



European Food Safety Authority

ANNUAL REPORT 2004

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1. Message from the Chairman of the Board

EFSA Annual Report 2004

The year 2004 was one of rapid developments at 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 look 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, regional and national levels.

Despite the turbulence caused by moving, EFSA's core business, the provision of high quality, independent scientific opinions and advice, expanded rapidly during the year. Over 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 geographical bovine spongiform encephalopathy (BSE) risk and testing for transmissible spongiform encephalopathy (TSE).

In May 2004 we welcomed ten new EU Member States as full members of the Advisory Forum, although, due 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 and also spread 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, with consumer and other stakeholder groups and with national and international organisations working in the same or related areas in different parts of the world. A successful stakeholder colloque was held in Berlin in November and I welcome the decision to set up a permanent Stakeholder Forum.

On behalf of the Management Board, I would like to thank Geoffrey Podger and the whole of 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 to the work of the scientific Committee and Panels so that they can further increase their output of scientific opinions and advice. However, I am confident that EFSA's hard working and dedicated staff can meet them.

Stuart Slorach

2. Message from the Executive Director

2004 has been a critical year for the growth of the European Food Safety Authority as it continued its build up 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 179 requests for scientific advice have been addressed to the Authority in 2004, in addition to the 242 questions already registered in 2003.

EFSA's Scientific Panels delivered in 2004 opinions on a wide range of topics such as: Genetically Modified Organisms, 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 equally 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 risks assessment and risk communications. Throughout the past year, the Authority has continued to build its relationships with the new entrant states and forged links with countries and organisations beyond the European 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.

In parallel, it has been of primary importance to EFSA to pursue in 2004 an on-going dialogue with its stakeholders in an open manner. The challenge for the Authority is to develop its relationship with stakeholders together 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 scheduled to achieve its completion in the autumn of 2005, 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. I would like on this occasion 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

3. 2004: an overview of objectives

Having established itself as an independent European Agency during 2003, the Authority focused in 2004 on building capacity so as to deliver its mandate and meet the expectations of European and national institutions, stakeholders and the public at large.

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

- Install a constant recruitment drive in all departments in order to balance with the growing working load;
- Provide scientific opinions and advice to questions formally addressed to the Authority or by self-tasking;
- Assess the risks and maximum residue levels of existing and new pesticides and monitor specific risk factors and diseases;
- Promote and apply new and harmonised scientific approaches for hazard and risk assessment methodologies;
- Foster exchange and transfer of scientific expertise and knowledge;
- Promote the Authority as an organisation dedicated to scientific excellence, openness and transparency whilst ensuring that communication messages are relevant and understandable and address food safety concerns;
- Develop an overall strategy on international relations for the Authority building on those relations already established during 2003;
- Ensure a smooth and swift relocation of the Authority to Parma.

People represented the cornerstone of the Authority's development and growth in 2004; an essential aim for the Authority therefore was to be able to recruit and retain the best staff possible at all levels in order to deliver successfully its objectives for 2004 and beyond.

Another important aim in 2004 was the significant development of both EFSA's scientific and communications functions by appropriate operational and administrative support, including the deployment of human and financial resources. The Authority undertook to focus on building capacity within its scientific departments 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. In this respect, 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 proposed to further engage 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 early movers taking up residence towards the end of the year. Significant planning, personnel and logistical issues were foreseen in order to achieve a smooth relocation, both in-house and with the scientific panels and Committee members, the Management Board and the Italian Authorities.

4. EFSA in 2004: key achievements and highlights

Under the guidance of its Management Board and Executive Director, the Authority has further built 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 the putting in place of the appropriate structures to facilitate the move, and resources. By the end of the year, a core group of staff had already made the move and were continuing work as usual 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 for the Authority to develop into an efficient and effective organisation. Staff was selected for their excellence and know-how at all levels of seniority and experience from all parts of the EU area including the Accession states.

Throughout the year, the Scientific Committee and Panels have established extensive work programmes for the uninterrupted publication of **scientific opinions** covering the questions posed to them as well as 'self tasking' activities, considered as a priority. The establishment of further in-house support to the work of the panels, to be continued in the future, reflects the overall intent of the Authority to ensure scientific rigour in all its scientific work and in particular in its risk assessment and safety evaluation procedures.

Throughout its activities and 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**.

4.1.Overall management activities and organisational effectiveness

- The Management Board

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

Over the year the Management Board adopted the 2004 work programme, the 2005 budget and preliminary work programme and discussed such wide-ranging issues as media handling guidelines for the Scientific Committee and Panels and EFSA's animal welfare policy. A very successful Management Board Team Building was organised in connection with the March meeting in Dublin.

On 19 May 2004, the Management Board sent a letter to the Council, the Commission and the European Parliament.

The Management Board of EFSA had learned of the insertion at the drafting stage of administrative review clauses in two draft Regulations which, if they became legislation, would empower the Commission to require the Authority to withdraw its decisions or undo its acts. In addition, these texts would enable the European Commission, on its own initiative or in response to a request from a Member State or from any person directly or individually concerned, to review acts or decisions adopted or taken by the Authority.

The matter was formally raised at the 27 April 2004 Management Board meeting of the Authority. 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.

At the last Management Board meeting of 2004, the Board adopted an important own-initiative paper on Progress Indicators and the revised document on the guidance of Declarations of Interest.

As for the role of the Management Board in EFSA's evaluation process foreseen during the course of 2005, the Terms of Reference of the evaluation put it as follows: The management of the project will be conducted by a Steering group, composed of Members of the Management Board and a Technical Group, composed of civil servants from EFSA and the Commission services. The dissemination of the evaluation results and the implementation of recommendations fall under the responsibility of the Board.

- **EFSA Director and Staff**

Four distinct bodies make up EFSA. 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 legal representative of the Authority; he is in charge of day-to-day management and is responsible for all staff matters. The post is for five years, renewable, and is answerable to the Management Board. It was filled on the basis of a list of candidates proposed by the European Commission after an open competition and confirmed following a hearing in the European Parliament. Assisting the Executive Director is the EFSA management team that includes the Deputy Executive Director and Director of Science, Dr. Herman B.W.M. Koëter and the functional directors of Accounts; Communications; Facilities; Finance; Human Resources; Information Technology; Institutional Affairs; Legal Affairs; Quality Management and Science.

When fully operational, the Authority is expected to count more than 300 staff. EFSA staff is responsible for:

- supporting the Scientific Committee and Scientific Expert Panels and their working groups, and investing in fore-front 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 comprehensive achievements of each of EFSA's functions in 2004.

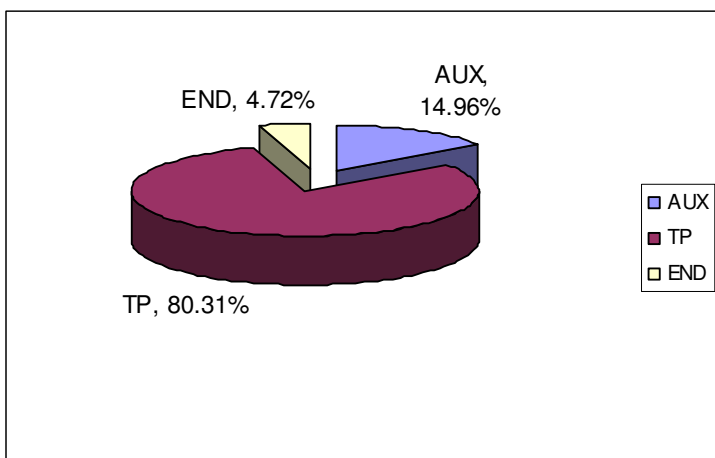
- **Staffing and Human Resources**

Current staffing levels

On 31 December 2004, EFSA staff amounted to 127 in total: 102 staff members of which 100 temporary agents and 2 officials, and 19 auxiliary agents. Additionally, 6 seconded national experts were hired.

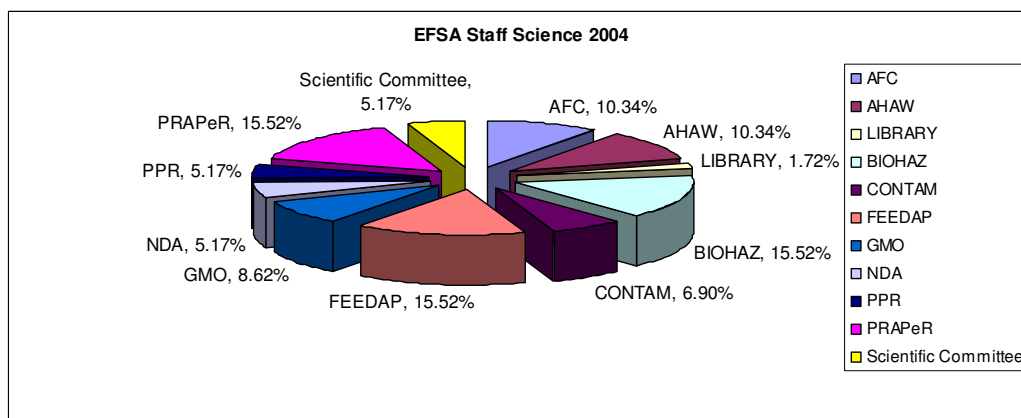
TABLE 1

AUX	19	14.96%
TEMP & FT	102	80.31%
END	6	4.72%
Total staff	127	



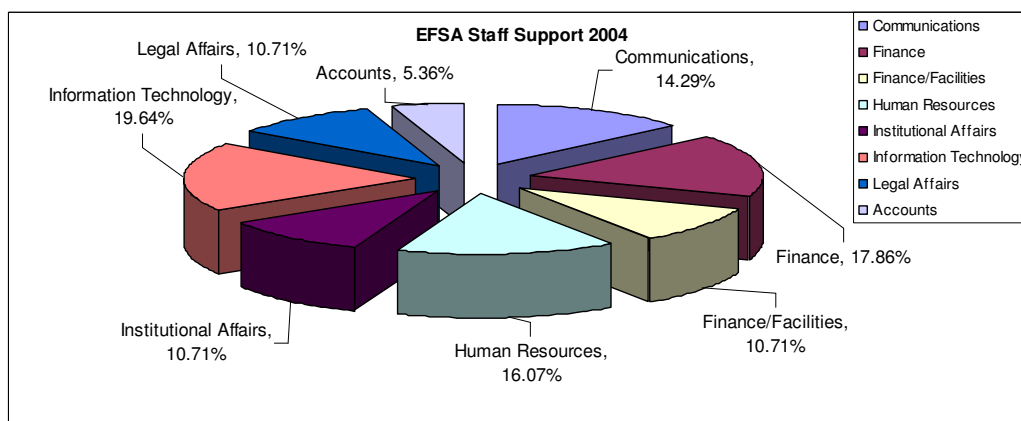
Overall 75 new staff members were recruited in 2004, among which 42 were recruited in the Science department.

