

EXECUTIVE DIRECTORATE

## Annual Activity Report 2007

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### I Highlights

1. This Annual Activity Report should reflect the Workplan 2007 but has been revised to reflect the Workplan 2008 so is, in fact, a transitional format to reflect both Workplans.
2. In 2007, the European Food Safety Authority (EFSA) was in its fifth year of operation and by the end of the year its output of scientific opinions had exceeded 500 and its staff numbers had reached 300. During the year, more than 180 opinions were adopted and more than 1000 applications and renewals were received. As an organisation, EFSA continued to review its activities, operational procedures and structures, as its remit continued to evolve in line with changes in the policy and legislative environments within which the Authority operates.
3. EFSA's core scientific work was at the heart of its activities in 2007 as it strove to address the increasing number of requests for scientific advice under Community legislation. New risk assessment challenges were also addressed as new challenges emerged or re-emerged e.g. cloning, nanotechnology, food colours and hyperactivity in children, and GMO applications, as well as the many questions relating to other public health, food safety and nutrition, animal health and welfare, plant health and environmental issues. In addition, many self-tasks were initiated.
4. EFSA also addressed a growing number of questions relating to the evaluation of: cloned animal products, GMOs, pesticides, additives, flavourings, feed additives to name but a few. EFSA's management had to ensure that the appropriate balance was found between these demands and the need to continue to carry out its other work, improve methods and practices of risk assessment and keep EFSA at the forefront of risk assessment science.
5. Highlights of EFSA's scientific activities in 2007 included the work of EFSA and the members of the Scientific Committee and Panels on BSE/TSE, nutrition, cloning, Qualified Presumption of Safety (QPS), transparency, contaminants, flavourings, additives, pesticides, animal welfare aspects of seal killing, and zoonoses.
6. The Fifth Anniversary of EFSA's inception provided an excellent opportunity for EFSA to increase its visibility, locally in Parma and also among the European institutions in Brussels and the public at large. A series of well attended, high-profile events were held in Parma and Brussels, accompanied by a very successful publicity campaign. A post-event survey yielded an 88% satisfaction rating with the events.
7. EFSA's activities in 2007 continued to be guided by the key recommendations from the independent external evaluation undertaken in 2005. It strengthened its organisational structure to reflect the core activities in both the science and communications departments and to enable more targeted support and management.

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8. To coordinate cooperative activities and provide assistance to the risk assessment units, the Scientific Cooperation & Assistance department was created in 2007.
9. EFSA worked closely with the national agencies in the MS and beyond to share and exchange scientific information. By the end of 2007, EFSA had signed Focal Point agreements with 18 MS and issued calls for 12 Article 36 proposals, several of which were initiated during the year.
10. In the area of communication, EFSA continued to increase the visibility of its scientific work and collaborated with the national and EU agencies, authorities and institutions to build greater coherence in its communications on food and feed safety. EFSA re-launched its website with a steady growth in traffic and re-branded the Authority's logo. Media coverage was increased by 60% in relation to 2006.
11. EFSA policy towards holding open dialogue with stakeholders was built upon. In addition to regular contacts with stakeholders and consultations on specific scientific and management aspects, EFSA evaluated its stakeholder strategy and the recommendations of that evaluation will be implemented in 2008.
12. 2007 saw EFSA further develop its policy towards collaboration with international and third country food safety organisations with the objective of sharing information, best practice and experience. EFSA assisted the European Commission with its work in Codex Alimentarius and forged greater contacts with key international partners to ensure that the risk assessments carried out by EFSA to support European food and feed law could become more and more globally recognised. A landmark agreement to facilitate the sharing of non-public information was signed with the US Food and Drug Administration and negotiations on other data-sharing agreements are ongoing with the Japanese Food Safety Commission, Food Standards Australia New Zealand and the New Zealand Food Safety Authority.
13. The Management Board continued to play its key governing role in guiding the Authority through 2007, in particular by ensuring that the necessary resources were available to fulfil and carry out the Authority's missions and tasks within the budget available to it and that the Authority developed into an efficient, effective organisation with well qualified and motivated staff.
14. Emphasis was placed on the consolidation and strengthening of the Authority's scientific work following the principles of scientific excellence, independence, openness and transparency. A comprehensive update of processes for handling Declarations of Interest made by EFSA's scientific experts, management and staff was undertaken in 2007 to safeguard the independence of its scientific work.
15. In relation to recruitment, by the end of 2007 EFSA had recruited 310 staff (including 273 Temporary Agents and Official Agents) from 25 different European countries. Approximately 55% of staff were scientific, 10% dedicated to communications and the rest supporting the management and administration of the Authority.

