breeding flocks of fowl were mandatory in Member States. Already 15 Member States reported *Salmonella* levels that were below the reduction target of 1% laid down by EU law.
- Listeriosis cases in humans were the same as 2006, although the 20% mortality rate was higher, particularly among vulnerable groups, such as the elderly. *Listeria* was seldom detected above the legal safety limit in ready-to-eat foods, but findings over this limit were most often found in smoked fish, meat products and cheese.



2.2 Scientific highlights

Animal cloning: A complex and evolving issue

As animal cloning advances, the possibility of food products from clones or their offspring could become a commercial reality. Therefore, the European Commission requested an EFSA scientific opinion on the implications of animal cloning on food safety, animal health and welfare, and the environment. EFSA asked its Scientific Committee (SC) to prepare this opinion.

The Scientific Committee based its opinion on published peer reviewed scientific papers, data and other information deemed reliable. It also requested scientific contributions from third parties. In the SC's risk assessment uncertainties were identified due to the limited number of studies available. In particular, knowledge gaps in animal welfare issues were recognised. Only pigs and cattle were considered, as there were insufficient data for other species.

The SC issued its draft opinion for public consultation in January 2008 and received 285 submissions of scientific input from more than 64 parties, including individuals, non-governmental organisations, industry organisations and national assessment bodies. These were considered in finalising the opinion, adopted by the Scientific Committee at its plenary in July 2008.

Some of the key conclusions that emerged included:

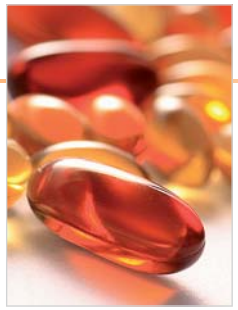
- Significant animal health and welfare issues for a proportion of surrogate mothers and clones were detected. These can be more frequent and severe than for conventionally bred animals.
- The most common technique for cloning animals, Somatic Cell Nucleus Transfer (SCNT), can produce healthy cattle and pig clones, and healthy offspring.
- There is no indication that differences exist in terms of food safety for meat and milk from healthy clones and their offspring, compared with those from conventionally bred animals.
- There was no indication that clones or their offspring would pose any new or additional environmental risks, but the available data were limited.

The Scientific Committee recommended that the health and welfare of clones be studied and monitored throughout their life. Further risk assessments should be performed on food animals other than pigs and cattle that have also been produced via SCNT, when relevant data become available.

In addition, the SC advised that the causes of pathologies and mortality observed in clones be further investigated. The susceptibility of clones and their offspring to disease in conventional husbandry conditions should also be studied.

The European Commission will consider whether any further action or measures are required in relation to cloned animals, their offspring and their products, such as meat and milk.

Cloning attracts a huge amount of interest internationally, for scientific and ethical reasons. Ethics are not part of EFSA's remit and were independently considered by the European Group on Ethics in Science and New Technology.



Health claims: Ensuring informed and meaningful consumer choices

More and more food claiming nutrition and health benefits are showing up on shelves in the EU. Nutritional claims refer to beneficial nutritional properties, such as 'low in fat' or 'high in fibre', or containing 'no added sugar'. A health claim suggests a relationship between the consumption of a given food and health, such as 'bone growth' or 'reduced cholesterol levels'.

Providing guidance and scientific advice

Trust in such claims is essential to help consumers make informed and meaningful dietary choices. Therefore, in December 2006, EU decision-makers adopted a regulation on the use of nutrition and health claims for foods, establishing harmonised rules including the need for products bearing claims to meet certain nutrient profiles. The regulation ensures that any claims made about foods are clear, accurate and substantiated by scientific evidence. The only products that will be allowed to refer to health or nutritional benefits on labels or in marketing will be those that genuinely offer benefits.

EFSA has provided scientific advice to assist the Commission, and Member States, in establishing nutrient profiles. It has also issued guidance for applicants on the submission of health claims. In 2008, its two main tasks in supporting the implementation of the regulation included:

- Providing scientific advice for the establishment of an EU-wide list of permitted 'function' health claims (such as 'calcium is good for you') by January 2010;
- Assessing whether new function health claims based on newly developed scientific evidence, or claims regarding disease risk reduction and child development or health are scientifically reliable and justified.

List of "function" claims in process

The "function" claims under Article 13 of the Regulation are health claims referring to the role of a nutrient or substance in growth, development and function of the body, to psychological and behavioural functions or to slimming and weight control or the reduction of hunger. In July 2008, the European Commission asked EFSA to prepare a scientific opinion on the Community list of permitted health claims, providing EFSA with a draft list of 2,870 main entries. This list was a consolidation of some 44,000 claims supplied by Member States and examined by the Commission. The July list was updated by the Commission in November and December 2008. The updates included further claims submitted by Member States and some amendments to claims previously submitted. Each entry in the list comprises a food component, its health relationship and an example of wording. By the end of 2008, EFSA had received a total of 4185 main health claim entries, taking into account the conditions of use and references available for around 10,000 similar health claims.

Prior to scientific evaluation of the claims, EFSA pre-screened the claims in the draft list. This process identified a number of claims for which further clarification of information is required before evaluation.

In order to streamline the scientific work, the NDA Panel established a number of sub-working groups of scientific experts with expertise in various types of claims. In 2008, EFSA performed



a considerable amount of preparatory work, and aims to meet the deadline of 31 July 2009 for those claims included in the July list and for which sufficient data were received.

40 opinions in 2008

By the end of December 2008, the NDA Panel had also adopted more than 35 opinions on claims related to disease risk reduction and child development or health and five opinions related to claims based on newly developed scientific evidence. EFSA's role is to verify whether the health claims are substantiated by scientific evidence, delivering its opinion within five months from receipt of the completed applications. The opinions have been adopted and published within the deadline specified in the regulation and are now available on EFSA's website. Based on these opinions, the Commission and Member States will decide whether, and how, to authorise these claims for future use in foods.

Rapid response to public health risks

EFSA seeks to be a highly responsive, reliable source of support for decision-makers and risk managers. In 2008 several incidents relating to contaminated food products required urgent response from EFSA to risk managers in order to enable them to act quickly to protect consumers.

The contamination of sunflower oil from Ukraine, the discovery of melamine in imported Chinese milk products and dioxins in Irish pork were all sudden food safety issues that needed quick answers. Within days EFSA provided the necessary advice and assistance to the European Commission. EFSA's Concise European Food Consumption Database, established in 2008, was of great benefit for estimating exposure and responding in a timely manner.

Contamination of sunflower oil

In April 2008, EFSA received a request from the European Commission for rapid advice on sunflower oil imported from Ukraine found to be contaminated with high levels of mineral oil. On the same day, EFSA provided an initial view based on the data available at the time.

After receiving additional analytical data on 21 May, EFSA calculated exposure estimates and updated the initial view. The statement subsequently, published on 27 May, noted that exposure to sunflower oil contaminated with high viscosity mineral oil would be undesirable for human consumption but was not a public health concern in the case at hand. The Commission then imposed special conditions governing the import of the Ukrainian sunflower oil.



Melamine in composite food

In September 2008, some 300,000 cases of infants and children suffering from kidney failure, sometimes resulting in death, were reported in China. It was discovered that milk powder used for infant formula was contaminated with melamine, a substance not allowed in food. It could not be excluded that Chinese composite food products, such as biscuits and chocolate, containing contaminated milk powder might have reached the EU market. In September, the Commission asked EFSA to provide rapid scientific advice on the human health risks and to consider worst-case scenarios in the risk assessment. EFSA developed theoretical exposure scenarios based on European consumption figures of biscuits and chocolate, and the contamination levels reported.

Within a week, EFSA stated that the estimated exposure did not raise concerns for the health of adults in Europe, even in a worst-case scenario. However, children who consume both such biscuits and chocolate potentially could exceed the tolerable daily intake by as much as a factor of three. The statement stressed that it remained unknown to date whether such theoretical, high-level exposure scenarios could occur in Europe.

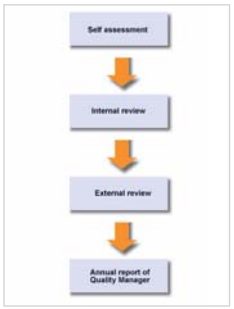
The European Commission immediately adopted interim measures to protect EU consumers.

Dioxins in pork

During routine monitoring of Irish pork in December 2008, elevated levels of polychlorinated biphenyls (PCBs) were found. The European Commission asked EFSA to provide advice on the risk to human health posed by dioxins in pork and the presence of contaminated pork products in composite foods. Working with a limited data set and under the assumption that exposure to the raised levels began in September 2008, EFSA delivered a statement within two days which included several exposure scenarios for both average and high consumers assuming different levels of contamination and proportions of contaminated meat.

EFSA concluded that in the unlikely event of high levels of consumption of Irish pork, all of which was contaminated at the highest recorded concentration of dioxins, throughout the period of the incident, the safety factor built into the tolerable weekly intake would be compromised, but would not necessarily lead to adverse health effects. In the more likely scenario of average consumption levels, of which 10% of the pork was contaminated, for the 90 days the incident occurred, the body burden would increase by approximately 10%. EFSA considered that whilst presence of dioxins in food is undesirable, this increase in body burden was of no concern for this single exposure event.

Due to the rapid delivery of the scientific advice, risk managers – the European Commission and Member States – could discuss and agree on guidelines for measures to be taken on the same day as the release of the EFSA statement.




New review system to enhance quality assurance

Scientific excellence and independence are defining elements of EFSA's work. Both are critical to building and maintaining credibility and public confidence in the European food safety system. EFSA operates within a framework of policies and procedures that ensures best practice and independence at all stages of the scientific process.

Internal and external review

EFSA's Scientific Committee (SC) in 2008 developed a proposal for a review system to assess the quality of scientific outputs through the use of a self-evaluation survey form during the preparation of all scientific opinions and other outputs.

The review system has three modules:

- Self-review during the development of a scientific document. This checks compliance with best practice.
- Internal review by senior scientific staff at EFSA on a random selection of scientific documents.
- External review by high-level independent external experts.

The self and internal review were launched in 2008, and the external review is to be implemented in 2009.

Strengthening the Declaration of Interests system

The independence of scientific experts involved in EFSA's activities, and of all EFSA staff members, is ensured by a mandatory declaration of their independence and a Declaration of Interests (DoI). Following a Management Board decision in 2007 to improve the handling of DoIs, the process has been further strengthened in 2008.

In summer 2008, all scientific experts used by EFSA were asked to make their annual declarations of interests electronically for the first time. The web-based system replaced the paper forms previously provided by experts and EFSA staff. All versions are electronically archived, and can be easily evaluated. Experts are automatically notified when updates are needed and when their declarations are accepted and made public on the EFSA website. Each expert has one annual declaration for all their activities, even if they sit on several working groups for different panels. The new system will also make it easier to update annual declarations, if situations change.

Furthermore, in order to address interests of relevance which are linked to a specific activity, interests are also declared in a Specific Declaration of Interest according to the agenda before the meeting takes place, without prejudice to the oral request for declarations of interest at the beginning of any meeting.

The electronic process that was developed further helps the Authority to screen scientists for potential conflicts of interests. This allows EFSA to steer scientists away from specific discussions, if a conflict of interest has been identified. A revision of the implementation of the DoI policy in October 2008 allows a review procedure in cases where the involvement of an expert in a particular EFSA opinion is called into question.

Together, such new procedures reinforce transparency and clarity for the experts, EFSA and the outside world.

The Advisory Forum meets in Rome, April 2008

3. FOSTERING CLOSER COOPERATION WITH MEMBER STATES

To play its role in Europe's food safety system, EFSA needs to share data, information and best practices, identify emerging risks and communicate coherently on risks in the food chain. To do this in 2008, EFSA continued to build even closer bridges with Member States through bilateral visits, and by working closely together through EFSA's Advisory Forum and with the network of national Focal Points. In addition, grants awarded to the nearly 400 Member State organisations that can help the Authority prepare opinions or collect data, under Article 36 of EFSA's Founding Regulation, and contracts awarded to research organisations to carry out scientific work have also grown. In 2008, EFSA spent €5.5 million on grants and contracts, compared to the €2.9 million spent in 2007.

Advisory Forum: Strengthening pan-European cooperation

Strengthening Europe-wide cooperation

EFSA's Strategy on Cooperation and Networking, which outlines the framework and priorities for cooperation between the Authority and Member States, was developed with the assistance of the Advisory Forum. The Advisory Forum connects EFSA with national food safety authorities in all 27 EU Member States, and has observers from Norway, Iceland, Switzerland and the European Commission. The Forum is at the heart of EFSA's collaborative approach to working with EU Member States in addressing European risk assessment and risk communications issues.

In 2008, members were also implementing a strategy for closer networking which specially focused on sharing scientific information, pooling resources and coordinating work programmes in animal and plant health. Considering EFSA's increasing workload in these fields, the meetings aimed to set priorities and streamline the work of EFSA and national authorities. The Advisory Forum held two kick-off meetings on these topics in 2008.

Animal Health – Targeting rapid data exchange

In May 2008, Advisory Forum representatives on animal health came together for the first time in Parma. At the meeting, representatives became acquainted with past and current activities of EFSA's Animal Health & Welfare Panel (see p.20). In the light of the EU's overall Animal Health Strategy 2007-2013, which provides the framework for the EU's animal health and welfare measures over the next six years, EFSA's goals to improve its integrated approach were discussed. This included a possible procedure for quick, efficient cooperation between EFSA and Member States. Particular effort will be made to accelerate the delivery of scientific advice through rapid data exchange between EFSA and relevant partner organisations, and through mobilising and coordinating EU-wide scientific expertise on issues within EFSA's remit. In this context, EFSA drew attention to its electronic Information Exchange Platform that started in 2008 (see p.41).