TABLE 2



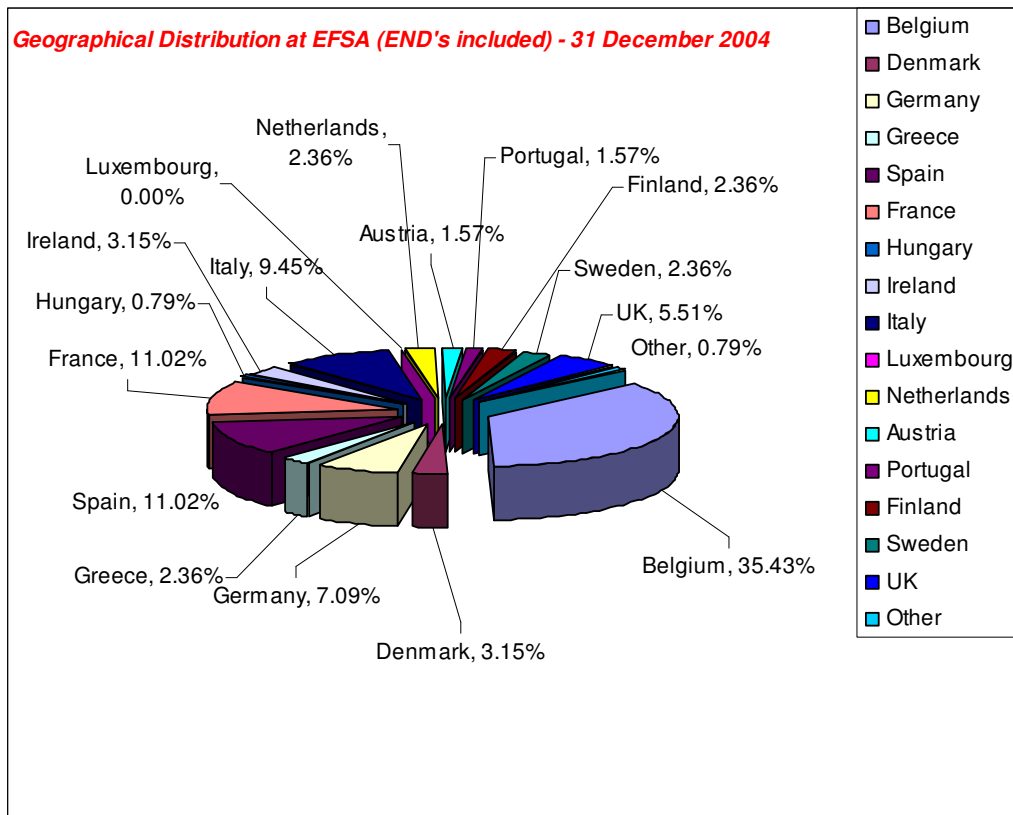
Distribution of recruitment per department.

TABLE 3



The next table shows the **geographical distribution per grade**. 15 nationalities of the European Union are represented and one member of staff from a new Member State was already hired in 2004.

TABLE 4



The **male/female ratios** were 8.82% vs 91.18% in the C level posts, raising to a 50/50 split in the B level posts and 44% vs 56% in the A level posts for temporary agents.

TABLE 5

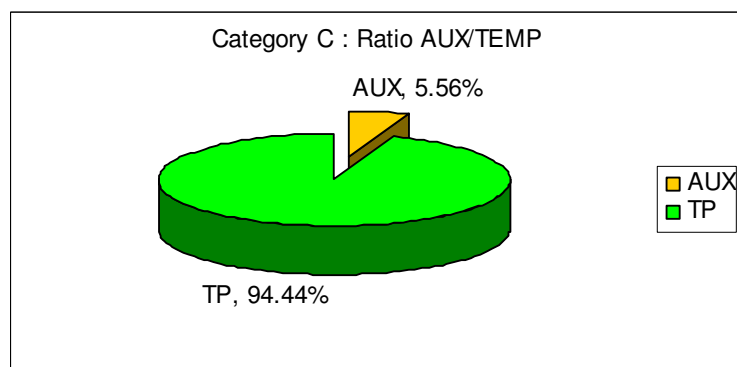


TABLE 6

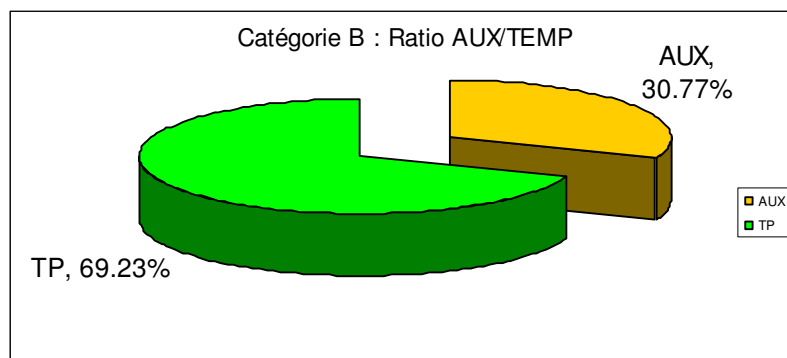
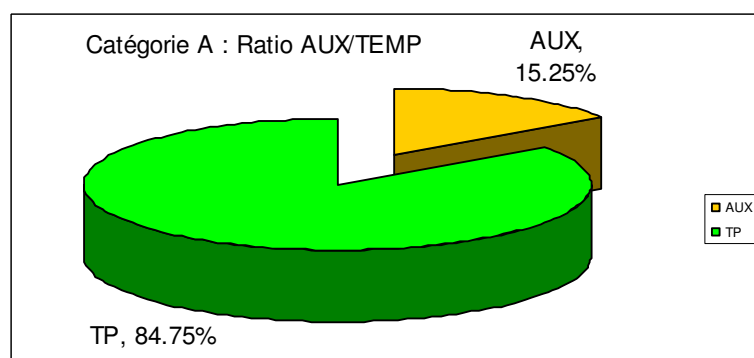


TABLE 7



Recruitment policy

Throughout 2004, EFSA maintained a very high pace of recruitment. All posts were published on the EFSA website. In its recruitment procedures, EFSA applies a policy of equal opportunities. 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.

Notwithstanding continuous recruitment throughout the year, the increasing workload, as attested by the growing number of requests for scientific opinions from EFSA's scientific panels, required even more efforts in the recruitment of scientific staff. Many staff were recruited from reserve lists of calls launched in 2003.

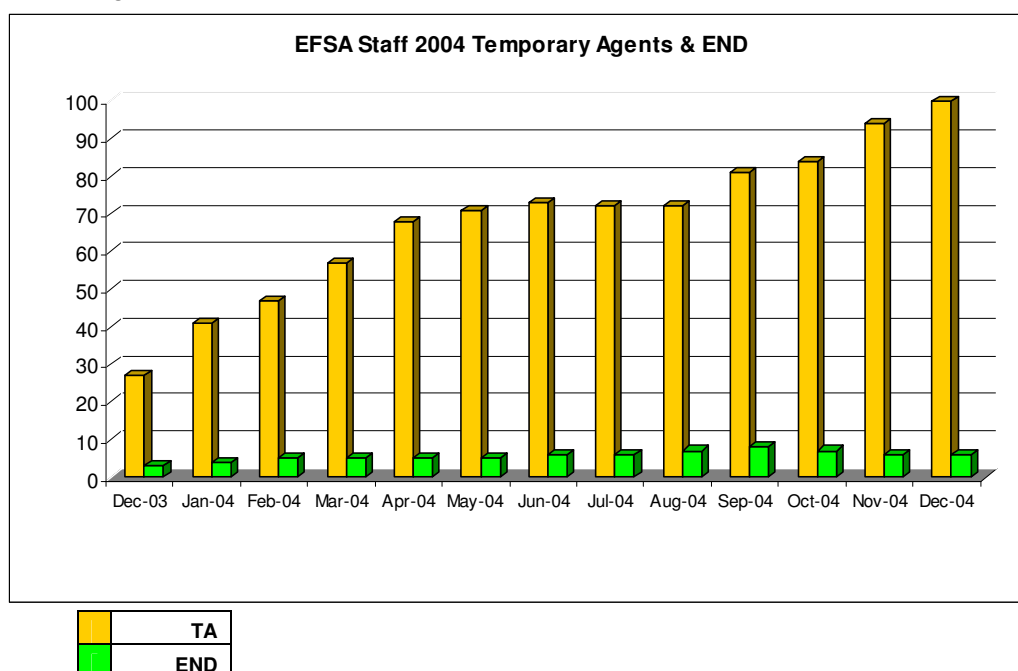
In addition, four targeted calls were launched during the year: one call combining the vacancy notices for the posts of Press Officer, Publications Officer, Internal Communications Officer and Web Editor; two calls for junior and senior Scientific staff in Pesticides; and one call for the post of Internal Auditor.

Late in the year, a call for Receptionists for our Parma premises was launched.

Altogether, 1848 candidates have submitted applications following the four calls launched in 2004.

- Press Officer (250)
- Publications Officer (165)
- Internal Communications Officer (363)
- Web Editor (108)
- Junior Scientific staff in Pesticides (490)
- Senior Scientific staff in Pesticides (179)
- Internal Auditor (293)
- Receptionist (500)

TABLE 8



In addition, the move to Parma has required a significant investment throughout the organisation, and in particular for the Human Resources Department in order to prepare EFSA and EFSA staff for this important transition and change.

2004 was also a year for establishing structures, policies and procedures in order to facilitate daily work processes and gain in efficiencies.

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

- Legal Affairs

In 2004 the Legal Department has continued to fulfil its mission to establish and maintain a legally sound and secure environment in compliance with Community law for all EFSA activities.