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16. The Management Team of the Authority ensured that EFSA followed best management practice, continuously reviewed its priorities and that it had in place the necessary infrastructure to maintain its efficiency.
17. In 2007, EFSA has improved and enhanced its Progress Indicators and also to develop compliance with horizontal legal requirements applicable to it as an independent legal entity.
18. EFSA is committed to sound and timely budgetary planning forecasting and implementation. Close contacts and cooperation with the Budgetary Authority were reinforced within the annual budgetary cycle. In 2007, EFSA was able to utilise 91% of the budget made available to it during 2007, an improvement on 2006.
19. The ABB (activity based budget) has been adopted for 2007.
20. During 2007, budgetary reporting was enhanced and financial workflows streamlined. The verification and processing of the financial operations i.e. commitments, payments and recovery orders were further strengthened.
21. EFSA continued the implementation of the 24 internal control standards. These standards cover (i) the procedures put in place to ensure economic, efficient and effective achievement of the objectives, (ii) the adherence to management policies and regulations, (iii) the safeguarding of assets and information, (iv) the prevention and detection of fraud and error, (v) the quality of accounting records and (vi) the timely production of reliable financial and management information.
22. In relation to Article 36, 12 calls for proposals were issued to organisations authorised to assist EFSA in its activities and several grants were awarded.
23. In line with its policy on openness and transparency, EFSA published documents from its Management Board, Advisory Forum and Scientific Committee and Panels on its web. It also held open consultations on guidance documents and on reports prepared in particular in the pesticides area.
24. During 2007, EFSA strove to develop strong links with its institutional partners to ensure that it is available to inform risk managers on scientific matters and to also enter into dialogue concerning the future development and work of the Authority as proposals on these aspects were developed in the European Parliament and Council. EFSA held several meetings with Commissioners Kyprianou, Dimas, Frattini and Fischer Boel and EFSA developed an increased presence in the European Parliament with the appointment of a liaison MEP, Mrs. Liotard. Several EFSA staff members have participated in Council Working Parties and liaison with Council Presidencies increased significantly during the year.

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25. EFSA worked closely with other EU Agencies in 2007, for example, with ECDC on zoonoses and Avian influenza (AI), with EPPO in relation to pest risk assessment, and with EMEA on matters linked to GMOs and other areas where there was a need to share information and expertise.
26. During 2007, EFSA worked closely with the new MS, Romania and Bulgaria, to facilitate their full participation in EFSA's activities. In addition, EFSA embarked on similar integration activities with the Pre-accession countries of Croatia, Turkey and Macedonia.
27. EFSA continued to foster good relations with the national, regional, provincial and commune authorities in Italy and Parma to ensure that the impact on the area remained positive and of mutual interest and benefit. In this respect, EFSA worked closely with the local authorities, in particular in relation to the Fifth Anniversary celebrations, the Final Seat project, Parma Airport and, above all, the European School.
28. During 2007, EFSA increased its dialogue with stakeholders, with an increased number of consultations. An external review of stakeholder activities was undertaken which will inform the Stakeholder Strategy which will be developed in 2008.
29. EFSA continued to work with the local administration in Parma on the permanent seat of EFSA in Viale Piacenza, Parma and plans for the building were developed by the appointed architects.
30. The monumental part of the Palazzo Ducale, the representative seat of EFSA, continued to accommodate meetings. Accommodation for 160 EFSA staff was provided in the Fratti Building adjacent to the current headquarters.
31. Objectives carried over into 2008 include:
  - International strategy for external relations
  - Evaluation of the impact of media initiatives
  - Crisis management exercise
  - Enhanced recognition of EFSA scientific experts

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# II Risk Assessment and Scientific Cooperation

## II.1 Scientific Committee (SC)

32. During 2007, the SC provided scientific advice on methods of assessment of the quality of EFSA's scientific work and on approaches to enhancing EFSA's responsiveness to urgent questions. In addition, it adopted an opinion introducing a Qualified Presumption of Safety (QPS) approach for the assessment of the safety of selected microorganisms in food and feed, and a guidance document (for public consultation) on the safety assessment of botanicals and botanical preparations. In addition, the public was consulted 4 times to either provide data for its evaluations or to receive comments on draft opinions, guidance documents or other reports developed by the SC.
33. The SC had fruitful meetings with Management Board members at the plenary meetings on 15-16 February and 16-17 April on the workload of the Panels. The Chair and Vice-Chairs of the SC participated in 3 meetings of the Steering Group on Cooperation (March, May and November), composed of members of the SC and the Advisory Forum, which has been established to advise EFSA on scientific cooperation activities involving EFSA and the MS. The Chair of the SC also participated in all Management Board meetings, with the exception of the December meeting in Lisbon.

## II.2 General Requests for Scientific Opinions and Advice

### Scientific Committee

#### Questions attributed to the Scientific Committee

34. In March, the SC received a request from the EC related to the implications of live cloned animals obtained through somatic cell nucleus transfer (SCNT) for food safety, animal health, animal welfare and the environment. The SC elaborated a working strategy and EFSA launched a request for scientific contributions from Third Parties for consideration in the preparation of the opinion. The Advisory Forum and Scientific Panel members were consulted in establishing a well-balanced working group, consisting of 14 members and covering a broad range of expertise. The working group met 6 times, not including 3 telephone conferences, to prepare a draft opinion. In December, the SC approved a draft for public consultation on EFSA's website. The SC expects to adopt a final opinion at its plenary meeting in April 2008.
35. EFSA received a request in from the EC in July for an initial scientific opinion on the risks associated with nanoscience and nanotechnologies in relation to food and feed safety and the environment. The question was submitted to the SC and discussed extensively at its plenary



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meetings in July and September. In November, the SC created a working group of 15 experts on nanotechnology and it is expected that the SC will endorse the draft opinion for public consultation by mid-July 2008.