First Focal Points meeting in Parma, March 2008

Plant Health – more guidance through EFSA

Twenty national plant health experts of EFSA's Advisory Forum met plant experts from EFSA and the European Commission in October 2008. EFSA and national experts discussed harmonising pest risk assessment (PRA) methodologies and the data needed for different types of risk assessments. Participants agreed that harmonising methodologies was of primary importance as current guidelines were developed under different frameworks.

EFSA's Plant Health Panel listed the current issues and future challenges in pest risk assessment and referred to the guidance document for evaluating PRAs, which it is preparing (see p.27). This document could play a central role in the assessment of plant pests which threaten crop production and biodiversity, and could be of particular use to national authorities across the EU. Participants welcomed EFSA's initiative in putting together an inventory of data sources for pest risk assessments. This inventory will soon be available to national authorities.

Focal Points in all Member States

Focal Points support Advisory Forum members in their tasks, for example, by ensuring scientific information is exchanged between EFSA and Member States, and by raising EFSA's visibility.

In 2008, all 27 EU Member States have established Focal Points and have signed Focal Point agreements. Also Norway has officially nominated its Focal Point and Switzerland is participating as an observer. Three Focal Point meetings were held during the year to coordinate activities and to exchange experiences on the implementation of their tasks. National Focal Points also put substantial effort into setting up national networks. These will aid in collecting and disseminating scientific information that is essential to the Authority's work.

Support for EFSA's expert database

By testing and promoting EFSA's Expert Database (see p.30), the Focal Points played a key role in its successful launch in June, as well as in its further development. All Focal Points disseminated information about the database to their national networks of over 140 institutions and 6,400 experts. With their help, Member States and EFSA have received a continuously growing number of applications from scientific experts, who are ready to assist Member States and EFSA in scientific ad-hoc activities. By year end, over 1,000 experts had submitted their applications.

In addition to helping to promote the expert database, the Focal Points helped promote the call to renew EFSA's Scientific Committee and eight of EFSA's panels by distributing advertising materials, giving presentations within their countries and by linking from their websites to the call on EFSA's website. They also contributed to two seminars aimed at increasing the number of applications of experts from the newer Member States.



Facilitating pan-European information exchange

The Focal Points effectively contributed to the exchange of information about national risk assessment activities between EFSA and Member States.

An electronic tool for sharing scientific information within Member States and EFSA has been developed. This Information Exchange Platform facilitates the timely exchange of information, particularly of documents that are not easily accessible. To develop the platform, the Focal Points formed a working group which first met in May 2008. The platform was launched four months later.

Various questionnaires were also sent by EFSA to the Focal Points requesting assistance in collecting answers to specific questions. For instance, they replied directly or forwarded questionnaires to the relevant experts or institutions in their countries (such as on bee colony mortality). This finally led to further research in collaboration with Member States' organisations (see p.43).

Helping to enhance EFSA's visibility

To make the work of EFSA more widely known in their respective countries, Focal Points developed various supporting materials in close collaboration with members of the Advisory Forum Communications Working Group. For example, they produced newsletters, brochures and leaflets describing the role of Focal Points, their activities and how they cooperate with EFSA. Additionally, Focal Points have organised more than 40 national scientific events and meetings in Member States to raise EFSA's visibility and to explain how to become involved with EFSA.

Making use of national know-how: ESCO working groups

A key priority for EFSA is mobilising scientific resources throughout Europe. Therefore, EFSA established working groups for carrying out scientific cooperation (ESCOs). Participants in ESCO projects include national experts nominated by Member States through the Advisory Forum, members of the Scientific Panels or Scientific Committee, and EFSA's scientific staff.

In 2008, five ESCO working groups (see box p. 42) were actively engaged in scientific areas of particular interest to Member States and EFSA, two of which have completed their tasks. Their work will support the work of EFSA's Panels and Scientific Committee.



ESCO working groups in 2008

Botanicals and botanical preparations

This working group worked on a draft guidance document for the safety assessment of botanicals and botanical preparations.

Emerging risks

This working group is defining 'indicators' for emerging risks, and is developing procedures and best practices to collect, analyse and evaluate data in order to identify emerging risks. It has also recommended research activities in this area.

Setting up EFSA's database of external scientific experts

This working group established a database of external scientific experts (launched on 5 June 2008) to support the activities of EFSA's Scientific Committee, Scientific Panels, and working groups (see p.30).

The analysis of risks and benefits of fortification of food with folic acid

This working group shares experiences and scientific information on folic acid food fortification to prevent neural tube defects.

Fostering harmonised risk assessment approaches in Member States

This working group was set up to better understand how risk assessments are carried out by Member States (see right).

Fostering harmonised risk assessment approaches in Member States

Harmonising risk assessment approaches among Member States is important for EFSA. This harmonisation does not aim at standardising risk assessment methodologies, but at identifying possible discrepancies between the approaches used by different Member States. Harmonising the different approaches used will increase transparency and trust among Member States in each others' risk assessments.

EFSA promoted harmonisation by establishing an ESCO working group to map the institutional framework, organisational structure and procedural aspects of risk assessments in the EU Member States, Norway and Switzerland. For this, in 2008, the working group collected information from the relevant national risk assessment bodies via a questionnaire disseminated by Focal Points. The high response rate was a clear indication of the importance and interest that Member States have in harmonising risk assessment approaches across Europe.

The working group provided EFSA's Executive Director with a detailed report in December 2008 on the survey results, including a set of recommendations. While countries organise their risk assessment activities differently, many of the procedures in place appear to be either in line, or not in conflict, with



procedural guidelines developed and applied by EFSA. One of the challenges in performing scientific risk assessments lies in the lack of available and reliable data. Cooperation in the area of data retrieval, data collection and data sharing shall therefore continue to be a key priority for EFSA and Member States.

To move the harmonisation process forward, the working group recommended the following:

- EFSA and Member States should develop so-called 'country profiles' for a better understanding of the role and competencies of national risk assessment institutions in the different countries;
- Relevant risk assessment outputs of national organisations should be made publicly available;
- Quality management tools should be implemented in the risk assessment process;
- Risk assessment approaches need to be further harmonised within the specific scientific areas.

Increasing scientific assistance

Entrusting scientific and technical tasks through grants and procurement to competent organisations are some of the many ways EFSA cooperates scientifically with Member States. In line with Article 36 of EFSA's Founding Regulation, the Management Board in 2006 approved a list of organisations from which EFSA could request assistance, through calls for proposals. This list is based on nominations from Member States.

In December 2008, the EFSA Management Board approved an updated list of Article 36 organisations. This added 128 newly-designated organisations to the 243 previously on the list – an increase of over 50%, considerably strengthening and widening the scientific expertise and competence available to EFSA. The Focal Points helped EFSA update and maintain this list by identifying appropriate institutions in their countries.

During 2008, EFSA launched 18 Article 36 calls for proposals for scientific support worth €2.2 million in total.

Article 36 calls were launched in 2008 in the following fields:

- Data compilation and analysis, and other preparatory work contributing to the Authority's scientific opinions, in the areas of contaminants, animal health, and feed additives.
- Preparatory work in the development of new and harmonised methodological approaches and guidance documents, in the areas of zoonoses, pesticides, plant health, and animal welfare.
- Data collection and analysis, including the development of databases, for facilitating risk assessment in the areas of pesticides, chemical mixtures, bee health and exposure assessment.

4. RISK COMMUNICATION: INCREASING EFSA'S OUTREACH

EFSA remains committed to communicating its scientific advice actively and widely. The Authority aims to deliver relevant, accurate and meaningful information in a timely fashion to risk managers, risk assessors, scientists, and other stakeholders and interested parties.

Underpinning this approach are the three overarching objectives of the Authority's communication strategy:

- Promoting coherence in its communications through strengthening cooperation with relevant authorities throughout Europe;
- Ensuring dissemination of accessible and understandable messages;
- Raising awareness and understanding of EFSA and its scientific work.

Translating these objectives into action, in 2008, EFSA's communications made significant advances: more proactive, consolidated and strengthened communications reaching EFSA´s target audiences, and through them a broader public. In addition, closer cooperation with national food safety authorities contributed to greater overall coherence in risk communications, leading to consistent messages being heard throughout Europe and beyond.

Coherent risk communication: A clear voice throughout Europe

Networking: strength from diversity

Communicating complex scientific issues can be challenging in itself. Add to this, EFSA's daily role of influencing the influencers, reaching policy makers, risk managers, stakeholders, media and scientists throughout Europe, and the challenge increases. To facilitate outreach in Member States, EFSA works closely with national food safety authorities in Member States. Such cooperation is critical to ensure that Europe's culturally and linguistically diverse population of almost 500 million citizens receives understandable and consistent messages based on independent and evidence-based information.

Here, EFSA's Advisory Forum Communications Working Group (AFWGC) played again an important role, which was further strengthened in 2008. Connecting the communications departments of national food safety agencies, this working group builds a more collaborative and informed approach to the communication of risks in the food chain, and to the promotion of coherence of food safety messages across the EU.

Authorities in Member States were pre-notified of major communications issued by EFSA and were kept abreast of developments in key communications. Examples in 2008 included issues such as TSEs in the milk of small ruminants, animal cloning, nanotechnology, health claims and the safety of food colours. Such collaboration allowed national partners to prepare further communications adapted to the needs of individual consumer groups in their own countries.

Lessons learned and lessons shared from Member States and EU agencies

The working group also strives to develop best practices in risk communications. Learning from past experience is shared through the evaluation of communications initiatives and campaigns carried out by EFSA and national agencies. For example, the group analysed how Austria managed its communications about fruit plants treated with antibiotics to protect against epidemic fire blight, and how animal welfare issues were dealt with in Finland.

Together with several other EU agencies, EFSA also participated in the European Chemicals Agency's (ECHA) workshop on risk communication and the EU agencies' information and communication network.

Rapid response ensuring protection and trust

Fostering overall coherence in public communications on risks, EFSA coordinates its risk communications with risk managers, particularly the European Commission. This is essential during a crisis. Throughout 2008, EFSA responded rapidly to urgent situations such as the discovery of dioxins in Irish pork, the detection of melamine in composite foods containing milk from China or the contamination of Ukrainian cooking oil with mineral oil (see p.36). In the case of dioxins, a scientific statement and the related press release were published only two days after receipt of the Commission's request for urgent scientific assistance.



Widespread coverage

Media coverage in 2008 was 62% higher than in 2007, supported by an almost threefold increase in the number of media interviews given during the year compared to 2007, and a nearly 40% increase in press releases and press statements. This increase was helped by press briefings with Europe's media, such as the joint press briefing held with the European Commission in February on EFSA's opinion on nutrient profiles for products bearing nutritional and health claims. Then in July, the press briefing in Brussels on EFSA's final opinion on animal cloning was attended by over 30 media channels, newspapers and broadcasters. Influential media, ranging from the *Washington Post* to *Le Monde* and the *Financial Times*, as well as international radio and TV stations in several EU countries, all reported on EFSA's opinion on cloning.

Topics such as melamine, nanotechnology, pesticides, GMOs, health claims, and the renewal of Scientific Committee and Panels, also all received media coverage across Europe.

Simplicity: Towards greater understanding

Simplicity is a thread that runs throughout EFSA's communications, aiming to improve overall understanding about EFSA's work and its role in the European food and feed safety system among partners, stakeholders and the public. For example, a graphical workflow of how EFSA develops opinions was introduced on the EFSA website to present EFSA's risk assessment processes clearly and understandably. Also, the topics section – introduced in 2007 and covering themes such as foodborne diseases, animal health and dietary reference values – has been significantly built up with further thematic sections. Here, EFSA's work is presented in an easy-to-understand, cohesive way with a general introduction to the issue, the EU regulatory framework, an explanation of EFSA's scientific work and links to related opinions and other key documents.

Transparent processes

To help implement EFSA's Declarations of Interests (DoIs) policy efficiently, a major upgrade was made in 2008 so that the over 1,200 experts could complete their DoIs electronically, replacing the paper forms (see p.38). A new electronic DoI database has been integrated into the EFSA website, allowing users quick and simple access to up-to-date details of EFSA experts. This contributes to improving EFSA's overall accessibility and transparency.

Strengthening media relations for deepening understanding

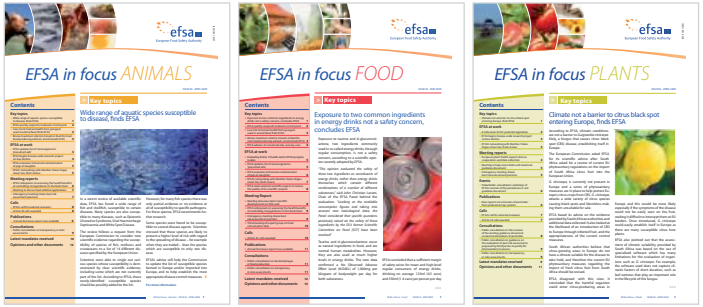
Frequent encounters with a wide variety of media increase and improve understanding of EFSA's work. Wherever EFSA's management was present in 2008 – whether visiting the Hungarian Food Safety Office in Budapest, attending a seminar in Helsinki, or running a workshop in Warsaw – meetings with the press were tied-in with the event. One-on-one interviews, press conferences, media breakfasts, briefings and roundtables were all ways to explain EFSA's mission and work to key national daily and business newspapers, agriculture and consumer magazines, scientific journals, TV and radio stations throughout Europe, as well as international news agencies.

