





Annual Report

2004













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Annual Report

2004













The year 2004 was one of major developments at the European Food Safety Autority (EFSA). The number of staff increased rapidly and now totals more than 100. The move to Parma began in November and is expected to be completed by autumn 2005. Initially, EFSA will be housed in temporary accommodation, but I am confident that a permanent solution will be found soon. The staff members are looking forward to moving to Parma and I am sure that they will have a very positive impact there. EFSA is grateful for the generous assistance kindly provided by the Italian authorities at the local, provincial, regional and national levels.

Despite the upheaval caused by moving, EFSA's core business, the provision of high quality, independent scientific opinions and advice, expanded rapidly during the year. 159 scientific opinions were produced by the Scientific Committee and Panels on a wide range of subjects. In addition, the Scientific Working Groups produced many important reports, for example those on the geographical bovine spongiform encephalopathy (BSE) risk and testing for transmissible spongiform encephalopathy (TSE). This work is extremely important in contributing to the public's trust in food safety and in the ability of public authorities to fully protect consumers.

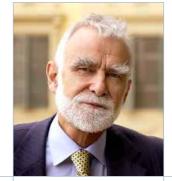
In May 2004, we welcomed ten new European Union (EU) Member States as full members of the Advisory Forum. Thanks to the foresight of the Executive Director, they were not new to the Forum, having participated in its work from the outset as observers. The Forum has proved to be a very useful channel for contact with the Member States and, during the year, it has provided valuable input into EFSA's work. It has also been very helpful in spreading information about EFSA and its work to stakeholders at the national level.

EFSA is committed to a policy of openness and transparency and, during 2004, our capacity to communicate developed rapidly. Contacts have been strengthened with the European institutions, and with consumer and other stakeholder groups, as well as with national and international organisations working in the same or related areas in different parts of the world. A successful Stakeholder Colloquium was held in Berlin in November and I welcome the decision to set up a permanent Stakeholder Consultative Platform.

On behalf of the Management Board, I would like to thank Geoffrey Podger, the EFSA staff, the Scientific Committee and Panels and others who contributed to making 2004 a successful and productive year for EFSA. In 2005, we face new and greater challenges, including expanding and strengthening in-house support for the work of the Scientific Committee and Panels so that they can increase their output of scientific opinions and advice even further. However, I am confident that EFSA's hard-working and dedicated staff can rise to the challenge.

Stuart Slorach

Stuis A. Froach.



Stuart Slorach, Chairman of the Management Board

Message from the Executive Director



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2004 has been a critical year for the growth of the European Food Safety Authority as it continued to build towards full operation.

The significant development of the Authority's scientific activities is reflected by the 180 opinions that, at the end of 2004, had been adopted by EFSA's Scientific Panels and Committee since their establishment in May 2003. A total of 180 requests for scientific advice were addressed to the Authority in 2004, in addition to the 242 questions already registered in 2003. In 2004, EFSA's Scientific Panels delivered opinions about a wide range of topics such as genetically modified organisms (GMOs), methylmercury in fish, the labelling of allergenic foods, trans fatty acids, animal health and welfare practises, parabens in foods and of course the ongoing BSE/TSE risk assessments. Other related scientific activities over the past year include the development of the Authority's in-house scientific expertise, the identification of emerging risks, networking and scientific data gathering, as well as the organisation of two Scientific Colloquia on specific themes.

2004 has also been marked by the strengthening of the existing collaboration between the Authority and the European Commission, the European Parliament and the competent national food safety agencies of the Member States, both in the areas of risk assessment and risk communications. Throughout the past year, the Authority has continued to build its relationships with the new entrant states and has forged links with countries and organisations beyond Europe's borders. The new Member States in particular have been members of EFSA's Advisory Forum since its inception. The first public event of the Advisory Forum, held in Berlin in November 2004, was a success, bringing together over 350 participants and paving the way for the creation of a strong European expert network to enhance risk assessments concerning the food chain.

At the same time, in 2004 it was of primary importance for EFSA to pursue an on-going and open dialogue with its stakeholders. The challenge for the Authority is to develop its relationship with stakeholders in order not only to develop a better understanding between them and EFSA, but also to help promote better understanding of each other. In that respect, a 2nd Stakeholder Colloquium was organised in November 2004, as a continuation of the dialogue started in Ostend the year before. Participants discussed issues such as how society perceives risk, the participation of stakeholders in the risk assessment process, and the way forward for EFSA from the stakeholders' point of view.

Last but not least, 2004 also saw EFSA's first staff members leaving for the Authority's permanent seat in Parma. The move started in November 2004 and is scheduled to achieve its completion in the autumn of 2005. It has been made much smoother thanks to the work of the local City, Provincial and Regional authorities.

2004 has been an important year of growth for EFSA. A significant step along the way to providing information and advice on risks associated with the food chain, and a sound scientific basis for the management of such risks by the EU institutions. On this occasion, I would like to extend my thanks both to our external Scientific Experts and to our own internal staff for their commitment and many achievements. My thanks also go to the members of EFSA's Management Board who have successfully advised and guided EFSA throughout 2004.

Geoffrey Podger

Georgey Podgr

2004 objectives



Having established itself as an independent European Agency during 2003, the Authority's objective for 2004 was to build capacity in order to deliver its mandate and meet the expectations of European and national institutions, stakeholders and the public at large.

EFSA's prime function is to contribute to the protection of human health throughout the EU in its area of responsibility. In close collaboration with national authorities and in open consultation with its stakeholders, EFSA provides objective scientific advice on all matters with a direct or indirect impact on food and feed safety, including animal health and welfare and plant protection. EFSA is also consulted on nutrition in relation to Community legislation.

EFSA's remit falls into two areas: risk assessment and risk communication. In particular, EFSA's risk assessments provide risk managers (EU institutions with political accountability, ie the European Commission (EC), European Parliament and Council) with a sound scientific basis for defining policy-driven legislation or regulatory measures.

The Authority's work contributes to ensure a high level of consumer protection with regard to food and feed safety, through which consumer confidence can be restored and maintained. This requires rapid expansion and the development of an effective organisational structure, as well as coherent targeted work programmes and activities.

The objectives set out at the beginning of 2004 were as follows:

- Establish the Authority as an organisation dedicated to scientific excellence, independence, openness and transparency;
- Provide scientific opinions and advice about questions formally addressed to the Authority, or by self-tasking;
- Assess the risks of regulated substances, and monitor specific risk factors and diseases;
- Promote and apply new and harmonised scientific approaches for hazard and risk assessment methodologies;
- Foster the exchange and transfer of scientific expertise and knowledge;
- Ensure that communication messages are timely, relevant and understandable, and address food safety concerns;
- Develop an overall strategy for international relations, building on those relations already established during 2003;
- Establish an ongoing recruitment drive in all departments to balance staff numbers with the growing workload;
- Ensure a smooth and swift relocation of the Authority to Parma.

People were at the heart of the Authority's development and growth in 2004. Therefore, an essential aim for the Authority was to be able to recruit and retain the best possible staff at all levels, in order to ensure the successful delivery of its objectives for 2004 and beyond.

Another important aim in 2004 was the significant development of EFSA's scientific and communications functions via appropriate operational and administrative support. This included the deployment of both human and financial resources. The Authority undertook to focus on building capacity within its scientific departments. This was particularly to ensure that it would be able to keep abreast of scientific developments and emerging issues, and apply the highest standards of scientific rigour. With regard to this, the Authority planned to work closely with its independent Scientific Committee and Panels.

EFSA also undertook to communicate its opinions and other advice in a clear and understandable manner to the European Commission, European Parliament, Member States, stakeholders and the public at large. The Authority suggested that it engage more deeply in dialogue with its key stakeholders and customers, collecting feedback in order to ensure that its goals, priorities and outputs would be clearly communicated and in line with expectations.

During 2004, the Authority began preparing its move to Parma with the early movers taking up residence towards the end of the year. Significant planning, personnel and logistical issues were provided for in order to achieve a smooth relocation. These applied to Authority staff, as well as to the Scientific Panels and Committee members, the Management Board and the Italian authorities.





Under the guidance of its Management Board and Executive Director, the Authority expanded its capacity in all areas of competence during 2004.

One of the highlights for 2004 was the reality of the move to Parma. Emphasis lay on establishing the appropriate structures and resources to facilitate the move. By the end of the year, a core group of staff had made the move and were working at full speed from Parma.

During 2004, the Authority carried out a significant recruitment drive to contribute to the growth and the development of the areas assigned to it under the founding Regulation. The appointment of competent and qualified staff is fundamental to the Authority's ability to develop into an efficient and effective organisation. Staff from all EU Member States, including the new Member States, were

selected for their excellence and know-how at all levels of seniority and experience.

Throughout the year, the Scientific Committee and Panels have established extensive work programmes for the uninterrupted development of scientific opinions. These cover not only those questions addressed to them, but also the 'self-tasking' activities which were considered to be a priority. The establishment of further in-house support for the Panels' work, which will be continued in the future, reflects the Authority's overall intent to ensure scientific rigour in all its scientific work, and in particular in its risk assessment and safety evaluation procedures.

Thanks to its activities and the developments during the course of 2004, the Authority has strengthened its reputation as an organisation dedicated to its founding principles of scientific excellence, independence, openness and transparency.



Stuart Slorach (SE) Deputy Director-General, Swedish National Food Administration

Geslain-Lanéelle (FR) Vice-Chair

Directrice régionale et interdépartementale de l'Agriculture et de la Forêt de la région d'Ile-de-France



Deirdre Hutton (UK)

Vice-Chair President, National Consumer Council



Prof. Dr. Matthias Horst (DE)

Hauptgeschäftsführer, Bund für Lebensmittelrecht und Lebensmittelkunde e.V (BLL); Bundesvereinigung der Deutschen Ernährungsindustrie e. V.



Peter Gaemelke (DK) President, Danish Agricultural Council

Dr. Patrick Wall (IE) Adjunct Professor of Food Safety, University College



Ernst Bobek (AT) Leiter i.R. der Sektion in Bundesministerium für soziale Sicherheit



Robert Madelin (EC) Director-General for Health and Consumer Protection, European Commission



Senior Vice-President, Safety and Environmental Assurance at Unilever N.V.



Dr. Bart Sangster (NL)



Carlos Escribano Mora (ES) Asesor del Secretario General de Agricultura y Alimentación. Ministerio de Agricultura, Pesca y Alimentación





Pirkko Raunemaa (FI) Retired Director at the National Food Agency in Finland





Prof. Dr. Giorgio Calabrese (IT) Vice Presidente Scientifico del Consiglio Istituto Nazionale di Ricerca per gli Alimenti e la Nutrizione (INRAN)



4.1. Overall management activities and organisational effectiveness

The Management Board

The Management Board (photos) is responsible for ensuring that the Authority functions effectively and efficiently. Six Management Board meetings were held in 2004, two of which took place in Parma. In 2004, the Management Board re-elected three of its members to hold the offices of Chair and Vice Chair. Stuart Slorach (Sweden) was once again voted in as Chair at the Board's June meeting, for a further two years.

Over the course of the year, the Management Board adopted the 2004 work programme, the 2005 budget and the preliminary work programme. It also discussed such wide-ranging issues as media handling guidelines for the Scientific Committee and Panels and EFSA's animal welfare policy. The latter includes the welfare of both food producing animals and experimental animals used for hazard and risk assessment studies. A very successful Management Board Team Building exercise was organised in connection with the March meeting in Dublin.

During the first part of 2004, the EFSA Management Board learned of the insertion, at the drafting stage, of administrative review clauses in two draft Regulations. If these became legislation, they would empower the Commission to require the Authority to withdraw its decisions or undo its acts. In addition, these clauses would enable the European Commission,



EFSA's Management Board, September 2004

EFSA Management Team







Anne-Laure Gassin.

Communications



François Monnart.

Finance



International and

Institutional Affairs



Antoine Cuvillier.

Legal Affairs



Human Resources



Lionel Rigaux.



Dr. Herman B.W.M. Koëter,Deputy Executive Director
and Director of Science

on its own initiative or in response to a request from a Member State or from any person directly or individually concerned, to review the acts or decisions adopted or taken by the Authority.

The matter was formally raised at the Authority's 27 April 2004 Management Board meeting. The Management Board decided unanimously to act by raising the issue with the Council, the Commission and the European Parliament as these draft articles seemed to embody principles which are contrary to EFSA's understanding of its independence and are seen to be of little administrative use in practice. As a result, the Management Board sent a letter to the Council, the Commission and the European Parliament on 19 May 2004. In response, the Commission has made it clear that these procedures will not be used to undermine EFSA's scientific independence.

At the last Management Board meeting of 2004, the Board adopted an important paper on its own initiative about Progress Indicators and a revised document about guidance regarding Declarations of Interest. The Management Board had previously requested the establishment of Progress Indicators for the Authority as a means of helping it to fulfil its role in supervising EFSA's performance. The Paper suggested six Progress Indicators and the means by which they might be monitored for the Board's consideration, following the changes proposed at the September 2004 Management Board meeting. In September, the Board also suggested that the next step after the introduction of quantitative Progress Indicators should be Qualitative Indicators, and that methodology should be introduced to carry out an impact assessment of the Indicators measured. The Authority considers that Oualitative Indicators may be used at a future stage, following the implementation of the current Progress Indicators.

Progress Indicators were defined as a means whereby the Management Board can monitor EFSA's progress in quantitative terms in a number of key performance areas on a quarterly basis. The purpose of such an exercise is:

- (i) to give the Board a basis for ensuring that progress in on track;
- (ii) to highlight areas where, for whatever reason, progress is not being made in the intended manner;
- (iii) to give some indication of EFSA's impact on the outside world:
- (iv) to provide a basis for further discussion within EFSA's Management Board.

During 2004 the Board also played a key role in progressing the Evaluation of EFSA which is legally scheduled to take place during 2005 by agreeing the Terms of





FFSA staff in Brussels

Reference for the Evaluation process and determining how it would ensure that the evaluation stays on track. The Board agreed that the management of the project would be conducted by a Steering Group comprising members of the Management Board, along with a Technical Group made up of staff members from EFSA and the Commission services. The dissemination of evaluation results will be the Board's responsibility in 2005. Any changes requiring amendments to current legislation would necessarily involve the EU institutions (European Commission, Council and the European Parliament).

EFSA Executive Director and Staff

EFSA is made up of four distinct bodies. They are the Management Board, the Executive Director and staff, the Advisory Forum, and the Scientific Committee and Panels.

The Executive Director, Geoffrey Podger, is the Authority's legal representative. He is in charge of day-to-day management and is responsible for all staff matters. The post is for a renewable five year period and the holder is answerable to the Management Board. It was filled on the basis of a list of candidates submitted by the European Commission after an open competition, and confirmed following a hearing in the European Parliament. Assisting the Executive Director is EFSA's Management Team which comprises the Deputy Executive Director and Director of Science, Dr. Herman B.W.M. Koëter, as well as the functional directors of Accounts, Communications, Finance, Human Resources, Information Technology, International and Institutional Affairs and Legal Affairs.

FFSA staff in Parma

When it is fully operational, the Authority is expected to number more than 350 staff. EFSA's staff members are responsible for:

- supporting the Scientific Committee and Panels and their Working Groups, and investing in leading-edge science;
- providing scientific expertise on food and feed safety matters, including emerging risks;
- gathering scientific data and information;
- defining and implementing the Authority's communications programme;
- supporting the Board and Advisory Board;
- ensuring liaison and collaboration with stakeholders, national and European institutions and international bodies;
- assisting the EU institutions in crisis management;
- providing appropriate administrative and specialist support in the area of finance, legal affairs, quality management, information technology and human resources.

This activity report outlines the achievements of each of EFSA's functions in 2004.

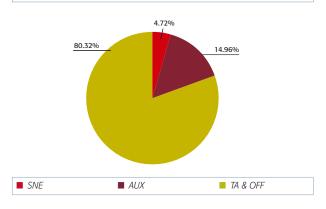
Staffing and Human Resources

Current staffing levels

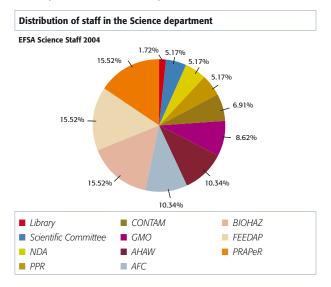
On 31 December 2004, EFSA staff numbered a total of 127. This included 102 staff members, of which there are 100 temporary agents (TA), 2 officials (OFF) and 19 auxiliary agents (AUX). In addition, 6 seconded national experts (SNEs) joined EFSA during the year.

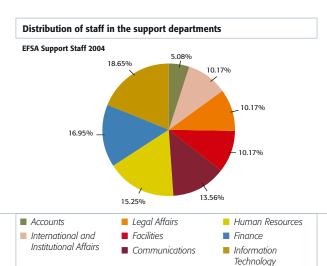
AUX	19	14.96%
TA & OFF	102	80.32%
SNE	6	4.72%
Total Staff	127	100%

Current staffing levels

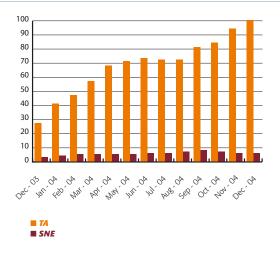


There were 75 new staff members recruited in 2004, 42 of whom joined the Science department.





EFSA staff in 2004 (Temporary Agents and Seconded National Experts)



Challenges

In 2004, EFSA faced a number of challenges in terms of Human Resources management. It had to maintain a very high rate of recruitment, despite challenges such as the parallel move to Parma and the increasing workload in all departments, especially in the Science department.

The increased workload, as seen by the growing number of requests for scientific opinions from EFSA's Scientific Panels, emphasised the urgency of recruiting staff.

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EFSA's aim in the scientific area is to attract the very best European specialists in their fields, both to staff the actual Authority and to serve as independent scientific experts on EFSA's Scientific Panels. Clearly, people with such profiles are rarities in the European labour market.

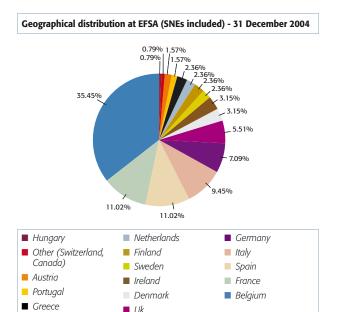
The move to Parma has also required a significant investment from the organisation, and in particular from the Human Resources department, in order to prepare EFSA and its staff for this important transition. The department has been involved in establishing rules and procedures and supporting the relocation process, as well as providing language courses. As part of its efforts to assist families with their relocation, EFSA has had significant involvement in the establishment of a pilot project for a European School in Parma.

In 2004, the Human Resources department also devoted a large amount of work to establishing structures, policies and procedures of a wider nature, in order to facilitate day-to-day work processes and increase efficiency.

The first staff committee representing the interests of EFSA staff was also launched.



The table below shows the geographical distribution of staff. Fifteen nationalities of the European Union are represented, including one from a new Member State.