The Department has reinforced its resources and organisation in order to better serve the needs of the Authority in this critical year of growth and consolidation of structures and activities. It has been particularly active in the following:

- Completing the scheme of internal rules and decisions allowing EFSA to operate effectively. Highlights include rules of procedures for EFSA constitutive bodies, guidance on conflicts of interests, 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 Scientific Panels. This has been particularly challenging in view of experience gained with implementation of EFSA's founding Regulation and new legislation affecting EFSA directly, e.g. Regulations 1829/2003 and 1831/2003.
- 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 provisional and permanent accommodation in Parma.
- Procurement and contract management, both concerning handling of individual projects and establishing our procedures for the smooth planning, functioning and monitoring of this activity.

Access to documents

This section is being introduced on the basis of Article 8 of the EFSA decision concerning access to documents (MB 16.09.2003), under which EFSA is to publish annually, as part of the annual activity report, information concerning statistics on 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 1049/2001, the majority of which were launched towards the end of the year. Subject to the respect for private and public interests in accordance with Regulation 1049/2001 access was eventually granted in 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 conclusion in early 2005. The Authority is fully committed to its obligations under Regulation 1049/2001 and is implementing tools and procedures to ensure that requests are tracked and processed both in an efficient and lawful manner. EFSA expects applications under Regulation 1049/2001 to sharply increase in 2005.

Financial Affairs

Given the substantial increase of EFSA's activities in 2004, the Finance team was very much focused on budgetary and financial execution. Additional resources have been hired during the year in order to reinforce the centralised financial verification and to put in place the basis for the implementation in 2005 of the Internal Control Standards.

Internal Control Standards are geared to ensure economic, efficient and effective achievement of the objectives and the adherence to management policies and regulations. The timely 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 are equally covered by these standards.

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 the 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 on the 2004 budget as initially adopted by the Management Board. The final 2004 budget therefore amounted to EUR 29.1 million.

The EFSA evaluation process pursuant to Art. 61 of the Regulation 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. The Terms of Reference were tendered out in December and the award decision taken in January 2005. The objectives of EFSA's evaluation are firstly to improve present and future design, mission and tasks of the organisation and secondly to provide transparency and accountability in reporting results of its activities and impacts to European citizens. The Management Board shall examine the conclusions of the evaluation and issue to the Commission such recommendations as may be necessary regarding changes in the Authority and its working practices.

From an infrastructural point of view, the investigation of available alternatives pertaining to a provisional operational headquarter in Parma were finalised in May. On the basis of the requirements of EFSA and the technical and economical merits terms of the identified alternatives, a proposal was submitted to the Management Board and then to the Budgetary Authority.

Facilities

The seat decision taken by the European Council in December 2003 made 2004 a challenging year. In addition to providing EFSA with professional office spaces in Brussels in a phase of strong growth and developing appropriate contract, supply, maintenance and security services, a new office building had to be found in Parma. The investigations started in March and lead to the signature of a rental contract in June after approval of the European Parliament.

The building occupied is part of the DUS complex and situated in the inner ring of Parma. Some works (e.g. inter-connections of the various parts of the building, additional partitioning) had to be done in order to cope with the Authority's requirements. The works were carried out and completed under EFSA's supervision. From October onwards, EFSA staff started to relocate to the Authority's new operational seat.

Nice picture of the DUS building to be inserted

- **Information Technology**

In 2004, the IT Department focused its efforts on its main internal “clients”; Science, Communications and EFSA corporate. The Department will maintain this focus in 2005.

With regard to Science, the IT Department delivered Extranets to each Scientific Panel so that scientific information could be securely exchanged amongst EFSA and panel members. The Department also provided internet-based systems that support specific regulations for dossier submissions and public or private consultation. This was notably the case with the AFC, FEEDAP, and GMO panels and the Pesticide Risk Assessment expert service. One of the largest scientific projects of 2004 (due for completion in 2006) was the implementation of the online Zoonose Community Report and associated online systems for base-line studies. Finally, the IT team provided a register of scientific questions, available on EFSA’s website.

In the field of Communications, IT provided an initial web content management system that allowed EFSA to launch its new web site in March 2004 and maintain it up-to-date throughout 2004. To further improve its responsiveness, EFSA’s IT Department purchased a commercial web content management system to be rolled out in 2005. IT also supported the Communications team for all its 2004 webcasts and will continue to do so in 2005.

To support the work of EFSA’s Advisory Forum, the IT Department delivered an experimental extranet (in production in June 2005) and launched a major project to provide all European National food safety agencies and EFSA with on-demand videoconference capabilities (available in April 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 seamlessly available in both locations. Moreover, network equipment and corporate servers can be moved to Parma with minimum disruption for EFSA staff.

Finally, concerning corporate projects, the IT unit also enhanced the robustness of its systems and in particular made its mail and document management systems redundant. The team revamped and documented most of its operating procedures, offering live, onsite support between 8:00 and 18:00. The IT function launched a major effort to scan and store EFSA’s 300000-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

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

- 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 supported by the respective Panels or the Scientific Committee also contributed to the scientific output of EFSA. 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 Bovine Spongiform Encephalopathy (BSE) Risk (GBR);
- Task Force on Zoonoses Monitoring and Data Collection;
- Pesticides Risk Assessment Peer Review Expert Group.

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

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

**NUMBER OF SCIENTIFIC EXPERT OPINIONS DELIVERED
ON QUESTIONS RECEIVED FROM THE EUROPEAN COMMISSION IN 2004**

Scientific expert panel	questions received	scientific opinions
Panel on food additives, flavourings, processing aids and materials in contact with food (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 food (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
PRAPeR	—	6	23
Total	63	98	331

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

Additives and Products or Substances Used in Animal Feed

The Panel on Additives and Products or Substances Used in Animal Feed (FEEDAP) met 10 times in plenary session in 2004, issuing 32 opinions. In May 2004 the 10th Plenary Meeting of the Panel was held in Barcelona and included a special session open for all stakeholders. The FEEDAP Panel 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 that new guidelines are established. A new Working Group has started the work on the development of guidelines for silage additives.

The FEEDAP Panel initiated three self-tasks in 2004. The first task is related to the updating of the criteria in the assessment of 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 was related to environmental risk assessment models for feed additives, in particular for aquatic environment. 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 on the assessment of herbal products for use in animal nutrition. A Working Group to be established 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 (on stunning, transport, microclimate during transport, piglet castration, the welfare of laying hens, and *Mycobacterium avium paratuberculosis*). The opinion on the welfare of laying hens will be co-adopted by the Panels on biological hazards (BIOHAZ) and contaminants in the food chain (CONTAM) in 2005, addressing the implications of the different laying hen production systems on egg safety. The Animal Health and Welfare Panel received 10 questions in 2004 most of them from the European Commission (DG SANCO, DG Development and DG Environment). AHAW Panel experts also contributed to the scientific opinion on vaccination of Salmonella in poultry adopted by the BIOHAZ Panel.

<< I propose a picture of an animal transport, nothing shocking though>>

The Panel's Working Groups on 'Transport', 'Stunning' and 'Piglet Castration' each published a comprehensive scientific review report containing all available relevant 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 with added references to the scientific reports for the specific details of the substantial number of species concerned. These scientific reports were published on the Internet together with the scientific opinions. In developing its opinions on 'welfare of laying hens' and 'piglet castration' the AHAW Panel also took into account a global approach and, consequently, also addressed possible impacts on food safety.

In addition to the development of opinions as 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 a contribution from EFSA to the Commission's DG RTD' next framework program.

Biological Hazards

In 2004, the Panel on Biological Hazards met eight times in plenary. On Food Microbiology, Food Hygiene, food-borne Zoonoses and Meat Inspection, the Panel counted twelve *ad-hoc* Working Groups to deal with requests received from the European Commission. On BSE questions the Panel established nine *ad-hoc* Working Groups to deal with requests received from the European Commission, Member States or the European Parliament. On animal by products (ABP), the Panel established two *ad hoc* Working Groups to deal with requests received from the European Commission.

The BIOHAZ Panel adopted 16 opinions in 2004 following the requests for scientific opinion from the European Commission. In the area of Food Microbiology, Food Hygiene, food-borne Zoonoses and Meat Inspection, two opinions were adopted on 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 under the Health and Consumer Protection Directorate General (DG SANCO). One Opinion on microbiological risks on infant formulae identified *Salmonella* and *Enterobacter sakazakii* as the microorganisms 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 as *Salmonella* in poultry were the focus of two major opinions on the advantages and disadvantages of antimicrobials and vaccines to control *Salmonella* in poultry, especially those serotypes of major concern to Public Health in Europe.

<< please insert a picture of a baby sucking from a bottle>>

In the area of Transmissible Spongiform Encephalopathy (TSE), the Expert Working Groups of the Scientific Panel on Biological Hazards received most questions from the European Commission (DG SANCO) in 2004. In addition, one question was received from the European Parliament on the safety of goat milk and goat milk products and one from a Member State (France) on the Bovine Spongiform Encephalopathy (BSE) situation in Portugal. From the general questions received, opinions were adopted on the review of the Over Thirty Months (OTM) rule of the United Kingdom (UK) and its application for moderate risk status in terms of BSE. A mandate on Chronic Wasting Disease (CWD) resulted in an opinion on the suggested plans for surveillance for this disease in the European cervid population, which will now be followed up by EC action in initiating this survey for the 25 MS. An opinion on the risks of stunning and the dissemination of central nervous system tissue (CNS) and thus the risk of spreading of BSE into the carcass was adopted as well as an opinion on BSE-related culling in cattle and an opinion on BSE risk from bovine tonsil and consumption of bovine tongue. The review of the BSE situation in Portugal was carried out following a request by France and this resulted in an adaptation of the export conditions of Portuguese beef to other Member States (MS). The review of the age limit for removal of Specified Risk Material (SRM), a mandate on the Quantitative Risk Assessment on residual BSE risk in certain bovine derived products, such as tallow and gelatin are 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 fertilizer, biogas and compost treatment standards and the biological safety of heat treatment of manure. A series of methods for safe disposal of category 1 ABP's 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.

Picture of Milking Goat / Herd of white tailed deer / Elk

Towards the end of the year, the discovery of a suspicion of BSE in a goat was the subject of two questions from the European Commission and one from the European Parliament. This work was initiated in 2004 and a statement on goat milk and goat milk products was already issued whereas the update of current opinions is continuing. This topic was also the subject of press releases prepared by the Communication department and statements issued by the Scientific Panel on Biological Hazards. Other highlights included the release of the opinions on 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 Assessment reports (GBR) of 7 countries.