Building global and local recognition

EFSA also created events and targeted material to present itself, its work and its role in the EU food safety system to international, European, regional and local audiences (see "Greater awareness by scientists and stakeholders"). Every other year in May, Parma hosts the CIBUS international food exhibition with 2,400 exhibitors. Here EFSA engaged in dialogue with food industry professionals on its exhibition stand or during roundtable discussions. A joint press conference to launch the week-long Festa dell'Europa was also organised by EFSA in cooperation with the Commune of Parma, the Province of Parma and Europass. Over 2,000 visitors from in and around Parma were attracted to EFSA-organised activities and its exhibition stand. Europass conferences and roundtables in various regional cities also gave EFSA further opportunities to present its work on animal feed safety, nutrition and health claims, and future challenges and emerging risks.

Visibility: A growing presence

In 2008, increasing scientific visibility remained a priority for EFSA. This was achieved through numerous publications and events.





New thematic newsletters launched

EFSA's new thematic family of three easy-to-read newsletters called 'EFSA in focus' was launched in 2008. Aimed primarily at risk managers, risk assessors and policy-makers, each issue focuses on a particular topic (food, animals or plants) providing a snapshot of EFSA's latest activities along with a round-up of events, contracts, mandates and scientific opinions in each area. The newsletters provide stakeholders with a tailored source of information about EFSA's activities in their respective areas of interest. Available in English, French, German and Italian, these issues are distributed widely throughout the Member States, by EFSA and by the Focal Points. They complement the 'Moving together' newsletter on European food safety cooperation that was first published in December 2007.

Greater awareness by scientists and stakeholders

Awareness of EFSA's work was further raised within the international scientific community in 2008. This was achieved through the publication of supplements in leading scientific journals - 'Trends in Food Science and Technology' and 'Preventive Veterinary Medicine' - and through promotion campaigns which supported the renewal of members of EFSA's Scientific Committee and Panels, and awareness of its new Expert Database (see p.30). The national Focal Points helped EFSA promote both campaigns (see p.40).

EFSA's Scientific Colloquia actively engage scientists in stimulating exchanges of information and debate on current scientific issues. In 2008, EFSA hosted two such colloquia. One addressed carcinogenicity of acrylamide, while the other covered assessments of the health benefits of controlling *Campylobacter* in the food chain. Each attracted around 85 scientific experts from EU Member States, the US, New Zealand and Brazil.

The Authority's participation in major international conferences, such as, the International Congress of Plant Pathology, Prion2008, and the European Open Science Forum, were additional opportunities for EFSA to raise its profile globally. At the events, scientists, policymakers, professional societies, non-governmental organisations and industry representatives, as well as the general public were able to visit EFSA exhibitions stands, participate in EFSA lectures and become better acquainted with EFSA and its work.

Visibility in the Member States was further reinforced through joint events organised by EFSA and national food safety authorities, explaining EFSA and Member States' roles and how they cooperate. In 2008, EFSA was involved in conferences with its relevant institutions in Denmark, Hungary, France, The Netherlands, Slovenia and Norway.

Steady growth

In 2008, the EFSA website, the Authority's main communication channel, registered 2.1 million visits, an over 40% rise compared to 2007. EFSA's other communications products similarly rose, compared to the year before - newsletter subscribers, media coverage, media inquiries, interviews and events all registered significant increases in 2008 (see table right).

Communications indicators

Indicators	2008	Increase compared to 2007
Web visits	2.1 m	+43 %
Newsletter subscribers (EFSA Highlights)	21,140	+19 %
Media coverage	11,652	+62%
Media inquiries	676	+59%
Interviews	123	+180%
Events	18	+29%
Publications	25	+47%

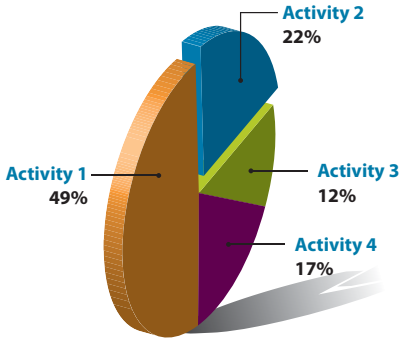


III. FINANCIAL REPORT



In 2008, the €66.4 million available budget (including the pre-accession programme in 2008) had an increased execution rate of 97% (2007: 91%).

Budget by activity



Activity 1: Provide scientific opinions and advice to the European Commission, European Parliament and Member States

Activity 2: Enhance risk assessment methodologies in Europe

Activity 3: Communicate scientific advice and dialogue with interested parties

Activity 4: Manage and provide administrative support

Almost half of the executed budget (€30.2 million, 47%) represented personnel expenses, which were committed to the level of 98%. Infrastructure – building, equipment and miscellaneous operational expenditures – accounted for 18% of the executed budget (€11.8 million). Its 99% execution rate came very close to the planned spending level. Operational expenditures include scientific contracts or subventions, external relations and risk communications, and their related meeting costs. They represent 35% (€22.2 million) of the executed budget. Operational expenditure was up to 94%. The slight underspend was due to less being spent on scientific and communication activities than anticipated.

The activity-based budgeting shows that, like in 2007, about two-thirds of the budget was allocated to the scientific work of EFSA. The largest share (49%) belonged to activities providing scientific opinions and advice to the European Commission, the European Parliament and Member States. 22% was dedicated to activities to enhance risk assessment methodologies in Europe.

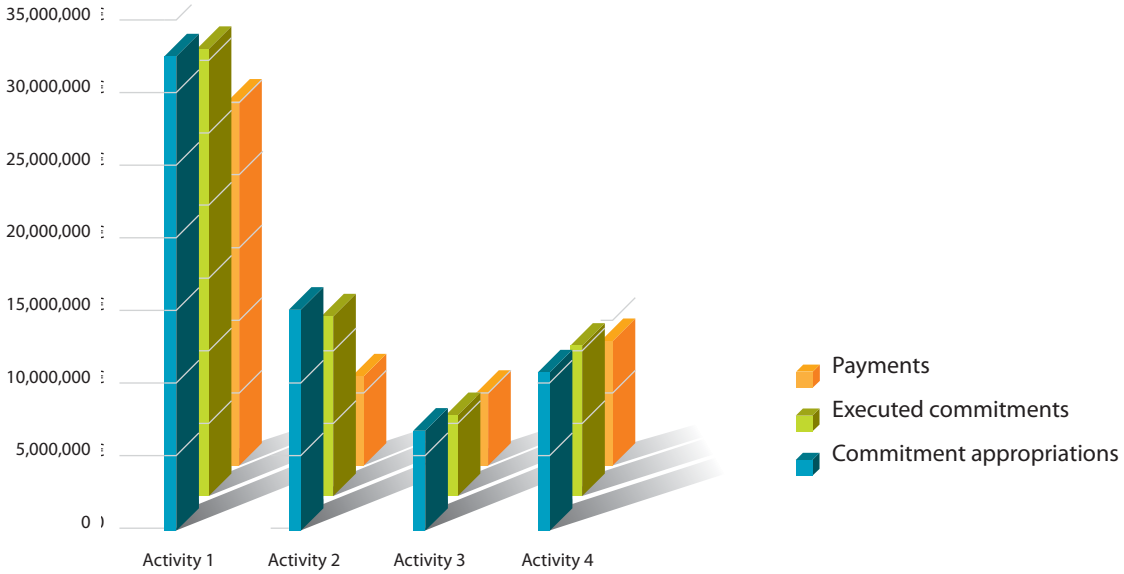
Activities related to communicating scientific advice and dialogue between interested parties accounted for 12% of the executed budget. Activities related to management and providing administrative support slightly decreased to 17% (2007: 19%). The payment rate stabilised at 73% (2007: 74%) with €48.7 million of the total appropriations being paid. €15.5 million or 23% will be carried forward for payment in 2009. ▮

Budget by activity

Activity	2008 Execution (M€)	2008 Budget (M€)	Execution Budget
1	31.3	32.3	97%
2	14.3	14.8	97%
3	7.6	8.1	93%
4	11	11.1	99%
TOTAL	64.2	66.4	97%

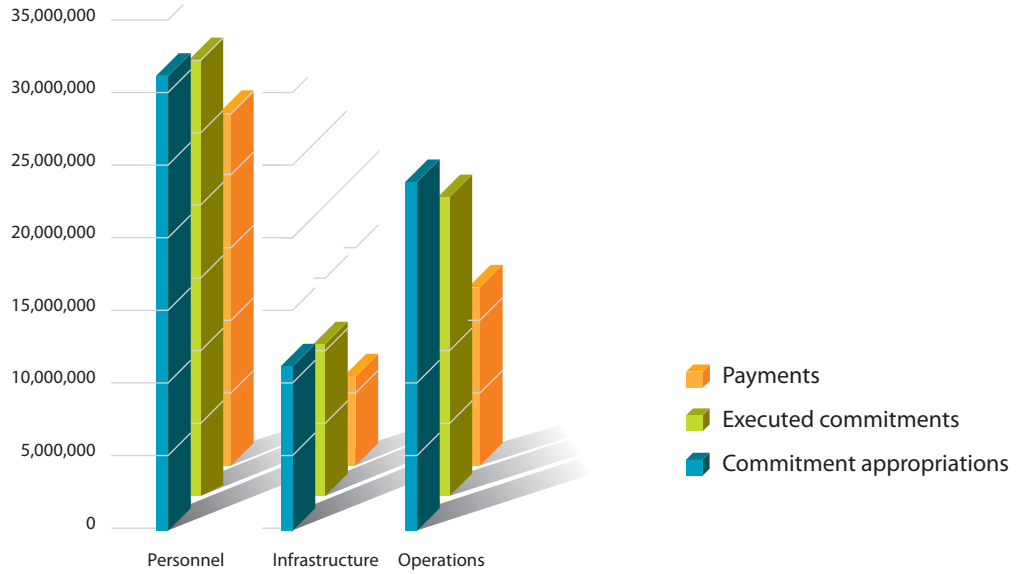
Activity Based Budgeting execution

Activity	Initial Appropriations (M€)	Appropriations (M€)	Commitments (M€)	% Committed	Payments (M€)	% Paid	RAL (M€)
Activity 1	32.7	32.3	31.3	97%	25.4	78%	5.9
Activity 2	13.5	14.8	14.3	97%	8.7	59%	5.6
Activity 3	9.5	8.1	7.6	93%	5.5	68%	2.0
Activity 4	10.7	11.1	11.0	99%	9.1	82%	1.9
TOTAL	66.4	66.4	64.2	97%	48.7	73%	15.5





Budget execution



Title	Initial Appropriations (M€)	Appropriations (M€)	Commitments (M€)	% Committed	Payments (M€)	% Paid	RAL (M€)
Personnel	34.1	30.9	30.2	98%	28.9	94%	1.3
Infrastructure	8.7	11.9	11.8	99%	6.9	58%	4.9
Operations	23.6	23.6	22.2	94%	12.9	55%	9.3
Pre-accession	0.5	0.5	0.4	81%	0.3	59%	0.1
TOTAL	66.4	66.4	64.2	97%	48.7	73%	15.5

IV. EFSA PROACTIVELY FACES THE FUTURE



While EFSA's primary objective is to provide a robust scientific evidence base to underpin consumer protection and ensure the safety of Europe's food and feed chain, it must operate in a world of increasing complexity. Scientific and technological innovations, global trade and travel, climate change, aging populations and changes in consumer expectations and perceptions all impact on EFSA's work, necessitating ongoing evaluation.

As many of today's food-related risks are global in nature, it is also vitally important that EFSA takes a stronger and more decisive role in the international risk assessment arena, and contributes to the scientific work needed to address global risks.

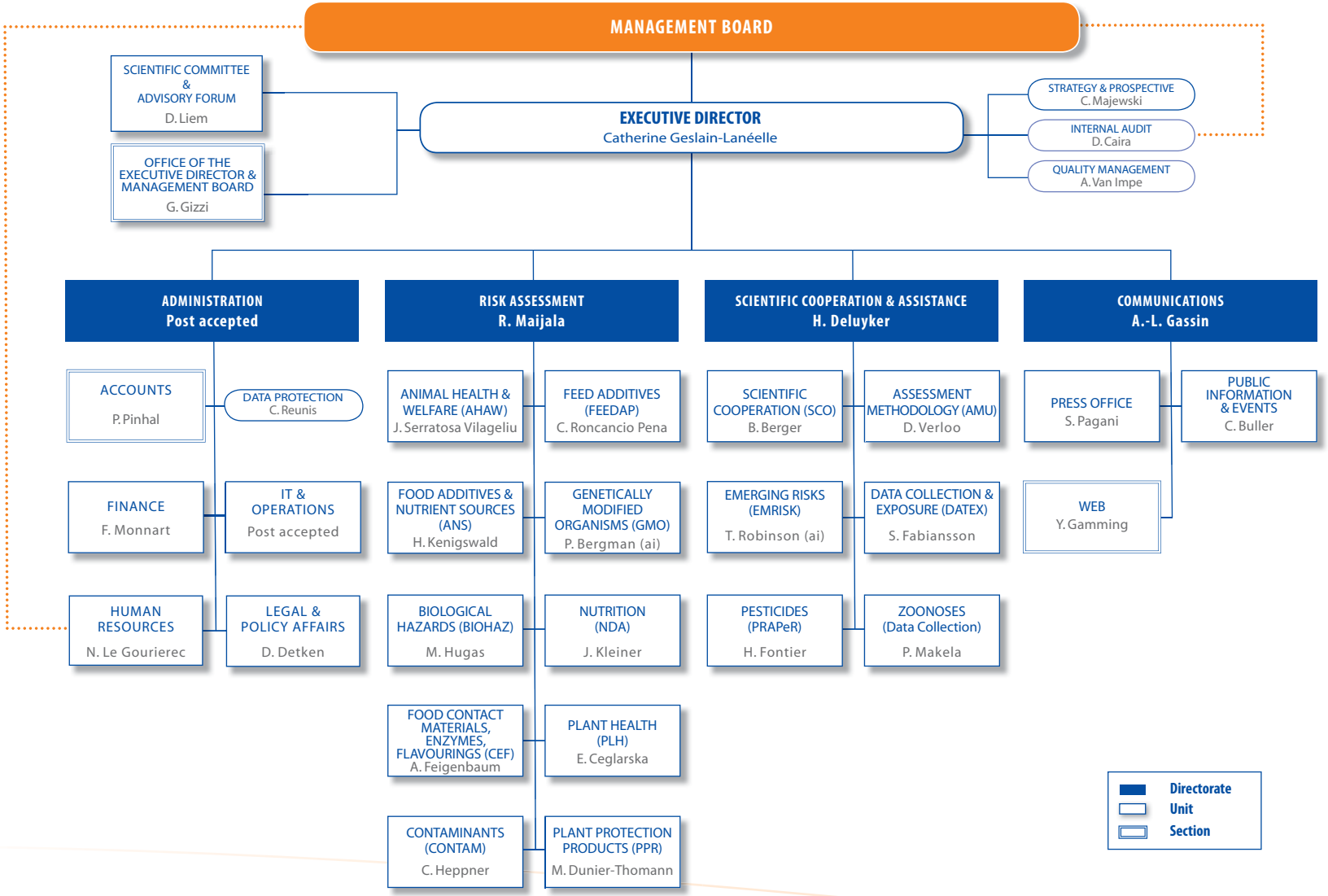
Consequently, in 2008, EFSA took stock and looked ahead. In December, EFSA's Management Board adopted a Strategic Plan for the period 2009-2013, which identified and analysed key drivers of change. This enabled the Authority to map out its future direction, priorities and organisation for the medium to long term. The Strategic Plan also forms the basis for EFSA's annual work plans. Therefore, looking to 2009, EFSA aims to:

- Fortify its integrated approach from farm to fork, drawing on its outstanding multidisciplinary expertise;
- Strengthen its capacity to identify emerging risks;
- Ensure the effective delivery of timely, high-quality scientific advice;
- Enhance the excellence of its scientific output through quality assurance measures comprising self, internal and external reviews;
- Further progress its Strategy for Cooperation and Networking, including harmonising approaches across the EU and consolidating EU-wide data collection;
- Implement its strategic approach to its international activities.

However, providing excellent science and advice to risk managers is only one part, albeit an essential part, of EFSA's work. Reinforcing credibility and trust in EFSA, and the EU food safety system through effective and coherent risk communication with partners and stakeholders will remain a fundamental priority in 2009 and beyond.

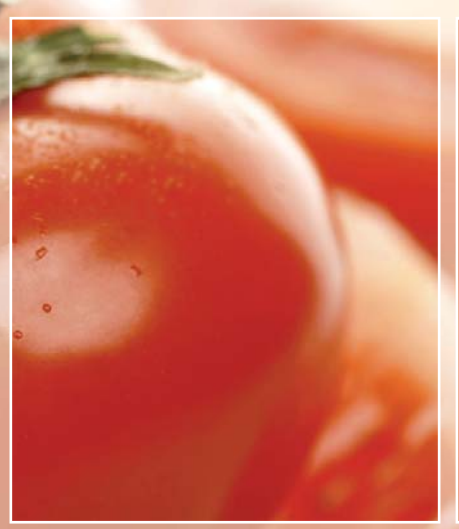
In conclusion, after the growth and development of previous years, EFSA has now matured into an organisation well prepared for the challenges of tomorrow.

ANNEX I - EFSA 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
Post accepted
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
Post accepted
HUMAN RESOURCES
N. Le Gourierec
LEGAL & POLICY AFFAIRS
D. Detken
ANIMAL HEALTH & WELFARE (AHAW)
J. Serratosa Vilageliu
FEED ADDITIVES (FEEDAP)
C. Roncancio Pena
FOOD ADDITIVES & NUTRIENT SOURCES (ANS)
H. Kenigswald
GENETICALLY MODIFIED ORGANISMS (GMO)
P. Bergman (ai)
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 (ai)
DATA COLLECTION & EXPOSURE (DATEX)
S. Fabiansson
PESTICIDES (PRAPeR)
H. Fontier
ZOONOSES (Data Collection)
P. Makela
PRESS OFFICE
S. Pagani
PUBLIC INFORMATION & EVENTS
C. Buller
WEB
Y. Gamming
Directorate
Unit
Section


Annex II

ADI	Acceptable Daily Intake
AFC	Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods
Afssa	Agence Française de Sécurité des Aliments
AFWGC	Advisory Forum Communications Working Group
AGES	Austrian Agency for Health and Food Safety
AHAW	Scientific Panel on Animal Health and Welfare
AMR	Antimicrobial Resistance
AMU	Assessment Methodology Unit
ANS	Scientific Panel on Food Additives and Nutrient Sources added to Food
BIOHAZ	Scientific Panel on Biological Hazards
BPA	Bisphenol A
BSE	Bovine Spongiform Encephalopathy
BVE	Federation of the German Food and Drink Industry
CEF	Scientific Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CCD	Colony Collapse Disorder
CFRI	Hungarian Central Food Research Institute
CIBUS	International Food Exhibition, Parma
CONTAM	Scientific Panel on Contaminants in the Food Chain
DATEX	Data Collection and Exposure Unit
DG SANCO	Health and Consumers Directorate-General
DRV(s)	Dietary Reference Value(s)
DoI	Declaration of Interests
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMEA	European Medicines Agency
EMM	Europe Media Monitor
EMRISK	Emerging Risks Unit
ESCO	European Scientific Cooperation
EU	European Union
FAO	United Nations Food and Agriculture Organization
FEEDAP	Scientific Panel on Additives and Products or Substances used in Animal Feed Food Pest Risk Analysis
GM	Genetically modified
GMO(s)	Genetically modified organism(s)
FGE	Flavouring Groups Evaluations
JRC	Joint Research Centre
MRL(s)	Maximum Residue Level(s)
MRSA	Methicillin-Resistant *Staphylococcus aureus*
NDA	Scientific Panel on Dietetic Products, Nutrition and Allergies
OIE	World Organisation for Animal Health
PCB(s)	Polychlorinated Biphenyls
PLH	Scientific Panel on Plant Health
PPR	Scientific Panel on Plant Protection Products and their Residues
PRA	Pest Risk Analysis
PRAPeR	Pesticide Risk Assessment Peer Review Unit
RA	Risk Assessment Directorate
RASFF	European Commission's Rapid Alert System for Food and Feed
SC	Scientific Committee
SCA	Scientific Cooperation and Assistance Directorate
SCNT	Somatic Cell Nucleus Transfer
SCO	Scientific Cooperation Unit
TDI	Tolerable Daily Intake
TSE	Transmissible Spongiform Encephalopathy
UK	United Kingdom
US	United States
WHO	World Health Organization



Annex III

Scientific Committee (SC)

Scientific Opinions

Scientific Opinion of the Scientific Committee on a request from the European Commission on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals.
Adopted: 15 July 2008 Published: 24 July 2008

Guidance Documents

Draft Guidance document of the Scientific Committee on the "Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements".
Adopted: 22 April 2008 – for further testing by the ESCO Working Group on Botanicals Published: 20 June 2008

Scientific or technical reports

Safety assessment of botanicals and botanical preparations intended for use as ingredients in food supplements. Report back on comments received during the public consultation and how they have been addressed by the EFSA Scientific Committee.
Issued on 10 April 2008

Public comments received during public consultation of EFSA draft scientific opinion on Food Safety, Animal Health and Welfare and Environmental Impact of Animals derived from Cloning by Somatic Cell Nucleus Transfer (SCNT) and their Offspring and Products Obtained from those Animals (compilation).
Issued on 24 July 2008

Outcome of Public Consultation on the EFSA Draft Animal Cloning Opinion.
Issued on 24 July 2008

Interim Report of the ESCO Working Group on Botanicals and Botanical Preparations.
Adopted by the Advisory Forum on 21 November 2008 and by the Scientific Committee on 1 December 2008

ESCO Report prepared by the EFSA Scientific Cooperation Working Group on Fostering Harmonised Risk Assessment Approaches in Member States.
Issued on 3 December 2008

Food additives, flavourings, processing aids and materials in contact with food (AFC)

Scientific Opinions

Vanadium citrate, bismaltolato oxo vanadium and bsiglycinato oxo vanadium added for nutritional purposes to foods for particular nutritional uses and foods (including food supplements) intended for the general population and vanadyl sulphate, vanadium pentoxide and ammonium monovanadate added for nutritional purposes to food supplements	
Adopted: 29 January 2008	Published: 26 February 2008
Use of lycopene as a food colour	
Adopted: 30 January 2008	Published: 14 April 2008
18th list of substances for food contact materials	
Adopted: 31 January 2008	Published: 19 February 2008
Flavouring Group Evaluation 34: One tetrahydroquinoline derivative from chemical group 28	
Adopted: 31 January 2008	Published: 27 August 2008
Flavouring Group Evaluation 69: Consideration of aromatic substituted secondary alcohols, ketones and related esters evaluated by JECFA (57th meeting) structurally related to aromatic ketones from chemical group 21 evaluated by EFSA in FGE.16	
Adopted: 31 January 2008	Published: 10 November 2008
Flavouring Group Evaluation 76: Consideration of sulphur-containing heterocyclic compounds evaluated by JECFA (59th meeting) structurally related to thiazoles, thiophene, thiazoline and thienyl derivatives from chemical group 29, miscellaneous substances from chemical group 30 evaluated by EFSA in FGE.21	
Adopted: 31 January 2008	Published: 25 November 2008
FGE.10 Rev1: Aliphatic primary and secondary saturated and unsaturated alcohols and esters containing an additional oxygenated functional groups and lactones from chemical group 9, 13, and 30	
Adopted: 31 January 2008	To be published in 2009
FGE.18 Rev1: Aliphatic, alicyclic and aromatic saturated and unsaturated tertiary alcoholc and esters with esters containing tertiary alcohols. Esters may contain any acid component. From chemical group 6	
Adopted: 31 January 2008	To be published in 2009

→ → → AFC continued

FGE.64 aliphatic acyclic diols, triols, and related agents evaluated by JECFA Adopted: 31 January 2008 To be published in 2009
FGE.45 One tertiary amine from chemical group 28 Adopted: 31 January 2008 To be published in 2009
FGE.74 Simple Aliphatic Sulfides and Thiols evaluated by JECFA Adopted: 31 January 2008 To be published in 2009
FGE.77 Pyridines evaluated by JECFA Adopted: 31 January 2008 To be published in 2009
Opinion on mixed tocopherols, tocotrienol tocopherol and tocotrienols as sources for vitamin E added as a nutritional substance in food supplements Adopted: 22 February 2008 Published: 10 March 2008
Flavouring Group Evaluation 73: Consideration of alicyclic primary alcohols, aldehydes, acids and related esters evaluated by JECFA (59th meeting) structurally related to primary saturated or unsaturated alicyclic alcohol, aldehyde and esters evaluated by EFSA in FGE.12 Adopted: 6 March 2008 Published: 10 November 2008
FGE.46 Ammonia and two ammonium salts from chemical group 30 Adopted: 6 March 2008 To be published in 2009
FGE.78 Hydrocarbons evaluated by JECFA Adopted: 6 March 2008 To be published in 2009
Flavouring Group Evaluation 88: Consideration of Phenol and Phenol Derivatives Adopted: 6 March 2008 Published: 6 November 2008
Asessment of the results of the study by McCann et al. (2007) on the effect of some colours and sodium benzoate on children's behaviour Adopted: 7 March 2008 Published: 14 March 2008

→ → → AFC continued

Use of rosemary extracts as a food additive	
Adopted: 7 March 2008	Published: 12 June 2008
Flavouring Group Evaluation 84: Consideration of Anthranilate derivatives evaluated by JECFA	
Adopted: 1 April 2008	Published: 6 November 2008
Flavouring Group Evaluation 75: Consideration of tetrahydrofuran derivatives and a furanone derivative evaluated by JECFA (63rd meeting) structurally related to tetrahydrofuran derivatives evaluated by EFSA in FGE.33	
Adopted: 1 April 2008	Published: 15 December 2008
Flavouring Group Evaluation 33: Six Tetrahydrofuran Derivatives from Chemical Groups 13, 14, 16 and 26	
Adopted: 1 April 2008	Published: 15 December 2008
Flavouring Group Evaluation 25: Aliphatic and aromatic hydrocarbons from chemical group 31	
Adopted: 1 April 2008	Published: 16 December 2008
Flavouring Group Evaluation 83: Consideration of 6-keto-1,4-dioxane derivatives substances evaluated by JECFA	
Adopted: 1 April 2008	Published: 16 December 2008
Flavouring Group Evaluation 80: Consideration of alicyclic, alicyclic-fused and aromatic-fused ring lactones evaluated by JECFA (61st meeting) structurally related to a aromatic lactone evaluated by EFSA in FGE.27	
Adopted: 1 April 2008	Published: 16 December 2008
Flavouring Group Evaluation 9, Revision 1: Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical groups 8 and 30, and an ester of a phenol carboxylic acid from chemical group 25	
Adopted: 1 April 2008	Published: 5 January 2008
FGE.56 - 22 monocyclic and bicyclic secondary alcohols, ketones and related esters evaluated by JECFA	
Adopted: 01 April 08.	To be published in 2009