As the table shows, the most common nationality amongst the staff is currently Belgian. As with most international institutions, the host country provides the major proportion of staff. It is clear that EFSA will continue to aim at providing the most equitable balance of national representation, while trying to attract the best professionals from less well-represented states and new Member States. However, it can be



predicted that the proportion of Italian staff will increase over the next few years. Indeed, recruitment drives since the announcement of EFSA's establishment in Parma have attracted a greater number of Italian applicants than in the past.



Recruitment policy

All posts were published on the EFSA website.

EFSA applies a policy of equal opportunities in its recruitment procedures. It considers applications without distinction on the grounds of age, race, political, philosophical or religious conviction, gender or sexual orientation, and regardless of disabilities, marital status or family situation.

The male/female ratios were 8.82% to 91.18% for the C level posts, rising to a 50/50 split for the B level posts and with a ratio of 44% to 56% in the A level posts for temporary agents. EFSA therefore has a majority of female staff overall, as well as in each grade and category, including the most senior level (ie A grades).

Legal Affairs

In 2004, the Legal department continued to fulfil its mission to establish and maintain a legally sound and secure environment in compliance with Community law for all of EFSA's activities.

The department has bolstered its resources and organisation in order to serve the needs of the Authority more effectively in this critical year of growth and consolidation of structures and activities. It has been particularly active in the following areas:

 Completing the scheme of internal rules and decisions, thereby allowing EFSA to operate effectively. Highlights include rules of procedure for EFSA constitutive bodies; guidance on conflicts of interest; establishment of internal rules on transparency and confidentiality; and access to documents (see specific section below);

- Legal and procedural advice on questions applicable both horizontally and vertically to the Scientific Committee and Panels. This has been particularly challenging in view of the experience gained with the implementation of EFSA's founding Regulation and new legislation which affects EFSA directly, e.g. Regulations (EC) 1829/2003 on genetically modified food and feed and 1831/2003 on additives for use in animal nutrition:
- Legal aspects concerning the establishment of EFSA in Parma, in particular with regard to the implementation of the Seat Agreement and legal and contractual issues linked to EFSA's provisional and permanent accommodation in Parma:
- Procurement and contract management, both concerning the handling of individual projects and establishing EFSA's procedures for the smooth planning, functioning and monitoring of this activity.

Access to documents

Under Article 8 of EFSA's decision regarding access to documents (MB 16.09.2003), EFSA undertakes, as part of the annual activity report, the annual publication of information regarding the number of requests for access to documents, the number of refusals and the reasons for such refusals.

In 2004, EFSA received 9 applications under Regulation (EC) 1049/2001. Most of these were received towards the end of the year. In line with the applicable legal requirements, access was granted to all requests finalised in 2004. In some cases, the complexity of the application and the need for third party consultations required an extension of the deadline, allowing

the process to be concluded in early 2005. The Authority is fully committed to its legal obligations under Regulation (EC) 1049/2001 and is implementing tools and procedures to ensure that requests are monitored and processed in both an efficient and lawful manner. EFSA expects applications under this Regulation to continue to increase in 2005.

Financial Affairs

Given the substantial increase of EFSA's activities in 2004, the Finance team was highly focused on budgetary and financial matters. Additional staff were hired during the year in order to bolster the centralised financial verification and to establish the basis for the implementation of the Internal Control Standards in 2005.



Internal Control Standards are geared to ensure that objectives are reached economically, efficiently and effectively and that management policies and regulations are adhered to. These standards also cover the well-timed production of reliable financial and management information, the safeguarding of assets and information, the prevention and detection of fraud and error, and the quality of accounting records.

During the year, two supplementary and amending budgets were approved. They related to (i) the release by the Parliament of the 10% reserve initially taken in relation to operational activities and (ii) the result of the 2003 budget out-turn. The impact of these two supplementary and amending budgets was a EUR 1.3 million increase to the 2004 budget as initially adopted by the Management Board. The final 2004 budget therefore amounted to EUR 29.1 million.

EFSA's evaluation process pursuant to Art. 61 of Regulation (EC) 178/2002 was launched in cooperation with the Commission services and led to the adoption of the Terms of Reference by the Management Board in November. A call for tender, based on these Terms of Reference, was issued in December and the award decision taken in January 2005. The first objective of EFSA's evaluation is to establish the possible need to improve the organisation's present and future design, mission and tasks. The second is to provide transparency and accountability in reporting the results of its activities to European citizens and their impact on them. The Management Board will examine the conclusions of the evaluation and issue such recommendations to the Commission as may be necessary regarding changes in the Authority and its working practises. The evaluation and the recommendations will be made public.

As far as infrastructure is concerned, the investigation of available alternatives regarding a provisional operational headquarters in Parma was finalised in May. On the basis of EFSA's requirements and the technical and economical merits in terms of the alternatives found, a proposal was submitted to the Management Board and then to the Budgetary Authority. The outcome is described in the following section.

José Fernández Bayo, Facilities



Facilities

The decision taken by the EU Heads of State and Government in December 2003 about the site of EFSA headquarters made 2004 a challenging year. In addition to providing EFSA with professional office space in Brussels during a phase of strong growth and developing appropriate contract, supply, mainte-

nance and security services, a new office building had to be found in Parma. The investigations started in March and led to the signature of a rental contract in June after approval by the European Parliament.

The building occupied is part of the DUS complex and is situated within the inner ring of Parma. Some work (for instance, connecting the different parts of the building or creating additional partitions) had to be done in order to meet the Authority's requirements.

This work was carried out and completed under EFSA's supervision. From October onwards, EFSA staff started to relocate to the Authority's new operational headquarters.





Information Technology

In 2004, the Information Technology (IT) department focused its efforts on servicing its main clients, namely the Science department, the Advisory Forum, the Communications department and EFSA corporate. The department will maintain this focus in 2005.

With regard to Science, the IT department delivered Extranet facilities to each Scientific Panel so that scientific information could be exchanged securely between EFSA and Panel members. The department also provided Internetbased systems that support specific regulations for dossier submissions and public or private consultation. This was notably the case with the Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods (AFC), the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP), the Panel on Genetically Modified Organisms (GMO), and the Unit for Pesticide Risk Assessment (PRAPeR). One of the largest scientific projects of 2004 (due for completion in 2006) was the implementation of the online Zoonoses Community Report and associated online systems for baseline studies. Finally, the IT team provided a register of scientific questions, available on EFSA's website.

To support the work of EFSA's Advisory Forum, the IT department delivered an experimental Extranet (in production in July 2005) and launched a major project to provide all European national food safety agencies and EFSA with on-demand videoconference capabilities (available in June 2005).

In the field of Communications, IT provided an initial web content management system that allowed EFSA to launch its new website in March 2004 and to keep it up-to-date throughout 2004. To improve its responsiveness further, EFSA's IT department purchased a commercial web content management system which will be rolled out in 2005. IT also supported the International and Institutional Affairs and Communications departments in order to ensure webcasts of Management Board meetings which will continue in 2005.

With regard to the move to Parma, the IT department established a high-bandwidth network between its Parma and Brussels offices. With this arrangement, all information and communication services have been available in both locations. Moreover, network equipment and corporate servers can be moved to Parma with minimum disruption for EFSA staff.

Finally, regarding corporate projects, the IT department also enhanced the robustness of its main information systems. More specifically, the department deployed failover solutions for its mail and document management systems.



ΙT

The department revamped and documented most of its operating procedures, offering live, onsite support between 08:00 and 18:00. The IT department launched a major effort to scan and store EFSA's 300,000-page scientific archive (completion date: June 2005). It also improved EFSA's recruitment applications, provided a financial forecast application and provided systems to automate expert meetings.

4.2. Scientific activities



Scientific Committee, plenary meeting

The scientific activities in 2004 were, to a large extent, a continuation of work already started in 2003. The scientific activities were grouped around the following four major themes:

- Providing scientific opinions, guidance and advice in response to questions formally posed to the Authority or at the Authority's own initiative (self-tasks);
- Assessing the risk of regulated substances and development of proposals for risk-related factors;
- Monitoring of specific risk factors, zoonoses and animal diseases;

• Development, promotion and application of new and harmonised scientific approaches and methodologies for hazard and risk assessment of food and feed.

The scientific activities were predominantly carried out by the 8 Scientific Expert Panels and the Scientific Committee. A number of Scientific Expert Working Groups, often supported by the respective Panels or the Scientific Committee, also contributed to EFSA's scientific output. These expert groups included the:

- Scientific Expert Working Group on Transmissible Spongiform Encephalopathy (TSE) Testing;
- Scientific Expert Working Group on the Assessment of the Geographical BSE Risk (GBR);
- Task Force on Zoonoses Monitoring and Data Collection;
- Unit for the Pesticide Risk Assessment Peer Review (PRAPeR).

In addition, EFSA's Scientific Expert Service Division, although very much in its early days and clearly still understaffed, has already provided specific technical assistance to the Panels and Scientific Committee where needed. It has also initiated specific scientific activities at the request of, or otherwise supported by, the Scientific Committee.

The scientific activities highlighted do not represent a full and detailed overview of all the tasks and projects carried out in 2004. They are primarily intended to provide an illustration of the breadth of the scientific work and to emphasise the specific activities considered part of EFSA's core scientific mission and tasks.

2004 was a year full of challenges. The total number of formal questions received from the Commission, European Parliament and Member States was again substantial (180) and covered a wide variety of issues, some of which were very complex, others of which were relatively straightforward. An extremely important and detailed opinion was the one released in March about the transport of animals. This opinion and the accompanying scientific report, together totalling more than 200 pages, covered the specific aspects of animal health and welfare for the transport of a wide variety of mammals, poultry and aquatic species. On the other hand, the Panel on Dietetic Products, Nutrition and Allergies (NDA) adopted a series of opinions about the likelihood of adverse reactions in allergic individuals to specific product ingredients. Although thorough assessments were made, the NDA Panel managed to adopt a range of opinions (about different ingredients) in a relatively short time. Hence the number of opinions issued by a Panel is not in itself an indication of its productivity.

The table on the next page shows the numbers of meetings held by the various Panels and their subsidiary Working Groups. It provides further information about the level of activity of the different Panels. The overall number of almost 400 meetings organised in 2004 is a clear indicator of the dynamic development and operation of EFSA's scientific work.

NUMBER OF SCIENTIFIC EXPERT OPINIONS DELIVERED AND QUESTIONS RECEIVED IN 2004					
Scientific expert Panel	Questions received	Scientific opinions			
Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods (AFC)	51	49			
Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)	39	32			
Panel on Plant Health, Plant Protection Products and their Residues (PPR)	9	7			
Panel on Genetically Modified Organisms (GMO)	15	7			
Panel on Dietetic Products, Nutrition and Allergies (NDA)	31	31			
Panel on Biological Hazards (BIOHAZ)	18	16			
Panel on Contaminants in the Food Chain (CONTAM)	4	10			
Panel on Animal Health and Welfare (AHAW)	9	6			
Scientific Committee (SC)	4	1			
Total	180	159			

NUMBER OF PLENARY MEETINGS AND WORKING GROUP MEETINGS						
Scientific expert Panel	Number of plenary meetings	Number of Working Groups	Number of Working Group meetings			
Panel on Food Additives, Flavourings, Processing Aids and Materials in contact with Foods (AFC)	5	5	22			
Panel on Additives and Products or Substances used in Animal Feed (FEEDAP)	10	22	40			
Panel on Plant Health, Plant Protection Products and their Residues (PPR)	6	4	19			
Panel on Genetically Modified Organisms (GMO)	10	6	33			
Panel on Dietetic Products, Nutrition and Allergies (NDA)	5	5	20			
Panel on Biological Hazards (BIOHAZ)	8	23	63			
Panel on Contaminants in the Food Chain (CONTAM)	5	7	27			
Panel on Animal Health and Welfare (AHAW)	7	11	41			
Scientific Committee (SC)	6	4	19			
BSE / TSE Assessments	_	3	17			
Task Force on Zoonoses Monitoring	1	2	6			
Pesticide Risk Assessment Peer Review (PRAPeR)	_	6	23			
Total	63	98	330			

PROVIDING SCIENTIFIC OPINIONS AND ADVICE ABOUT QUESTIONS FORMALLY ADDRESSED TO THE AUTHORITY

Additives and Products or Substances used in Animal Feed

The Scientific Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) met 10 times in plenary session in 2004 and issued 32 opinions. In May 2004, the Panel's 10th plenary meeting was held in Barcelona and included a special session open to all stakeholders. The FEEDAP Panel has established various Working Groups in order to address its extensive work programme on the assessment of feed additives in accordance with community legislation including Regulation (EC) 1831/2003. This Regulation defines new groups of feed additives and thus requires the establishment of new guidelines. A new Working Group has started work on the development of guidelines for silage additives.

The FEEDAP Panel initiated three self-tasks in 2004. The first task is related to updating the criteria in assessing bacteria for antibiotic resistance. The Working Group established to tackle this issue developed a draft document that was issued for public consultation at the end of the year. The second self-task is related to environmental risk assessment models for feed additives, in particular for aquatic environments. The Working Group established for this subject met twice during 2004. A third request for a self-task was accepted by EFSA at the end of the year, and concerned the assessment of herbal products for use in animal nutrition. A Working Group will be established and will meet for the first time in 2005.

Animal Health and Welfare

The Scientific Panel on Animal Health and Welfare (AHAW) adopted 6 opinions in 2004 (about stunning, transport, microclimate during transport, piglet castration, the welfare of laying hens, and Mycobacterium avium paratuberculosis). The opinion about the welfare of laying hens will be submitted for co-adoption by the Scientific Panel on Biological Hazards (BIOHAZ) and the Scientific Panel on Contaminants in the Food Chain (CONTAM) in 2005. It will address the implications of the different laying hen production systems for egg safety. The AHAW Panel received 10 guestions in 2004, most of them from the European Commission (EC) Health and Consumer Protection Directorate-General (DG SANCO), the EC Development Directorate-General (DG DEV) and the EC Environment Directorate-General (DG ENV). AHAW Panel experts also contributed to the scientific opinion about Salmonella vaccination in poultry adopted by the BIOHAZ Panel.



The Panel's Working Groups on transport, stunning and piglet castration each published a comprehensive scientific review report. These contained all the relevant available data necessary for the risk assessment of these three subjects. This procedure was followed in order to allow for a more concise format of the respective opinions. References were added to scientific reports relating to specific details about the substantial number of species covered. These scientific reports were published on the Internet, together with the scientific opinions. In developing its opinions about the welfare of laying hens and piglet castration, the AHAW Panel also took a comprehensive view and, consequently, addressed possible impacts on food safety.

In addition to developing the opinions described above, the Panel also produced two discussion documents: "Priorities on possible areas for self-tasking in animal health and animal welfare" and "Recommendations for future research and new concerns related to AHAW issues". The second document was addressed to the Scientific Committee, as one of EFSA's contributions to the next framework programme of the Commission's DG RTD (Research Directorate-General).

Biological Hazards

In 2004, the Scientific Panel on Biological Hazards (BIOHAZ) met 8 times in plenary session. On food microbiology, food hygiene, food-borne zoonoses and meat inspection, the Panel held 12 ad hoc Working Groups to deal with requests received from the European Commission. On BSE questions, the Panel established 9 ad hoc Working Groups to deal with requests received from the European Commission, Member States or the European Parliament. On animal by-products

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Transport of pigs, loading on a truck



Members of the BIOHAZ Team

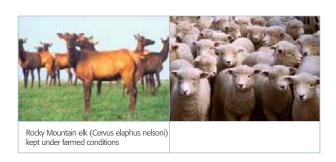
(ABP), the Panel established 2 ad hoc Working Groups to deal with requests received from the European Commission.

The BIOHAZ Panel adopted 16 opinions in 2004, following requests for scientific opinions received from the European Commission. In the area of food microbiology, food hygiene, food-borne zoonoses and meat inspection, 2 opinions were adopted about the revision of meat inspection procedures for lambs and goats, and also for beef. They form part of a series of opinions which started with the former SCVPH Committee (Scientific Committee of Veterinary measures relating to Public Health) under the Health and Consumer Protection Directorate-General (DG SANCO). One opinion about microbiological risks in infant formulae identified Salmonella and Enterobacter sakazakii as the micro-organisms of major concern for high risk babies. In the food hygiene area, one opinion was published related to freezing requirements for meat infected with cold tolerant strains of Trichinella. Food-borne zoonoses, such as Salmonella in poultry, were the focus of two major opinions about the advantages and disadvantages of antimicrobials and vaccines to control Salmonella in poultry, especially those serotypes of major concern to public health in Europe.



In the area of Transmissible Spongiform Encephalopathy (TSE), the BIOHAZ Panel Working Groups received the greatest number of questions from the European Commission (DG SANCO) in 2004. In addition, one question was received from the European Parliament about the safety of goat milk and goat milk products and one from a Member State (France) about the BSE situation in Portugal. From the general questions received, opinions were adopted about the review of the United Kingdom (UK)'s Over Thirty Months (OTM) rule and its application for moderate risk status in terms of BSE. A mandate on Chronic Wasting Disease (CWD) resulted in an opinion about the suggested plans for surveillance of this disease in the European cervid population, which will now be followed up by European Commission action to initiate this survey in the 25 Member States. An opinion was adopted about the risks of stunning and the dissemination of central nervous system tissue (CNS) and thus the risk of spreading of BSE into the carcass, as were opinions about BSE-related culling in cattle and about BSE risk from bovine tonsils and the consumption of bovine tongue. The review of the BSE

situation in Portugal was carried out following a request by France and an adaptation of the conditions for Portuguese beef exported to other Member States. The review of the age limit for removal of Specified Risk Material (SRM), a mandate on the Ouantitative Risk Assessment on residual BSE risk in certain bovine derived products, such as tallow and gelatine, were additional topics initiated in 2004. In the field of animal by-products (ABP), several topics were covered, such as the biological safety and use of organic fertilisers, biogas and compost treatment standards, and the biological safety of heat treated manure. A range of methods for the safe disposal of category 1 ABPs not intended for human consumption were assessed and opinions adopted, such as the Biodiesel process, combustion of tallow in a boiler process and the process of High Pressure Hydrolysed Biogas (HPHB) production.



Towards the end of the year, the discovery of suspected BSE in a goat (subsequently confirmed) was the subject of two questions, one from the European Commission and the other from the European Parliament. This work was initiated in 2004 and a statement on goat milk and goat milk

products has already been issued, while the update of current opinions, notably with respect to the safety of goat meat, is continuing. This topic was also the subject of a statement issued by the BIOHAZ Panel. Other highlights included the release of opinions about the OTM rule in the UK, the re-classification of the BSE risk in the UK to moderate level and the publication of the Geographical BSE Risk (GBR) Assessment reports of 7 countries.

Contaminants in the Food Chain



Members of the CONTAM Team

In 2004, the Scientific Panel on Contaminants in the Food Chain (CONTAM) adopted 10 opinions and received 4 additional questions. The opinion about the assessment of health risks to consumers associated with the exposure to organotins in foodstuffs was an important milestone, because the Commission's Scientific Committee on Health and Environmental Risks (SCHER)¹ will use this opinion to prepare an overall risk assessment including non-food exposure.