Contaminants in the Food Chain

In 2004 the Scientific Panel on Contaminants in the Food Chain (CONTAM) adopted 10 opinions and received 4 additional questions. The opinion on the assessment of health risks to consumers associated with the exposure to organotins in foodstuffs was an important milestone as the Commission SCHER¹ Committee will use this opinion to prepare an overall risk assessment including non-food exposure. In February 2004 the Panel adopted an opinion on the risks of methyl mercury in food which contributed to discussion in Europe on the risks and benefits of eating fish. As a result 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 to ensure expertise in different areas, including beneficial effects of eating fish. A second request from the European Parliament related to the health risk of the consumption of Baltic herring which was received later in the year will also be addressed in this opinion. The CONTAM Working Group on SWAFF already met 4 times 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 *Gempylidae* (e.g. Escolar and Oilfish). This opinion was adopted in August 2004.

The Panel's Working Group on non-dioxin like PCBs met eight times in 2004 to prepare an opinion concerning the presence of these PCBs in feed and food. The adoption is foreseen for the spring of 2005. In September EFSA organised a session entitled "Risk Assessment of non-dioxin-like PCB" at the World Dioxin Congress² to stimulate scientific discussions and to provide further guidance to the work which is carried out by the WG.

The CONTAM Panel initiated two self-tasks. The first task was related to findings from the US 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 request the CONTAM Panel to compile a scientific report comprising

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

currently available data on methods of analysis, occurrence, formation, exposure and toxicity. The report on provisional findings of furan in food was published in December 2004, and outlined further research needs in order to draw a conclusion with respect to human health. The second self-task was related to perfluorooctane sulfonate (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 end of 2004 and the Working Group will meet for the first time in 2005.

Dietetic Products, Nutrition and Allergies

The Panel on Dietetic Products, Nutrition and Allergies (NDA) met five times in plenary in 2004. In addition to the four 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 opinion 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 assessment of 21 applications on allergen derivatives submitted for temporary labelling exemption. The remaining 8 applications will be finalized in early 2005.
- Setting tolerable upper levels of intake for the following vitamins and minerals: vitamin C, iron, boron, vanadium, and silicon. The remaining 7 nutrients will be finalized in early 2005.
- Presence of *trans* fatty acids in foods and the effect on human health of the consumption of *trans* fatty acids.
- 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 on Enova oil pursuant to the Novel Food Regulation (EC) N° 258/97.

In addition to these requests, the NDA Panel was also requested by the European Commission in 2004 to provide scientific opinions on 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 on unsaponifiable matter, for which the expected date of completion 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 date of completion is April 2005.
- Nutrition claims related to unsaturated fat, poly-unsaturated fat, mono-unsaturated fat and omega-3 fatty acids. The expected date of completion is July 2005.

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

[still waiting for basic information from AFC]

Genetically Modified Organisms

In 2004 the GMO Panel received 15 questions: a general question from the European Commission (DG ENV), four questions related to applications under Directive 2001/18/EC, and eight applications under Regulation (EC) 1829/2003. The Panel initiated a self-tasking activity on post-market environmental monitoring (PMEM) and proposed a mandate to start a self task on the use of animal feeding trials for the safety evaluation of GM food/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 in order to discuss the new tasks assigned to EFSA with regard to this Regulation. The Panel adopted 7 Opinions.

Three ad hoc Working Groups of the GMO Panel dealt with a specific question such as: 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 arranged a system for on-line consultation to provide the opportunity for stakeholders to submit comments on the draft guidance document electronically. On 25 May 2004 the GMO Panel held a Stakeholders Consultation meeting in Brussels to answer the many comments received on the draft guidance document. Some 80 participants, representing all sectors, i.e. non-governmental organisations (NGOs), Industry and competent authorities participated in 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 as a glossy publication in early 2005

The self-tasking Working Group on PMEM addresses the requirements for post market environmental monitoring in order to produce guidance for both applicants and regulatory authorities. The PMEM WG initiated a series of consultation workshops with different stakeholders (applicants, environmental NGOs and scientific institutes, experts from Member States) to establish a rationale and general framework for General Surveillance as a component of Post Market Environmental Monitoring. The PMEM WG met four times, two of which were stakeholder workshops. Their activity still 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 six times in 2004 and held nineteen Working Group meetings. The Panel issued six opinions in three sectors: toxicology, environment and ecotoxicology, or combinations of two or more sectors. The opinions issued in toxicology concerned the following active substances: daminozide (carcinogenic mechanism of action of a metabolite), dinocap (two questions, one on an eye effect on dog and one on the dermal absorption), methamidophos (value for the degree of dermal absorption) and on alachlor (two questions, one on occurrence of nasal turbinate tumours in rat and one on the relevance of metabolites). The opinions in the sector of environment were related to the Review Programme under Council Directive 91/414/EEC - Second stage addressing the FOCUS models used at EU level for the risk assessment of the fate and behaviour of pesticides in soil and water. One Opinion was delivered on FOCUS ground water (comparability of the available FOCUS ground water models) and another Opinion was on FOCUS surface water (appropriateness of using the FOCUS surface water scenarios in particular situations as 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 behaviors). A self-task requested by the EFSA PRAPeR Expert Group on the long-term toxicity of dimoxystrobin in fish will be adopted early 2005.

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

A comprehensive list of all published opinions in 2004 will be inserted here (+/- 3 A4 p)

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

Additives and Products or Substances Used in Animal Feed

EFSA received close to 9000 notifications of existing feed additives within the year of the entry into force of Regulation (EC) 1831/2003. EFSA was requested to verify that all information required has been submitted. The Authority started on this extensive activity in 2004 and shall notify the completeness of all notifications to the Commission by November 2005.

Seven opinions on coccidiostats intended for use for either chickens for fattening, chickens reared for laying, turkeys and/or rabbits were adopted in 2004 and two further updates were adopted following submission of new data. A total of 15 opinions on micro-organisms and enzyme products intended for use as a feed additive 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 foreseen in early 2005. The Panel has also been requested to assess the safety of all carotenoids used in animal nutrition. Besides a technical hearing on the subject with industry representatives, four Working Group meetings have been held also addressing the work on the MRL's for canthaxanthin. In July 2004 a new WG on product Hydroxy-vitamin-D₃ (calcifediol) was established to review safety and efficacy of the product for use in different poultry species. The work involved three meetings in 2004 and will continue in 2005. Following a request in March 2004 to assess L-histidine for use in salmonids a WG was established, and it met twice. This opinion is to be completed in 2005.

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

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

[still waiting for basic information from AFC]

Genetically Modified Organisms

The GMO Panel received four questions related to applications under Directive 2001/18/EC and eight applications under Regulation (EC) 1829/2003. With many applications to work on the Panel had for each dossier three working groups to focus on (1) environment risk assessment; (2) molecular characterisation and (3) food and feed safety.

The GMO Panel adopted 7 opinions in 2004 related to:

- 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
- 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
- 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
- The use of antibiotic resistance genes as marker genes in genetically modified plants
- Request from the Commission related to the Greek invoke of Article 23 of Directive 2001/18/EC
- Request from the Commission related to the Austrian invoke of Article 23 of Directive 2001/18/EC
- 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.

In addition to the central role for EFSA with respect to GMO risk assessment, Regulation (EC) 1829/2003 on GM food and feed also imposes important administrative and management tasks onto EFSA. For this purpose, EFSA has set up a collaborative electronic tool, the GMO EFSA^{net}, to exchange information with the Commission and with national agencies and competent authorities involved in the risk assessment of GMOs. EFSA's support unit for the GMO Panel has contributed to explore 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 for substances of the second stage of the EU review programme following Council Directive 91/414/EEC continued. For all 52 substances the initial assessments were received from the respective designated rapporteur 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 provision of comments.

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 is assisted in the peer review by the EPCO project (EFSA Plant Protection Products Peer Review Coordination) organised jointly with the German Federal Office for Consumer Protection and Food Safety (BVL) and the British Pesticide Safety Directorate (PSD). It provides administrative and scientific support and also holds EPCO expert meetings for scientific discussion of 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 its first conclusion on the risk assessment to the European Commission. While the notifiers for 2 active substances (triazamate and naled) withdrew their participation from the review program, EFSA is expecting to finalise the peer review and to submit its conclusions for the remaining 49 active substances in 2005.

For new active substances, EFSA received in 2004 the initial assessment, i.e. the draft assessment reports, from the respective rapporteur 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, ZOO NOSES AND ANIMAL DISEASES

BSE/TSE Assessment

The EFSA Expert Group on GBR received its mandate in 2003 and continued to collect and analyze data and discuss re-assessments of the GBR of different countries. Assessments for seven countries were finalised and published in 2004. These countries are 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 Group on the Evaluation of TSE Tests continued with the mandate received from DG SANCO on the evaluation of post mortem BSE tests for cattle, scrapie tests for sheep and goats and applications for live animal BSE tests which were all submitted following a call for expression of interest. In 2004 the main outcome of the work of this Expert Group included: (i) two protocols on evaluation of post mortem BSE tests and one on the evaluation of live animal tests for BSE; (ii) a report for approval of inclusion in the legislation of 7 new BSE post mortem tests in cattle and (iii) an almost finished 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

EFSA prepared itself in 2004 for its new responsibility to provide the annual Community Summary Report on zoonoses, zoonotic agents and antimicrobial resistance. In addition, EFSA has received the additional mandate to further develop the data collection and

reporting system in cooperation with the Commission and the Member States. To this end, a Task Force on Zoonoses Monitoring was set up to assist and advise EFSA in this exercise. This Task Force comprises contact persons from all Member States for zoonoses as well as representatives from the Commission and other interested parties, such as OIE and WHO. Two Working Groups were established under the Task Force to consider the revision of the annual Zoonoses reports and possible improvements of the data collection system, respectively. All information technology support needed to set up a modern web-based reporting system and a related database has been provided by EFSA. Furthermore, following a call for tender, EFSA has selected its Zoonoses Collaboration Centre (the Danish Institute for Food and Veterinary Research), which has already started to assist EFSA in the collection of data and the preparation of 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 have been made in order to secure close cooperation in the area of food-borne outbreaks and base-line 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 six times in plenary session. It continued its activities aimed at the development, implementation and promotion of 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 seven times for the preparation of an opinion on an appropriate strategy for exposure assessments in EFSA, and an opinion on uncertainties in exposure assessment. The adoption of both opinions is foreseen in the first half of 2005. The opinions on exposure assessment are intended to provide further guidance to the work to be carried out by the Scientific Panels. The SC Working Group on Genotoxic and Carcinogenic Substances (GENTOX) prepared an opinion on a harmonised approach for the risk assessment of substances that are both genotoxic and carcinogenic. The GENTOX Working Group met five times. Once the SC considers the proposal sufficiently developed to allow a public consultation, the draft document will be published on the EFSA website for public consultation. The final adoption of the GENTOX opinion is foreseen in June 2005.