→ → → AFC continued

FGE.60 Eugenol related substances by JECFA	
Adopted: 1 April 08.	To be published in 2009
FGE.32 Phenol derivatives containing ring-alkyl1, ring-alkoxy, and side-chains with an oxygenated functional group (Flavonoids)	
Adopted: 1 April 08.	To be published in 2009
FGE.82 Epoxides evaluated by JECFA	
Adopted: 1 April 08.	To be published in 2009
FGE.04: 2-Ethylhexyl derivatives from chemical group 2	
Adopted: 03 April 2008	To be published in 2009
19th list of substances for food contact materials	
Adopted: 22 April 2008 (by written procedure)	Published: 28 April 2008
Opinion on certain bisglycinates as sources of copper, zinc, calcium, magnesium and glycinate nicotinate as source of chromium in foods intended for the general population (including food supplements) and foods for particular nutritional uses	
Adopted: 22 May 2008	Published: 9 June 2008
Safety of aluminium from dietary intake	
Adopted: 22 May 2008	Published: 15 July 2008
Camphor in flavourings and other food ingredients with flavouring properties	
Adopted: 22 May 2008	Published: 30 July 2008
Flavouring Group Evaluation 85: Consideration of miscellaneous nitrogen-containing substances evaluated by JECFA	
Adopted: 22 May 2008	Published: 22 September 2008
Flavouring Group Evaluation 31: One Epoxide from Chemical Group 32	
Adopted: 22 May 2008	Published: 14 November 2008

→ → → AFC continued

Flavouring Group Evaluation 86: Consideration of aliphatic and aromatic amines and amides evaluated by JECFA	
Adopted: 22 May 2008	Published: 28 November 2008
Flavouring Group Evaluation 47: Bicyclic secondary alcohols, ketones and related esters from chemical group 8	
Adopted: 22 May 2008	Published: 4 December 2008
Flavouring Group Evaluation 87: Consideration of bicyclic secondary alcohols, ketones and related esters evaluated by JECFA (63rd meeting) structurally related to bicyclic secondary alcohols, ketones and related esters evaluated by EFSA in FGE.47	
Adopted: 22 May 2008	Published: 16 December 2008
Flavouring Group Evaluation 36: Two triterpene glycosides from the priority list	
Adopted: 22 May 2008	Published: 18 December 2008
Flavouring Group Evaluation 49: Xanthin alkaloids from the Priority list from chemical group 30	
Adopted: 22 May 2008	Published: 5 January 2009
Flavouring Group Evaluation 35: Three quinine salts from the Priority list from chemical group 30	
Adopted: 22 May 2008	Published: 5 January 2009
FGE.29 - A : Substance from the Priority list: Vinylbenzene	
Adopted: 22 May 2008	To be published in 2009
FGE.86 Aliphatic and aromatic amines and amides evaluated by JECFA	
Adopted: 22 May 2008	To be published in 2009
Safety in use of the treatments for the removal of manganese, iron and arsenic from natural mineral waters by oxyhydroxide media	
Adopted: 12 June 2008	Published: 16 September 2008
Flavouring Group Evaluation 17, Revision 1: Pyrazine derivatives from chemical group 24	
Adopted: 30 June 2008	Published: 25 September 2008

→ → → AFC continued

Opinion on Pyridoxal 5'-phosphate as a source for vitamin B6 added for nutritional purposes in food supplements	
Adopted: 8 July 2008	Published: 21 July 2008
Magnesium L-lysinate, calcium L-lysinate, zinc L-lysinate as sources for magnesium, calcium and zinc added for nutritional purposes in food supplements	
Adopted: 8 July 2008	Published: 21 July 2008
Coumarin in flavourings and other food ingredients with flavouring properties	
Adopted: 8 July 2008	Published: 7 October 2008
Selenium-enriched yeast as source for selenium added for nutritional purposes in foods for particular nutritional uses and foods (including food supplements) for the general population	
Adopted: 9 July 2008	Published: 22 July 2008
Toxicokinetics of Bisphenol A	
Adopted: 9 July 2008	Published: 23 July 2008
Flavouring Group Evaluation 48: Aminoacetophenone from chemical group 33	
Adopted: 9 July 2008	Published: 17 September 2008
Flavouring Group Evaluation 44: cis-2-Heptyl-cyclopropanecarboxylic Acid from Chemical Group 30	
Adopted: 9 July 2008	Published: 25 September 2008
Flavouring Group Evaluation 38: 3-Butenyl isothiocyanate	
Adopted: 9 July 2008	Published: 31 October 2008
FGE.66 Furfuryl alcohol and related flavouring agents evaluated by JECFA	
Adopted: 9 July 2008	To be published in 2009
FGE.218: Alpha, beta-Unsaturated aldehydes and precursors from subgroup 4.2 of FGE.19: Furfural derivatives	
Adopted: 9 July 2008	To be published in 2009

Panel Statement	**Possibility to assess the safety of nutrient sources added for nutritional purposes in food supplements and the bioavailability of the nutrients from these sources based on the supporting dossiers** Adopted: 1 April 2008 Published: 28 April 2008
Guidance Document	**Guidelines on the submission and preparation of applications for the safety evaluation of recycling processes for plastics intended for food contact** Adopted: 22 May 2008 Published: 01 July 2008

Food additives and nutrient sources added to food (ANS)

Scientific Opinions	**Pantethine as source for pantothenic acid added as a nutritional substance in food supplements** Adopted: 23 September 2008 Published: 13 November 2008
	Calcium sulphate for use as a source of calcium in food supplements Adopted: 24 September 2008 Published: 6 October 2008
	Benfotiamine, thiamine monosphate chloride and thiamine pyrophosphate chloride, as sources of vitamin B1 added for nutritional purposes to food supplements Adopted: 24 September 2008 Published: 13 November 2008
	5'-deoxyadenosylcobalamin and methylcobalamin as sources for Vitamin B12 added as a nutritional substance in food supplements Adopted: 25 September 2008 Published: 10 October 2008
	Calcium L-threonate for use as a source of calcium in food supplements Adopted: 24 October 2008 Published: 24 November 2008

→ → → ANS continued

Panel Statements

Mixture of chromium di- and tri-nicotinate as a source of chromium added for nutritional purposes in food supplements and in foods for particular nutritional uses Adopted: 26 November 2008 Published: 18 December 2008
Sodium monofluorophosphate as a source of fluoride added for nutritional purposes to food supplements Adopted: 27 November 2008 Published: 11 December 2008 , EFSA-Q-2006-295
Magnesium aspartate, potassium aspartate, magnesium potassium aspartate, calcium aspartate, zinc aspartate, and copper aspartate as sources for magnesium, potassium, calcium, zinc, and copper added for nutritional purposes to food supplements Adopted: 27 November 2008 Published: 18 December 2008
Calcium fluoride as a source of fluoride added for nutritional purposes to food supplements Adopted: 27 November 2008 Published: 17 December 2008
Calcium L-methionate, magnesium L-methionate and zinc mono-L-methionine sulphate added for nutritional purposes to food supplements Adopted: 17 December 2008 Published: 29 January 2009
Inability to assess the safety of stannic chloride added for nutritional purposes as a source of tin in food supplements and the bioavailability of tin from this source based on the supporting dossier Adopted: 26 November 2008 Published: 10 December 2008
Inability to assess the safety of a silver hydrosol added for nutritional purposes as a source of silver in food supplements and the bioavailability of silver from this source based on the supporting dossier Adopted: 26 November 2008 Published: 17 December 2008

Food contact materials, enzymes, flavourings and processing aids (CEF)

Scientific Opinions

20th list of substances for food contact materials Adopted: 25 September 2008 Published: 9 October 2008
FGE.202 3-Alkylated aliphatic acylic alpha, beta unsaturated aldehydes and precursors with or without additional double-bonds from chemical subgroup 1.1.2 of FGE.19 Adopted: 25 September 2008 To be published in 2009
FGE.201 2-Alkylated aliphatic acylic alpha, beta unsaturated aldehydes and precursors with or without additional double-bonds from chemical subgroup 1.1.2 of FGE.19 Adopted: 25 September 2008 To be published in 2009
21st list of substances for food contact materials Adopted: 27 November 2008 Published: 16 December 2008
FGE.213 Alpha,beta-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.7 of FGE.19 Adopted: 27 November 2008 To be published in 2009
FGE.212 Alpha,beta-Unsaturated alicyclic ketones and precursors from chemical subgroup 2.6 of FGE.19 Adopted: 27 November 2008 To be published in 2009
FGE.203 Alpha,beta-Unsaturated aldehydes and precursors from chemical subgroup 1.1.4 of FGE.19 with two or more conjugated double-bonds and with or without additional non-conjugated double-bonds Adopted: 27 November 2008 To be published in 2009
FGE.216 Alpha,beta-Unsaturated aldehydes and precursors from chemical subgroup 3.3 of FGE.19: 2-Phenyl-2-alkenales Adopted: 27 November 2008 To be published in 2009
FGE.214 Alpha,beta-Unsaturated aldehydes and precursors from chemical subgroup 3.1 of FGE.19: Cinnamyl derivatives Adopted: 27 November 2008 To be published in 2009

→ → → CEF continued

Panel Statements

Genotoxicity Test Strategy for Substances belonging to Subgroups of FGE.19
Adopted: 31 October 2008 Published: 11 December 2008

List of alpha, beta-Unsaturated Aldehydes and Ketones representative of FGE.19 substances for Genotoxicity Testing
Adopted: 27 November 2008 Published: 11 December 2008

EFSA Statement

Statement of EFSA on a study associating bisphenol A with medical disorders. Prepared by the Unit on food contact materials, enzymes, flavourings and processing aids (CEF) and the Unit on Assessment Methodology (AMU)
Adopted: 22 October 2008 Published: 24 October 2008

Animal health and welfare (AHAW)

Scientific Opinions

Tuberculosis testing in deer
Adopted: 31 January 2008 Published: 11 March 2008

Scientific opinion on Avian Influenza
Adopted: 07 May 2008 Published: 05 June 2008

Scientific opinion on bluetongue virus
Adopted: 19 June 2008 Published: 16 July 2008

Animal welfare aspects of husbandry systems for farmed fish - Atlantic salmon
Adopted: 19 June 2008 Published: 10 July 2008

Scientific opinion on risk of bluetongue transmission during transit
Adopted: 11 September 2008 Published: 18 November 2008

	Request for a scientific opinion on susceptible species with regard to the diseases listed in Annex IV part II to Directive 2006/88/EC Adopted: 11 September 2008 Published: 13 November 2008
	Animal welfare aspects of husbandry systems for farmed fish - European eal Adopted: 11 September 2008 Published: 20 October 2008
	Animal welfare aspects of husbandry systems for farmed fish - Trout species Adopted: 11 September 2008 Published: 20 October 2008
	Animal welfare aspects of husbandry systems for farmed fish - Sea bass and gilthead seabream Adopted: 22 October 2008 Published: 26 November 2008
	Animal welfare aspects of husbandry systems for farmed fish - Carp species Adopted: 22 October 2008 Published: 17 December 2008
	Animal health safety of fresh meat derived from pigs vaccinated against Classic Swine Fever Adopted: 11 December 2008 Published: 30 January 2009
	Control and eradication of Classic Swine Fever in wild boar Adopted: 11 December 2008 Published: 30 January 2009
Panel Statement	**Statement of the AHAW panel on usage of definitions for "disease", "susceptible disease" and "vector" and related issues in aquaculture** Adopted at the XXXIV plenary meeting - 6-7 May 2008

Biological hazards (BIOHAZ)

Scientific Opinions

Hydrolysis on farm of dead pigs Adopted:23 January 2008	Published: 05 February 2008
Hydrolysis on farm of dead rabbits Adopted: 23 January 2008	Published: 05 February 2008
Quantitative microbiological risk assessment on *Salmonella* in meat Adopted: 24 January 2008	Published: 18 February 2008
Assessment of the possible effect of the four antimicrobial treatment substances on the emergence of antimicrobial resistance Adopted: 06 March 2008	Published: 02 April 2008
Consumption of beef tongue Adopted: 17 April 2008	Published: 29 April 2008
Microbiological risk assessment in feedingstuffs for food producing animals Adopted: 05 June 2008	Published: 15 July 2008
Request for an assessment on the risk related to Transmissible Spongiform Encephalopathies (TSEs) from carcasses of ovine and caprine animals below 6 months of age intended for human consumption Adopted: 05 June 2008	Published: 15 July 2008
Foodborne antimicrobial resistance as a biological hazard Adopted: 09 July 2008	Published: 04 August 2008
Overview of methods for source attribution for human cases of foodborne microbiological hazards Adopted: 09 July 2008	Published: 21 July 2008

	Risk for human and animal health related to the revision of the BSE monitoring regime in some Member States Adopted: 10 July 2008 Published: 17 July 2008
	Further consideration of age-related parameters on the Risk for Human and Animal Health related to the revision of the BSE Monitoring regime in some Member States Adopted: 10 July 2008 Published: 17 July 2008
	TSE infectivity in milk products from small ruminants Adopted: 22 October 2008 Published: 06 November 2008
	Food Safety aspects of Animal welfare of husbandry systems for farmed fish Adopted: 23 October 2008 Published: 18 December 2008
	Maintenance for the QPS list for microorganisms used for feed and food production Adopted: 10 December 2008 Published: 16 December 2008
Scientific or technical reports	**Scientific and technical support in the interpretation and consideration of certain aspects of the conclusions of the Opinion of 8 March 2007 of the Scientific Panel on Biological Hazards on certain aspects related to the risk of Transmissible Spongiform Encephalopathies (TSEs) in ovine and caprine animals** Adopted: 24 January 2008 Published: 13 February 2008
	Prospective challenges facing the EFSA Biological Hazards Panel Adopted: 23 October 2008 Published: 19 December 2008
Other scientific documents	**Addition of nitrites in meat products** Published: 10 April 2008
	EFSA reply to the European Commission's request for clarification on the basis of Regulation (EC) 178/2002, Article 30 (4) Published: 25 February 2008