In February 2004, the Panel adopted an opinion about the risks of methylmercury in food which contributed to discussion in Europe about the risks and benefits of eating fish. As a result, in the same month, EFSA received its first request from the European Parliament for a safety assessment of farmed and wild fish. In order to address this comprehensive question, the CONTAM Panel established a Working Group on the Safety of Wild and Farmed Fish (SWAFF), comprising experts from other Panels such as NDA, FEEDAP and AHAW. This was to ensure expertise in different areas, including the beneficial effects of eating fish. A second request from the European Parliament, relating to the health risk of the consumption of Baltic herring and which was received later in the year, will also be addressed in this opinion. The CONTAM Panel's Working Group on SWAFF held 4 meetings in 2004 and the opinion is expected to be available by mid 2005. The Panel was also asked to assess the effective risk to the consumer from the consumption of fishery products belonging to the family of Gemphylidae (e.g. Escolar and Oilfish). This opinion was adopted in August 2004.

The Panel's Working Group on non-dioxin-like polychlorinated biphenyls (PCBs) met 8 times in 2004 to prepare an opinion concerning the presence of these PCBs in feed and food. The adoption is expected during spring 2005. In September, EFSA organised a session entitled "Risk Assessment of non-dioxin-like PCBs" at the World Dioxin Congress² to stimulate scientific discussions and to provide further guidance for the work which the Group is conducting.

The CONTAM Panel initiated 2 self-tasks. The first task related to findings from the US Food and Drug Administration

(FDA) that canned and jarred foods which undergo heat treatment may contain furan, a carcinogenic substance. EFSA considered this an emerging issue in food safety and decided to ask the CONTAM Panel to compile a scientific report comprising currently available data about methods of analysis, occurrence, formation, exposure and toxicity. The report on provisional findings of furan in food was published in December 2004 and highlighted the need for further research in order to draw a conclusion with respect to human health. The second self-task related to perfluorooctane sulphonate (PFOS) and its salts, as there are indications that their levels in the environment and the general population are increasing. An initial co-ordination meeting took place at the end of 2004 and the Working Group will meet for the first time in 2005.



CONTAM Panel, plenary meeting

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¹ EU Scientific Committee on Health and Environmental Risks (SCHER)

² 24th International Symposium on Halogenated Environmental Organic Pollutants and Persistent Organic Pollutants (POPs) - DIOXIN 2004, Berlin, 6-10 September 2004.

Dietetic Products, Nutrition and Allergies

The Scientific Panel on Dietetic Products, Nutrition and Allergies (NDA) met 5 times in plenary session in 2004. In addition to the 4 Working Groups on food allergy, infant formulae, novel foods and upper levels for vitamins and minerals, already established in 2003, the NDA Panel set up a new Working Group on trans fatty acids. The NDA Panel adopted 31 opinions in 2004 following requests for scientific opinions from the European Commission. These NDA opinions fall into the following main areas:

 Evaluation of the 12 allergenic foods for labelling purposes (Annex IIIa of Directive 2000/13/EC) and the assessment of 21 applications on allergen derivatives submitted for temporary labelling exemption. The remaining 8 applications will be finalised in early 2005;



- Setting tolerable upper levels of intake for the following vitamins and minerals: vitamin C, iron, boron, vanadium, and silicon. The assessment of the remaining 7 nutrients will be finalised in early 2005;
- Presence of trans fatty acids in foods and the effect of the consumption of trans fatty acids on human health;
- Safety assessment and suitability of goats' milk protein and fructooligosaccharides as ingredients of infant formulae and follow-on formulae;
- Safety assessment of a novel food application for Enova oil pursuant to the Novel Food Regulation (EC) N° 258/97.

In addition to these requests, the European Commission also asked the NDA Panel to provide scientific opinions about the following subjects:

- Safety assessment of the following novel foods: rape seed oil
 high in unsaponifiable matter, maize germ oil high in unsaponifiable matter, betaine and lycopene. The expected date
 of completion for these requests is early 2005, except for
 the two applications about unsaponifiable matter, for which
 the expected completion date is three months after the
 receipt of the additional data requested from the applicant;
- Two scientific articles related to safety aspects of phytosterols. The expected completion date is April 2005;
- Nutritional claims related to unsaturated fat, poly-unsaturated fat, mono-unsaturated fat and omega-3 fatty acids. The expected completion date is July 2005.

Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods

The Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods (AFC) met 5 times in plenary session in 2004, issuing 49 opinions and 3 statements. The Panel evaluated 3 new food additives, ethyl cellulose, pullulan and tertiary-butylhydroquinone (TBHQ), as well as re-evaluated 8 others, namely sucrose esters of fatty acids, titanium dioxide and 6 para hydroxybenzoates (parabens). For the latter, the Acceptable Daily Intake (ADI) for propylparabens was withdrawn because of estrogenic effect. The Panel also issued opinions and one statement about calcium-L-methyl folate, calcium sulphate, magnesium aspartate, creatine monohydrate, and boric acid and sodium borate as sources of nutrients and other substances added to food or supplements.



Members of the AFC Team

In the area of flavourings, the Panel adopted its first 5 flavouring group evaluations of chemically defined flavourings. In all, these covered 128 substances within the framework of Regulation (EC) 1565/2000 of 18 July 2000. The Panel recommended that one of these 128 substances, pentane-2,4-one, should not to be used in food because of

genotoxic properties. The rest were found not to cause health problems when the potential exposure was calculated using the Maximised Survey-derived Daily Intake (MSDI) method, which was also previously used by the Scientific Committee on Food (SCF) and the Food and Agriculture Organisation (FAO)/World Health Organisation (WHO) Joint Expert Committee on Food Additives (JECFA). This method is based on exposure estimates derived from annual production volumes. When using an alternative method, the modified Theoretical Added Maximum Daily Intake (mTAMDI) method, which calculates potential exposure to the flavourings based on levels added to foods as reported by industry, several of the substances were found to potentially exceed the specified levels of concern. The Panel therefore initially requested data to allow for a more refined intake estimate for these substances.

The Panel also issued opinions about coumarin, furfural and hydrocyanic acid in the process of evaluating active princi-

ples in Annex II of the Flavourings Directive 88/388/EEC and adopted a guidance document about how to submit a dossier concerning smoke flavourings.

The Panel continued to evaluate monomers and additives for food contact materials and adopted opinions about 5 lists containing a total of 33 substances. The Panel also adopted an opinion about whether it is appropriate to apply the so-called Fat (consumption) Reduction Factor (FRF) for foods intended for infants and children, as well as an opinion about mineral hydrocarbons in foods packed in jute and sisal bags.

Genetically Modified Organisms

In 2004, the Scientific Panel on Genetically Modified Organisms (GMO) received 15 questions. These included a general question from the European Commission (DG ENV), 4 questions related to applications under Directive 2001/18/EC and 8 applications under Regulation (EC) 1829/2003.



Members of the GMO Team

The Panel initiated a self-tasking activity on post-market environmental monitoring (PMEM) and proposed a mandate to start a self-task about the use of animal feeding trials for the safety evaluation of genetically modified (GM) food and feed. The Panel had an eventful year with the implementation of the new Regulation (EC) 1829/2003 which came into force on 1 April 2004. Several meetings took place to discuss the new tasks assigned to EFSA regarding this Regulation. The Panel adopted 7 opinions.

Three ad hoc GMO Panel Working Groups each dealt with a specific question, namely the development of a GM Plant Guidance Document, Guidance on GM Micro-organisms and Post Market Environmental Monitoring. The Working Group on the GM Plant Guidance Document established an on-line



consultation process to provide stakeholders with the opportunity to submit comments electronically about the draft guidance document. On 25 May 2004, the GMO Panel held a Stakeholders Consultation meeting in Brussels to answer the many comments received about the draft guidance document. Some 80 participants, representing all sectors, ie consumer and other non-governmental organisations (NGOs), industry, academics and competent authorities attended this meeting. Further Working Groups were arranged to discuss the comments in more detail and to review the document. The guidance document for the risk assessment of genetically modified plants and derived food and feed was adopted at the GMO plenary meeting in September and will be published off-line in early 2005.

The self-tasking Working Group on Post Market Environmental Monitoring (PMEM) addresses the requirements for post market environmental monitoring in order to produce guidance for both applicants and regulatory authorities. The PMEM Working Group initiated a series of consultation workshops with different stakeholders (applicants, environmental NGOs and scientific institutes, experts from Member States) to establish a rationale and a general framework for General Surveillance as part of PMEM. The Working Group met 4 times, 2 of which were held as stakeholder workshops. This activity continues in 2005.

Plant Health, Plant Protection Products and their Residues

The Scientific Panel on Plant Health, Plant Protection Products and their Residues (PPR) met in plenary session 6 times in 2004 and held 19 Working Group meetings. The Panel issued 7 opinions in 3 sectors: toxicology, en-



vironment and ecotoxicology, or combinations of two or more sectors. The opinions issued in toxicology concerned the active substances daminozide (a metabolite's carcinogenic action), dinocap (two questions, one about its effect on dogs' eyes and one about dermal absorption), methamidophos (establishing a value for the degree of dermal absorption) and alachlor (two questions, one about the occurrence of nasal turbinate tumours in rats and one about the relevance of metabolites). The environmental sector opinions were related to the Review Programme under Council Directive 91/414/EEC - Second stage addressing the Forum for the co-ordination of pesticide fate models and their use (FOCUS). These are the models used at FU level for the risk assessment of the fate and behaviour of pesticides in soil and water. One opinion was delivered about FOCUS ground water (comparability with the available FOCUS ground water models). Another was about FOCUS surface water

(whether the use of the FOCUS surface water scenarios is appropriate in particular situations, such as the use of seed dressings and granular formulations). The opinion issued in 2004 in ecotoxicology concerned methamidophos (exposure of birds and mammals to contaminated diets, avoidance behaviours). A self-task requested by EFSA's Unit for the Pesticide Risk Assessment Peer Review (PRAPeR) about the long-term toxicity of dimoxystrobin in fish will be adopted early in 2005.

The Panel also received a request for a scientific opinion about the appropriate variability factor(s) to be used for the acute dietary exposure assessment of pesticide residues in fruit and vegetables. The Panel expects to finalise this opinion in the first quarter of 2005.



ASSESSING THE RISK OF REGULATED SUBSTANCES AND DEVELOPING PROPOSALS FOR RISK-RELATED FACTORS

Additives and Products or Substances used in Animal Feed

EFSA received close to 9,000 notifications of existing feed additives within a year of Regulation (EC) 1831/2003 coming into force. EFSA was asked to verify that all the required information has been submitted. The Authority started this extensive task in 2004 and will inform the Commission regarding the completeness of all notifications by November 2005.

Seven opinions about coccidiostats intended for use either in fattening chickens, or in rearing laying chickens, turkeys and/or rabbits were adopted in 2004, and 2 further updates were adopted following submission of new data. A total of 15 opinions about micro-organisms and enzyme products intended for use as feed additives were adopted by the Panel.

The work of the FEEDAP Working Group on the use of iodine in animal nutrition continued with two more meetings and an opinion is expected in early 2005. The Panel has also been asked to assess the safety of all carotenoids used in animal nutrition. As well as a technical hearing on the subject with industry representatives, 4 Working Group meetings were also held addressing the work on the Maximum Residue Levels (MRLs) for canthaxanthin. In July 2004, a new Working Group on product Hydroxy-vitamin-D3 (calcifediol) was established to review the product's safety and efficacy in different poultry species. The work involved 3 meetings in 2004 and will continue in 2005. Following a request in March 2004 to assess L-histidine for use

in salmonids, a Working Group was established, and has met twice. This opinion will be completed in 2005.

The FEEDAP Panel was further asked to assess the safety of formaldehyde as a feed additive for poultry, KDF (Potassium Diformate) Preservative, a product based on potassium diformate to preserve fish material and potassium formate for use in sows. These 3 opinions were adopted in 2004. One opinion was issued about the safety of a histomonostat product, one about the use of zeolite to prevent milk fever, one about a yeast product as a source of protein and one about the environmental impact of astaxanthin-rich Phaffia rhodozyma.

Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods

In the food contact area, the Panel allocated a Tolerable Daily Intake (TDI) for bisphenol A-diglycidyl ether (BADGE) and its hydrolysis products. It concluded that BADGE chlorohydrins are not genotoxic and so the limit established following previous evaluations still remains appropriate. In another opinion about ESBO (epoxydised soybean oil), the Panel noted that ESBO is neither carcinogenic nor genotoxic, but that there is a risk that, with the present migration pattern, some children might exceed the TDI. It is therefore recommended that a lower migration limit for foods, especially those intended for children, be considered.

Genetically Modified Organisms

The GMO Panel received 4 questions related to applications under Directive 2001/18/EC and 8 applications under Regulation (EC) 1829/2003. With many applications to work on, the Panel had 3 Working Groups for each dossier to focus on, namely environmental risk assessment, molecular characterisation and food and feed safety.



The GMO Panel adopted 7 opinions in 2004 relating to:

- Notification (Reference C/NL/98/11) for the marketing, importing and processing by Monsanto of herbicide-tolerant oilseed rape GT73, under Part C of Directive 2001/18/EC;
- Notification (Reference C/DE/02/9) for the marketing, importing and processing by Monsanto of insect-protected genetically modified maize MON 863 and MON 863 x MON 810, under Part C of Directive 2001/18/EC;
- The safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for which a marketing request was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto;
- The use of antibiotic resistant genes as marker genes in genetically modified plants;
- Request from the Commission related to Greece invoking Article 23 of Directive 2001/18/EC;
- Request from the Commission related to Austria invoking Article 23 of Directive 2001/18/EC;
- Notification (Reference C/NL/00/10) for the marketing, importing and processing by Pioneer Hi-Bred International/Mycogen Seeds of insect-tolerant genetically modified maize 1507, under Part C of Directive 2001/18/EC.

In addition to EFSA's central role with respect to GMO risk assessment, Regulation (EC) 1829/2003 on GM food and feed

also places important administrative and management tasks on EFSA. This is why EFSA has set up a collaborative electronic tool, the GMO EFSAnet, to exchange information with the Commission and with national agencies and competent authorities involved in GMO risk assessment. EFSA's support unit for the GMO Panel has contributed to exploring possible networking with Member States. The GMO unit has also dealt with several requests for public access to documents. In addition, the GMO Panel and EFSA's support unit for this Panel have responded to numerous requests from stakeholders and journalists regarding GMO matters.

Pesticide Risk Assessment Peer Review

During 2004, the risk assessment of existing active substances used in pesticides continued for substances in the second stage of the EU review programme following Council Directive 91/414/EEC. For all 52 substances, the initial assessments were received from the respective designated reporting Member State during the course of the year. The peer review of the active substances was initiated by distributing these draft assessment reports to the Member States and the notifiers for comment.

The first 39 substances were discussed in evaluation meetings with representatives from the Member States to identify the need for submission of further data, or issues for further detailed discussion at expert level which took place for the first 12 substances. EFSA was assisted in the peer review by the EPCO (EFSA Plant Protection Products Peer Review Coordination) project, organised jointly with the German Federal Office for Consumer Protection and Food Safety (Bundesamt für Verbraucherschutz und

Lebensmittelsicherheit, BVL) and the British Pesticide Safety Directorate (PSD). It provides administrative and scientific support and also holds EPCO expert meetings for scientific discussion by experts from Member States and EFSA, related to the areas of physical-chemical properties, mammalian toxicology, residues, fate and behaviour and ecotoxicology.

In October 2004, EFSA finalised the peer review for one active substance (tribenuron) and provided the European Commission with its first conclusion about the risk assessment. While the notifiers for 2 active substances (triazamate and naled) withdrew their participation from the review programme, EFSA is expecting to finalise the peer review and to submit its conclusions for the remaining 49 active substances in 2005.

In 2004, EFSA received the initial assessment, i.e. the draft assessment reports, for new active substances from the respective reporting Member States for 6 chemical and 2 biological active substances. The peer review was initiated following the same procedure as for existing substances.





MONITORING OF SPECIFIC RISK FACTORS, ZOONOSES AND ANIMAL DISEASES

BSE/TSE Assessment

The EFSA Expert Working Group on Geographical BSE Risk (GBR) received its mandate in 2003 and continues to collect and analyse data and discuss re-assessments of the GBR from different countries. Assessments for 7 countries were finalised and published in 2004. These countries are the USA, Canada, Mexico, Norway, Sweden, South Africa and Australia. The assessments of a number of other countries are close to finalisation and will be published in the first few months of 2005. A BSE surveillance model (BSurvE) established by the Community Reference Laboratory for TSE was also analysed and a scientific report published.

The EFSA Expert Working Group on the evaluation of TSE Tests continued with the mandate it received from DG SANCO. This was for the evaluation of post mortem BSE tests on cattle, scrapie tests on sheep and goats, and applications for live animal BSE tests, all of which were submitted fol-



BSE Expert Working Group meeting

lowing a call for expression of interest. In 2004, the main outcome of this Expert Working Group's work included two protocols on evaluation of post mortem BSE tests and one on the evaluation of live animal BSE tests, plus a report for approval of 7 new post mortem BSE tests on cattle to be included in the legislation and a report on 6 tests, specifically for the detection of scrapie in sheep and goats, which is expected to be completed in the first quarter of 2005.

Monitoring of zoonoses

In 2004, EFSA prepared for its new responsibility of providing the annual Community Summary Report about zoonoses, zoonotic agents and antimicrobial resistance. In addition, EFSA received the mandate to extend the development of the data collection and reporting system in cooperation with the Commission and the Member States. For this purpose, a Zoonoses Monitoring Task Force was set up to assist and advise EFSA in this exercise. This Task Force comprises contact people for zoonoses from all the Member States, as well as representatives from the Commission and other interested parties, such as the World Organisation for Animal Health (OIE) and the World Health Organisation (WHO). Two Working Groups were established under the Task Force to consider the revision of the annual zoonoses reports and



Task Force on Zoonoses Data Collection

possible improvements of the data collection system respectively. EFSA provided all the information technology support needed to set up a modern web-based reporting system and a related database. Furthermore, following a call for tender, EFSA selected its Zoonoses Collaboration Centre (the Danish Institute for Food and Veterinary Research), which has already started to help EFSA to collect data and to prepare the Community Summary Report.

Immediately following the announcement of the appointment of the Executive Director to the newly established European Centre for Disease Prevention and Control (ECDC), contacts were made to ensure close co-operation in the area of foodborne outbreaks and baseline studies.

INVESTING IN FOOD SCIENCE: DEVELOPMENT, PROMOTION AND APPLICATION OF NEW AND HARMONISED SCIENTIFIC APPROACHES AND METHODOLOGIES FOR HAZARD AND RISK ASSESSMENT OF FOOD AND FEED

Scientific Committee

In 2004, the Scientific Committee (SC) met 6 times in plenary session. It continued its activities designed to develop, implement and promote new and harmonised scientific approaches and methodologies for risk assessments in the area of food and feed safety. The SC Working Group on Exposure Assessment (EXPOSURE) met 7 times to prepare an opinion about an appropriate strategy for exposure assessments by EFSA, and an opinion about uncertainties in exposure assessment. The adoption of both opinions is expected in the first half of 2005. The opinions about exposure assessment are intended to provide further guidance for the work which

the Scientific Panels will carry out. The SC Working Group on Genotoxic and Carcinogenic Substances (GENTOX) prepared an opinion about a harmonised approach for the risk assessment of substances that are both genotoxic and carcinogenic. The GENTOX Working Group met 5 times. Once the SC considers that the proposal is sufficiently developed to allow public consultation, the draft document will be published on the EFSA website. The final adoption of the GENTOX opinion is expected in June 2005.