In December 2004, the first meeting took place with the contractor that will assist the Authority in building up its capability in the identification and evaluation of emerging risks. Prior to this, the SC Working Group on Emerging Risks (EMRISK) met five times to evaluate the tenders and to prepare the work to be conducted in collaboration with the contractor. 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 the preparation of an opinion on a generic approach for the safety evaluation of micro-organisms used in food and feed, referred to as QPS, using a working document which was prepared by a joint working group of the former SCAN, SCF and SCP in 2003 as

starting point. It met two times to plan its activities and to prepare the scientific colloquium that took place on 13 and 14 December in Brussels. The objective of this colloquium was to have an open scientific debate on the proposed approach and to explore options on how to develop and implement the concept of QPS within EFSA's risk assessments.

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

- The development of a pro-active EFSA policy in the area of animal welfare. 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 to prepare guidance for the Scientific Panels and Committee on the implementation of EFSA's animal welfare policy;
- 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 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 interfacing between risk assessment and risk management could not be finalised due to the high workload of the Scientific Panels; the Committee intends to agree on an advice 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 the preparation of 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 to achieve a better understanding of the fundamental scientific issues related to risk assessment on food and feed. Rather than being composed of series of lectures, they provide ample opportunity for interactive exchange of expert views. To that end the Science Colloquia are sufficiently informal to allow for substantial debates if needed but, at the same time, are adequately structured and managed to enable participants to reach conclusions and make recommendations, as appropriate. Two colloquia with 60-100 experts in the field were organized in 2004.

The first one addressed the science behind setting tolerable intake levels for dioxins and dioxin-like PCBs. There was a general consensus on the toxicology of dioxins with respect to the state of knowledge and future research needs. However, participants recognised key differences in approaches due to the evaluation of uncertainties in the data and participants agreed that research should focus on further reducing these uncertainties. The call for increasing transparency fits well with EFSA's project on increasing transparency in risk assessment.

The second colloquium on micro-organisms in food and feed: qualified presumption of safety (QPS) addressed the scientific principles behind the QPS approach and explored options on how the concept can be further developed for possible implementation by EFSA to safety assessments within the framework of current and proposed legislation. QPS is an attempt to provide a mechanism for approving microorganisms that are relatively safe while focusing fuller assessments on those microorganisms 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 and that QPS appears in principle to be applicable to food, feed and products. A working group of the EFSA Scientific Committee 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 available as glossy publications in the EFSA Science Colloquium Report Series.

<<please add a photo of the cover of the DIOXIN Colloquium>>

In 2005 EFSA will continue the Scientific Colloquium Series and 3 meetings are already planned covering the following topics: 'Harmonised EU Food consumption database', 'nutritional profiling' and 'risk assessment approaches and animal welfare'.

Additional Horizontal Science Issues: (=Scientific networks (??))

Initiatives have been taken to start the development of a National Expert Database to include the details of experts in all areas of EFSA's scientific mission. This database, once fully operational, will be made available to national authorities, members of the Scientific Committee, all Panels and EFSA Working Groups via the password protected EFSA Extranet. This database would allow Panels to select the best available experts in case a Panel needs temporary outside expertise. It will also assist in-house staff in tracing 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. Once these national institutions have been nominated by their national authorities and included in EFSA's data base, cooperation in projects will be relatively easy and no longer hampered by extensive and time-consuming tender procedures.

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

4.3. Communications Activities

- **Public information and events**

Along with the scientific programme of the Authority, Communications was a key area of growth in 2004. The overall aim of EFSA 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 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 with regards to food safety concerns.

By providing risk managers with independent scientific assessments of the highest quality 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.

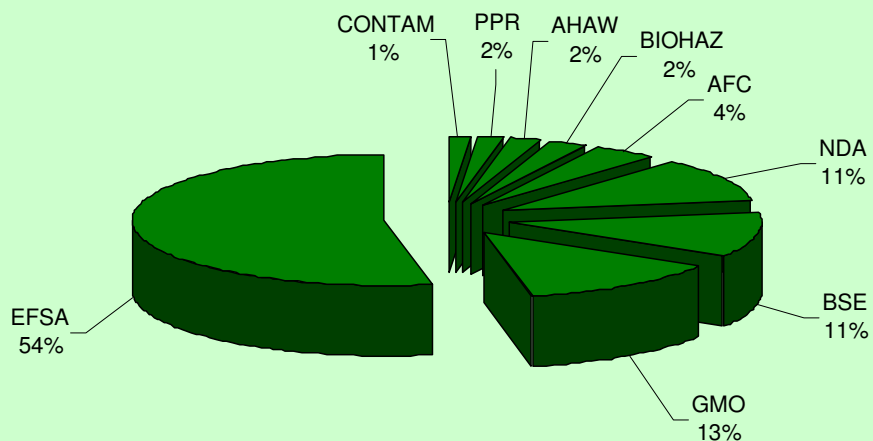
More specifically, EFSA's objectives in the area of risk communications which the Authority continued to pursue in 2004 were as follows:

- Establish the Authority as an expert and trusted source of information on food and food safety issues amongst its stakeholder 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

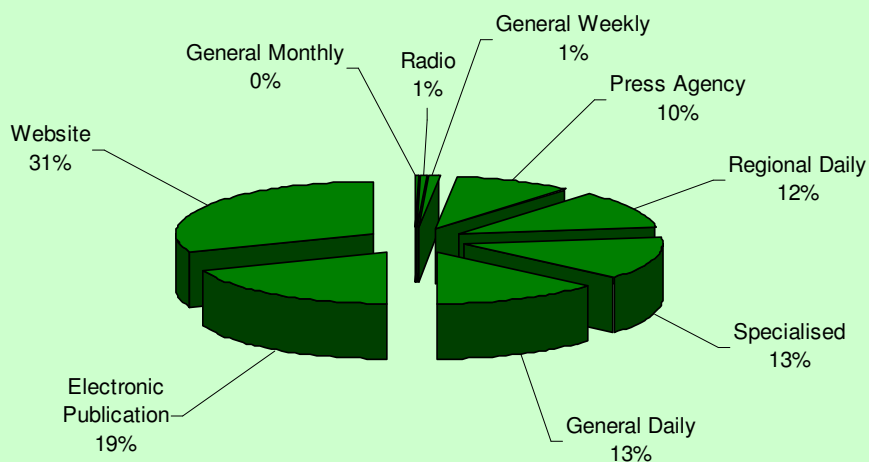
EFSA increased its level of media relations activity with the publication of 27 press releases following the publication of opinions as well as the issuing of news concerning corporate activities including its future move to Parma and key decisions from meetings of its Management Board. Approximately 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 as a result 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.

Distribution of Articles per Category 2004



EFSA organised several press briefings during the course of the year, including the public announcement of the opinion of the NDA panel on the dietary intakes and health effects of trans fatty acids, in Brussels in September and in the context of the first public event of the Advisory Forum held in Berlin in November. In addition to presenting EFSA's work, such briefings provide the opportunity of informing and dialogue with journalists.

Type of Media



The Communications Department has also made significant efforts to build good relations with the media in Italy, particularly in Parma, in order to ensure that they are kept informed of all of EFSA's activities, and in particular progress made in its move to Parma.

Media Tool-Kit

One of the priorities for the Communications Department for 2004 was the development of a media tool-kit including the creation of fact sheets and background documents on the Authority. Resources have also been devoted to the creation of a database of national and international contacts from the written, broadcast and online media. .

EFSA Awareness

In order to raise awareness about EFSA, the Communications Department has also facilitated one to one media interviews with staff members and has also contributed articles to various publications. EFSA was also present at the CIBUS fair held in Parma in May 2005 in order to begin building the Authority's presence in Parma and foster contacts with Italian authorities, media, industry, consumers and other stakeholders.

- **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 its objectives, organisation, and activities.

EFSAnews is the organisation'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, to name but a few. In December, following the EFSA Advisory Forum public event "Creating a European network to enhance risk assessments regarding the food chain," a special edition entirely devoted to this initiative was published. 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 on a regular basis via e-mail by subscribing on the EFSA home page (<http://www.efsa.eu.int>) or sending an e-mail to newsletter@efsa.eu.int.

Nearly 6000 copies of the EFSA newsletter are distributed.

EFSA now has a portfolio of six facts sheets. Five of the fact sheets provide information relating to corporate matters (e.g. structure of EFSA, History, Advisory Forum, Science, Communication) and the sixth explains 12 different EFSA-related issues under the format of "frequently asked questions." Furthermore a concise pocket edition, the EFSA brochure, was published in order to provide 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.

With regard to scientific matters, in December 2004 EFSA started the *EFSA Scientific Colloquium* series which provides summary reports of EFSA Science 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 obtained free of charge and ordered by e-mail (newsletter@efsa.eu.int) 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 “Newsletter” mailings.

Scientific output from the Authority increased dramatically over the year with the adoption of 159 Scientific Opinions. The website expanded to accommodate them and evolved to activate new areas where EFSA Scientific Reports and Statements could also be published. In addition, some of the work of EFSA’s Scientific Services went online including a section dedicated to Zoonoses Monitoring and Data Collection and another to TSE assessments.

The EFSA Scientific Colloquium series is fully covered in the science section of the website.

EFSA Management Board meetings continued to draw a large number of webstream viewers to its meetings throughout 2004. The webstream makes it possible for many of those who cannot attend the Management Board meetings to have visual and sound access to the full public proceedings as well as being able to find all the documents under discussion in the Management Board pages.

New areas of the Management Board pages were activated in 2004 to take account of statutory texts, Management Board Initiatives and correspondence.

The Advisory Forum also moved into new areas, creating a new section on its pages to cover working group activity and one for events. A full report of the Advisory Forum event held in Berlin during the Autumn of 2004 is to be found in these pages including abstracts and presentations.

The website reflects the importance for EFSA of the outreach to stakeholders in a section dedicated to the Authority’s stakeholders and those items that are important to them – consultations and events such as the Colloque, also held in Berlin in November 2004.