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

36. The evaluation of the safety of exposure to dietary aluminium that was started in 2006 was progressed and the draft opinion was discussed during the 26th Plenary meeting of the AFC Panel (27–29 November 2007). The opinion is expected to be adopted by Spring 2008. A request was received from the EC for an initial scientific opinion on the risks arising from nanoscience and nanotechnologies on food and feed safety and the environment. The AFC Panel received a request for an evaluation of the safety of taurine and D-glucoronolactone as constituents of so-called "energy" drinks.
37. The AFC Panel was requested to undertake a review of a study examining the effect of mixtures of certain food colours and a preservative on children's behaviour. The outcome of this work will be published in Spring 2008.

### Animal health and welfare (AHAW)

38. AHAW Panel activities in 2007 included 18 WGs on issues such as AI, Bluetongue (BT), aquatic diseases, welfare issues associated with methods for killing and skinning seals, and pig welfare. The scientific opinions on both BT and AI were reflected in DG SANCO legislative decisions and measures in 2007.
39. New mandates were received on BT, classical swine fever and AI and the Panel self-mandated an opinion on the guidelines for risk assessment in animal welfare. The mandate on AI identified the need to update the previous 5 scientific opinions and to assess risk factors for introduction of highly pathogenic AI into poultry holdings.
40. On pig welfare, 3 questions were adopted: (i) health and welfare aspects of different housing and husbandry systems for adult breeding boars, pregnant, farrowing sows and unweaned piglets; (ii) fattening pigs; and (iii) tail biting. In December, AHAW adopted the opinion launched by DG ENV on "seal killing and skinning". AHAW held, for this particular mandate, a Stakeholder meeting on October 4, with participation of more than 30 organizations.
41. On animal diseases, 4 scientific opinions relating to vaccines were adopted: (i) vaccination against AI H5 and H7 subtypes in domestic poultry and captive birds; (ii) vaccination against AI H5 and H7 subtypes as a preventive measure carried out in MS in birds kept in zoos under Community-approved programmes; (iii) a review of Newcastle disease focusing on vaccination worldwide in order to determine its optimal use for control purposes; and (iv) BT vectors and vaccines. For BT, EFSA also launched a self-mandate on the origin and occurrence of the

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outbreaks in the EU. For all these opinions, meetings were held with stakeholders, mainly with vaccine manufacturers from the EU and worldwide. Furthermore for BT, due to its sensitivity and particular epidemiological situation in the EU, an additional meeting was held with MS experts through the Advisory Forum.

42. On aquatic diseases, three opinions were adopted on possible vector species transmitting disease and live stages of susceptible species not transmitting disease, as regards: (i) fish diseases; (ii) crustaceans; and (iii) molluscs.
43. Two further opinions were adopted: (i) on assessment of the risk of tick introduction into UK, Republic of Ireland, and Malta as a consequence of abandoning National rules; and (ii) an opinion on the review of the Community Report on Trends and Sources of Zoonoses, Zoonotic Agents and Antimicrobial Resistance for the year 2005, adopted jointly with the BIOHAZ Panel.

## Biological hazards (BIOHAZ)

44. On BSE/TSE-related subjects, the BIOHAZ Panel adopted 12 opinions with different mandates from DG SANCO and covered subjects such as: quantitative risk assessment on residual BSE risk in sheep meat and meat products; quantitative histological studies and the re-assessment of the BSE-related risk of bovine intestines after processing into natural sausage casings; certain aspects related to the risk of TSEs in ovine and caprine animals; the likelihood of the infectivity in specified risk materials (SRM) derived from cattle at different age groups estimated by back calculation modelling; and the assessment of TSE-related risks of the use of bovine blood in feeds for fish. The Panel's work in the area of BSE/TSE testing included an opinion on the CRL report on batch testing of TSE rapid tests, opinions on the protocols for the evaluation of new rapid TSE *post mortem* tests in both cattle and small ruminants, and the preliminary evaluation of *ante mortem* TSE tests for ruminants. This preparatory work supported the EC in its launch of the new call for expressions of interest for TSE test evaluation in October. Other major BSE-related activities included the revision of the methodology for Geographical BSE Risk (GBR) assessment.
45. The BIOHAZ Panel dealt with two mandates from the European Parliament, resulting in opinions on the health risks of feeding ruminants with fishmeal and certain aspects related to the feeding of animal proteins to farm animals. The Panel further resolved a divergence of opinion with the Bundesinstitut für Risikobewertung and the Friedrich-Loeffler Institut on the quantitative risk assessment of residual BSE risk in bovine-derived products, in particular tallow.
46. On food hygiene and microbiology, the BIOHAZ Panel adopted 3 opinions: (i) "Microbiological risks in infant formulae and follow-on formulae with regard to Enterobacteriaceae as indicators" reviewed the former opinion of the Panel on that topic; (ii) microbiological criteria and targets based on risk analysis (self-tasked); and (iii) an update on the previous risk assessment on *Listeria monocytogenes* in ready-to-eat foods (used by the EC to establish the EU position on *L. monocytogenes* criteria in the Codex Committee on Food Hygiene).