In December 2004, the first meeting took place with the contractor selected to assist the Authority in building up its capability in identifying and evaluating emerging risks. Prior to this, the SC Working Group on Emerging Risks (EMRISK) met 5 times to evaluate the tenders and to prepare the work which will be carried out with the contractor's assistance. In October 2004, the first meeting of a new SC Working Group on Qualified Presumption of Safety (QPS) took place. The QPS Working Group is charged with preparing an opinion about a general approach for the safety evaluation of microorganisms used in food and feed. As a starting point, they will use a working document which was prepared by a joint



Prof. Vittorio Silano, Chair of EFSA's Scientific Committee



Working Group made up from the former Scientific Committee on Animal Nutrition (SCAN), the Scientific Committee on Food (SCF) and the Scientific Committee on Consumer Products (SCP) in 2003. The QPS Working Group met twice to plan its activities and to prepare the Scientific Colloquium that took place on 13 and 14 December in Brussels. The objective of this conference was to have

an open scientific debate on the proposed approach and to explore options about how to develop and implement the concept of QPS within EFSA's risk assessments.

In addition to the activities of the 4 Working Groups as described above, the Committee considered a number of additional issues in 2004 and initiated or supported activities to develop a number of these issues further. These include, among others:

• The development of a pro-active EFSA policy regarding the welfare of animals used in food production and experimentation. Following discussions of this policy by the Management Board and considering the subsequent questions and issues resulting from the Management Board discussions, the SC agreed to establish a new Working Group on Animal Welfare. This Working Group will prepare guidance for the Scientific Panels and Committee on implementing EFSA's policy of taking an active role in improving the welfare of food producing animals, and in developing risk assessment approaches resulting in the refinement, reduction and replacement of experimental animals;

- The Scientific Committee prepared a discussion paper to express its concerns about the possible health effects related to the wide use of botanicals and botanical preparations in food supplements. The discussion paper was brought to the attention of the Advisory Forum which agreed to contribute to an inventory so as to develop a clearer picture of the extent of the issue. This inventory was almost finished by the end of the year and follow-up work is expected in 2005;
- The discussion on appropriate principles and approaches for a proper interface between risk assessment and risk management could not be finalised due to the Scientific Panels' heavy workloads. The Committee intends to come to an agreement about a recommendation to EFSA, based on comments received from the Scientific Panels and its members, in the first half of 2005;
- The Scientific Committee was also involved in preparing the Terms of Reference for EFSA's evaluation and gave advice on a new activity related to improving transparency in EFSA's risk assessments.

EFSA Scientific Colloquia

The EFSA Scientific Colloquium Series was initiated in 2004 with the aim of achieving a better understanding of the fundamental scientific issues related to risk assessment on food and feed. Rather than simply being a series of lectures, they provide ample opportunity for an exchange of expert opinions. To that end, the Scientific Colloquia are sufficiently informal to allow for substantial debates if necessary. At the same time, they are suitably structured and managed to enable participants to reach conclusions and make recommendations, as appropriate. Two colloquia with 60-100 experts in their fields were organised in 2004.

The first colloquium addressed the scientific basis for setting tolerable intake levels for dioxins and dioxin-like polychlorinated byphenyls (PCBs). There was a general consensus on the toxicology of dioxins with respect to the current state of knowledge and future research needs. However, participants recognised that there were key differences in approach, due to uncertainties in evaluating the data, and agreed that research should focus on further reducing these uncertainties. The call for increasing transparency fits well with EFSA's project for increasing transparency in risk assessment.



1st Scientific Colloquium on Dioxins, 28-29 June 2004, Brussels

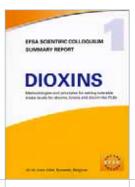
The second colloquium focused on the qualified presumption of safety (QPS) approach regarding micro-organisms in food and feed, and addressed the scientific principles behind this approach. It explored options for developing the concept further for its possible implementation by EFSA in safety assessments within the framework of current and proposed legislation. QPS is an attempt to provide a mechanism for approving micro-organisms that are relatively safe, while focusing fuller assessments on those micro-organisms that are more hazardous. If introduced into Europe, QPS will permit the identification of what is required to make an adequate risk assessment. Participants concluded that the scientific principles behind the QPS approach are valid



2nd Scientific Colloquium on QPS, 13-14 December 2004, Brussels

and that QPS appears, in principle, to be applicable to food, feed and products. An EFSA Scientific Committee Working Group is currently revising the original DG SANCO working document on QPS (see also Scientific Committee).

The summary reports of the colloquia are published on the EFSA website and are also available as hard copy publications in the EFSA Scientific Colloquium Report Series.



In 2005, EFSA will continue the Scientific Colloquium Series and 3 meetings have already been planned covering the following topics: 'Harmonised EU Food consumption database', 'Nutritional profiling' and 'Risk assessment approaches and experimental animal welfare'.

First issue of EFSA's Scientific Colloquium Series

Additional Horizontal Science Issues

Initiatives have been taken to develop a National Expert Database which will include information about experts and contact details in all the areas of EFSA's scientific mission. Once it is fully operational, this database will be made available, via the password protected EFSA Extranet, to national authorities, members of the Scientific Committee and all EFSA Working Groups and Panels. This database would allow Panels to select the best available experts should they need temporary outside expertise. It will also assist in-house staff in identifying Europe's best experts in times of crises. In addition, work has started to identify national institutions and laboratories in the context of Article 36 of EFSA's Founding Regulation.

A Working Group is currently being established to address a number of fundamental issues in risk assessment methodologies. Its aim is to make risk assessment more transparent and less rigid in terms of data requirements. The Working Group will start to develop criteria for the acceptance and rejection of studies, as well as addressing uncertainty factors. The Scientific Committee and Panel members will be actively involved in this project which has been initiated under the aegis of the Scientific Committee.



4.3. Communications Activities

Public information and events

Along with the Authority's scientific programme, Communications was a key growth area in 2004. The overall aim of EFSA's risk communications is to provide appropriate, consistent, accurate and timely communications on food safety issues, to all stakeholders and the public at large, based on the Authority's own risk assessments and scientific expertise. A critical success factor in achieving this goal lies in EFSA's ability to establish itself as an authoritative and trusted voice when it comes to food safety concerns.

By providing risk managers with the highest quality independent scientific assessments and disseminating such advice through effective risk communications in collaboration with the European Commission and Member States, EFSA strives to build public confidence in the risk assessment process.

More specifically, EFSA's objectives in the area of risk communications, which the Authority continued to pursue in 2004, were as follows:

- Establish the Authority as an expert and trusted source of information about food and food safety issues amongst its stakeholders and the public at large;
- Build and promote the Authority's reputation as an organisation dedicated to scientific excellence, independence, openness and transparency;

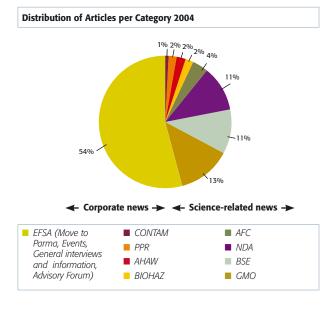


- Ensure that messages are relevant, understandable and address food safety concerns;
- Enhance / improve the coherence of information and food safety matters across the Community.

Media Relations

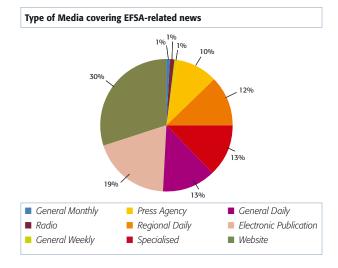
EFSA increased its level of media relations activity with the publication of 27 press releases in total, of which 18 were dedicated to science. It also issued news about its corporate activities, including its future move to Parma and key decisions from meetings of its Management Board. Approximately half of the publicity originating from EFSA public announcements related to the activity of its Scientific Panels. Press releases concerning opinions of the BIOHAZ, GMO and NDA Panels generated the greatest interest from the media because of

such topical issues as BSE, the safety of GM maize and the health effects of trans fatty acids. The issue of BSE infection in goats also contributed to the high level of media interest.



EFSA organised several press briefings during the course of the year. These included the public announcement in Brussels in September of the NDA Panel's opinion about the dietary intakes and health effects of trans fatty acids, as well as briefings at the Advisory Forum's first public event held in Berlin in November.

The Communications department has also made significant efforts to build relations with the media in Italy, particularly



in Parma, to ensure that they are kept informed about all of EFSA's activities, and specifically about the progress made in its move to Parma. EFSA was also present at the CIBUS International Food Fair held in Parma in May 2004, in order to begin establishing the Authority's presence there and fostering contacts with the Italian authorities, media, industry, consumers and other stakeholders.

Media Toolkit

One of the priorities for the Communications department for 2004 was the development of a media toolkit, including the creation of fact sheets and background documents about the Authority. Resources have also been devoted to creating a database of national and international contacts from the written, broadcast and online media.

Publications

What does EFSA do? How is the Authority structured? What do EFSA's scientific activities consist of? Throughout 2004, EFSA's Communications department met its objective of ensuring that these questions and many others now have precise written responses. In addition to the 2003 Annual Report, the department issued a series of publications in 2004 aimed at providing updated information regarding EFSA's objectives, organisation and activities.

EFSAnews is the Authority's monthly newsletter, first published in April 2004, which provides information relating to all of EFSA's activities, including scientific work, events, website developments and news about Parma. In December, a special edition entirely devoted to the EFSA Advisory Forum public event "Creating a European network to enhance risk assessments regarding the food chain," was published following the event. Editions of EFSAnews are available on the EFSA website (http://www.efsa.eu.int/press_room/efsa_journal_2004/catindex_en.html), and can also be received via e-mail on a regular basis by subscribing on the EFSA home page (http://www.efsa.eu.int) or sending an e-mail to newsletter@efsa.eu.int. Distribution of EFSAnews has reached nearly 6,000 copies.

EFSA now has a portfolio of 6 fact sheets. Five of the fact sheets provide information relating to corporate matters



(e.g. structure of EFSA, History, Advisory Forum, Science, Communication), while the sixth explains different EFSA-related issues in a frequently asked questions (FAQ) format. Furthermore a concise pocket edition, the EFSA brochure, was published in order to provide a succinct overview of EFSA, its role, organisation and achievements thus far.

The Annual Report, *EFSAnews*, the fact sheets and the brochure are all available in English, French, German and Italian.

EFSA started the *EFSA Scientific Colloquium Series* of publications in December 2004. These provide summary reports of EFSA Scientific Colloquia³. The first issue focuses on *DIOXINS: methodologies and principles for setting tolerable intake levels for dioxins, furans and dioxin-like-PCBs.*

Hard copies of EFSA publications can be ordered free of charge by e-mail (newsletter@efsa.eu.int) by providing complete postal details.

Web

EFSA launched its new website in March 2004, moving from a static to a dynamic form of online publication. With its new design and greater capacity, the website proved popular from the start, and visitors were quick to sign up for subscription to regular "Highlights" and *EFSAnews* mailings.

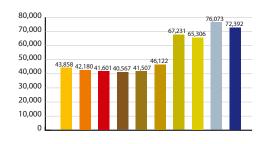
Scientific output from the Authority increased dramatically over the year, with the adoption of 159 opinions, of which 146 where published on the website. The EFSA website was expanded to accommodate the opinions and evolved to create new areas where EFSA Scientific Reports and Statements could also be published. In addition, some of the work of EFSA's Scientific

Expert Services went online, including a section dedicated to Monitoring of Zoonoses and Data Collection, and another to TSE assessments. The EFSA Scientific Colloquium Series is also fully covered in the science section of the website.

EFSA Management Board meetings continued to draw a large number of webstream viewers (around 580) to its meetings throughout 2004. The webstream gives many of those who cannot attend the Management Board meetings audio-visual access to the full public proceedings. In addition to live viewing, more viewers (around 1,070) access the video-ondemand after the event. Documents for discussion by the Management Board are published in advance of each meeting. New areas of the Management Board pages were activated in 2004 to take account of statutory texts, Management Board activities and initiatives.

As the Advisory Forum expanded its activities, new sections were created to cover Working Group activities and Advisory Forum events. A full report on the Advisory Forum event held in Berlin during the Autumn of 2004 can be found on these web pages, including abstracts and presentations.

Visitors to the EFSA website per month during 2004



The website reflects the importance EFSA attaches to reaching out to stakeholders. It does so in a section dedicated to the Authority's stakeholders and those items that are important to them, namely consultations and events, such as the Stakeholder Colloquium held in Berlin in November 2004.

Online submissions to many consultation processes are now a regular feature of the website. During 2004, these included submission of notifications about existing products used as additives in animal nutrition and submissions of applications for genetically modified food and feed. Visitors to the website can apply online to attend meetings, including Management Board meetings, or any of the Authority's public events.

Online application for positions advertised in the Opportunities section of the website elicited large numbers of applicants for each of the posts published, feeding into the recruitment drive. Several calls for tender also resulted in very strong responses.

In March 2004, there were 43,858 visitors to the newly launched website. The figures for December 2004 show the steady rise in interest that has developed over the year, with a total of 72,392 visitors in that month.

The total number of subscribers to the «Highlights» e-mail delivery service stands at 5,087. *EFSAnews* is distributed essentially via the website. Approximately 80% of copies are delivered in electronic format from the Newsletter subscription service on the website.

³ Scientific Colloquia are meetings aimed at achieving a better understanding of the fundamental scientific issues related to risk assessment on food and feed. They provide ample opportunity for an interactive exchange of expert views.

Key achievements and highlights



4.4. The Advisory Forum

The Advisory Forum is EFSA's consultative body, which brings together EFSA and the national food safety agencies and authorities who undertake tasks similar to EFSA. It held its first meeting in March 2003. It also includes observers from Norway, Iceland and Switzerland, and a representative from the European Commission. The Advisory Forum is chaired by EFSA's Executive Director. In 2004, the Advisory Forum focused on fostering greater collaboration and co-operation on food safety matters across Europe and, through its meetings, identified emerging issues of concern.

EFSA's Advisory Forum held its first public event on 8 and 9 November 2004 in Berlin, hosted by the German Federal Institute for Risk Assesment (Bundesinstitut für Risikobewertung). Over 350 visitors from international organisations, national food safety agencies and university and research centres attended this gathering. Participants and experts were able to express their views, exchange their experiences and take part in discussions about European co-operation in risk assessment.

A special *EFSAnews* dedicated to this event was published shortly afterwards and all the information about the event, including abstracts, is available on EFSA's website.

The Forum also had 4 normal meetings in 2004 in different capitals throughout Europe. These were held on 13 February in Dublin, 6 April in Helsinki, 8 June in Budapest and 30 September- 1 October in Rome. Amongst other items, the meeting in Dublin addressed the threat of Avian Influenza

and the issue of salmon and dioxins. The Management Plan for 2004 was discussed during the same meeting.

Scientific issues discussed in Helsinki on 6 April concerned the issue of methylmercury in fish, the call for national dietary intake data and an update and reminder concerning requested data on semicarbazide (SEM).



Advisory Forum, Rome, September 2004

The first Forum meeting after the EU enlargement was held in a new Member State, Hungary. Under discussion were the setting up of an Advisory Forum Extranet and an information paper about Stakeholder meetings of the GMO and FEEDAP Panels, amongst others.

The Advisory Forum organised its final meeting in 2004 in EFSA's future home country, Italy. This was held in two parts as ESFA had prepared a crisis scenario exercise to take the national agencies, with EFSA and the Commission, through a potential crisis situation. The exercise was useful in pinpointing exactly what the roles and responsibilities of the key players should be in the event of a crisis. At the ordinary meeting that followed the crisis exercise, the use of botanicals and botanical preparations were among the subjects discussed. The Forum also held a preparatory discussion on the composition of EFSA's Scientific Panels and the experts required, while members also exchanged ideas about the Work Programme for 2005.

Detailed minutes of the meetings, together with papers can, as always, be found on the EFSA website.

The Advisory Forum has two Working Groups in place, one on Communications and one on IT, both of which met several times in 2004 and made good progress.

The Communications Working Group is chaired by EFSA and links the Communications departments in the national food

safety agencies. The objective of this group is to build a more collaborative and informed approach to communicating risks in the food chain. The Group, which met 4 times in 2004, followed the activities of the Advisory Forum and the initiatives of EFSA and the national authorities in order to learn lessons about communications for the future. The Group has developed a template for key issues, which helps the members to inform each other about the communications activities in their own countries. The Group specifically followed the crisis scenario exercise, held by the Advisory Forum, in order to establish further communications links and tools when these kinds of incidents occur. With a view to building best practices in risk communications, the Working Group reviewed communications on semicarbazide and baby food in 2004, following an opinion issued by EFSA in October 2003.

The IT Working Group, chaired by EFSA and comprising the national authorities' IT experts, also had regular contacts, through meetings and via electronic means. These were held in order to continue development of the Advisory Forum Extranet (started with a test phase in 2004) and the Videoconference facilities. Both projects made such progress that full operation can be expected in 2005.

4.5. External Relations

Stakeholder relations

EFSA considers that it is extremely important to pursue an ongoing dialogue with stakeholder organisations which have a legitimate interest in EFSA's areas of work and remit. As part of its policy towards stakeholders and its overall policy of transparency and openness, EFSA continued its activities in relation to stakeholders in 2004.

Building on EFSA's first Stakeholder Colloquium, which took place in Ostend (Belgium) in October 2003, EFSA's Management Board agreed on a series of initiatives in April 2004 which aimed to strengthen relations with stakeholders. Many of these activities took place during 2004, culminating in the second Stakeholder Colloquium in Berlin in November 2004. Below, is an indication of the activities which were implemented in 2004:

- the Management Board meetings were open to the public as well as being webstreamed;
- the documents for the Management Board and Advisory Forum meetings were available on the website ahead of meetings;
- the agendas and meetings of the Scientific Committee and Panels were published on the website;
- pre-notification of EFSA information to key stakeholder organisations prior to publication;

Key achievements and highlights

- regular bilateral meetings with stakeholder organisations about various topics took place throughout the year, as well as regular participation in meetings hosted by stakeholders;
- an e-mail notification system was set up to alert subscribers to what's new on EFSA's website and an EFSA newsletter is now regularly published;
- the register of scientific questions was made more transparent to allow the status of questions addressed to EFSA to be tracked:
- scientific consultations were held, notably in the area of GMOs (May 2004 and December 2004) and feed additives (May 2004);
- Scientific Colloquia were organised (June and December 2004).