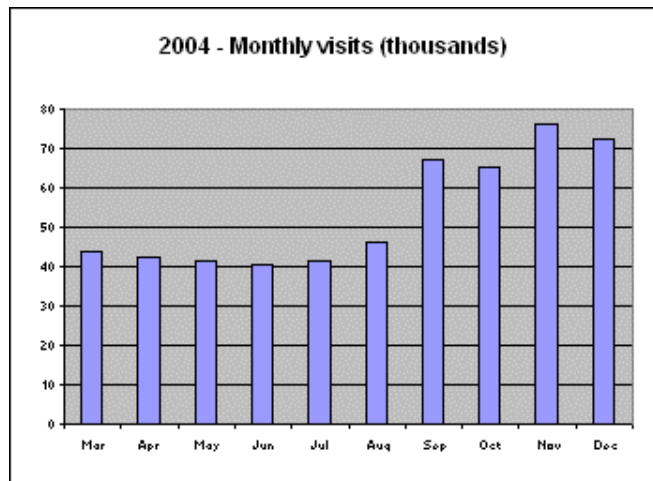
Online submissions for GM Food and Feed Additives, authorisations for Feed Additives and to many consultation processes are now a regular feature of the website where you can also sign up to attend meetings – including Management Board meetings - or any of the public events organised by the Authority.

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.

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 a very strong response.

In March 2004, there were 43,858 visitors to the website in stark contrast to the figures for February 2004 and the old website of only 498 visitors. The figures for December 2004 show the steady rise in interest that has grown over the year bringing the visitor total to 72,392 in that month.

The total number of subscribers to the Highlights email delivery service stands at 5,087 and the Newsletter at 4,899.



(since EFSA relaunch – March 2004)

4.4. Advisory Forum

The Advisory Forum is the European Food Safety Authority's (EFSA) consultative body bringing together EFSA and the national food safety agencies and authorities which undertake tasks similar to EFSA. It was created 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 the Executive Director of EFSA. In 2004 the Advisory Forum focussed on fostering greater collaboration and co-operation on food safety matters across Europe and identified through its meetings 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 Bundesinstitut für Risikobewertung. Over 350 visitors attended this gathering, at which participants and experts from international organisations, national food agencies and university and research centres could express their views, exchange their experiences and take part in discussions on European co-operation in risk assessment.

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

The Forum also gathered during four regular meetings in 2004 in different capitals throughout Europe, respectively 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 dioxin.

The Management Plan for 2004 was discussed during the same meeting.

Scientific issues discussed in Helsinki on 6 April concerned the issue of methyl mercury in fish, the call for national dietary intake data and an update and reminder concerning requested data on SEM. Furthermore, the EFSA's 1st scientific colloquium was announced.

The first Forum meeting after the enlargement was held in a new Member State – Hungary. Among other issues, the setting up of an Advisory Forum Extranet and an information paper on Stakeholder meetings of the GMO and FEEDAP panels were discussed.

The Advisory Forum organised its last meeting in 2004 in EFSA's future home country Italy. This was held in two parts as EFSA 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 the roles and responsibilities of the key players should a crisis arise. At the usual meeting that followed the crisis exercise, the use of botanicals and botanical preparations was discussed amongst other subjects. The Forum also held a preparatory discussion on the composition of EFSA's scientific panels and the experts required, and members exchanged ideas on the Work Programme for 2005.

Detailed minutes of the meetings can as always be found on the EFSA web site.

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

The group on communications is chaired by EFSA and links the Communications departments in the national food agencies together. 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 actions of the Advisory Forum and the initiatives of EFSA and the national authorities in order to learn lessons on communications for the future. The Group has developed a Template for key issues, which assists the members in informing each other about the communications activities in their countries. The group in particular followed the crisis scenario exercise – held by the Advisory Forum – in order to further establish communications links and tools once these kinds of incidents occur. In view of building best practices in risk communications, the working group reviewed in 2004 communications on semicarbazide and baby food following an opinion issued by EFSA in October 2003.

The IT working group, chaired by EFSA and composed of the IT experts of the national authorities, also had regular contacts – through meetings and via electronical means – to further develop the AF Extranet (started with a test phase in 2004) and the Videoconference facilities. Both developments made that much progress, that formal starts can be expected in 2005.

4.5. External Relations

- Stakeholder relations

It is of primary importance to EFSA to pursue an on-going dialogue with stakeholder organisations with a legitimate interest in the areas of work and remit of EFSA. As part

of its policy towards stakeholders and its overall policy on transparency and openness EFSA pursued its activities *vis-à-vis* stakeholders in 2004.

Building on the first EFSA stakeholder colloque which took place in Ostend (Belgium) in October 2003, EFSA's Management Board agreed in April 2004 on a series of initiatives which aimed at strengthening relations with stakeholders and stakeholder organizations. Many of these activities were put in place in the course of 2004 culminating in the second Stakeholder Colloque in Berlin in November 2004. As an indicative example, the following actions were implemented in 2004:

- the meetings of the Management Board were open to the public in addition to 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 Panel were published on the website;
- pre-notification of EFSA information to key stakeholder organisations prior to publication;
- regular bilateral meetings with stakeholder organisations on various topics throughout the year as well as regular participation in stakeholder hosted meetings;
- an e-mail notification system was put in place 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 for the tracking of the state of play of questions addressed to EFSA;
- scientific consultation were held, notably in the area of GMOs (May 2004 and December 2004) and feed additives (May 2004);
- scientific colloquia were organized (June and December 2004)

The 2nd Stakeholder colloque which was held in Berlin in November 2004 marked a significant step forward with regard to EFSA's strategy towards stakeholders⁴. The Berlin Colloque provided an open interactive opportunity for stakeholder organisations from across the range of issues covered by EFSA to share their view on the future of EFSA and in particular the future relations between EFSA and their organisations. As a follow up of that meeting and recurrent demands from stakeholder organisations, EFSA agreed to set up a Stakeholder Consultative Committee which will be consulted on general issues which affect the work of EFSA. The Committee will advise EFSA on its work priorities, the matters that EFSA should consider for wide consultation, the methods of consultation as well as stakeholder views on issues for self-tasking.⁵ The Stakeholder Consultative Committee will be operational in 2005.

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

Public consultations on specific topics and scientific colloquia run in 2004 have been extremely appreciated by stakeholder organisations and were successful exercises for EFSA, not only in terms of participation but also with regard to the quality of the contributions and fruitful discussions. As an illustrative example, the public consultation on 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 of this hearing and written contributions, the document was revised by the GMO Panel and finally adopted in September 2004 and published on the website. Similar exercises were 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 a significant direct impact on a wide range of legislative proposals and this can be seen in the high numbers of varied questions to EFSA from the Commission. Therefore EFSA provides many of its scientific opinions as a direct result of legislative provisions which require a substance to be assessed prior to it being allowed to be used as a foodstuff or being used in or on food e.g. for food additives, GMOs flavourings, 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, contaminants.

In all cases the scientific opinions given by EFSA may be used along with other factors legitimately considered by risk managers to form the basis for a risk management decision by the European Commission, Parliament and Council. EFSA's institutional activities in 2004 therefore focused on the need to ensure a seamless 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 Institutional Relations Department, EFSA increased its ability during 2004 to participate in meetings of the European Parliament, Council and 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 resources of EFSA 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 and any scientific aspects were understood and issues of concern on both sides could be communicated pro-actively. As legislation goes through the European Institutions EFSA was therefore able to keep abreast of the potential impact on the human and other resources of the Authority, to gauge the potential workload at an early stage, while helping to inform those considering proposals of 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, OIE, Food and Agriculture Organisation, OECD). EFSA initiated exchanges of information with its international partners on 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 engaged in the expansion and maintenance of expert networks with both the international organisations and third country authorities and institutions.

Meetings were held with World Health Organisation collaborators in 2004 and such contacts have been maintained and build upon leading to joint collaborative work. Several initiatives were planned and initiated in 2004 e.g. the planning for a joint workshop of the Scientific Committee with WHO and 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 US (FDA) to cooperate closely in the area of pesticide risk assessment.

5. EFSA speaking engagements in 2004

(Please note that this will include all EFSA speaking engagements in the form of a map with the listings of all the conferences – see 2003 Annual Report).

EFSA 2004 SPEAKING ENGAGEMENTS			
Date	Description	Speaker	Where
09 January 2004	Visit Voedsel en Warenautoriteit (Food and Consumer Product Safety Authority) and Nederlandse Gezondheidsraad (Health Council of the Netherlands)	Herman Koëter	Den Haag, Netherlands
27 January 2004	Forum Barcelona 2004 : Seguretat Alimentaria, normatives i tecnologia al servei de la qualitat i seguretat dels aliments del segle XXI (organised by the Veterinary College in Barcelona COVB)	Geoffrey Podger	Barcelona, Spain
29 January 2004	International Colloquium	Geoffrey Podger	ENA, Paris, France
30 January 2004	International Food Safety Conference	Geoffrey Podger	CIES, Barcelona, Spain
04 February 2004	Westminster Diet & Health Forum	Geoffrey Podger	London, United Kingdom
12 February 2004	Visit Food Safety Authority of Ireland	Herman Koëter	Dublin, Ireland

16-17 February 2004	NFU Annual Conference	Geoffrey Podger	NFU, Birmingham, United Kingdom
20 February 2004	Visit Food Standards Agency	Herman Koëter	London, United Kingdom
08 March 2004	FLEEP Forum Panel	Geoffrey Podger	European Environmental Health Offices, Basel, Switzerland
12 March 2004	Food Safety Conference 2004 – A new agenda for official food controls	Geoffrey Podger, Herman Koëter	Food Safety Authority of Ireland, Dublin
16 March 2004	Visit Danish Veterinary and Food Administration	Herman Koëter	Copenhagen, Denmark
17 March 2004	Food Congress 2004	Geoffrey Podger	Centre for Advanced Food Studies, Copenhagen, Denmark
19 March 2004	Conference on Food and traceability	Geoffrey Podger	European Policy Centre, Washington, USA
29 March 2004	Visit Istituto Superiore di Sanità	Herman Koëter	Rome, Italy
31 March 2004	Farmed salmon, facts and fiction	Herman Koëter	European Parliament Intergroup, Strasbourg, France
06 April 2004	Visit National Food Authority and EELA	Herman Koëter	Helsinki, Finland
24 April 2004	SAWM Annual Conference	Geoffrey Podger	SAWN, Edinburgh, United Kingdom
27 April 2004	DG SANCO Media Seminar - Presentation on "The role of European Food Safety Authority in protecting consumers"	Anne-Laure GASSIN	DG SANCO, Brussels
06-10 May 2004	CIBUS Food Fair	Geoffrey Podger	Parma
06 May 2004	FEEDAP Plenary Meeting	Herman Koëter	European Food Safety Authority, Barcelona, Spain
12 May 2004	Annual Conference	Geoffrey Podger	Federation of Bakers, London, United Kingdom
14 May 2004	BMPA Conference	Geoffrey Podger	BMPA, London, United Kingdom
14 May 2004	Vienna Globalization Symposium	Herman Koëter	EFTA Court; Vienna, Austria
16 May 2004	Food Safety Genomics Conference	Herman Koëter	EET Consortium, Amsterdam, Netherlands
25 May 2004	IUFoST Symposium	Geoffrey Podger	IUFoST, Berlin, Germany
28 May 2004	Annual Conference	Geoffrey Podger	Bundesverband der Deutschen Fleischwarenindustrie, Munich, Germany
03 June 2004	The Safe Food Conference: "Why risk it? - Presentation on "Risk communication in Europe: the role of the European Food Safety Authority"	Anne-Laure GASSIN	Food Safety Authority of Ireland, Cork
04 June 2004	AESGP 40th annual meeting	Geoffrey	Madrid, Spain