Contaminants in the food chain (CONTAM)

Scientific Opinions

Cross-contamination of non-target feedingstuffs by decoquinate authorised for use as a feed additive	
Adopted: 19 February 2008	Published: 21 April 2008
Cross-contamination of non-target feedingstuffs by halofuginone hydrobromide authorised for use as a feed additive	
Adopted: 19 February 2008	Published: 21 April 2008
Cross-contamination of non-target feedingstuffs by robenidine authorised for use as a feed additive	
Adopted: 19 February 2008	Published: 21 April 2008
Mercury as undesirable substance in animal feed	
Adopted: 20 February 2008	Published: 09 April 2008
Cross-contamination of non-target feedingstuffs by nicarbazin authorised for use as a feed additive	
Adopted: 09 April 2008	Published: 30 April 2008
Tropane alkaloids (from *Datura* sp.) as undesirable substances in animal feed	
Adopted: 09 April 2008	Published: 05 August 2008
Cross-contamination of non-target feedingstuffs by diclazuril authorised for use as a feed additive	
Adopted: 30 May 2008	Published: 30 May 2008
Ricin (from Ricinus communis) as undesirable substances in animal feed	
Adopted: 10 June 2008	Published: 12 September 2008
Theobromine as undesirable substances in animal feed	
Adopted: 10 June 2008	Published: 09 September 2008
Gossypol as undesirable substance in animal feed	
Adopted: 04 December 2008	Published: 28 January 2009
Perfluorooctane sulfonate (PFOS), perfluorooctanoic acid (PFOA) and their salts	
Adopted: 21 February 2008	Published: 21 July 2008

	Nitrate in vegetables Adopted: 10 April 2008	Published: 05 June 2008
	Marine biotoxins in shellfish – Azaspiracid group Adopted: 09 June 2008	Published: 08 October 2008
	Polycyclic Aromatic Hydrocarbons in Food Adopted: 09 June 2008	Published: 04 August 2008
	Marine biotoxins in shellfish – yessotoxin group Adopted: 02 December 2008	To be published in 2009
Panel Statements	**Statement of the Scientific Panel on Contaminants in the Food chain (CONTAM) on a request from the European Commission related to 3-MCPD esters** Adopted: 28 March 2008	Published: 31 March 2008
EFSA Statements	**EFSA statement on the contamination of sunflower oil with mineral oil exported from Ukraine** Adopted: 28 April 2008	Published: 29 May 2008
	Statement of EFSA on risks for public health due to the presence of melamine in infant milk and other milk products in China Adopted: 24 September 2008	Published: 25 September 2008
	Statement of EFSA on the risks for public health due to the presence of dioxins in pork from Ireland Adopted: 10 December 2008	Published: 10 December 2008

Additives and products or substances used in animal feed (FEEDAP)

Scientific Opinions

Safety and efficacy of the product Quantum™ Phytase 5000 L and Quantum™ Phytase 2500 D (6-phytase) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening and piglets (weaned)		
Adopted: 30 January 2008	Published: 08 February 2008	Comment: In co-adoption with GMO
Safety and efficacy of Mintrex®Mn (Manganese chelate of hydroxy analogue of methionine) as feed additive for all species		
Adopted: 15 April 2008	Published: 08 May 2008	
Safety and efficacy of Mintrex®Zn (Zinc chelate of hydroxy analogue of methionine) as feed additive for all species		
Adopted: 16 April 2008	Published: 08 May 2008	
Safety and efficacy of Mintrex®Cu (Copper chelate of hydroxy analogue of methionine) as feed additive for all species		
Adopted: 16 April 2008	Published: 08 May 2008	
Maximum Residue Limits for Clinacox 0.5% (diclazuril) for turkeys for fattening, chickens for fattening and chickens reared for laying		
Adopted: 16 April 2008	Published: 28 April 2008	
Safety of Clinacox 0.5% (diclazuril) used in rabbits for fattening and breeding		
Adopted: 16 April 2008	Published: 28 April 2008	
Efficacy and safety of L-valine from a modified *E.coli* K12 for all animal species		
Adopted: 17 April 2008	Published: 27 May 2008	Comment: In co-adoption with GMO
Safety and efficacy of Econase XT P/L as feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and piglets (weaned)		
Adopted: 21 May 2008	Published: 17 June 2008	Comment: In co-adoption with GMO
Withdrawal period for Elancoban® for chickens for fattening, chickens reared for laying and turkeys for fattening		
Adopted: 18 June 2008	Published: 09 July 2008	

→ → → FEEDAP continued

Withdrawal period for Coxidin® for chickens and turkeys for fattening and re-examination of the provisional Maximum Residue Limit		
Adopted: 18 June 2008	Published: 09 July 2008	
Safety and efficacy of the product Sorbiflore, a preparation of *Lactobacillus rhamnosus* and *Lactobacillus farciminis*, as feed additive for piglets		
Adopted: 15 July 2008	Published: 07 August 2008	
Safety and efficacy of Levucell SC20/Levucell SC10ME, a preparation of *Saccharomyces cerevisiae*, as feed additive for lambs for fattening		
Adopted: 16 July 2008	Published: 07 August 2008	
Safety and efficacy of Ecobiol® (*Bacillus amyloliquefaciens*) as feed additive for chickens for fattening		
Adopted: 16 July 2008	Published: 07 August 2008	
Proposal for MRLs and withdrawal period for Cycostat®66G for chickens and turkeys for fattening		
Adopted: 16 September 2008	Published: 03 October 2008	
Safety and efficacy of Biosaf Sc47 (*Saccharomyces cerevisiae*) as feed additive for dairy buffaloes		
Adopted: 21 October 2008	Published: 03 November 2008	
Safety and efficacy of Advastat® (containing 10% acarbose produced by *Actinoplanes utahensis* CBS 961.70) as feed additive for cattle for fattening and dairy cows		
Adopted: 22 October 2008	Published: 11 November 2008	
Compatibility of the microbial product BioPlus 2B (*Bacillus licheniformis* and *Bacillus subtilis*) with lasalocid sodium		
Adopted: 22 October 2008	Published: 11 November 2008	
Compatibility of the microbial product 035 (*Bacillus subtilis*) with decoquinate and narasin/nicarbazin		
Adopted: 22 October 2008	Published: 11 November 2008	
Safety and efficacy of the product Ronozyme® NP (6-phytase) for chickens for fattening		
Adopted: 18 November 2008	Published: 01 December 2008	Comment: In co-adoption with GMO

→ → → FEEDAP continued

Guidance Documents

Safety of L-valine for all animal species		
Adopted: 18 November 2008	Published: 05 December 2008	
Consequences for the consumer of the use of vitamin A in animal nutrition		
Adopted: 19 November 2008	Published: 02 February 2009	
Safety and efficacy of Probiotic LACTINA® (*Lactobacillus acidophilus, Lactobacillus helveticus, Lactobacillus bulgaricus, Lactobacillus lactis, Streptococcus thermophilus, Enterococcus faecium*) for chickens for fattening, piglets and pigs		
Adopted: 09 December 2008	Published: 28 January 2009	
Safety and efficacy of Natugrain® TS (endo-1,4-ß-xylanase and endo-1,4-ß-glucanase) as a feed additive for piglets (weaned), chickens for fattening, laying hens, turkeys for fattening and ducks		
Adopted: 09 December 2008	Published: 17 December 2008	Comment: In co-adoption with GMO
Safety and efficacy of Toyocerin® (*Bacillus cereus* var. *toyoi*) as feed additive for rabbit breeding does		
Adopted: 09 December 2008	Published: Under proof-reading.	
Safety and efficacy of Phyzyme XP 10000 (TPT/L), 6-phytase, as feed additive for chickens for fattening, laying hens, ducks for fattening, turkeys for fattening, piglets (weaned), pigs for fattening and sows		
Adopted: 10 December 2008	Published: 17 December 2008	
Functional groups of additives as described in Annex 1 of Regulation (EC) No 1831/2003		
Adopted: 11 December 2008	Published: 16 December 2008	
Technical Guidance - Compatibility of zootechnical microbial additives with other additives showing antimicrobial activity		
Adopted: 05 March 2008	Published: 12 March 2008	
Technical Guidance – Update of the criteria used in the assessment of bacterial resistance to antibiotics of human or veterinary importance		
Adopted: 18 June 2008	Published: 14 July 2008	

→ → → FEEDAP continued

Technical Guidance – Tolerance and efficacy studies in target animals	
Adopted: 17 July 2008	Published: 23 September 2008
Guidance for the preparation of dossiers for the re-evaluation of certain additives already authorised under Directive 70/524/EEC	
Adopted: 17 July 2008	Published: 23 September 2008
Guidance for the preparation of dossiers for technological additives	
Adopted: 16 September 2008	Published: 23 September 2008
Guidance for the preparation of dossiers for sensory additives	
Adopted: 16 September 2008	Published: 23 September 2008
Guidance for the preparation of dossiers for nutritional additives	
Adopted: 16 September 2008	Published: 23 September 2008
Guidance for the preparation of dossiers for zootechnical additives	
Adopted: 16 September 2008	Published: 23 September 2008
Guidance for the preparation of dossiers for coccidiostats and histomonostats	
Adopted: 16 September 2008	Published: 23 September 2008
Guidance for the preparation of dossiers for additives already authorised for use in food	
Adopted: 16 September 2008	Published: 23 September 2008
Technical Guidance for establishing the safety of additives for the consumer	
Adopted: 16 September 2008	Published: 23 September 2008
Technical Guidance – Extrapolation of data from major species to minor species regarding the assessment of additives for use in animal nutrition	
Adopted: 17 September 2008	Published: 23 September 2008
Technical Guidance – Studies concerning the safety of use of the additive for users/workers	
Adopted: 17 September 2008	Published: 23 September 2008

→ → → FEEDAP continued

Technical Guidance – Microbial studies Adopted: 21 October 2008 Published: 21 October 2008
Technical Guidance for assessing the safety of feed additives for the environment Adopted: 22 October 2008 Published: 29 October 2008
Administrative guidance to applicants on the preparation and presentation of applications for authorisation of additives for use in animal nutrition Issued in September 2008

Genetically modified organisms (GMO)

Scientific Opinions

Opinion on applications (References EFSA-GMO-UK-2005-25 and EFSA-GMO-RX-T45) for the placing on the market of the glufosinate-tolerant genetically modified oilseed rape T45, for food and feed uses, import and processing and for renewal of the authorisation of oilseed rape T45 as existing product, both under Regulation (EC) No 1829/2003 from Bayer CropScience Adopted: 30 January 2008 Published: 5 March 2008
Opinion on a request from the European Commission related to the notification (Reference C/NL/06/01) for the placing on the market of the genetically modified carnation Moonaqua 123.8.12 with a modified colour, for import of cut flowers for ornamental use, under Part C of Directive 2001/18/EC from Florigene Adopted: 12 March 2008 Published: 26 March 2008
Request from the European Commission related to the enzyme preparation of trade name "Danisco Xylanase G/L (endo-1-4-beta-xylanase)" as a feed additive for laying hens and chickens and ducks for fattening Adopted: 21 May 2008 Published: 28 May 2008

→ → → GMO continued

Request from the European Commission on the non authorised genetically modified event DAS 59132-8 in US maize	
Adopted: 22 May 2008	Published: 26 May 2008
Opinion on application (Reference EFSA-GMO-NL-2006-36) for the placing on the market of the glyphosate-tolerant genetically modified soybean MON89788, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto	
Adopted: 2 July.	Published: 11 July 2008
Request from the European Commission related to the safeguard clause invoked by Hungary on maize MON810 according to Article 23 of Directive 2001/18/EC	
Adopted: 2 July 2008	Published: 11 July 2008
Request from the European Commission related to the safeguard clause invoked by Greece on maize MON810 according to Article 23 of Directive 2001/18/EC	
Adopted: 2 July 2008	Published: 11 July 2008
Request from the European Commission related to the safeguard clause invoked by France on maize MON810 according to Article 23 of Directive 2001/18/EC and the emergency measure according to Article 34 of Regulation (EC) No 1829/2003	
Adopted: 29 October 2008	Published: 31 October 2008
Request from the European Commission to review scientific studies related to the impact on the environment of the cultivation of maize Bt11 and 1507	
Adopted: 29 October 2008	Published: 31 October 2008
Opinion on application (Reference EFSA-GMO-UK-2005-20) for the placing on the market of the insect-resistant and herbicide-tolerant genetically modified maize 59122 x NK603, for food and feed uses, and import and processing under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International	
Adopted: 19 November.	Published: 1 December 2008