The 2nd Stakeholder Colloquium, held in Berlin in November 2004, marked a significant step forward with regard to EFSA's strategy towards stakeholders⁴. The Berlin Colloquium provided an open, interactive opportunity for stakeholder organisations involved in the range of issues covered by EFSA to share their views on the future of EFSA, and in particular about the future relations between EFSA and their organisations. As a follow-up to that meeting and recurrent demands from stakeholder organisations, EFSA agreed to set up a Stakeholder Consultative Platform which will provide advice about general issues which affect the work of EFSA. This Platform will advise EFSA on its work priorities, the matters that EFSA should consider for wider consultation, the methods of consultation, as well as stakeholder views on issues for self-tasking⁵. The Stakeholder Consultative Platform will start operating in 2005.



2nd Stakeholder Colloquium, Berlin, 9-10 November 2004

Public consultations about specific topics and Scientific Colloquia held in 2004 were highly appreciated by stakeholder organisations and were successful exercises for EFSA, not only in terms of participation but also regarding the quality of the contributions and fruitful discussions. For example, the public consultation about a guidance document for the risk assessment of GM plants and derived food and feed was followed up by a public hearing where interested parties had the opportunity to discuss the document with experts. As a follow-up to this hearing and written contribution, the document was revised by the GMO Panel. It was finally adopted in September 2004 and published on the website. A similar exercise was also run in the area of feed additives.

Institutional relations

It is important to understand the institutional context in which EFSA operates. The food and feed area is highly regulated by a complex range of European legislation. Many provisions require a scientific assessment from EFSA so that proportionate risk management measures can be drafted by the Commission. In contrast to other European Agencies, the Authority's scientific work has significant direct impact on a

wide range of legislative proposals. This can be seen in the large numbers of different questions the Commission asks EFSA. EFSA therefore provides many of its scientific opinions as a direct result of legislative provisions which require a substance to be assessed prior to permitting its use as a foodstuff or being used in or on food e.g. for food additives, GMOs, flavourings or pesticides. The other main body of scientific questions which may also stem from legislative requirements relate more to the public or animal health aspects of materials found in food or feed, e.g. microbiological safety questions, BSE, TSE or contaminants.

In all cases, the scientific opinions given by EFSA may be used by the European Commission, Parliament and Council, along with other factors legitimately considered by risk managers to form the basis for a risk management decision. EFSA's institutional activities in 2004 therefore focused on the need to ensure a proper interface between the risk assessment/risk management and risk communications activities of the Authority and those of its key institutional partners.

With the recruitment of staff to the International and Institutional Affairs department, during 2004 EFSA improved



International and Institutional Affairs

⁴ See http://www.efsa.eu.int/stakeholders/colloque_2/catindex_en.html

⁵ Read http://www.efsa.eu.int/mboard/mb_meetings/740/6mbreportfromstakeholderevent1.pdf

its ability to participate in meetings of the European Parliament, Council and in regulatory meetings convened by the Commission at which matters relevant to EFSA's work were discussed. During 2004, legislative proposals (e.g. New Regulations on Maximum Residue Levels, Health Claims) which could have a significant impact on the work and available EFSA's resources were discussed in the Council and Parliament and in Standing Committees managed by the Commission. EFSA maintained regular contact at all levels with the European Parliament, Council and Commission with the objective of ensuring that the impact of such new legislation on EFSA, as well as any scientific aspects, were understood and that issues of concern on both sides could be communicated pro-actively. As legislation goes through the European Institutions, EFSA is therefore able to keep abreast of the potential impact on the Authority's human and other resources, to gauge the potential workload at an early stage. At the same time, it was able to help to inform those considering proposals about any relevant practical and scientific issues relating to the Authority's work.

International relations

The Authority increased its visibility in the international arena during 2004. EFSA's activities, scientific opinions and communications materials were distributed widely to contacts in international organisations (World Health Organisation (WHO), World Organisation for Animal Health (OIE), Food and Agriculture Organisation (FAO), Organisation for Economic Co-operation and Development (OECD)). EFSA initiated exchanges of information with its international partners about significant reports and opinions in advance of publication, so that information could be shared and evaluated prior to final publication.

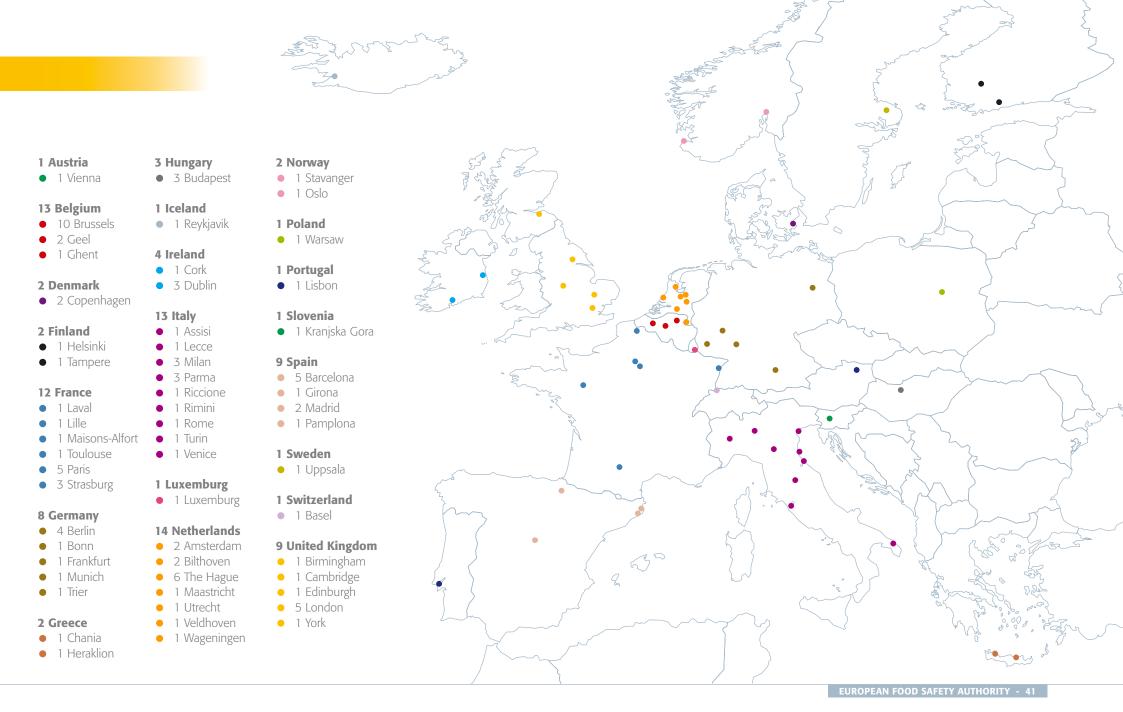
Strong links have been forged with food safety risk assessment bodies in third countries most notably in EU candidate countries, other European countries such as Norway and Switzerland and countries outside Europe, including Canada, Australia, Japan and the USA, and exchange visits have taken place. During 2004, EFSA was busy expanding and maintaining expert networks with both the international organisations and third country authorities and institutions.

Meetings were held with WHO colleagues in 2004 and such contacts have been maintained and built upon, leading to joint collaborative work. Several initiatives were planned and initiated in 2004, such as planning a joint workshop of the Scientific Committee with WHO and International Life Sciences Institute (ILSI) on harmonised approaches for the consideration of substances that are both genotoxic and carcinogenic. Initiatives were also taken with OECD, Canada (Health Canada) and the USA (FDA) to cooperate closely in the area of pesticide risk assessment.



EFSA speaking engagements

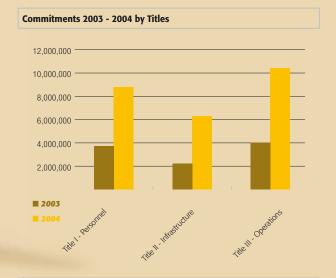


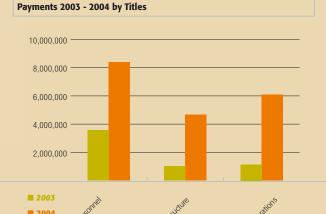


Financial report



In 2004, EUR 25.5 million was committed including carryover from 2003, compared to EUR 9.9 million in 2003. Payments in 2004 total EUR 19.1 million, compared with EUR 5.7 million in 2003. The details by Titles are as follows:





The budget appropriations for 2004 amounted to EUR 29.1 million. Of this, 73% was committed. The 75 new staff hired in 2004 did not fully bridge the recruitment gap which already existed in 2003. This was one of the main factors which contributed to reducing the anticipated roll-out of the 2004 budget. Whereas lower recruitment resulted in a 75% rate of commitment under Title I (personnel expenditures), it also cascaded into Title III (operations) where lower workforce translated into a lower activity level than expected and a 63% rate of commitment.

2004	Appropriations	Commitments	9/0	Payments	0/0	Carryover	0/0
Title I	11,508,947	8,641,035	75%	8,251,435	95%	389,600	5%
Title II	5,633,115	5,094,281	90%	3,617,234	71%	1,477,047	29%
Title III	11,950,000	7,516,929	63%	4,050,801	54%	3,466,128	46%
Total	29,092,062	21,252,245	73%	15,919,470	75%	5,332,775	25%

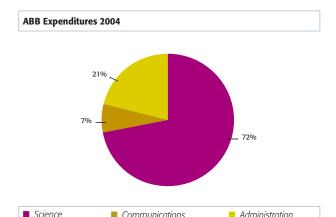
Within Title III, the under-spending mainly concerned the organisation of meetings, communications activities and IT system equipment. The rate of payment reached 75% in total, with 25% carried over to 2005. The carryover relates to contractual commitments entered into in 2004, but for which part of the services will be delivered in 2005, or services delivered late in 2004 for which payment will occur in 2005.

The commitment and payment patterns show that the lag between commitment and payment reduced over the year due to an acceleration of the payment execution from July onwards. Efforts to further accelerate payments in 2005 will be continued.

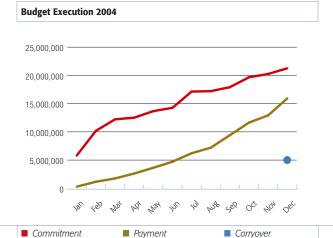
completion of its settlement phase. In spite of that, the level of activity achieved, as explained in the other parts of this Report, was already remarkable yet the financial resources were not fully utilised.

2004 was the Authority's first full operational year, still in the

From an Activity Based Budgeting (ABB) perspective ie after reallocation of staff and infrastructure expenditures by activity, the total expenditures for 2004 can be split as follows:



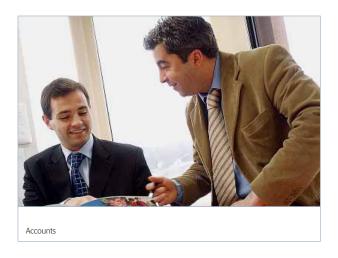
Administration includes the Human Resources, Legal, Finance, Facilities, Accounting and IT departments. The expenditures of the Directorate and the International and Institutional Affairs department are proportionally spread over the 3 reported activities.



Financial report

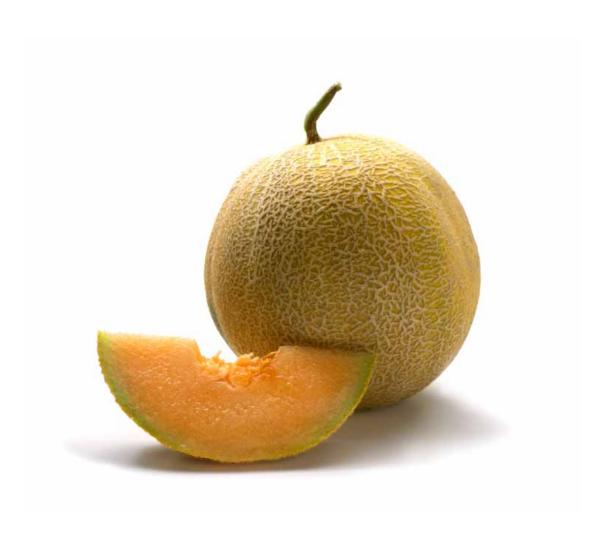
Accounts

EFSA has made continuous efforts in the area of accounting where the recast Financial Regulation requires the production of accrual accounts by 2005. Similar efforts were undertaken in changing its accounting organisation.



With the application of these new accounting rules, EFSA joins the group of public institutions which have made major efforts to improve their accounting practices.

The complete financial report can be found on our website under: http://www.efsa.eu.int/about_efsa/efsa_funding/accounts/catindex_en.html



Budget Out-turn account for 2004 and 2003	2004	2003
REVENUE		
Commission subsidy	22,566,000.00	10,284,000.00
Financial income		
Total revenue (a)	22,566,000.00	10,284,000.00
EXPENDITURE		
Personnel expenses - Budget title I		
Payments	8,251,435.31	3,566,745.61
Automatic carryovers (to n+1)	389,599.61	149,043.56
Non-automatic carryovers (to n+1)		
Administrative expenses - Budget Title II		
Payments	3,617,234.30	1,092,262.69
Automatic carryovers (to n+1)	1,477,046.63	1,189,370.95
Non-automatic carryovers (to n+1)		
Operational expenses - Budget Title III		
Payments	4,050,800.78	1,278,443.15
Automatic carryovers (to n+1)	3,466,128.32	2,894 ,873.62
Non-automatic carryovers (to n+1)	351,608.75	
Total expenditure (b)	21,603,853.70	10,170,739.58
Out-turn for the financial year (a-b)	962,146.30	113,260.42
Cancellation of unused carryovers	1,014,046.90	113,200.42
Exchange differences for the year	-1,401.25	-108.47
Balance carried over from year N-1	113,151.95	
Reimbursement to the EC	-113,151.95	
BALANCE OF THE OUT-TURN ACCOUNT FOR THE FINANCIAL YEAR	1,974,791.95	113,151.95
Interest yielded on the EC subvention funds and reimbursed to Commission		32,488.39
Interest yielded on the EC subvention funds and to be reimbursed to Commission	93,917.51	

Financial report

Economic Out-turn account	2004	2003
Operating revenues		
from third parties		
from consolidated EC entities	20,591,208.05	10,170,848.05
Other operating revenues		
from third parties		
from consolidated EC entities		
Total operating revenues	20,591,108.05	10,170,48.05
Administrative expenses	20,001,100.00	10,120,10.00
Staff expenses	-7,564,080.34	-3,213,187.56
Building and related expenses	-4,191,758.24	-781,477.49
Pensions expenses		·
Other expenses	-1,263,275.92	-535,597.85
Depreciation and write-offs	-333,113.81	-204,312.64
from consolidated EC entities		
Operating expenses	-6,431,114.93	-2,159,236.23
Other operating expenses		
from third parties		
from consolidated EC entities		
Total operating expenses	-19,783,343.24	-6,893,811.77
Surplus / (deficit) from operating activities	807,864.81	3,277,036.28
Financial operations revenues		
from third parties	392.02	969.18
from consolidated EC entities		
Financial operations expenses		
from third parties	-6,666.00	-2,991.34
from consolidated EC entities		
Surplus / (deficit) from non operating activities	-6,273.98	-2,022.16
Surplus / (deficit) from ordinary activities	801,590.83	3,275,014.12
Extraordinary gains		402 110.86
Extraordinary losses	-26,644.12	
Surplus / (deficit) from extraordinary items	-26,644.12	402,110.86
ECONOMIC RESULT FOR THE YEAR	774,946.71	3,677,124.98

Balance sheet 31/12/2003 & 2004					
ASS			LIABI	LITIES	
	2004	2003		2004	2003
A. NON-CURRENT ASSETS			A. FIXED CAPITAL		
Intangible fixed assets			Capital		
Computer software	422,909.75	362,222.00	Reserves		
Tangible fixed assets			Retained earning	3,677,124.98	
Land and buildings			Budgetary outturn not reimbursed		
Plants and equipment			Result of the year	774,946.71	3,677,124.98
Computer hardware	1,034,795.31	701,158.35	Total	4,452,071.69	3,677,124.98
Furniture and vehicles	150,751.96	106,348.87	B. PROVISIONS		
			Provisions for risks and liabilities		
Other tangible fixed assets			Financial liabilities		
Financial assets			Total	0.00	0.00
			C. LIABILITIES		
			Current liabilities		
			Employee benefits	12,975.98	7,832.26
Depreciation	-537,426.45	-204,312.64	Social security and taxes	77,316.89	
Total	1,071,030.57	965,416.58	Current payables		
B. CURRENT ASSETS			Sundry payables		
Stock			Consolidated EC Entities	2,068,709.46	145,640.34
Short-term receivables			Accrued expenses and deferred income	2,686,079.27	1,534,630.24
Advance third parties	323,380.50				
Employee benefits	49,720.35				
Current receivables	798.87	792.35			
Sundry receivables	35,893.98	40,459.29			
Consolidated EC Entities	4,568,127.72				
Prepaid expenses and accrued incomes	46,667.27	1,774.63			
Cash and equivalents					
Bank	3,201,534.03	4,341,784.97			
Cash					
Imprest account		15,000.00			
Total	8,226,122.72	4,399,811.24	Total	4,845,081.60	1,688,102.84
TOTAL ASSETS	9,297,153.29	5,365,227.82	TOTAL LIABILITIES	9,297,153.29	5,365,227.82

Future perspectives



Future perspectives

2005 will once again be a critical year for the growth of the European Food Safety Authority as it continues its build towards full operations in all areas of competence.

By the end of 2005, the Authority will have finalised its relocation to Parma in Italy. Excellent progress has been made thanks to great assistance from the Italian authorities, but it is clear that there will continue to be significant planning, personnel and logistical issues to address during the year.

It is expected that EFSA will need to increase its activities in most of the fields within its remit and this will need to be reflected in the number of staff available to deliver this. Staffing will therefore be pivotal to the success of the Authority's development and growth.

The significant development of both the Authority's Scientific and Communications functions in 2004 will continue in 2005, aided by the appropriate operational and administrative support. The emphasis will be on strengthening the Authority's reputation as an organisation dedicated to scien-

tific excellence, independence, openness and transparency. In particular, this will be achieved during 2005 by continuing to build the Authority's in-house scientific expertise, developing guidance documents about assessment approaches and arranging for scietific meetings with stakeholders. The breadth of the Authority's scientific work will be expanded to include the animal and human epidemiology of foodborne diseases, food health issues and plant risk analyses.

In 2005, EFSA will consolidate its communications strategy, building EFSA's reputation as an authoritative and trusted source of advice on risk assessment and food safety issues. EFSA will set up a number of key initiatives during 2005, notably the establishment of an Expert Advisory Group on risk communications and the initiation of consumer research concerning risk perception.

The work of the Advisory Forum in fostering closer collaborative relations with national agencies and authorities in the enlarged Europe will remain of great importance. The Forum which brings together the heads or scientific directors of the

national agencies will focus on developing its advisory role through its series of meetings and the increasing practice of exchanging information, from EFSA and national reports and data, both at and in between meetings.

In addition to this networking platform, the Authority will further establish its role as the keystone of European food safety networks for the EU institutions and stakeholders, becoming a true reference point for food safety matters of pan-European scope. The Authority will continue to foster links with similar organisations in countries within and outside Europe to ensure that it establishes collaborative working relationships with these countries and builds on its growing international reputation.