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47. On foodborne zoonoses, the BIOHAZ Panel adopted 4 opinions, 3 of which were self-mandates on scientific issues associated with further harmonization of the Annual Summary Zoonoses Report: (i) the monitoring of verotoxigenic *Escherichia coli* (VTEC) and identification of human pathogenic VTEC types; (ii) monitoring and identification of human enteropathogenic *Yersinia* spp.; and (iii) surveillance and monitoring of *Toxoplasma* in humans, food and animals. The objective of these opinions was to give advice and recommend the best methods for monitoring these microorganisms in animal populations and foodstuffs from a public health perspective. The ECDC was consulted throughout on the public health aspects of these opinions. An opinion on the public health risks associated with the human consumption of reptile meat was also adopted. The BIOHAZ Panel adopted its opinion on biological hazards while the chapter on chemical hazards was adopted by the CONTAM Panel.
48. Following the Council Conclusions of 6-7 December 2004 on Emerging Zoonotic Diseases, EFSA, in close collaboration with the ECDC, was invited to present a detailed analysis of the risk factors on the basis of the annual Community Summary Report. The BIOHAZ Panel in collaboration with the AHAW Panel and the ECDC drafted an opinion reviewing the Community Summary Report on Trends and Sources of Zoonoses, Zoonotic Agents and Antimicrobial Resistance in the European Union (EU) in 2005. Conclusions on the situation in the EU were made, and the main risk factors and public health priorities were identified, with suggestions for improvements in monitoring and reporting, and recommendations to further protect public and/or animal health in the EU.
49. The BIOHAZ Panel, with the collaboration of AHAW and FEEDAP Panel members, is developing an opinion on the microbiological risk assessment of feedingstuffs for food-producing animals from both the animal and public health perspectives. The terms of reference include microbiological hazards in feedingstuffs, quantification of the effect of control options, and identification of areas where it would be appropriate to set microbiological criteria and/or targets for feedingstuffs to ensure public and animal health protection.
50. The BIOHAZ Panel, in collaboration with other panels, contributed to the risk assessment on pig welfare by the AHAW Panel. The BIOHAZ Panel addressed the food safety implications of different housing and husbandry systems by adopting a single opinion covering 3 mandates: fattening pigs, breeding pigs (sows/boars), and tail biting.
51. BIOHAZ collaborated with the AFC Panel to provide a recommendation on the potential induction of antimicrobial resistance to 1,2-benzisothiazolin-3-one (BIT) and 2-methyl-4-isothiazolin-3-one (MIT).
52. With regard to foodborne zoonoses, the BIOHAZ Panel is currently undertaking a self-mandate on foodborne antimicrobial resistance as a biological hazard. The aim is to identify the extent to which food serves as a source for the acquisition by humans of antimicrobial resistant bacteria or bacteria-borne antimicrobial resistance genes, as well as naming potential control options for

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reducing exposure. The work is done in collaboration with experts from the FEEDAP and GMO Panels.

53. Following a request from the EC, the BIOHAZ Panel is working on an opinion on source attribution for human salmonellosis from meat where the relative contribution of different meat categories, such as carcasses, fresh meat and meat products, minced meat and meat preparations to cases of foodborne salmonella infections in humans will be assessed.
54. The BIOHAZ Panel is also dealing with a mandate from the EC to carry out a quantitative risk assessment of Salmonella in slaughter and breeder pigs in order to assess the public health risk of Salmonella, including a quantitative estimation of risk factors and the effect of mitigation options. The assessment should provide input for a future cost/benefit analysis of setting a target for reduction of Salmonella in slaughter pigs at the EU level. To undertake the mandate, EFSA launched its first call for a grant funded project under Article 36, entitled “Quantitative microbiological risk assessment of Salmonella in slaughter and breeder pigs”, and specifically requested that the proposal be addressed by consortia of eligible European partners.

## Contaminants in the food chain (CONTAM)

55. In 2007, the CONTAM Panel adopted 14 opinions in response to requests from the EC. An opinion on the public health impact of raising current maximum levels of aflatoxins in almonds, hazelnuts and pistachios from 4 µg/kg (EU maximum level) to 8 or 10 µg/kg was linked to the Codex Alimentarius where levels higher than the current EU maximum are being discussed. It concluded that changing the current EU maximum levels to 8 or 10 µg/kg in almonds, hazelnuts and pistachios would have minor effects on estimates of dietary exposure, cancer risk and Margin of Exposure. However, the CONTAM Panel also stated that exposure to aflatoxins from all sources should be as low as reasonably achievable, because aflatoxins are genotoxic and carcinogenic.
56. The CONTAM Panel started its work on the evaluation of current limits with regard to human health and methods of analysis of various marine biotoxins. This activity was initiated by a request from a Member State for alternative methods to replace the mouse and rat bioassays (the officially recommended reference methods) for shellfish toxin evaluation and then re-worked into a request from the EC. Overall, a series of 9 risk assessments will be carried out. The CONTAM Panel adopted its first opinion on the okadaic acid-group toxins (OA) in November 2007. The Panel concluded that, to protect a 60-kg adult from exceeding the acute reference dose of 0.3 µg OA equivalents/kg body weight established by the Panel, a 400-g portion of shellfish should not contain more than 18 µg toxin, i.e. 45 µg OA equivalents/kg shellfish meat. This value is lower than the current European regulatory limit of 160 µg OA equivalents/kg shellfish meat. The CONTAM Panel noted that the recommended mammalian bioassays have shortcomings and are not considered appropriate tools for assessing the current European regulatory limit. One biomolecular (phosphoprotein-phosphatase assay) and