→ → → GMO continued

Opinion on application (Reference EFSA-GMO-NL-2007-37) for the placing on the market of the insect-resistant genetically modified maize MON89034, for food and feed uses, import and processing under Regulation (EC) No 1829/2003 from Monsanto		
Adopted: 3 December 2008	Published: 18 December 2008	
Request from the European Commission related to the safeguard clause invoked by Austria on maize MON810 and T25 according to Article 23 of Directive 2001/18/EC		
Adopted: 4 December 2008	Published: 10 December 2008	
Efficacy and safety of L-valine from a modified *E.coli* K12 for all animal species		
Adopted: 30 January 2008	Published: 27 May 2008	Comment: In co-adoption with FEEDAP
Safety and efficacy of the product Quantum™ Phytase 5000 L and Quantum™ Phytase 2500 D (6-phytase) as a feed additive for chickens for fattening, laying hens, turkeys for fattening, ducks for fattening and piglets (weaned)		
	Published: 8 February 2008	Comment: In co-adoption with FEEDAP
Safety and efficacy of Econase XT P/L as feed additive for chickens for fattening, chickens reared for laying, turkeys for fattening, turkeys reared for breeding and piglets (weaned)		
Adopted: 16 April 2008	Published: 17 June 2008	Comment: In co-adoption with FEEDAP
Safety and efficacy of the product Ronozyme® NP (6-phytase) for chickens for fattening		
Adopted: 29 October 2008	Published: 1 December 2008	Comment: In co-adoption with FEEDAP
Safety and efficacy of Natugrain® TS (endo-1,4-ß-xylanase and endo-1,4-ß-glucanase) as a feed additive for piglets (weaned), chickens for fattening, laying hens, turkeys for fattening and ducks		
Adopted: 3 December 2008	Published: 17 December 2008	Comment: In co-adoption with FEEDAP
Scientific Opinion of the Panel on Dietetic Products, Nutrition and Allergies on a request from the European Commission on the safety of 'Ice Structuring Protein (ISP)'		
Adopted: 2 July 2008	Published: 8 August 2008	Comment: In co-adoption with NDA

Panel Statement

Statement of the Scientific Panel on Genetically Modified Organisms in response to the request of the European Commission on the need for a 90 day rodent feeding study with genetically modified rice LLRICE62
Adopted: 2 July 2008 Published: 21 July 2008

Scientific or technical reports

Safety and Nutritional Assessment of GM Plants and derived food and feed: The role of animal feeding trials
Published: 10 March 2008

Dietetic products, nutrition and allergies (NDA)

Scientific Opinions

The setting of nutrient profiles for foods bearing nutrition and health claims pursuant to Article 4 of the Regulation (EC) No 1924/2006
Adopted: 31 January 2008 Published: 26 February 2008

Safety of Synthetic Lycopene
Adopted: 10 April 2008 Published: 30 April 2008

Safety of Lycopene oleoresin from tomatoes
Adopted: 24 April 2008 Published: 30 April 2008

Safety of synthetic Zeaxanthin as an ingredient in food supplements
Adopted: 24 April 2008 Published: 25 June 2008

Safety of Ice Structuring Protein (ISP)
Adopted: 09 July 2008 Published: 08 August 2008 Comment: In co-adoption with GMO

Safety of leaves from *Morinda citrifolia* L.
Adopted: 10 July 2008 Published: 11 August 2008

Safety of fungal oil from *Mortierella alpina*
Adopted: 10 July 2008 Published: 11 August 2008

→ → → NDA continued

Scientific substantiation of a health claim related to linolenic acid and linoleic acid and growth and development of children pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 11 July 2008 Published: 21 August 2008
Scientific substantiation of a health claim related to regulat®.pro.kid IMMUN and immune system of children during growth pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 11 July 2008 Published: 21 August 2008
Scientific substantiation of a health claim related to plant sterols and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 11 July 2008 Published: 21 August 2008
Scientific substantiation of a health claim related to "Femarelle®" and "induces bone formation and increases bone mineral density reducing the risk for osteoporosis and other bone disorders" pursuant to Article 14 of the Regulation (EC) No 1924/2006 Adopted: 04 August 2008 Published: 21 August 2008
Scientific substantiation of a health claim related to dairy foods and healthy body weight pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 08 August 2008 Published: 21 August 2008
Scientific substantiation of a health claim pursuant related to dairy products (milk and cheese) and dental health to Article 14 of Regulation (EC) No 1924/2006 Adopted: 12 August 2008 Published: 21 August 2008
Scientific substantiation of a health claim related to Elancyl Global Silhouette® and "regulation of body composition in people with light to moderate overweight" pursuant to Art. 13(5) of Regulation (EC) No 1924/2006 **Adopted: 12 August 2008** Published: 21 August 2008
Scientific substantiation of a health claim related to NeOpuntia® and improvement of blood lipid parameters associated with cardiovascular risk, especially HDL-cholesterol, pursuant to Art. 14 of Regulation (EC) No 1924/2006 Adopted: 13 August 2008 Published: 21 August 2008

→ → → NDA continued

Scientific substantiation of a health claim related to Docosahexaenoic Acid (DHA) and Arachidonic Acid (ARA) and support of the neural development of the brain and eyes pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 08 September 2008 Published: 25 September 2008
Scientific substantiation of a health claim related to Lactobacillus helveticus fermented Evolus® low-fat milk products and reduction of arterial stiffness pursuant to Article 14 of the Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 22 October 2008
Scientific substantiation of a health claim related to regulat®.pro.kid BRAIN and mental and cognitive developments of children pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 22 October 2008
Scientific substantiation of a health claim related to I omega kids®/Pufan 3 kids® and serenity pursuant to Article14 of Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 22 October 2008
Scientific substantiation of a health claim related to I omega kids®/Pufan 3 kids® and calming pursuant to Article14 of Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 22 October 2008
Scientific substantiation of a health claim related to I omega kids®/Pufan 3 kids® and vision pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 22 October 2008
Scientific substantiation of a health claim related to vitamin D and bone growth pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 22 October 2008
Scientific substantiation of a health claim related to calcium and vitamin D and bone strength pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 22 October 2008

→ → → NDA continued

Scientific substantiation of a health claim related to calcium and bone growth pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 22 October 2008
Safety, bioavailability and suitability of lutein for the particular nutritional use by infants and young childrenCategory: Infant Formulae. Adopted: 02 October 2008 Published: 14 November 2008
Scientific substantiation of a health claim related to plant stanol esters and lower/reduced blood cholesterol and reduced risk of (coronary) heart disease pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 02 October 2008 Published: 31 October 2008
Vitamin K2 added for nutritional purposes in foods for particular nutritional uses, food supplements and foods intended for the general population and Vitamin K2 as a source of vitamin K added for nutritional purposes to foodstuffs, in the context of Regulation (EC) N° 258/97 Adopted: 02 October 2008 Published: 14 November 2008
Scientific substantiation of a health claim related to I omega kids®/Pufan 3 kids® and mental development pursuant to Article14 of Regulation (EC) No 1924/2006 Adopted: 24 October 2008 Published: 31 October 2008
Scientific substantiation of a health claim related to I omega kids®/Pufan 3 kids® and concentration pursuant to Article14 of Regulation (EC) No 1924/2006 Adopted: 24 October 2008 Published: 31 October 2008
Scientific substantiation of a health claim related to I omega kids®/Pufan 3 kids® and thinking capacity pursuant to Article14 of Regulation (EC) No 1924/2006 Adopted: 24 October 2008 Published: 31 October 2008

Scientific substantiation of a health claim related to I omega kids®/Pufan 3 kids® and learning ability pursuant to Article14 of Regulation (EC) No 1924/2006
Adopted: 24 October 2008 Published: 31 October 2008

Scientific substantiation of a health claim related to LACTORAL (a combination of three probiotic strains: *Lactobacillus plantarum, Lactobacillus rhamnosus, Bifidobacterium longum*) and building of the natural intestinal barrier pursuant to Article 14 of Regulation (EC) No 1924/2006
Adopted: 28 October 2008 Published: 10 December 2008

Scientific substantiation of a health claim related to LACTORAL (a combination of three probiotic strains: *Lactobacillus plantarum, Lactobacillus rhamnosus, Bifidobacterium longum*) and maintenance of natural intestinal microflora during travel, pursuant to Article 14 of Regulation (EC) No 1924/2006
Adopted: 28 October 2008 Published: 10 December 2008

Scientific substantiation of a health claim related to LACTORAL (a combination of three probiotic strains: *Lactobacillus plantarum, Lactobacillus rhamnosus, Bifidobacterium longum*) and living probiotic bacteria, pursuant to Article 14 of Regulation (EC) No 1924/2006
Adopted: 28 October 2008 Published: 10 December 2008

Scientific substantiation of a health claim related to LACTORAL (a combination of three probiotic strains: *Lactobacillus plantarum, Lactobacillus rhamnosus, Bifidobacterium longum*) and normal functioning of the alimentary tract pursuant to Article 14 of Regulation (EC) No 1924/2006
Adopted: 28 October 2008 Published: 10 December 2008

Scientific substantiation of a health claim related to LACTORAL (a combination of three probiotic strains: *Lactobacillus plantarum, Lactobacillus rhamnosus, Bifidobacterium longum*) and improvement of the general immunity pursuant to Article 14 of Regulation (EC) No 1924/2006
Adopted: 28 October 2008 Published: 10 December 2008

Scientific substantiation of a health claim related to LGG® MAX and reduction of gastro-intestinal discomfort pursuant to Article 13(5) of Regulation (EC) No 1924/2006
Adopted: 30 October 2008 Published: 14 November 2008

→ → → NDA continued

Scientific substantiation of a health claim related to xylitol chewing gum/pastilles and reduction the risk of tooth decay pursuant to Article 14 of Regulation (EC) No 1924/200	
Adopted: 30 October 2008	Published: 14 November 2008
Scientific substantiation of a health claim related to animal protein and bone growth pursuant to Article 14 of Regulation (EC) No 1924/2006	
Adopted: 31 October 2008	Published: 14 November 2008
Scientific substantiation of a health claim related to Efalex® and learning ability pursuant to Article14 of Regulation (EC) No 1924/2006	
Adopted: 04 December 2008	Published: 19 December 2008
Dairy product enriched with milk peptide and magnesium and help to moderate signs of anxiety in mildly stress-sensitive adult pursuant to Article 13(5) of Regulation (EC) No 1924/2006	
Adopted: 04 December 2008	Published: 19 December 2008
Scientific substantiation of a health claim related to Eye q® and brain functions pursuant to Article 14 of Regulation (EC) No 1924/2006	
Adopted: 04 December 2008	Published: 19 December 2008
Scientific substantiation of a health claim related to Eye q baby® and central nervous system development pursuant to Article 14 of Regulation (EC) No 1924/2006	
Adopted: 04 December 2008	Published: 19 December 2008
Scientific substantiation of a health claim related to Efalex® and eye development and function pursuant to Article14 of Regulation (EC) No 1924/2006	
Adopted: 04 December 2008	Published: 19 December 2008
Scientific substantiation of a health claim related to Efalex® and concentration pursuant to Article14 of Regulation (EC) No 1924/2006	
Adopted: 04 December 2008	Published: 19 December 2008

Scientific substantiation of a health claim related to Efalex® and brain development and function pursuant to Article14 of Regulation (EC) No 1924/2006 Adopted: 04 December 2008 Published: 19 December 2008
Scientific substantiation of a health claim related to Eye q® and concentration pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 04 December 2008 Published: 19 December 2008
Milk product, rich in fibre and protein, and reduction of the sense of hunger pursuant to Article 13(5) of Regulation (EC) No 1924/2006 Adopted: 04 December 2008 Published: 19 December 2008
Scientific substantiation of a health claim related to Efalex® and coordination pursuant to Article14 of Regulation (EC) No 1924/2006 Adopted: 04 December 2008 Published: 19 December 2008
Scientific substantiation of a health claim related to Mumomega® and central nervous system development pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 04 December 2008 Published: 19 December 2008
Safety of Lycopene Cold Water Dispersible Products from *Blakeslea trispora* Adopted: 04 December 2008 Published: 19 December 2008
Scientific substantiation of a health claim related to black tea from *Camellia sinensis* and helps to focus attention, pursuant to Article 13(5) of Regulation (EC) No 1924/2006 Adopted: 04 December 2008 Published: 22 December 2008
Scientific substantiation of a health claim related to dairy fresh cheese and bone growth pursuant to Article 14 of Regulation (EC) No 1924/2006 Adopted: 04 December 2008 Published: 15 January 2009

Plant Health (PLH)

Scientific Opinions

Pest risk assessment made by France on Hop stunt viroid (HSVd) Adopted: 20 February 2008 Published: 21 May 2008
Pest risk assessment made by France on *Citrus exocortis* virus (CEVd) Adopted: 20 February 2008 Published: 21 May 2008
Pest risk assessment made by France by Banana bract mosaic virus Adopted: 20 February 2008 Published: 31 March 2008
Pest risk assessment made by France on *Ralstonia* sp pathogenic agent of banana blood disease Adopted: 21 February 2008 Published: 31 March 2008
Pest risk assessment made by France on *Mycosphaerella fijiensis* Adopted: 21 February 2008 Published: 31 March 2008
Pest risk assessment made by France on Banana streak virus (BSV) Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on Citrus chlorotic dwarf virus Adopted: 12 March 2008 Published: 21 May 2008
Pest risk assessment made by France on Citrus yellow mosaic virus or Citrus mosaic badnavirus Adopted: 12 March 2008 Published: 21 May 2008
Pest risk assessment made by France on *Erionota thrax L* Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on *Nacoleia octasema* Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on *Odioporus longicollis* Adopted: 12 March 2008 Published: 31 March 2008

→ → → PLH continued

Pest risk assessment made by France on *Ralstonia solanacearum* race 2 Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on *Xanthomonas campestris pv. Musacearum* Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on *Aceria sheldoni* (Ewing) Adopted: 12 March 2008 Published: 21 May 2008
Pest risk assessment made by France on *Brevipalpus californicus, Breviplapus phoenicis* and *Brevipalpus obovatus* (Acari: *Tenuipalpidae*) Adopted: 12 March 2008 Published: 21 May 2008
Pest risk assessment made by France on *Mycosphaerella eumusae* Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on *Fusarium oxysporum f.sp. cubense* Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on *Trachysphaera fructigena* Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on *Phyllosticta musarum* (Cooke) van der Aa Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on Banana bunchy top virus (BBTV) Adopted: 12 March 2008 Published: 31 March 2008
Pest risk assessment made by France on *Sphaeropsis tumefaciens* Hedges Adopted: 13 March 2008 Published: 21 May 2008
Pest risk assessment made by France on *Panonychus citri* Adopted: 13 March 2008 Published: 21 May 2008

→ → → PLH continued

	Pest risk assessment made by France on P*rays citri* Adopted: 13 March 2008 Published: 21 May 2008
	Pest risk assessment made by France on *Prays endocarpa* Adopted: 13 March 2008 Published: 21 May 2008
	Pest risk assessment made by France on *Xanthomonas axonopodis pv.citri* Adopted: 13 March 2008 Published: 21 May 2008
	Pest risk assessment made by France on *Metcalfa pruinosa* (Say) Adopted: 24 April 2008 Published: 21 May 2008
	Pest risk assessment made by France on *Parlatoria ziziphi* (Lucas) Adopted: 30 April 2008 Published: 21 May 2008
	Pest risk assessment made by France on *Mycosphaerella citri* Adopted: 30 April 2008 Published: 21 May 2008
	Pest risk assessment made by France on *Ceratocystis fimbiata* Adopted: 30 April 2008 Published: 21 May 2008
	Scientific opinion on a pest risk assessment and additional supporting evidence provided by South Africa on *Guignardia citricarpa* Kiely Adopted: 17 December 2008 Published: 20 January 2009
Guidance Document	**Development of a Guidance Document on the evaluation of pest risk assessments for phytosanitary measures made by third parties to justify phytosanitary measures under Directive 2000/29/EC Endorsed for public consultation on 18 December 2008** Published for public and stakeholder consultation on 16 January 2009 (deadline 2 March).