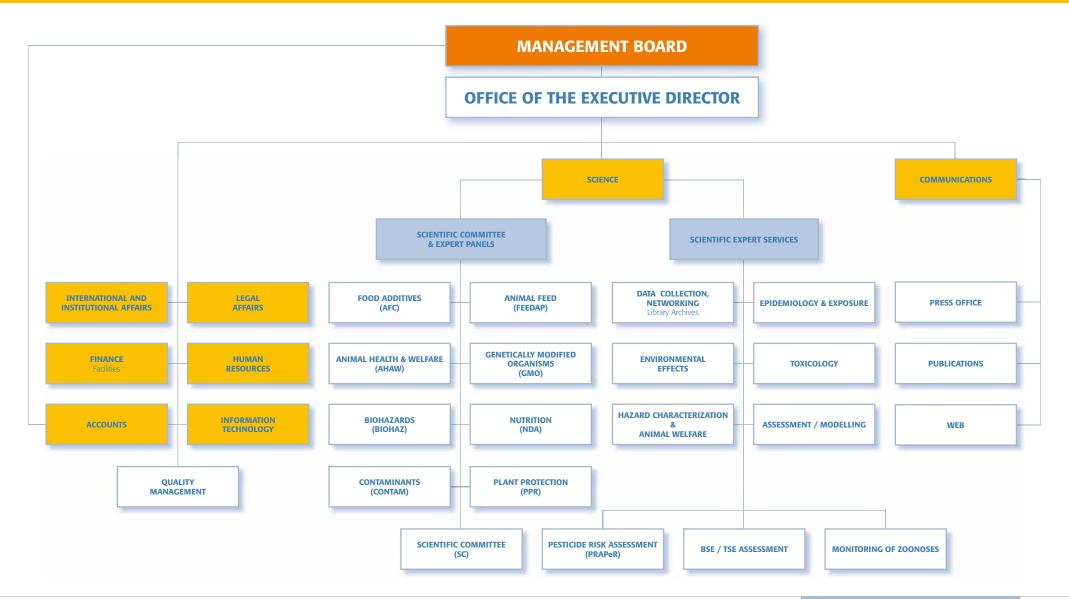
EFSA will continue to engage in dialogue and seek feed-back from its stakeholders in order to ensure that its goals, priorities and outputs are in line with expectations. It will also continue to develop close contacts and dialogue with interested parties in civil society and with its institutional partners.

Annex I: EFSA Organisational Chart 2004



Annex I:

EFSA Organisational Chart 2004



Annex II: List of adopted scientific opinions



Annex II:

The following table includes all the opinions adopted since the establishment of EFSA until March 2005.

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date
1	GMO	EFSA-Q-2003-001	Opinion of the GMO Panel on a question from the Commission related to the Austrian notification of national legislation governing GMO under Article 95(5) of the Treaty.	4 July 2003
2	FEEDAP	EFSA-Q-2003-056	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the enzymatic product Avizyme 1300® for use as feed additive for laying hens.	9 September 2003
	SC	EFSA-Q-2003-100	Advice from the SC on a general format for scientific opinions of the EFSA	17 September 2003
	SC	EFSA-Q-2003-101	Advice from the SC on EFSA guidelines for the preparation of requests for EFSA scientific opinions	30 September 2003
3a	AFC	EFSA-Q-2003-230A	Opinion of the AFC Panel on a request from the Commission related to a 1st list of substances for food contact materials: Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters	1 October 2003
3b	AFC	EFSA-Q-2003-231	Opinion of the AFC Panel on a request from the Commission related to a 1st list of substances for food contact materials: Alcohols C12-C14 Secondary. beta(2-hydroxyethyoxy)-ethoxylated	1 October 2003
3c	AFC	EFSA-Q-2003-232	Opinion of the AFC Panel on a request from the Commission related to a 1st list of substances for food contact materials: 9,10-dihydroxy stearic acid	1 October 2003
3d	AFC	EFSA-Q-2003-233	Opinion of the AFC Panel on a request from the Commission related to a 1st list of substances for food contact materials: Oleic acid, cobalt salt	1 October 2003
4	PPR	EFSA-Q-2003-006	Opinion of the PPR Panel on a request from the Commission related to the evaluation of mepanipyrim in the context of Council Directive 91/414/ EEC	23 October 2003
5	PPR	EFSA-Q-2003-007	Opinion of the PPR Panel on a request from the Commission related to the evaluation of azinphos-methyl in the context of Council Directive 91/414/ EEC	3 November 2003
6	FEEDAP	EFSA-Q-2003-008	Opinion of the FEEDAP Panel on a request from the Commission on micro-organism product "BioPlus 2B", authorised as feed additive in accordance with Council Directive 70/524/EEC	12 November 2003
7	FEEDAP	EFSA-Q-2003-054	Opinion of the FEEDAP Panel on a request from the Commission on the safety of product "Yea Sacc" for Leisure horses	13 November 2003
8	FEEDAP	EFSA-Q-2003-048	Opinion of the FEEDAP Panel on a request from the Commission on the re-evaluation of coccidiostat Stenorol in accordance with article 9G of Council Directive 70/524/EEC	13 November 2003

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date
9	GMO	EFSA-Q-2003-002	Opinion of the GMO Panel on a request from the Commission related to the safety of foods and food ingredients derived from herbicide-tolerant genetically modified maize NK603, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto	25 November 2003
10	GMO	EFSA-Q-2003-003	Opinion of the GMO Panel on a request from the Commission related to the Notification (Reference CE/ES/00/01) for the placing on the market of herbicide-tolerant genetically modified maize NK603, for import and processing, under Part C of Directive 2001/18/EC from Monsanto	25 November 2003
11	BIOHAZ	EFSA-Q-2003-028	Opinion of the BIOHAZ Panel on the process of High Pressure Hydrolysis Biogas (HPHB) as method for safe disposal of category 1 Animal by-Products (ABP) not intended for human consumption	26 November 2003
12	BIOHAZ	EFSA-Q-2003-029	Opinion of the BIOHAZ Panel on the interpretation of results of EU surveillance of transmissible spongiform encephalopathies (TSEs) in ovine and caprine animals, culling strategies for TSEs in small ruminants and the TSE-related safety of certain small ruminant products.	26 November 2003
13	BIOHAZ	EFSA-Q-2003-025	Opinion of the BIOHAZ Panel on a request from the Commission related on "Tuberculosis in Bovine Animals: Risks for human health and control strategies"	26 November 2003
14	BIOHAZ	EFSA-Q-2003-026A	Opinion of the BIOHAZ Panel on the request from the Commission related to the effects of Nitrites/Nitrates on the Microbiological Safety of Meat Products.	26 November 2003
15	NDA	EFSA-Q-2003-075	Opinion of the NDA Panel on a request from the Commission related to a Novel Food application from Forbes Medi-Tech for approval of plant sterol-containing milk-based beverages	26 November 2003
	SC	EFSA-Q-2003-102	Advice from the SC in relation to EFSA's activities in a crisis	30 November 2003
16	FEEDAP	EFSA-Q-2003-041	Opinion of the FEEDAP Panel on the request from the Commission on the efficacy and safety of the coccidiostat Koffogran	3 December 2003
17	FEEDAP	EFSA-Q-2003-044	Opinion of the FEEDAP Panel on a request from the Commission on the coccidiostat DECCOX in accordance with article 9G of Council Directive 70/524/EEC.	3 December 2003
18	GMO	EFSA-Q-2003-004	Opinion of the GMO Panel on a request from the Commission related to guidance notes supplementing Part B of Annex II to Council Directive 90/219/EEC, as amended by Directive 98/81/EC, on the contained use of genetically modified micro-organisms	11 December 2003
19	AFC	EFSA-Q-2003-229	Opinion of the AFC Panel on a request from the Commission related to L-Carnitine-L-tartrate for use in foods for particular nutritional uses	3 November 2003
20	AFC	EFSA-Q-2003-124	Opinion of the AFC Panel on a request from the Commission related to Calcium sulphate for use in foods for particular nutritional uses	10 December 2003

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date
21	AFC	EFSA-Q-2003-130	Opinion of the AFC Panel on a request from the Commission related to N-Acetyl-L-cysteine for use in foods for particular nutritional uses and in foods for special medical purposes	10 December 2003
22	AFC	EFSA-Q-2003-131	Opinion of the AFC Panel on a request from the Commission related to N-Acetyl-L-methionine for use in foods for special medical purposes	10 December 2003
23	BIOHAZ	EFSA-Q-2004-028	Opinion of the BIOHAZ Panel on "Biodiesel Process" as a method for safe disposal of category I Animal by-Products (ABP)	2 June 2004
24a	AFC	EFSA-Q-2003-211	Opinion of the AFC Panel on a request from the Commission related to a 2nd list of substances for foods contact materials: Ethylene carbonate	7 January 2004
24b	AFC	EFSA-Q-2003-212	Opinion of the AFC Panel on a request from the Commission related to a 2nd list of substances for foods contact materials: Methacrylic acid, 2-sulphoethyl ester	7 January 2004
24c	AFC	EFSA-Q-2003-179	Opinion of the AFC Panel on a request from the Commission related to a 2nd list of substances for foods contact materials: Antimony trioxide	7 January 2004
24d	AFC	EFSA-Q-2003-182	Opinion of the AFC Panel on a request from the Commission related to a 2nd list of substances for foods contact materials: cis-endo-bicyclo[2.2.1]heptane-2,3-dicarboxylic acid, disodium salt	7 January 2004
24e	AFC	EFSA-Q-2003-196	Opinion of the AFC Panel on a request from the Commission related to a 2nd list of substances for foods contact materials: Pimelic acid, calcium salt	7 January 2004
25	FEEDAP	EFSA-Q-2003-011	Opinion of the FEEDAP Panel on a request from the Commission on the safety of enzyme preparation "Finase", as feed additive for laying hens, turkeys, sows	27 January 2004
26	FEEDAP	EFSA-Q-2003-053	Opinion of the FEEDAP Panel on a request from the Commission on the safety of 'Biosprint BCCMTM/MUCL39885' for the dairy cow	27 January 2004
27	FEEDAP	EFSA-Q-2004-003	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the enzymatic product Belfeed B1100 MP/ML for use as feed additive for laying hens	28 January 2004
28	FEEDAP	EFSA-Q-2003-051	Opinion of the FEEDAP Panel on the safety of the micro-organism product Turval B0399® for use as feed additive for weaned piglets	28 January 2004
29	GMO	EFSA-Q-2003-078	Opinion of the GMO Panel on a request from the Commission related to the Notification (Reference C/NL/98/11) for the placing on the market of herbicide-tolerant oilseed rape GT73, for import and processing, under Part C of Directive 2001/18/EC from Monsanto	11 February 2004
30	NDA	EFSA-Q-2003-019	Opinion of the NDA Panel on a request from the Commission relating to the evaluation of goats' milk protein as a protein source for infant formulae and follow-on formulae	19 February 2004

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date
31	NDA	EFSA-Q-2003-020	Opinion of the NDA Panel on a request from the Commission relating to the safety and suitability for particular nutritional use by infants of fructooligosaccharides in infant formulae and follow-on formulae	19 February 2004
32	NDA	EFSA-Q-2003-016	Opinion of the NDA Panel on a request from the Commission relating to the evaluation of allergenic foods for labeling purposes	19 February 2004
33	NDA	EFSA-Q-2003-018F	Opinion of the NDA Panel on a request from the Commission related to the Tolerable Upper Intake Level of Vanadium	19 February 2004
34	CONTAM	EFSA-Q-2003-030	Opinion of the CONTAM Panel on a request from the Commission related to mercury and methylmercury in food	24 February 2004
35	AFC	EFSA-Q-2003-116	Opinion of the AFC Panel on a request from the Commission related to Ethyl Cellulose as a food additive	17 February 2004
36	AFC	EFSA-Q-2003-125	Opinion of the AFC Panel on a request from the Commission related to Creatine monohydrate for use in foods for particular nutritional uses	17 February 2004
37a	AFC	EFSA-Q-2003-198	Opinion of the AFC Panel on a request from the Commission related to a 3rd list of substances for food contact materials: Polyethylene wax	15 March 2004
37b	AFC	EFSA-Q-2003-200	Opinion of the AFC Panel on a request from the Commission related to a 3rd list of substances for food contact materials: Polypropylene wax	15 March 2004
37c	AFC	EFSA-Q-2003-207	Opinion of the AFC Panel on a request from the Commission related to a 3rd list of substances for food contact materials: 2,4,4'-Trichloro-2'-hydroxydiphenyl ether (triclosan)	15 March 2004
39	CONTAM	EFSA-Q-2003-035	Opinion of the CONTAM Panel on a request from the Commission related to Aflatoxin B1 as undesirable substance in animal feed	3 February 2004
40	BIOHAZ	EFSA-Q-2003-090	Opinion of the BIOHAZ Panel on the safety vis-à-vis biological risk including TSEs of the application on pastureland of organic fertilisers and soil improvers.	3 March 2004
41	BIOHAZ	EFSA-Q-2003-095	Opinion of the BIOHAZ Panel on BSE risk from bovine tonsil and consumption of bovine tongue	4 March 2004
42	FEEDAP	EFSA-Q-2003-045	Opinion of the FEEDAP Panel on the request of the Commission on the reevaluation of coccidiostat Elancoban in accordance with article 9G of Council Directive 70/524/EEC	4 March 2004
43	FEEDAP	EFSA-Q-2003-112	Opinion of the FEEDAP Panel on environmental impact of Astaxanthin-rich Phaffia rhodozyma (Ecotone®) as feed additive in accordance with Council Directive 70/524/EEC	1 April 2004
44	AHAW	EFSA-Q-2003-094	Opinion of the AHAW Panel on a request from the Commission related to the welfare of animals during transport	30 March 2004
45	AHAW	EFSA-Q-2003-093	Opinion of the AHAW Panel on a request from the Commission related to the welfare aspects of the main systems of stunning and killing the main commercial species of animals	15 June 2004

 $[\]boldsymbol{\ast}$ Missing numbers indicate either a combined opinion or withdrawal of a question

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date
* 48	GMO	EFSA-Q-2003-109	Opinion of the GMO Panel on the use of antibiotic resistance genes as marker genes in genetically modified plants	2 April 2004
49	GMO	EFSA-Q-2003-089	Opinion of the GMO Panel on a request from the Commission related to the Notification (Reference C/DE/02/9) for the placing on the market of insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for import and processing, under Part C of Directive 2001/18/EC from Monsanto	2 April 2004
50	GMO	EFSA-Q-2003-121	Opinion of the GMO Panel on a request from the Commission related to the safety of foods and food ingredients derived from insect-protected genetically modified maize MON 863 and MON 863 x MON 810, for which a request for placing on the market was submitted under Article 4 of the Novel Food Regulation (EC) No 258/97 by Monsanto	2 April 2004
51	FEEDAP	EFSA-2004-001	Opinion of the FEEDAP Panel on the safety of product Oralin for dogs	15 April 2004
52	FEEDAP	EFSA-2003-055	Opinion of the FEEDAP Panel on the safety of product "MLB" Lactobacillus acidophilus for dogs	15 April 2004
53	FEEDAP	EFSA-Q-2003-042	Opinion of the FEEDAP Panel on the reevaluation of coccidiostat Avatec in accordance with article 9G of Council Directive 70/524/EEC	15 April 2004
54	BIOHAZ	EFSA-Q-2003-027	Opinion of the BIOHAZ Panel on the request from the Commission on Meat Inspection Procedures for Lambs and Goats.	22 April 2004
55	BIOHAZ	EFSA-Q-2003-013A	Opinion of the BIOHAZ Panel on the application of the United Kingdom for Moderate Risk BSE status	21 April 2004
56	BIOHAZ	EFSA-Q-2003-013B	Opinion of the BIOHAZ Panel on the scientific justification for proposing amendments to the United Kingdom Date Based Export Scheme (DBES) and to the Over Thirty Months (OTM) rule	21 April 2004
57	BIOHAZ	EFSA-Q-2003-098	Opinion of the BIOHAZ Panel on a request from the Commission on BSE-related Culling in Cattle	21 April 2004
58	BIOHAZ	EFSA-Q-2003-234	Opinion of the BIOHAZ Panel on "Combustion of Tallow in a Thermal Boiler" process as method for safe disposal of category 1 Animal by-Products (ABP) not intended for human consumption	22 April 2004
59	NDA	EFSA-Q-2003-018A	Opinion of the NDA Panel on a request from the Commission related to the Tolerable Upper Intake Level of Vitamin C (L-Ascorbic acid, its calcium, potassium and sodium salts and L-ascorbyl-6-palmitate)	28 April 2004
60	NDA	EFSA-Q-2003-018H	Opinion of the NDA Panel on a request from the Commission related to the Tolerable Upper Intake Level of Silicon	28 April 2004
61	PPR	EFSA-Q-2003-120	Opinion of the PPR Panel on a request from the Commission related to the evaluation of daminozide in the context of Council Directive 91/414/EEC1	11 May 2004
62	FEEDAP	EFSA-Q-2003-086	Opinion of the FEEDAP Panel on the efficacy of product Toyocerin for pigs for fattening	7 May 2004

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date
63	FEEDAP	EFSA-2003-050	Opinion of the FEEDAP Panel on a request from the Commission on the evaluation of coccidiostat Kokcisan® 120G	7 May 2004
	AFC	EFSA-Q-2003-193A	Statement of the AFC Panel on the re-classification of some phthalates for consistency with the new SCF guidelines for food contact materials: phthalic acid, dicyclohexyl ester	19 May 2004
64	AFC	EFSA-Q-2003-073	Opinion of the AFC Panel on a request from the Commission related to the use of epoxidised soybean oil in food contact materials	26 May 2004
65a	AFC	EFSA-Q-2003-210	Opinion of the AFC Panel on a request from the Commission related to a 4th list of substances for food contact materials: N,N'-Bis[4-(ethoxycarbonyl)phenyl]-,4,5,8naphthalenetetracarboxydiimide	26 May 2004
65b	AFC	EFSA-Q-2003-223	Opinion of the AFC Panel on a request from the Commission related to a 4th list of substances for food contact materials: Trimellitic acid & Trimellitic anhydride	26 May 2004
65c	AFC	EFSA-Q-2003-187	Opinion of the AFC Panel on a request from the Commission related to a 4th list of substances for food contact materials: Methylsilsesquioxane	26 May 2004
65d	AFC	EFSA-Q-2003-202	Opinion of the AFC Panel on a request from the Commission related to a 4th list of substances for food contact materials: Silver-containing glass (Silver-magnesium-calcium-phosphate-borate)	26 May 2004
65e	AFC	EFSA-Q-2003-203	Opinion of the AFC Panel on a request from the Commission related to a 4th list of substances for food contact materials: Silver sodium hydrogen zirconium phosphate	26 May 2004
65f	AFC	EFSA-Q-2003-221	Opinion of the AFC Panel on a request from the Commission related to a 4th list of substances for food contact materials: Benzoic acid, 4,4'-(1,3,6,8-tetrahydro-1,3,6,8-tetraoxbenzo[lmn][3,8]phenanthroline-2,7-diyl)bis, diethyl ester	26 May 2004
	AFC	EFSA-Q-2003-188	Statement of the AFC Panel on mixture of (50% w/w) phthalic acid n-decyl n-octyl ester, (25% w/w) phthalic acid di-n-decyl ester, (25% w/w) pthlaic acid di-n-octyl ester	26 May 2004
	AFC	EFSA-Q-2003-193B	Statement of the AFC Panel on the re-classification of some phthalates for consistency with the new SCF guidelines for food contact materials: phthalic acid, diesters with hexadecanol and/or octadecanol - phthalic acid, diethyl ester - phthalic acid di-n-octyl / n-decyl ester - phthalic acid, n-hexadecyl n-octadecyl ester - phthalic acid, bis (alkoxyalkyl C3-C18) ester - phthalic acid, bis (2-methoxyethyl) ester - phthalic acid, bis (methylcyclohexyl) ester - phthalic acid, di-n-heptyl ester - phthalic acid, diisoottyl ester - phthalic acid, dimethyl ester - phthalic acid, di-n-octyl ester - phthalic acid, di-n-octyl ester - phthalic acid, di-n-octyl ester - phthalic acid, di-n-ottyl ester - phthalic acid, di-n-tridecyl ester - phthalic acid, mixed esters with butyl glycolate and alcohols, aliph. Monoh., (C1-C4) - phthalic acid, mixed esters with butyl glycolate and butanol - phthalic acid, mixed esters with ethyl glycolate and ethanol - o-phthalic acid, n-pentyl benzyl ester	26 May 2004