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one chemical method (liquid chromatography-mass spectrometry) have great potential for the detection of OA-group toxins below the current European regulatory limit.

57. The CONTAM Panel was requested by the EC to evaluate: (i) whether new data are available on substances with hormonal activity that might be used legally in Third Countries for growth promoting purposes in bovine meat; (ii) to assess potential risks to human health of such substances; and (iii) to indicate whether such new data would call for a revision of the previous risk assessments of the Scientific Committee on Veterinary Measures relating to Public Health (SCVPH). It was concluded by the CONTAM Panel that at present, epidemiological data provide convincing evidence for an association between the amount of red meat consumed and certain forms of hormone-dependent cancers. Whether hormone residues in meat contribute to this risk is currently unknown. Furthermore, the CONTAM Panel concluded that the new data that are publicly available do not provide quantitative information that would be informative for risk characterisation and therefore do not call for a revision of the previous assessments of the SCVPH.
58. The EC requested an assessment of risks to human health related to the presence of ethyl carbamate and hydrocyanic acid in food and alcoholic beverages, in particular stone-fruit brandies. A risk characterisation was performed using the Margin of Exposure approach. The Panel concluded that exposure to ethyl carbamate in food excluding alcoholic beverages represents a low risk to human health. However, the Panel concluded that, for high consumers, ethyl carbamate in alcoholic beverages may be of concern, particularly with respect to stone-fruit brandies and tequila.
59. The CONTAM Panel adopted its first 6 opinions on cross-contamination of non-target feedingstuffs by authorised coccidiostats (narasin, lasalocid, salinomycin, semduramicin, maduramicin, monensin sodium). In this series, 5 opinions remain in the pipeline for possible adoption in 2008.
60. The Panel continued its series of opinions relating to the revision of Annex I of the Directive 2002/32/EC on undesirable substances in animal feed. The opinions adopted cover pyrrolizidine alkaloids, heptachlor, chlordane and glucosinolates. In this series, 7 draft opinions related to mercury, nitrite, free gossypol, tropane alkaloids, saponins from *Madhuca sp.*, ricin and theobromine as undesirable substances in animal feed remain in the pipeline for adoption in 2008.
61. EFSA received 5 new requests that fall within the remit of the CONTAM Panel. These included cadmium, lead and polycyclic aromatic hydrocarbons (PAHs) in food from the EC, and a request from a Member State related to uranium in foodstuffs, particularly mineral water. An urgent request on the presence of melamine and structurally related compounds in protein sources intended for use in feed and food was received by the EC and addressed by CONTAM using the fast-track response procedure for the first time.

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

62. The FEEDAP Panel received a request from EC to assess the safety for the consumer of high levels of vitamin A in products of animal origin, consumed individually or in combination with other sources of vitamin A, e.g. food supplements or dietetic foods. The safety for target animals and the potential zootechnical implications of reducing vitamin A levels should also be evaluated. In this regard, MS were invited to provide data on vitamin A supplementation in all categories of livestock in the EU, as well as human vitamin A consumption data. The WG of the FEEDAP Panel is currently analysing the information received and an opinion is scheduled for spring 2008.

### Genetically modified organisms (GMO)

63. The GMO Panel adopted a statement on the safe use of the nptII antibiotic resistance marker gene in GM plants on request of the EC and following information provided by the European Agency for the Evaluation of Medicinal Products (EMA). Upon request for scientific advice from the EC, EFSA issued a statement on the fate of recombinant DNA or proteins in the meat, milk or eggs of animals fed with GM feed.
64. EFSA received a request from the EC with regard to a scientific publication on the statistical analysis of a 90-day rat feeding study with MON 863 maize. EFSA established a Task Force to consider the request and organised a technical meeting with the authors of the publication. In June 2007, the GMO Panel adopted a statement on MON 863 maize.
65. EFSA and the GMO Panel provided scientific support to the EC on activities of the Codex Ad Hoc Intergovernmental Task Force on Foods Derived from Biotechnology by commenting on the "Proposed Draft Guideline for the Conduct of Food Safety Assessment of Foods Derived from Recombinant - DNA Animals", the "Proposed Draft Annexes to the Guidelines for the Conduct of Food Safety Assessment of Food Derived from Recombinant-DNA Plants: Food Safety Assessment of Food Derived from Recombinant-DNA Plants Modified for Nutritional or Health Benefits" and the "Food Safety Assessment in situations of low-level presence of r-DNA plant material in food".