Other scientific outputs

Report of 10th EFSA Scientific Colloquium: Pest risk assessment – Science in support of phytosanitary decision making in the European Union Published August 2008

Plant protection products and their residues (PPR)

Scientific Opinions

Opinion on the evaluation of the suitability of existing methodologies and identification of new approaches to assess cumulative and synergic risks from pesticides to human health with a view to set MRLs.	
Adopted: 15 April 2008	Published: 30 May 2008
Opinion on the science behind the Guidance Document on risk assessment for birds and mammals	
Adopted: 17 June 2008	Published: 24 July 2008
Opinion on the developmental neurotoxicology of deltamethrin	
Adopted: 9 December 2008	Published: 13 January 2009
The usefulness of total concentrations and pore water concentrations of pesticides in soil as metrics for the assessment of ecotoxicological effects.	
Adopted: 10 December 2008	Published: 23 January 2009

Assessment Methodology (AMU)

EFSA Statement	**Statement of EFSA on a study associating bisphenol A with medical disorders. Prepared by the Unit on food contact materials, enzymes, flavourings and processing aids (CEF) and the Unit on Assessment Methodology (AMU)**	Adopted: 22 October 2008	Published: 24 October 2008
Scientific or technical report	**Bee Mortality and Bee Surveillance in Europe - A Report from the Assessment Methodology Unit in Response to Agence Francaise de Securite Sanitaire des Aliments (AFSSA)**	Adopted: 11 May 2008	Published:11 August 2008
	Statistical Report on the study by McCann et al. (2007) on the effect of some colours and sodium benzoate on children's behaviour		Published: 11 March 2008

Data collection and exposure (DATEX)

EFSA Statements	**Statement of EFSA on risks for public health due to the presence of melamine in infant milk and other milk product in China**	Adopted: 24 September 2008	Published: 25 September 2008	
	Statement of EFSA on the risks for public health due to the presence of dioxins in pork from Ireland	Adopted: 10 December 2008	Published: 10 December 2008	
Guidance Documents	**Guidance Document for the use of the Concise Food Consumption Database in Exposure Assessment**		Published: 17 March 2008	
Scientific or technical report	**Consumption of Food and Beverages with Added Plant Sterols in the European Union**	Adopted: 20 February 2008	Published: 4 March 2008	Updated: 17 March 2009

Emerging risks (EMRISK)

Scientific or technical report		
EFSA Emergency Manual	Issued: 5 February 2009	

Pesticide Risk Assessment Peer Review (PRAPeR)

Conclusion regarding the peer review of the pesticide risk assessment of the active substances:

Benfluralin	Finalised: 3 March 2008	Published: 28 July 2008
Flutolanil	Finalised: 3 March 2008	Published: 28 July 2008
Fluazinam	Finalised: 26 March 2008	Published: 29 July 2008
Epoxiconazole	Finalised: 26 March 2008	Published: 28 July 2008
Bromuconazole	Finalised: 26 March 2008	Published: 28 July 2008
Buprofezin	Finalised: 3 March 2008	Published: 28 July 2008
Napropamide	Finalised: 26 March 2008	Published: 28 July 2008
Tralkoxydim	Finalised: 26 March 2008	Published: 28 July 2008
Mepiquat	Finalised: 14 April 2008	Published: 28 July 2008
Imidacloprid	Finalised: 29 May 2008	Published: 28 July 2008
Fenpropimorph	Finalised: 14 April 2008	Published: 29 July 2008

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Metazachlor	Finalised: 14 April 2008	Published: 29 July 2008
Abamectin	Finalised: 29 May 2008	Published: 29 July 2008
Tetraconazole	Finalised: 31 July 2008	Published: 16 Oct. 2008
Acetochlor	Finalised: 31 July 2008	Published: 16 Oct. 2008
Sulcotrione	Finalised: 31 July 2008	Published: 16 Oct. 2008
Flurprimidol	Finalised: 31 July 2008	Published: 16 Oct. 2008
Aclonifen	Finalised: 31 July 2008	Published: 21 Oct. 2008
Dodemorph	Finalised: 17 Sept. 2008	Published: 17 Oct. 2008
Cymoxanil	Finalised: 17 Sept. 2008	Published: 17 Oct. 2008
Cyromazine	Finalised: 17 Sept. 2008	Published: 21 Oct. 2008
Dimethachlor	Finalised: 17 Sept. 2008	Published: 30 Oct. 2008
Tebuconazole	Finalised: 25 Sept. 2008	Published: 17 Oct. 2008
Triadimenol	Finalised: 25 Sept. 2008	Published: 17 Oct. 2008
Penconazole	Finalised: 25 Sept. 2008	Published: 30 Oct. 2008
2,5 dichlorobenzoic acid methylester	Finalised: 26 Sept. 2008	Published: 21 Oct. 2008
Bensulfuron	Finalised: 26 Sept. 2008	Published: 21 Oct. 2008
Metamitron	Finalised: 29 Sept. 2008	Published: 22 Oct. 2008

→ → → PRAPeR continued

Calcium phosphide	Finalised: 29 September 2008	Published: 22 October 2008
Teflubenzuron	Finalised: 29 September 2008	Published: 15 January 2009
Aluminium phosphide	Finalised: 29 September 2008	Published: 15 January 2009
Zeta-cypermethrin	Finalised: 30 September 2008	Published: 15 January 2009
Copper compounds	Finalised: 30 September 2008	Published: 22 October 2008
Magnesium phosphide	Finalised: 30 September 2008	Published: 15 January 2009
Diphenylamine	Finalised: 30 September 2008	Published: 15 January 2009
Fenpyroximate	Finalised: 16 October 2008	Published: 30 October 2008
Metam	Finalised: 26 November 2008	Published: 15 January 2009
Chlormequat	Finalised: 29 September 2008	Published: 25 February 2009
Triflumuron	Finalised: 30 September 2008	Published: 6 March 2009
Propaquizafop	Finalised: 26 November 2008	Published: 17 March 2009
Chlorsulfuron	Finalised: 26 November 2008	Published: 6 March 2009
Paraffin oil (CAS 8042-47-5, chain lengths C17-C31)	Finalised: 19 December 2008	Published: 9 March 2009

→ → → PRAPeR continued

Conclusions finalised but not yet published

These conclusions will be published on the EFSA website.

Triazoxide
Tri-allate
Triflusulfuron
Lufenuron
Tebufenpyrad
Bifenthrin
Sodium 5-nitroguaiacolate, sodium o-nitrophenolate and sodium p-nitrophenolate
Chlorthal-dimethyl
Quizalofop-P
Etofenprox
Ethanol
Sulphur
2-phenyphenol
Difenacoum
Didecyldimethylammonium chloride

Paraffin oil (CAS 8042-47-5, chain lengths C18-C30)
Paraffin oils (CAS 64742-46-7, 72623-86-0 and 97862-82-3)
Methomyl
Ethephon

Reasoned opinions

Addendum to the Reasoned Opinion on the potential chronic and acute risk to consumers' health arising from proposed temporary EU MRLs according to regulation (EC) 396/2005 on maximum residue levels of pesticides in food and feed of plant and animal origin	Published: 15 March 2008	Adopted: 15 February 2008
MRLs of concern for the active substances:		
Methamidophos	Published: 27 November 2008	Adopted: 15 September 2008
Fenarimol	Published: 27 November 2008	Adopted: 15 September 2008
Carbendazim	Published: 27 November 2008	Adopted: 15 September 2008
Fenamiphos	Published: 27 November 2008	Adopted: 15 September 2008
Ethephon	Published: 27 November 2008	Adopted: 15 September 2008
Procymidone	Published: 27 November 2008	Adopted: 15 September 2008
Oxydemeton-methyl	Published: 27 November 2008	Adopted: 16 September 2008

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Pirimiphos-methyl	Published: 27 November 2008	Adopted: 18 September 2008
Vinclozolin	Published: 27 November 2008	Adopted: 16 September 2008
Methomyl and thiodicarb	Published: 27 November 2008	Adopted: 26 September 2008
Benfuracarb and carbosulfan	Published: 27 November 2008	Adopted: 26 September 2008
Dimethoate and omethoate		Adopted: 20 October 2008
Azoxystrobin in turnips	Published: 27 November 2008	Adopted: 24 November 2008
Fludioxonil in pomegranates	Published: 27 November 2008	Adopted: 18 November 2008
Azoxystrobin in passion fruit	Published: 18 December 2008	Adopted: 12 December 2008
Teflubenzuron on peppers	Published: 17 December 2008	Adopted: 12 December 2008
Trifloxystrobin in passion fruit	Published: 22 December 2008	Adopted: 18 December 2008
Fluroxypyr in leeks	Published: 22 December 2008	Adopted: 18 December 2008
Thiram in bananas	Published: 22 December 2008	Adopted: 16 December 2008

Scientific or technical report

Evaluation of the European Union Pesticide Safety Review Process Issued by the working group on the review of the efficiency of the pesticide peer-review process on 27 August 2008

Scientific Cooperation (SCO)

Scientific or technical reports

ESCO REPORT. Prepared by the EFSA Scientific Cooperation Working Group on Fostering Harmonised Risk Assessment Approaches in Member States. Issued on 03 December 2008

Colloquium Reports

EFSA Scientific Colloquium Report 8: Environmental Risk Assessment of Genetically Modified Plants - Challenges and Approaches
EFSA Scientific Colloquium Report 9: Nutrient Profiling For Foods Bearing Nutrition and Health Claims
EFSA Scientific Colloquium Report 10: Pest risk assessment - Science in support of phytosanitary decision making in the European Community
EFSA Scientific Colloquium Report 11: Acrylamide carcinogenicity - New evidence in relation to dietary exposure

Zoonoses Data Collection

Zoonoses Data Collection Reports

Zoonoses country reports 2006 Published: 10 January 08
Report on Evaluation of the Community Reporting system for Food-borne Outbreaks under Directive 2003/99/EC Endorsed: 01 December 2007 Published: 07 March 2008
Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline survey on the prevalence of *Salmonella* in turkey flocks, in the EU, 2006-2007 - Part A: *Salmonella* prevalence estimates Adopted: 28 April 2008 Published: 13 May 2008

→ → → Zoonoses Data Collection continued

Guidance Documents

Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline survey on the prevalence of *Salmonella* in slaughter pigs, in the EU, 2006-2007 Part A: *Salmonella* prevalence estimates
Adopted: 30 May 2008 Published: 09 June 2008

Report of Task Force on Zoonoses Data Collection on proposed technical specifications for a coordinated monitoring programme for *Salmonella* and *Campylobacter* in broiler meats at retail in the EU
Adopted: 29 August 2008 Published: 02 September 2008

Report of the Task Force on Zoonoses Data Collection on the Analysis of the baseline survey on the prevalence of *Salmonella* in turkey flocks, in the EU, 2006-2007: Part B: factors related to *Salmonella* flock prevalence and distribution of *Salmonella* serovars
Adopted: 10 October 2008 Published: 28 October 2008

Report of the Task Force on analysis of the baseline survey on the prevalence of *Salmonella* in slaughter pigs, in the EU, 2006-2007 - Part B: factors associated with *Salmonella* infection in lymph nodes, *Salmonella* surface contamination of carcasses, and the distribution of *Salmonella* serovars
Adopted: 14 November 2008 Published: 22 December 2008

Report from the Task Force on Zoonoses Data Collection including guidance for harmonized monitoring and reporting of antimicrobial resistance in commensal *Escherichia* coli and *Enterococcus* spp. from food animals
Adopted: 11 March 2008 Published: 03 April 2008

Report of the Task Force on Zoonoses Data Collection Manual for Reporting on Zoonoses, Zoonotic Agents and Antimicrobial Resistance in the framework of Directive 2003/99/EC and of some other pathogenic microbiological agents for information derived from the reporting year 2007
Adopted: 11 March 2008 Published: 03 April 2008.

ISBN: 978-92-9199-095-5

doi: 10.2805/14793

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TM-AB-08-002-EN-C

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ISBN 978-92-9199-095-5