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date
66	FEEDAP	EFSA-2003-012	Opinion of the FEEDAP Panel on the safety of the change of strain of the producing micro-organism of the enzyme preparation Bio-Feed Phytase	31 May 2004
67	AFC	EFSA-Q-2003-236	Opinion of the AFC Panel on a request from the Commission related to Furfural and Furfural Diethylacetal	2 June 2004
68	FEEDAP	EFSA-Q-2003-082	Opinion of the FEEDAP Panel on a request from the Commission on the safety and the efficacy of product Nutrigrow as a source of protein	7 June 2004
69	FEEDAP	EFSA-Q-2003-043	Opinion of the FEEDAP Panel on a request from the Commission on the re-evaluation of coccidiostat Cycostat 66G in accordance with article 9G of Council Directive 70/524/EEC	8 June 2004
70	BIOHAZ	EFSA-Q-2003-088	Opinion of the BIOHAZ Panel on a surveillance programme for Chronic Wasting Disease in the European Union	3 June 2004
71	CONTAM	EFSA-Q-2003-032	Opinion of the CONTAM Panel on a request from the Commission related to lead as undesirable substance in animal feed	2 June 2004
72	CONTAM	EFSA-Q-2003-033	Opinion of the CONTAM Panel on a request from the Commission related to cadmium as undesirable substance in animal feed	2 June 2004
73	CONTAM	EFSA-Q-2003-036	Opinion of the CONTAM Panel on a request from the Commission related to Deoxynivalenol (DON) as undesirable substance in animal feed	2 June 2004
	SC	EFSA-Q-2003-106	Discussion paper of the SC on Botanicals and Botanical Preparations widely used as food supplements and related products: coherent and comprensive risk assessment and consumer information approaches	23 June 2004
74	PPR	EFSA-Q-2004-026	Opinion of the PPR Panel on a request from the Commission related to the evaluation of dinocap in the context of Council Directive 91/414/EEC	30 June 2004
	BIOHAZ	EFSA-Q-2004-074	Scientific Report of the BIOHAZ Panel on the assessment of the geographical BSE-Risk (GBR) of South Africa	July 2004
	BIOHAZ	EFSA-Q-2003-083A	Scientific Report of the BIOHAZ Panel on the Assessment of the geographical BSE-Risk (GBR) of Canada, United States of America, Mexcico, Australia, Sweden and Norway	July 2004
75	FEEDAP	EFSA-Q-2003-009	Opinion of the FEEDAP Panel on a request from the Commission on the safety and the efficacy of product "BIO-COX 120G" as feed additive in accordance with Council Directive 70/524/EEC	1 July 2004
76	FEEDAP	EFSA-Q-2003-047	Opinion of the FEEDAP Panel on a request from the Commission on the re-evaluation of coccidiostat Sacox® 120 microGranulate in accordance with article 9G of Council Directive 70/524/EEC	30 June 2004
77	FEEDAP	EFSA-Q-2004-076	Update of an opinion of the FEEDAP Panel on the re-evaluation of coccidiostat Avatec in accordance with article 9G of Council Directive 70/524/EEC	1 July 2004

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date
78	GMO	EFSA-Q-2004-062A	Opinion of the GMO Panel on a request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC	8 July 2004
79	GMO	EFSA-Q-2004-062B	Opinion of the GMO Panel on a request from the Commission related to the Greek invoke of Article 23 of Directive 2001/18/EC	8 July 2004
80	NDA	EFSA-Q-2003-018E	Opinion of the NDA Panel on a request from the Commission related to the Tolerable Upper Intake Level of Boron (Sodium Borate and Boric Acid)	8 July 2004
81	NDA	EFSA-Q-2003-022	Opinion of the NDA Panel on a request from the Commission related to the presence of trans fatty acids in foods and the effect on human health of the consumption of trans fatty acids	8 July 2004
82	AFC	EFSA-Q-2004-054	Opinion of the AFC Panel on a request from the Commission related to the use of certain food additives in Jelly mini cups	12 July 2004
83	AFC	EFSA-Q-2004-063	Opinion of the AFC Panel on a request from the Commission related to para hydroxybenzoates (E 214 – 219)	13 July 2004
84	AFC	EFSA-Q-2003-141	Opinion of the AFC Panel on a request from the Commission related to tertiary-Butylhydroquinone (TBHQ)	12 July 2004
85	AFC	EFSA-Q-2003-138	Opinion of the AFC Panel on a request from the Commission related to Pullulan PI-20 for use as a new food additive	13 July 2004
86	AFC	EFSA-Q-2003-178	Opinion of the AFC Panel on a request from the Commission related to 2,2-bis(4-hydroxyphenyl)propane bis(2,3-epoxypropyl) ether (Bisphenol A diglycidyl ether, BADGE) – Ref. No 15310 and 39700	13 July 2004
88	FEEDAP	EFSA-Q-2004-070	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the change of the producing micro-organism of the enzyme preparation Bio Feed Phytase for use in salmonids	22 July 2004
89	CONTAM	EFSA-Q-2003-037	Opinion of the CONTAM Panel on a request from the Commission related to Zearalenone as undesirable substance in animal feed	28 July 2004
90	FEEDAP	EFSA-Q-2003-046	Opinion of the FEEDAP Panel on a request from the Commission on the re-evaluation of efficacy and safety of the coccidiostat Monteban® G100 in accordance with article 9G of Council Directive 70/524/EEC	27 July 2004
91	AHAW	EFSA-Q-2003-091	Opinion of the AHAW Panel on a request from the Commission related to welfare aspects of the castration of piglets	13 July 2004
92	CONTAM	EFSA-Q-2004-016	Opinion of the CONTAM Panel on a request from the Commission related to the toxicity of fishery products belonging to the family of Gempylidae	30 August 2004
93	PPR	EFSA-Q-2004-058	Opinion of the PPR Panel on a request from EFSA on the FOCUS groundwater models comparability and the consistency of this risk assessment of ground water contamination	14 September 2004

 $[\]boldsymbol{\ast}$ Missing numbers indicate either a combined opinion or withdrawal of a question

Opinion N°	Panel	Question Reference	Opinion Title			
94	PPR	EFSA-Q-2004-060	Opinion of the PPR Panel on a request from the Commission related to the evaluation of methamidophos in toxicology in the context of Council Directive 91/414/EEC			
95	FEEDAP	EFSA-Q-2004-004	Opinion of the FEEDAP Panel on a request from the Commission on efficacy of Endofeed (endo-1, 3(4)-beta-glucanase and endo-1, 4-beta-xylanase produced by Aspergillus niger) for laying hens	14 September 2004		
96	FEEDAP	EFSA-Q-2004-032	Opinion of the FEEDAP Panel on a request from the Commission on safety of formaldehyde for poultry as feed additive in accordance with Council Directive 70/524/EEC	14 September		
97	FEEDAP	EFSA-Q-2004-069	Opinion of the FEEDAP Panel on the safety of the product Bio Feed Alpha CT and L regarding the ability of the production strain to produce toxins	15 September 2004		
98	FEEDAP	EFSA-Q-2004-108	Opinion of the FEEDAP Panel on a request from the Commission to update the opinion on the safety of "Cycostat 66G" based on robenidine hydrochloride, as a feed additive in accordance with Council Directive 70/524/EEC (Article 9g)	1 October 2004		
99	GMO	EFSA-Q-2003-005	Guidance document of the GMO Panel for the risk assessment of genetically modified plants and derived food and feed			
100	CONTAM	EFSA-Q-2003-034	Opinion of the CONTAM Panel on a request from the Commission related to Fluorine as undesirable substance in animal feed	22 September 2004		
101	CONTAM	EFSA-Q-2003-039	Opinion of the CONTAM Panel on a request from the Commission related to ochratoxin A (OTA) as undesirable substance in animal feed	22 September 2004		
102	CONTAM	EFSA-Q-2003-110	Opinion of the CONTAM Panel on a request from the Commission to assess the health risks to consumers associated with exposure to organotins in foodstuffs			
	BIOHAZ	EFSA-Q-2004-083	Scientific Report of the BIOHAZ Panel on the BSE surveillance model (BSurvE) established by the Community Reference Laboratory for TSE	established by the Community Reference Laboratory for TSE October 2004		
103	AFC	EFSA-Q-2003-070	Opinion of the AFC Panel on a request from the Commission related to the introduction of a Fat (consumption) Reduction Factor for infants and children			
104	AFC	EFSA-Q-2003-118	Opinion of the AFC Panel on a request from the Commission related to Coumarin			
105	AFC	EFSA-Q-2003-145	Opinion of the AFC Panel on hydrocyanic acid in flavourings and other food ingredients with flavouring properties	7 October 2004		
106	AFC	EFSA-Q-2003-139	Opinion of the AFC Panel on Sucrose esters of fatty acids, E473 and sucroglycerides, E474 based on a request from the Commission related to Sucrose Esters of Fatty Acids (E473)			

Opinion N°	Panel	Question Reference	Opinion Title			
107	AFC	EFSA-Q-2003-146	Opinion of the AFC Panel on a request from the Commission related to Flavouring Group Evaluation 3 (FGE.03): Acetals of branched- and straight-chain aliphatic saturated primary alcohols and branched- and straight-chain saturated aldehydes, and an orthoester of formic acid, from chemical groups 1 and 2 (Commission Regulation (EC) No 1565/2000 of 18 July 2000)	7 October 2004		
108	AFC	EFSA-Q-2003-149	Opinion of the AFC Panel on a request from the Commission related to Flavouring Group Evaluation 6 (FGE.06): Straight- and branched-chain aliphatic unsaturated primary alcohols, aldehydes, carboxylic acids, and esters from chemical groups 1 and 4 (Commission Regulation (EC) No 1565/2000 of 18 July 2000)	7 October 2004		
109a	AFC	EFSA-Q-2004-034	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: Acrylic acid, 2-ethylhexyl ester & 2-ethylhexyl acrylate-acrylic acid copolymer	22 October 2004		
109b	AFC	EFSA-Q-2004-053	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: 1,4-butanediol	22 October 2004		
109c	AFC	EFSA-Q-2004-044	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: Caprolactone	22 October 2004		
109d	AFC	EFSA-Q-2004-097	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: Alpha-methylstyrene	22 October 2004		
109e	AFC	EFSA-Q-2004-045	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: Perfluoromethyl perfluorovinyl ether	22 October 2004		
109f	AFC	EFSA-Q-2004-033	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: syrups, hydrolysed starch, hydrogenated	22 October 2004		
109g	AFC	EFSA-Q-2003-213	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: 12-(Acetoxy)stearic acid, 2,3-bis(acetoxy)propyl ester	22 October 2004		
109h	AFC	EFSA-Q-2003-183	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: Charcoal, activated	22 October 2004		
109i	AFC	EFSA-Q-2003-218	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: Polyethyleneglycol-30 dipolyhydroxystearate (PEG-30 dipolyhydroxystearate)	22 October 2004		
109j	AFC	EFSA-Q-2003-201	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: Silicic acid, magnesium-sodium-fluoride salt			
109k	AFC	EFSA-Q-2004-041	Opinion of the AFC Panel on a request from the Commission related to a 5th list of substances for food contact materials: 1,3,5-Tris(4-benzoylphenyl) benzene			

Opinion N°	Panel	Question Reference	Opinion Title				
110	AHAW	EFSA-Q-2004-005	Opinion of the AHAW Panel on a request from the Commission related to the risk of Transmission of <i>Mycobacterium avium</i> subsp. <i>Paratuberculosis</i> via Bovine Semen	14 September 2004			
111	PPR	EFSA-Q-2004-048	Opinion of the PPR Panel on a request from the Commission related to the evaluation of alachlor in the context of Council Directive 91/414/EEC	28 October 2004			
112	AFC	EFSA-Q-2003-237	Opinion of the AFC Panel on a request from the Commission related to Calcium Sulphate as a mineral substance in foods intended for the general population	7 October 2004			
113	BIOHAZ	EFSA-Q-2003-111	Opinion of the BIOHAZ Panel on the request from the Commission related to the microbiological risks in infant formulae and follow-on formulae	9 September 2004			
114	BIOHAZ	EFSA-Q-2003-080	Opinion of the BIOHAZ Panel on the request from the Commission related to the use of vaccines for the control of Salmonella in poultry	21 October 2004			
115	BIOHAZ	EFSA-Q-2004-079	Opinion of the BIOHAZ Panel on the request from the Commission related to the use of antimicrobials for the control of <i>Salmonella</i> in poultry	21 October 2004			
117	FEEDAP	EFSA-Q-2004-067	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the product Avizyme 1200 for turkeys for fattening	28 October 2004			
118	FEEDAP	EFSA-Q-2004-111	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the product "Kemzyme W Dry" regarding the ability of <i>Bacillus</i> strains involved in the manufacture to produce toxins	19 November 2004			
119	FEEDAP	EFSA-Q-2003-115	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the product MLB for cats	27 October 2004			
120	FEEDAP	EFSA-Q-2004-027	Opinion of the FEEDAP Panel on a request from the Commission on the safety of product Bonvital (Provita E) for chickens for fattening	28 October 2004			
121	FEEDAP	EFSA-Q-2004-014	Opinion of the FEEDAP Panel on a request from the Commission related to the preliminary assessment of the safety of Nitrasone (4-nitrophenylarsonic acid), as a feed additive in accordance with Regulation (EC) No 178/2002 and Regulation (EC) No 1831/2003, article 15	28 October 2004			
122	AHAW	EFSA-Q-2003-085	Opinion of the AHAW Panel on a request from the Commission related to Standards for the microclimate inside animal road transport vehicles	20 October 2004			
123	BIOHAZ	EFSA-Q-2003-122	Opinion of the BIOHAZ Panel on BSE risk from dissemination of brain particles in blood and carcass following stunning	21 October 2004			
124	GMO	EFSA-Q-2004-011	Opinion of the GMO Panel on a request from the Commission related to the notification (Reference C/NL/00/10) for the placing on the market of insect-tolerant genetically modified maize 1507, for import and processing, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred International/Mycogen Seeds				
125	NDA	EFSA-Q-2003-018B	Opinion of the NDA Panel on a request from the Commission related to the Tolerable Upper Intake Level of Iron				

Opinion N°	Panel	Question Reference	Opinion Title				
126	NDA	EFSA-Q-2004-091A	Opinion of the NDA Panel on a request from the Commission related to a notification from AAC on wheat-based glucose syrups including dextrose pursuant to Art. 6 par. 11 of Directive 2000/13/EC				
127	NDA	EFSA-Q-2004-091B	Opinion of the NDA Panel on a request from the Commission related to a notification from AAC on wheat-based maltodextrins pursuant to Art. 6 par. 11 of Directive 2000/13/EC	19 October 2004			
128	NDA	EFSA-Q-2004-092	Opinion of the NDA Panel on a request from the Commission related to a notification from Finnsugar on glucose syrups produced from barley starch pursuant to Art. 6 par. 11 of Directive 2000/13/EC	19 October 2004			
129	NDA	EFSA-Q-2004-125A	Opinion of the NDA Panel on a request from the Commission related to a notification from AIIBP and FAIBP on acid hydrolysed vegetable protein from wheat pursuant to Art. 6 par. 11 of Directive 2000/13/EC	19 October 2004			
130	NDA	EFSA-Q-2004-120	Opinion of the NDA Panel on a request from the Commission related to a notification from CEPS on distillates made from cereals pursuant to Art. 6 par. 11 of Directive 2000/13/EC	19 October 2004			
131	NDA	EFSA-Q-2004-119	Opinion of the NDA Panel on a request from the Commission related to a notification from CEPS on distillates made from whey pursuant to Art. 6 par. 11 of Directive 2000/13/EC	19 October 2004			
132	NDA	EFSA-Q-2004-118	Opinion of the NDA Panel on a request from the Commission related to a notification from CEPS on distillates made from nuts pursuant to Art. 6 par. 11 of Directive 2000/13/EC	19 October 2004			
133	NDA	EFSA-Q-2004-122	Opinion of the NDA Panel on a request from the Commission related to a notification from FEDIOL and IMACE on fully refined peanut oil and fat pursuant to Art. 6 par. 11 of Directive 2000/13/EC	19 October 2004			
134	NDA	EFSA-Q-2004-084	Opinion of the NDA Panel on a request from the Commission related to a notification from the Winemaker's Federation of Australia on milk products, egg products and fish products used in the manufacture of wine pursuant to Art. 6 par. 11 of Directive 2000/13/EC				
135	AFC	EFSA-Q-2004-007	Opinion of the AFC Panel on a request from the Commission related to Calcium L-Methylfolate				
137	CONTAM	EFSA-Q-2004-109	Report of the CONTAM Panel on furan in food				
138	FEEDAP	EFSA-Q-2004-006	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the product Cyclatin for dogs and cats				
139	FEEDAP	EFSA-Q-2004-099	Opinion of the FEEDAP Panel on a request from the Commission on the safety and the efficacy of "Formi™ LHS", based on potassium diformate, as a feed additive for sows in accordance with Council Directive 70/524/EEC				

 $[\]boldsymbol{\ast}$ Missing numbers indicate either a combined opinion or withdrawal of a question