### Dietetic products, nutrition and allergies (NDA)

66. The Panel is addressing recommended nutrient intakes for the European population. This pertains to the establishment of nutrient-based recommendations, and in particular the review of existing advice of the Scientific Committee for Food (SCF, 1993) on population reference intakes for energy, nutrients and other substances with a nutritional or physiological effect. The Panel has prepared advice on energy, macronutrients and water, which is expected to be delivered by mid-2008.

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67. In preparation of the Community position for the meeting of the Codex Committee on Nutrition and Foods for Special Dietary Uses (CCNFSDU) in November, the Panel issued a statement on the definition of dietary fibre on request from the EC.

### Plant health (PLH)

68. The Panel's activities focused on the provision of scientific opinions related to the risk assessment of organisms harmful to plant or plant products and five scientific opinions were adopted:
- On a pest risk assessment (PRA) made by Spain on *Bactrocera zonata*, a fruit fly listed in the quarantine list of the Community plant health legislation (Council Directive 2000/29/EC);
  - On PRAs made by EPPO for invasive alien species that pose a threat to plant health, environment and biodiversity in the EPPO region, i.e. *Lysichiton americanus* and *Hydrocotyle ranunculoides*;
  - On responses made by Lithuania and Poland, respectively on a PRA made by both countries on *Ambrosia* spp.;
  - The opinions were presented and thoroughly discussed in the Standing Committee on Plant Health, providing a valuable opportunity for dialogue with risk managers;
  - The Panel also made considerable progress on opinions for 30 PRAs made by France on organisms considered harmful in 4 French overseas departments, i.e. Guadeloupe, Guyana, Martinique and Reunion. The deadline for delivery of these opinions is March 2008.

## II.3 Risk assessment of regulated substances and products

### AFC

69. The Panel continued the evaluation of substances intended for food contact materials. An increase in submission of dossiers was experienced during the last quarter of 2006 and the first quarter of 2007.
70. On re-evaluation of food additives, the AFC Panel adopted an opinion on the food colour Red 2G (E 128) on July 5. The use of this colour, which was only permitted in certain breakfast sausages and burger meat, raised potential health concerns. Based on the opinion of the Panel, the use of the substance was subsequently banned. This is the first opinion in a series of re-evaluations EFSA has undertaken on the safety of food additives, including colours, authorised



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in the EU. In the re-evaluation process of food additives currently authorised for use in the EU, priority has been given to food colours as they were among the first additives to be evaluated under European legislation. Since the first evaluations of additives, some 30 years ago, new studies have become available. Further to this evaluation, EFSA will assess in 2008 all colours currently permitted in the EU on a case-by-case basis.

71. New applications for food additives included 2 applications for steviol glycosides and in the area of processing aids, an application for an extraction solvent was received.
72. The ca. 500 dossiers on substances for use in food supplements, which were received during the summer of 2005, have been screened for the possibility of grouping dossiers whenever possible and giving a common opinion for classes of substances rather than individual substances. In 3 opinions, the Panel evaluated 8 substances for which a total of 14 dossiers were submitted. Despite the effort, it became evident that the evaluation process will continue beyond 2007. Around 300 of the dossiers, comprising more than 200 substances, contain very limited information. For these requests, a deadline has been set to the end of 2007 for the submission of additional information for an evaluation.
73. In relation to chemically defined flavouring substances, evaluation of the remaining substances in the Register continued and is expected to be finalised in 2008. In total, 26 flavouring group evaluations were completed in 2007, including reviews of previous opinions based on new data received as the result of requests from the Panel, and a review of JECFA evaluations.
74. The Panel continued to evaluate the safety of the remaining 13 smoke flavourings from the initial total of 16 that were started in 2005. These products are added to a range of foods and until recently were not subject to any authorisation process for use in Europe. As anticipated, the request and provision of additional data from applicants delayed the evaluation process. One of the smoke flavourings, named Primary Product FF-B, raised concern during the evaluation process. Consequently, the AFC Panel expressed a risk assessment on the 7th June 2007 in which it concluded that Primary Product FF-B can be regarded as weakly genotoxic *in vivo*. The Panel therefore could not establish its safety in use when added to food and, as a result, the product was removed from the market.
75. On evaluation of processes for treatment of natural mineral waters, EFSA was asked to evaluate the safety of the use of manganese and iron oxyhydroxide media for the removal of manganese, iron and arsenic from natural mineral waters. A variety of media is used for this purpose across Europe. A final opinion will be finished in 2008.

## BIOHAZ

76. The BIOHAZ Panel adopted an opinion on the safety vis-à-vis biological risk of the mesophilic process of biogas and compost treatment of animal by-products.