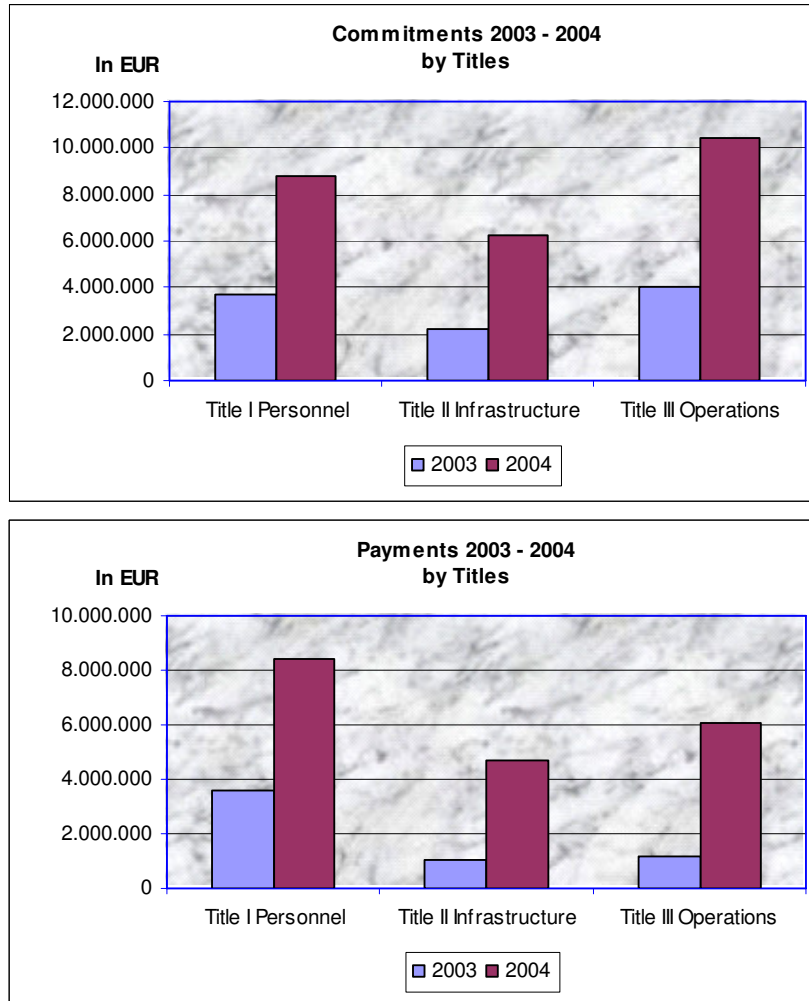
		Podger	
04 June 2004	Genomics and alternatives to animal use	Herman Koëter	Netherlands Genomics Initiative, Maastricht, Netherlands
07 June 2004	5th World Congress Foodborne Infection and Intoxications	Geoffrey Podger	Bundesinstitut für Risikobewertung, Berlin, Germany
07 June 2004	Visit Hungarian Food Safety Office and Ministry of Agriculture and Rural Development	Herman Koëter	Budapest, Hungary
10 June 2004	XXIIIrd FEFAC Congress	Geoffrey Podger	European Food Manufacture Federation, Venice, Italy
11 June 2004	NVT Jubilee Annual Meeting	Herman Koëter	Veldhoven, Netherlands
16 June 2004	Visit RIVM (National Institute for Public Health and the Environment) and TNO	Herman Koëter	Bilthoven / Zeist, Netherlands
17-18 June 2004	Conference	Geoffrey Podger	University College, Dublin, Ireland
18 June 2004	Forum on Etica e competitività nel mercato globale	Geoffrey Podger	Gruppo Giovani of Federalimentare, Lecce, Italy
23 June 2004	Round Table Conference	Geoffrey Podger	Ministry of Fisheries, Stavanger, Norway
24 June 2004	Food, Nutrition and Health in Poland integrated with European Union	Herman Koëter	National Food and Nutrition Institute, Warsaw, Poland
25 June 2004	EUWEP General Assembly	Geoffrey Podger	EUWEP, Budapest, Hungary
30 June 2004	13th European Food Law Conference	Geoffrey Podger	Brussels, Belgium
1/2 July 2004	Visit Food Safety Commission and other national institutes + Public meeting "Risk Analysis on Food in Europe"	Herman Koëter	Tokyo, Japan
6-8 July 2004	World Meat Hygiene Congress	Geoffrey Podger	Food Standards Agency, Cambridge, United Kingdom
11-16 July 2004	10th International Congress of Toxicology	Geoffrey Podger	Finnish Society of Toxicology, Tampere, Finland
27 August 2004	IX Peace Festival Int'l - IV w/e ecologico	Geoffrey Podger	United Artists for Peace, Assisi (Italy)
16 September 2004	Visit RIKILT (Institute of Food Safety)	Herman Koëter	Wageningen, Netherlands
17 September 2004	15th International Scientific EFLA Congress on Food Law and Innovation	Geoffrey Podger	EFLA, Paris, France
17 September 2004	Science Forum	Herman Koëter	Bayer CropScience, Gent, Belgium
20 September 2004	EU-US Dialogue	Geoffrey Podger	Duke University, Durham (USA)
27 September 2004	North West Regional Health Brussels Office	Geoffrey Podger	Brussels, Belgium
08 October 2004	NSW Food Authority	Geoffrey Podger	Sydney, Australia

11-12 October 2004	Australian Food Regulation Conference	Geoffrey Podger	Goldcoast, Australia
14 October 2004	Safe and Wholesome Food	Geoffrey Podger	Conference of the Nordic Council of Ministers, Reykjavik, Iceland
19 October 2004	2004 Annual European Meeting	Geoffrey Podger	The Toxicology Forum, Brussels, Belgium
25 October 2004	Symposium om EFSA in Milan organised by Gruppo Scientifico Italiano Studi & Ricerca.	Geoffrey Podger, Anne-Laure Gassin	Milan
27-29 October /2004	National Institute of Agronomic Research (INRA), France : Integrating Safety and Nutrition Research along the Food Chain : The new Challenge	Herman Koëter	INRA, Lille
29 October 2004	Visit of EFSA's new premises in Parma with the press. Interviews with Geoffrey Podger and Mayor Ubaldi - 10 journalists attended	Geoffrey Podger	Parma
03 November 2004	CREAL 2004	Geoffrey Podger	Paris, France
04 November 2004	Rendez-vous with reality : plant biotechnology in Europe	Herman Koëter	Genius Biotechnologie Frankfurt, Germany
05 November 2004	Programme Committee on alternatives to animal testing	Herman Koëter	Zon Mw., Den Haag, Netherlands
08-10 November 2004	Advisory Forum event and EFSA stakeholder event	Herman Koëter	EFSA, Berlin, Germany
08-09 November 2004	Creating a European network to enhance risk assessments regarding the food chain: where does EFSA's Advisory Forum stand today?	Geoffrey Podger	First public event of AF. German Federal Institute for Risk Assessment, Berlin
15 November 2004	Nutrition Foundation of Italy	Geoffrey Podger	Milan, Italy
18 November 2004	Europe 2004 Innovation seminar	Herman Koëter	Amsterdam, Netherlands
20 November 2004	Eurogroup for animal welfare : Annual Meeting	Herman Koëter	Brussels, Belgium
22 November 2004	Presentation about EFSA to a meeting sponsored by CertiQuality in Milan	Geoffrey Podger	Milan, Italy
22 November 2004	Voedsel en Waren Autoriteit : Directie Communicatie & Voorlichting	Herman Koëter	
25 November 2004	NCA Lustrum symposium	Herman Koëter	NCA, Utrecht, Netherlands
26 November 2004	Conference of the Committees on Agriculture	Herman Koëter	2e KamerStaaten-Generaal, Den Haag, Netherlands
29 November 2004	Visit Spanish Food Safety Authority	Herman Koëter	Madrid, Spain
02 December 2004	AFSSA Management Board Meeting	Herman Koëter	AFSSA, Maisons-Alfort, France
08 December 2004	European American Press Club - "A scientific assessment of food-related risks to human health" (Part of the French American Chamber of Commerce)	Geoffrey Podger	Paris
13 December 2004	Press Conference at Cariparma, Parma for the opening of the first bank account with EFSA's official bank	Geoffrey Podger	

15 December 2004	Voedsel en Waren Autoriteit: Directie Communicatie & Voorlichting / mini-symposium on Risk Communication	Anne-Laure Gassin	Den Haag, Netherlands
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6. Report on Finance

In 2004, EUR 25.5 million was committed including carry-over from 2003, compared to EUR 9.9 million in 2003. Total payments in 2004, at EUR 19.1 million, were notably over the EUR 5.7 million paid in 2003. The progressions by Titles are as follows:

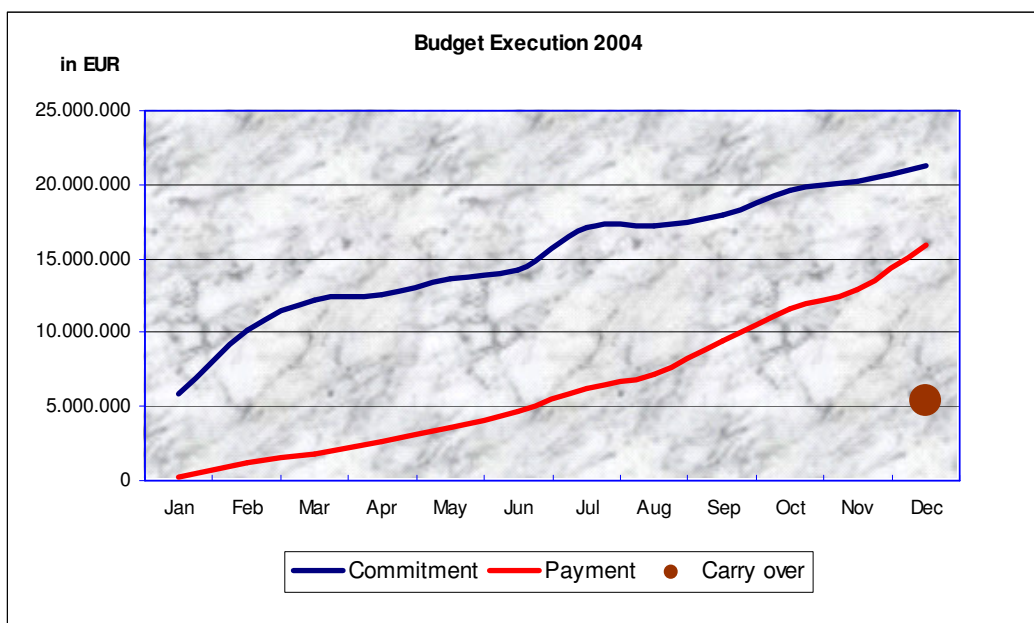


The budget appropriations for 2004 amounted to EUR 29.1 million. Of this, 73 % was committed. Recruitment delay resulting from relocation issues was one of the main factors which contributed to slower than anticipated roll-out of the 2004 budget. Whereas lower recruitment resulted in a 75 % rate of commitment 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.

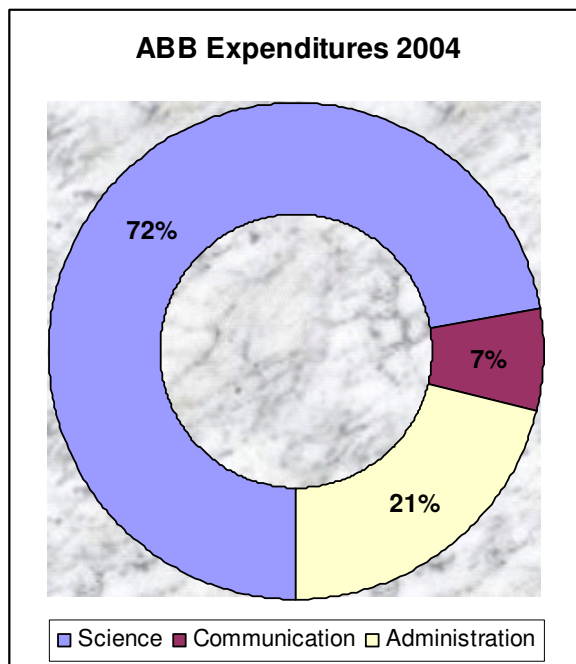
2004	Appropriations	Commitments	%	Payments	%	Carry over	%
Title I	11.508.947	8.641.035	75 %	8.251.435	95 %	389.600	5 %
Title II	5.633.115	5.094.281	90 %	3.617.234	71 %	1.477.047	29 %
Title III	11.950.000	7.516.929	63 %	4.050.801	54 %	3.466.128	46 %
Total	29.092.062	21.252.245	73 %	15.919.470	75 %	5.332.775	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 carry over 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.



From an Activity Based Budgeting perspective i.e., after reallocation of the staff and infrastructure expenditures by activity, the total expenditures 2004 can be split as follows:



Accounts

In recent years, the modernisation of public management has become a major concern. Public accounting practices, most often oriented towards recording payments and receipts, must, on the one hand, become a genuine management tool and on the other hand make the government's or public organisation's financial situation more readily understandable and reliable.

The European Communities have accomplished major improvements of its financial management and control systems since the adoption of the White Paper on Reform in March 2000. Further efforts were still necessary to achieve Reform's objectives, in particular in the area of accounting where the recast Financial Regulation requires the production of accrual accounts by 2005. This objective, in turn, has committed the European Communities to undertake a major change to its accounting framework.

Experience in the Member States shows that reforming public accounting systems represents a major upheaval both in terms of the introduction of new practices and in human resource terms, not to mention the financial resources required.

With the new accounting rules, the European Communities join the group of governments and public institutions which have undertaken important efforts in order to improve their accounting practices.

BUDGET OUT-TURN ACCOUNT FOR YEARS 2004 AND 2003

	2004	2003
Revenue		
Commission subsidy Financial income		
Total revenue (a)	0.00	0.00
Expenditure		
Personnel expenses - Budget title I Payments Automatic carryovers Non-automatic carryovers Administrative expenses - Budget Title II Payments Automatic carryovers Non-automatic carryovers Operational expenses - Budget Title III Payments Automatic carryovers Non-automatic carryovers		
Total expenditure (b)	0.00	0.00
Outturn for the financial year (a-b)	0.00	0.00
Cancellation of unused carryovers Exchange differences for the year Balance carried over from year N-1 Reimbursement to the EC		
Balance of the outturn account for the financial year	0.00	0.00
Interest yielded on the EC subvention funds and to be reimbursed to Commission		

RECONCILIATION BUDGETARY OUT-TURN VERSUS ECONOMIC RESULT

	2004	2003
		Revised
Budgetary revenue outturn (a)		
Adjustments		
Purchase of intangible fixed assets		
Purchase of tangible fixed assets		
Non-current receivables		
Prefinancing		
Other receivables		
Prepaid expenses and accrued incomes		
Carryovers cancellation		
Reversal other liabilities previous year		
Reversal accrued expenses previous year		
Reversal of countervalues		
Decrease in tangible fixed assets		
Depreciation		
Provision		
Other liabilities		
Accrued expenses		
Carryovers previous year		
recovery double payments		
c4/c5		
Extraordinary Gains		
Miscellaneous corrections		
Total adjustments (b)	0.00	0.00
ECONOMIC RESULT (a+b)	0.00	0.00

Economic Out-turn Account 2004 - 2003

	Note	2004	2003
Revenues from fines			
Recuperation of expenses			
Revenues from administrative operations			
From third parties			
<i>From consolidated EC entities</i>			
Other operating revenues			
From third parties			
<i>From consolidated EC entities</i>			
TOTAL OPERATING REVENUES	2.2.1	0.00	0.00
Administrative expenses	2.2.2		
Staff expenses			
Buildings and related expenses			
Pensions expenses			
Other expenses			
Depreciation and write offs			
<i>From consolidated EC entities</i>			
Operating expenses	2.2.3		
Other operating expenses			
From third parties			
<i>From consolidated EC entities</i>			
TOTAL OPERATING EXPENSES		0.00	0.00
<i>SURPLUS/ (DEFICIT) FROM OPERATING ACTIVITIES</i>		0.00	0.00
Financial operations revenues	2.2.4		
From third parties			
<i>From consolidated EC entities</i>			
Financial operations expenses	2.2.5		
From third parties			
<i>From consolidated EC entities</i>			
<i>SURPLUS/ (DEFICIT) FROM NON OPERATING ACTIVITIES</i>		0.00	0.00
<i>SURPLUS/ (DEFICIT) FROM ORDINARY ACTIVITIES</i>		0.00	0.00
Extraordinary gains			
Extraordinary losses			
<i>SURPLUS/ (DEFICIT) FROM EXTRAORDINARY ITEMS</i>		0.00	0.00
ECONOMIC RESULT OF THE YEAR		0.00	0.00

BALANCE SHEET 31/12/04 - 31/12/03

<u>ASSETS</u>			<u>LIABILITIES</u>		
	2004	2003		2004	2003
A. NON-CURRENT ASSETS			A. CAPITAL		
<i>Intangible fixed assets</i>			K		
Computer Software			<i>Reserves</i>		
<i>Tangible fixed assets</i>			<i>Retained earning</i>		
Land and buildings			<i>Budgetary outturn</i>		
Plants and equipment			<i>Result of the year</i>		
Computer Hardware			Total	0.00	0.00
Furniture and vehicles			B. NON-CURRENT LIABILITIES		
Other fixture and fittings			<i>Employee benefits</i>		
Other tangible fixed assets			<i>Provisions for risks and liabilities</i>		
Depreciation			<i>Financial Liabilities</i>		
Total	0.00	0.00	<i>Other Long term Liabilities</i>		
B. CURRENT ASSETS			Total	0.00	0.00
<i>Stock</i>			C. CURRENT LIABILITIES		
<i>Short-term pre-financing</i>			<i>Employee benefits</i>		
advance third parties			Social security and taxes		
<i>Short-term receivable</i>			<i>Provision for risks and liabilities</i>		
Employee benefits			<i>Financial Liabilities</i>		
Current receivable			<i>Accounts payables</i>		
Sundry receivable			Current payables		
Other			Sundry payables		
Consolidated EC Entities			Other		
Prepaid expenses and accrued incomes			Consolidated EC Entities		
Cash and equivalents			Accrued expenses and deferred income		
Bank			Total	0.00	0.00
Cash					
Imprest account					
Total	0.00	0.00			
TOTAL ASSETS	0.00	0.00	TOTAL LIABILITIES	0.00	0.00

7. Future perspectives

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

By the end of 2005 the Authority expects to have finalised its relocation to Parma in Italy. Very good progress has been made due to a high level of assistance from the Italian Authorities but it is clear that there will continue to be significant planning, personnel and logistical issues to address during 2005.

It is foreseen 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 human resources available to deliver this. Staff 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 to build in 2005, aided by appropriate operational and administrative support. The emphasis will be on strengthening the Authority's reputation as an organisation dedicated to scientific 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 on assessment approaches and arranging for scientific meetings with stakeholders. The breadth of the Authority's scientific work will be expanded to include animal and human epidemiology of food-borne 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 put in place a number of key initiatives during 2005 notably with 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 the fostering of 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, 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 of the EU institutions and stakeholders, becoming a true reference on food safety matters of pan-European scope.

EFSA will continue to engage in dialogue and seek feedback from its stakeholders in order to ensure that its goals, priorities and outputs are inline with expectations.