Opinion N°	Panel	Question Reference	Opinion Title	Adoption Date		
140	FEEDAP	EFSA-Q-2004-029	Opinion of the FEEDAP Panel on a request from the Commission on the safety and the efficacy of product "KDF Preservative" used for the preservation of raw fish material			
141	BIOHAZ	EFSA-Q-2003-026B	Opinion of the BIOHAZ Panel on Revision of Meat Inspection for Beef raised in Integrated Production Systems	1 December 2004		
142	BIOHAZ	EFSA-Q-2004-002	Opinion of the BIOHAZ Panel on the suitability and details of freezing methods to allow human consumption of meat infected with Trichinella or Cysticercus	1 December 2004		
143	BIOHAZ	EFSA-Q-2004-093	Opinion of the BIOHAZ Panel on the determination of the BSE risk status of Portugal	1 December 2004		
	AFC	EFSA-Q-2003-017	Statement of the AFC Panel related to Boric Acid and Sodium borate as nutrient sources of boron	8 December 2004		
	AFC	EFSA-Q-2004-095	Statement of the Working Group on Additives of the AFC Panel on studies designed to investigate the safety in use of taurine and D-glucurono-lactone in "energy" drinks	9 December 2004		
144	PPR	EFSA-Q-2004-059	Opinion of the PPR Panel on a request from the Commission related to the evaluation of methamidophos in ecotoxicology in the context of Council Directive 91/414/EEC	14 December 2004		
145	PPR	EFSA-Q-2004-055	Opinion of the PPR Panel on a request from EFSA on the appropriateness of using the current FOCUS surface water scenarios for estimating exposure of risk assessment in aquatic ecotoxicology in the context of Council Directive 91/414/EEC	14 December 2004		
146	NDA	EFSA-Q-2003-018G	Opinion of the NDA Panel on a request from the Commission related to the Tolerable Upper Intake Level on Nickel	25 January 2005		
147	NDA	EFSA-Q-2004-098	Opinion of the NDA Panel on a request from the Commission related to a notification from FEDIOL and IMACE on fully refined soybean oil and fat pursuant to Art. 6 par. 11 of Directive 2000/13/EC	2 December 2004		
148	NDA	EFSA-Q-2004-138	Opinion of the NDA Panel on a request from the Commission related to a notification from SOFRALAB on hydrolysed wheat gluten as fining agent in wines pursuant to Art. 6 par. 11 of Directive 2000/13/EC	luten as 2 December 2004		
149	NDA	EFSA-Q-2004-123	Opinion of the NDA Panel on a request from the Commission related to a notification from Brewers of Europe and BFBi on isinglass used as a clarifying agent in brewing pursuant to Art. 6 par. 11 of Directive 2000/13/EC			
150	NDA	EFSA-Q-2004-121	Opinion of the NDA Panel on a request from the Commission related to a notification from DSM on fish gelatine for use as a formulation acid (carrier) in vitamin and carotenoid preparations pursuant to Art. 6 par. 11 of Directive 2000/13/EC	lation 2 December 2004		
151	NDA	EFSA-Q-2004-126	Opinion of the NDA Panel on a request from the Commission related to a notification from Givaudan Schweiz AG on fish gelatine used as carrier for flavour pursuant to Art. 6 par. 11 of Directive 2000/13/EC			

Opinion N°	Panel	Question Reference	Opinion Title			
152	NDA	EFSA-Q-2004-135	Opinion of the NDA Panel on a request from the Commission related to a notification from GME on fish gelatine pursuant to Art. 6 par. 11 of Directive 2000/13/EC	2 December 2004		
153	NDA	EFSA-Q-2004-127	Opinion of the NDA Panel on a request from the Commission related to a notification from Kenney & Ross Ltd. on fish gelatine for different uses in food pursuant to Art. 6 par. 11 of Directive 2000/13/EC	2 December 2004		
154	NDA	EFSA-Q-2004-134	Opinion of the NDA Panel on a request from the Commission related to a notification from BSI on nuts (almonds, walnuts) extracts used as flavours in distillates pursuant to Art. 6 par. 11 of Directive 2000/13/EC	2 December 2004		
155	NDA	EFSA-Q-2004-129A	Opinion of the NDA Panel on a request from the Commission related to a notification from EFFA on celery leaf oil, celery seed oil and celery oleoresin pursuant to Art. 6 par. 11 of Directive 2000/13/EC	2 December 2004		
156	NDA	EFSA-Q-2004-129B	Opinion of the NDA Panel on a request from the Commission related to a notification from EFFA on mustard seed oil and mustard seed oleoresin pursuant to Art. 6 par. 11 of Directive 2000/13/EC	2 December 2004		
157	NDA	EFSA-Q-2004-128	Opinion of the NDA Panel on a request from the Commission related to a notification from IFF on mustard seed oil pursuant to Art. 6 par. 11 of Directive 2000/13/EC	2 December 2004		
158	NDA	EFSA-Q-2004-117	Opinion of the NDA Panel on a request from the Commission related to a notification from EPA on lactitol pursuant to Art. 6 par. 11 of Directive 2000/13/EC	2 December 2004		
159	NDA	EFSA-Q-2004-089	Opinion of the NDA Panel on a request from the Commission related to an application to market Enova oil as a novel food in the EU	2 December 2004		
160	FEEDAP	EFSA-Q-2003-059	Opinion of the FEEDAP Panel on the request from the Commission on the use of synthetic sodium aluminium silicate (zeolite) for the reduction of risk of milk fever in dairy cows	8 December 2004		
161a	AFC	EFSA-Q-2003-230B	Opinion of the AFC Panel on a request from the Commission related to a 6th list of substances for food contact materials: Acrylic acid, methyl ester, telomer with 1-dodecanethiol, C16-C18 alkyl esters	8 December 2004		
161b	AFC	EFSA-Q-2004-116	Opinion of the AFC Panel on a request from the Commission related to a 6th list of substances for food contact materials: 2,4-Bis(dodecylthiomethyl)-6-methylphenol			
161c	AFC	EFSA-Q-2004-047	Opinion of the AFC Panel on a request from the Commission related to a 6th list of substances for food contact materials: Iron Phosphide			
161d	AFC	EFSA-Q-2004-110	Opinion of the AFC Panel on a request from the Commission related to a 6th list of substances for food contact materials: Maleic anhydride-styrene, copolymer, sodium salt			

Opinion N°	Panel	Question Reference	Opinion Title			
161e	AFC	EFSA-Q-2004-052	Opinion of the AFC Panel on a request from the Commission related to a 6th list of substances for food contact materials: Polyester of adipic acid with glycerol or pentaerythritol, esters with even numbered unbranched C12-C22 fatty acids	8 December 2004		
161f	AFC	EFSA-Q-2004-141	Opinion of the AFC Panel on a request from the Commission related to a 6th list of substances for food contact materials: Polyethyleneglycol tridecyl ether phosphate	8 December 2004		
162	AFC	EFSA-Q-2003-072	Opinion of the AFC Panel on a request from the Commission related to the use of mineral oils in jute and sisal bags	7 December 2004		
163	AFC	EFSA-Q-2004-103	Opinion of the AFC Panel on a request from the Commission related to the safety in use of rutile titanium dioxide as an alternative to the presently permitted anatase form	7 December 2004		
164	AFC	EFSA-Q-2003-150	Opinion of the AFC Panel on a request from the Commission related to Flavouring Group Evaluation 7 (FGE.07): Saturated and unsaturated aliphatic secondary alcohols, ketones and esters of secondary alcohols and saturated linear or branched-chain carboxylic acids from chemical group 5 (Commission Regulation (EC) No 1565/2000 of 18 July 2000)	9 December 2004		
165	AFC	EFSA-Q-2003-152	Opinion of the AFC Panel on a request from the Commission related to Flavouring Group Evaluation 9 (FGE.09): Secondary alicyclic saturated and unsaturated alcohols, ketones and esters containing secondary alicyclic alcohols from chemical group 8 (Commission Regulation (EC) No 1565/2000 of 18 July 2000)	9 December 2004		
166	AFC	EFSA-Q-2003-154	Opinion of the AFC Panel on a request from the Commission related to Flavouring Group Evaluation 11 (FGE. 11): Aliphatiic dialcohols, diketones, and hydroxyketones from chemical group 10 (Commission Regulation (EC) No 1565/2000 of 18 July 2000)	9 December 2004		
167	AFC	EFSA-Q-2004-066	Opinion of the AFC Panel on a request from the Commission related to Magnesium Aspartate as a mineral substance when used as a source of magnesium in dietary foods for special medical purposes			
168	FEEDAP	EFSA-Q-2003-058	Opinion of the FEEDAP Panel on the request from the Commission on the use of iodine in feedingstuffs	25 January 2005		
169	FEEDAP	EFSA-Q-2003-052	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the product "Biomin BBSH 797" for piglets, pigs for fattening and chickens for fattening	25 January 2005		
170	FEEDAP	EFSA-Q-2004-156	Update of the Opinion of the FEEDAP Panel on a new request from the Commission related to the safety of "Bio-Cox® 120G" based on Salinomycin sodium as a feed additive in accordance with Council Directive 70/524/EEC			
171	FEEDAP	EFSA-Q-2005-008	Opinion of the FEEDAP Panel on the safety of the enzymatic product Avizyme® 1500 for use as feed additive for laying hens			
172	FEEDAP	EFSA-Q-2005-009	Opinion of the FEEDAP Panel on the safety of enzymatic product Avizyme® 1300 for use as feed additive for ducks			

Opinion N°	Panel Question Opinion Title				
173	173 BIOHAZ EFSA-Q-2003-081 Opinion		Opinion of the BIOHAZ Panel on the request from the Commission related to <i>Campylobacter</i> in animals and foodstuffs	27 January 2005	
174	BIOHAZ	EFSA-Q-2004-085	Opinion of the BIOHAZ Panel on safety of collagen and a processing method for the production of collagen	26 January 2005	
175	BIOHAZ	EFSA-Q-2004-010	Opinion of the BIOHAZ Panel on <i>Bacillus cereus</i> spp in foodstuffs	27 January 2005	
176	BIOHAZ	EFSA-Q-2004-017B	Opinion of the BIOHAZ Panel on the risk assessment of a simplified meat inspection for the presence of Cysticercosis cysts in veal calves kept under specific management conditions	27 January 2005	
177	PPR	EFSA-Q-2004-124	Opinion of the PPR Panel on a request from the Commission related to the appropriate variability factor(s) to be used for acute dietary exposure assessment of pesticide residues in fruit and vegetables	16 February 2005	
178	PPR	EFSA-Q-2004-081	Opinion of the PPR Panel on a request from EFSA related to the evaluation of dimoxystrobin	16 February 2005	
179	CONTAM	EFSA-Q-2003-068	Opinion of the CONTAM Panel on a request from the Commission related to Camphechlor as undesirable substance in animal feed	2 February 2005	
180	CONTAM	EFSA-Q-2003-031	Opinion of the CONTAM Panel related to Arsenic as undesirable substance in animal feed		
181	GMO	EFSA-Q-2004-072	Opinion of the GMO Panel on a request from the Commission related to the notification (Reference C/ES/01/01) for the placing on the market of insect-tolerant genetically modified maize 1507 for import, feed and industrial processing and cultivation, under Part C of Directive 2001/18/EC from Pioneer Hi-Bred Internation / Mycogen Seeds		
182	GMO	EFSA-Q-2004-087	Opinion of the GMO Panel on an application (reference EFSA-GMO-NL-2004-02) for the placing on the market of insect-tolerant genetically modified maize 1507, for food use, under Regulation (EC) No 1829/2003 from Pioneer Hi-Bred International / Mycogen Seeds		
	BIOHAZ	EFSA-Q-2003-083B	Scientific Report of the BIOHAZ Panel on the Assessment of Geographical BSE-Risk (GBR) of El Salvador, Nicaragua and Costa Rica	February 2005	
183	NDA	EFSA-Q-2004-136	Opinion of the NDA Panel on a request from the Commission related to a notification from CTPC on milk products, egg products and fish products used as fining agents in cider pursuant to Art. 6 par. 11 of Directive 2000/13/EC		
184	NDA	EFSA-Q-2004-137	Opinion of the NDA Panel on a request from the Commission related to a notification from ONIVINS on milk products, egg products and fish products used as fining agents in wines pursuant Art. 6 par. 11 of Directive 2000/13/EC	22 February 2005	
185	NDA	EFSA-Q-2004-142	Opinion of the NDA Panel on a request from the Commission related to a notification from DWV on milk products, egg products and fish products used in the manufacture of wine pursuant to Art. 6 par. 11 of Directive 2000/13/EC	cts and fish 22 February 2005	

Opinion N°	Panel	Question Reference	Opinion Title Opinion of the NDA Panel on a request from the Commission related to a notification from AMAFE on egg lysozyme used as additive in food pursuant to Art. 6 par. 11 of Directive 2000/13/EC			
186	NDA	EFSA-Q-2004-130				
187	NDA	EFSA-Q-2004-131	Opinion of the NDA Panel on a request from the Commission related to a notification from Raisio Life Sciences on plant stanol esters produced from soybean oil sterols pursuant to Art. 6 par. 11 of Diective 2000/13/EC	22 February 2005		
188	NDA	EFSA-Q-2004-132A	Opinion of the NDA Panel on a request from the Commission related to a notification from Cognis, ADM and Cargill on vegetable oils-derived phytosterols and phytosterols esters from soybean sources pursuant to Art. 6 par. 11 of Directive 2000/13/EC	22 February 2005		
189	NDA	EFSA-Q-2004-132B	Opinion of the NDA Panel on a request from the Commission related to a notification from Cognis, ADM and Cargill on natural mixed tocopherols (E306), natural D-alpha tocopherol, natural D-alpha tocopherol succinate from soybean sources pursuant to Art. 6 par. 11 of Directive 2000/13/EC	22 February 2005		
190	NDA	EFSA-Q-2004-125	Opinion of the NDA Panel on a request from the Commission related to a notification from AIIBP and FAIBP on acid hydrolysed vegetable protein from soy pursuant to Art. 6 par. 11 of Directive 2000/13/EC	22 February 2005		
191	NDA	EFSA-Q-2004-090	Opinion of the NDA Panel on a request from the Commission related to an application concerning the use of betaine as a novel food in the EU	22 February 2005		
192	NDA	EFSA-Q-2003-018C	Opinion of the NDA Panel on a request from the Commission related to the Tolerable Upper Intake Level of Fluoride	22 February 2005		
193	NDA	EFSA-Q-2003-018K	Opinion of the NDA Panel on a request from the Commission related to the Tolerable Upper Intake Level of Potassium	22 February 2005		
	AFC	EFSA-Q-2005-016	Statement of the AFC Panel on some octyltin compounds authorized to be used in food contact materials	23 February 2005		
194	FEEDAP	EFSA-Q-2005-029	Opinion of the FEEDAP Panel on the safety of the enzymatic product Kemzyme W Liquid for use as feed additive for laying hens	1 March 2005		
195	FEEDAP	EFSA-Q-2004-030	Opinion of the FEEDAP Panel on the safety and the bioavailability of product L-Histidine monohydrochloride monohydrate for salmonids	2 March 2005		
196	FEEDAP	EFSA-Q-2005-027	Opinion of the FEEDAP Panel on the safety of the enzymatic product Porzyme 9100 "two times concentrate" for use as a feed additive for piglets			
197	AHAW	EFSA-Q-2003-092	Opinion of the AHAW Panel on a request from the Commission related to the welfare aspects of various systems of keeping laying hens			
198	FEEDAP	EFSA-Q-2004-068	Opinion of the FEEDAP Panel on a request from the Commission on the safety of the enzyme preparation Natugrain Wheat + for chickens for fattening			

Annex III: List of acronyms



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ABB Activity Based Budgeting ABP Animal by-products ADI Acceptable Daily Intake AFC Scientific Panel on Food Additives, Flavourings, Processing Aids and Materials in Contact with Foods AHAW Scientific Panel on Animal Health and Welfare AUX Auxiliary Agents BADGE Bisphenol A-diglycidyl ether BIOHAZ Scientific Panel on Biological Hazards BSE Bovine Spongiform Encephalopathy BSURVE BSE surveillance model BVL Bundesamt für Verbraucherschutz und Lebensmittelsicherheit (German Federal Office for Consumer Protection and Food Safety) CNS Central Nervous System CONTAM Scientific Panel on Contaminants in the Food Chair CWD Chronic Wasting Disease DG DEV Development Directorate-General, European Commission DG ENV Environment Directorate-General, European Commission DG RTD Research Directorate-General, European Commission DG SANCO Health and Consumer Protection Directorate-General, European Commission DUS Direzionale uffici sanitari EC European Commission ECDC European Centre for Disease Prevention and Control EFSA European Food Safety Authority EMRISK Scientific Committee Working Group on Emerging Risks	EPCO ESBO EU EUR EXPOSURE FAO FAQ FDA FEEDAP FOCUS FRF GBR GENTOX GM GMO(s) HPHB ILSI IT JECFA KFD MB MRL MSDI mTAMDI NDA	EFSA Plant Protection Products Peer Review Coordination Epoxydised soybean oil European Union Euros Scientific Committee Working Group on Exposure Assessment Food and Agriculture Organisation Frequently Asked Questions Food and Drug Administration Scientific Panel on Additives and Products or Substances used in Animal Feed Forum for the coordination of pesticide fate models and their use Fat (consumption) Reduction Factor Geographical Bovine Spongiform Encephalopathy Risk Scientific Committee Working Group on Genotoxic and Carcinogenic Substances Genetically Modified (Scientific Panel on) Genetically Modified Organism(s) High Pressure Hydrolysed Biogas International Life Sciences Institute Information Technology Joint Expert Committee on Food Additives Potassium Diformate Management Board Maximum Residue Level Maximised Survey-derived Daily Intake modified Theoretical Added Maximum Daily Intake Scientific Panel on Dietetic Products, Nutrition and Allergies	NGO OECD OFF OIE OTM PCBS PFOS PMEM PPR PRAPER PSD QPS SC SCAN SCF SCHER SCP SCVPH SEM SNE(s) SRM SWAFF TA TBHQ TDI TSE UK WHO	Non-governmental organisation Organisation for Economic Co-operation and Development Officials World Organisation for Animal Health Over Thirty Months Polychlorinated biphenyls Perfluorooctane sulphonate Post-Market Environmental Monitoring Scientific Panel on Plant Health, Plant Protection Products and their Residues Pesticide Risk Assessment Peer Review Pesticide Safety Directorate (Scientific Committee Working Group on) Qualified Presumption of Safety Scientific Committee on Animal Nutrition Scientific Committee on Health and Environmental Risks Scientific Committee on Consumer Products Scientific Committee of Veterinary measures relating to Public Health Semicarbazide Seconded National Expert(s) Specific Risk Material Safety of Wild and Farmed Fish Temporary Agents Tertiary-butylhydroquinone Tolerable Daily Intake Transmissible Spongiform Encephalopathy United Kingdom World Health Organisation
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EUROPEAN FOOD SAFETY AUTHORITY

Operational and postal address in Brussels (until October 2005): 10, Rue de Genève B-1140 Brussels Belgium

Official seat in Parma: Palazzo Ducale Parco Ducale 3 I-43100 Parma Italy Operational and postal address in Parma: Largo N. Palli 5/A I-43100 Parma Italy Contacts:

Tel: +32 (0)2 337 21 11 Fax: +32 (0)2 726 68 13 E-mail: info@efsa.eu.int Website: www.efsa.eu.int ISBN: 92-9199-005-1