## FEEDAP



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77. The FEEDAP Unit performed completeness checks of applications submitted to EFSA and supported the FEEDAP Panel in the drafting of opinions. Overall, 23 opinions were adopted according to the terms of Regulation (EC) No 1831/2003, including 19 opinions under Article 4(1) (evaluation of new products/extension of use), 3 under Article 13(3) (modifications of the terms of the authorisation), and 1 under Article 25(1). The FEEDAP Panel also received requests from the EC to deliver scientific opinions under other legislation such as Regulation (EC) No 178/2002, Directive 70/524/EEC and Directive 93/74/EEC. Nine opinions were adopted under the terms of the above-mentioned legislative texts, notably following a negative opinion from EFSA. In March, the Panel adopted one opinion on the environmental risk assessment of additives, products or substances used in animal feed following a self-tasked initiative.
78. Of the questions received in 2007, 2 were submitted for re-evaluation under Article 10(2) of Regulation (EC) No 1831/2003 and 4 were received under Regulation (EC) No 1829/2003 (bacterial biomasses produced by genetically modified microorganisms) which are under evaluation.
79. The FEEDAP Panel carried out its work through several WGs, including 8 Standing WGs on enzymes, microorganisms, amino acids, trace elements, coccidiostats, colouring agents, organic acids and guidelines.
80. The FEEDAP Secretariat, with the support of the Panel, started to discuss with the EC, the CRL and industry associations the establishment of a detailed “priority” schedule for the re-evaluation of all existing feed additives in accordance with Article 10 of Regulation (EC) No 1831/2003. The deadline for submission of applications for re-evaluation is 7 November 2010, after which the re-evaluation will begin following the schedule that will be established by the EC and SCFCAH.
81. In 2007, 7 technical hearings were held with industry associations/applicants (e.g. EU Feed Additives and Premixtures Association (FEFANA), International Association of the European Manufacturers of Major, Trace and Specific Feed Mineral Materials (EMFEMA), DSM, Zinpro and Degussa) in order to discuss issues related to the general assessment and handling of applications as well as more specific items linked to specific dossiers.

## GMO

82. In 2007, EFSA received 35 GMO applications including 14 new applications, 20 requests for renewals under Regulation (EC) 1829/2003 and one application submitted under Directive 2001/18/EC.
83. The Panel adopted 5 scientific opinions on applications for the placing on the market of GM plants within the framework of GM Food and Feed Regulation (EC) No 1829/2003 relating to GM maize 59122 and GA21, GM Soybean A7204-12, GM cotton LLCotton25 and GM rice LLRice62 for food/feed uses, import and processing. In addition, the GMO Panel adopted

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annexes to these scientific opinions, comprising detailed answers to issues raised by MS. The Panel also finalised its review on the renewal application for GA21 maize.

84. Three opinions on feed additives (Quantum™ Phytase, Rovabio™ PHY AP/LC 3-phytase, and Danisco Xylanase) based on an enzyme preparation from a genetically modified microorganism were adopted by the GMO Panel for co-adoption with the FEEDAP Panel within the framework of Regulation (EC) No 1831/2003.
85. The GMO Unit checked the completeness of 19 applications, supported the Panel with draft risk assessments and evaluation of comments from MS and the public, and published 5 opinions according to the requirements of Regulation (EC) No 1829/2003.

## NDA

86. On the field of food allergy, Directive 2000/13/EC, as amended by Directive 2003/89/EC, on food labelling requires the mandatory labelling of ingredients present in foodstuffs, and establishes a list of ingredients that are known to trigger food allergies or food intolerances (Annex IIIa). Within the framework of this legislation, EFSA issued 22 opinions following the evaluation of dossiers submitted by manufacturers applying for permanent labelling exemptions for derived ingredients listed in Annex IIIa of the Directive.
87. The Panel dealt with 10 dossiers related to novel food applications. The Panel issued two opinions on the safety of the novel food ingredients alpha-cyclodextrin and Allanblackia seed oil and a statement on fruit juices and nectars with added phytosterols. The Panel started the evaluation of the suitability of lutein for infants and young children; an opinion is expected by mid-2008.

## Plant protection products and their residues (PPR)

88. The PPR Panel published 10 opinions and a statement covering the sectors of toxicology, residues, environmental fate of pesticides and ecotoxicology.
89. At the request of the EC, 3 opinions were adopted on the revision of Annexes II and III to Council Directive 91/414/EEC concerning the placing of plant protection products on the market: on fate and behaviour in the environment; on toxicological and metabolism; and on ecotoxicological studies. The three other opinions on physico-chemistry; analytical methods and residues were published in 2006, and the 6 opinions on Annexes II and III will contribute to the preparation of the revision of Directive 91/414/EEC.
90. At the request of the EC, two opinions were adopted in toxicology: one on the Acute Reference Dose (ARfD) for imazalil and the other on the clastogenic properties and classification of the TBSA metabolite of tritosulfuron. Two opinions were also adopted in the field of pesticide residues: one on the acute dietary intake assessment of pesticide residues in fruit and

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vegetables (a statement was also published) and one on the risks associated with an increase in the MRL for dieldrin on courgettes.

91. On request of the PRAPeR Unit, the PPR Panel self-mandated two questions and published one opinion on the final report of the FOCUS Air WG on Pesticides in Air relating to exposure assessment, as well as an opinion on the genotoxic and carcinogenic potential of buprofezin in the context of human risk assessment.
92. The PPR Panel also published an opinion on default Q10 values used to describe the effect of temperature on transformation rates of pesticides in soil (self-tasked question).

### II.4 Enhance risk assessment methodologies and scientific cooperation

#### Scientific Committee

##### *Opinions and Guidance Documents*

93. The SC adopted advice on approaches to enhance EFSA's responsiveness to urgent questions at its plenary meeting on 9-10 July. The advice is composed of 3 procedures to be handled in a flexible manner to allow different types of responses depending on the type of questions and timeframe allotted and on the experience gained in practice for the SC and the Panels which was adopted by the Management Board at its meeting in September 2007.
94. The SC adopted advice on a proposal for a review system to assess the quality of EFSA's scientific work by written procedure in August 2007. The proposal offers a strategy that should provide EFSA with the means to comprehensively review the quality of its scientific activities, both by internal review and by independent, external review processes, together with additional consultations with institutional and non-institutional stakeholders. The strategy is designed to give continuing feedback to the Authority about the quality of its work.
95. In November, the SC adopted its opinion introducing the Qualified Presumption of Safety (QPS) approach for a simplified safety assessment of selected microorganisms referred to EFSA, taking account of existing history of use and data available. Prior to the adoption, the content of the draft opinion was shared with DG SANCO who confirmed the compatibility of this EFSA internal tool for generic risk assessment with the existing legislation. An explanatory note and/or a Q&A document will accompany the publication of the opinion to highlight that, in the case of existing sectoral legislation, QPS status does not substitute the obligation for pre-market authorisation. As a follow-up, an inter-panel group of experts will be created and coordinated by the BIOHAZ Panel Secretariat to develop and maintain the list of microorganisms granted QPS.
96. At its plenary in November, the SC adopted a guidance document that proposes an approach for the safety assessment of botanicals and botanical preparation for public consultation. The consultation will take place over December and January, 2008 and comments will be reviewed

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for possible update of the guidance document. An EFSA Scientific Cooperation (ESCO) working Group, whose mandate was agreed between the SC and the Advisory Forum will be established and the group will be charged with testing the proposed safety assessment approach with real cases and further develop the information contained in the compendia attached to the guidance document. The anticipated timeframe for this activity is one year.

### *Public consultations*

97. In December 2006, the SC approved the draft opinion introducing the QPS approach for the safety assessment of selected microorganisms for public consultation. The public consultation of the draft opinion took place in the period from 11 January to 5 March 2007. The comments were taken into consideration in the finalisation of the draft opinion that was adopted by the SC at its plenary meeting of 19-20 November.
98. In December, the SC published a draft of the guidance document that proposes an approach for the safety assessment of botanicals and botanical preparations for public consultation (see further above).

### *Dedicated meetings*

99. Two meetings of an expert working group on food consumption data were held. The main task of this working group is to complete the EFSA concise food consumption database. It will also discuss possibilities for further harmonisation of strategies and approaches to the collection and collation of food consumption data in Europe. The Secretariat for this task has been transferred to the DATEX Unit for 2008.
100. The SC had productive meetings with some Management Board members at the plenary meeting of 15-16 February and of 16-17 April to discuss the workload of the Panels.
101. The SCAF Unit organised a joint EFSA/DG RTD meeting on 28 February to provide updates on respective activities, provide input on the indicative topics for the next year's call of the 7<sup>th</sup> Framework programme, and identify further areas of cooperation.
102. A meeting was organised with the Secretariat and Chair of the Committee on Herbal Medicinal Products of EMEA on 14 March in Brussels to provide updates on respective activities in the safety assessment of botanicals and botanical preparations which have traditional medicinal properties and are used as food supplements in some of the European countries.
103. On 2-3 May, an EFSA/EU-EuroFIR/Nordic Council of Ministers Joint Workshop was held related to bioactive compounds in major European food plants. Two databases on bioactive compounds, one on potential health-beneficial effects and the other on potential toxic effects, were presented and their usefulness for EFSA's work was explored.

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104. The Chair and Vice-Chairs of the SC participated in 3 meetings of the Steering Group on Cooperation (March, May and November), composed of members of the SC and the Advisory Forum, which has been established to advise EFSA on scientific cooperation activities involving EFSA and the MS.
105. In August, the draft guidance document for the safety assessment of botanicals and botanical preparations used in food as supplements was shared with EMEA's Herbal Medicinal Products Committee (HMPC) for comment.
106. In September, a meeting took place with DG SANCO to discuss possible implications of the draft opinion on the introduction of the QPS approach for the assessment of microorganisms notified to EFSA.

## Scientific Cooperation and Assistance

### Assessment Methodology

107. The Assessment Methodology unit (AMU) provided scientific assistance to BIOHAZ for the opinion on the quantitative risk assessment of residual BSE risk in sheep and to the opinion on the age-specific risk of Specified Risk Materials in bovine. The unit is also involved in the Article 36 QMRA Salmonella in pigs BIOHAZ project, serving as the technical link between the consortium and EFSA. The unit was involved in the MON 863 task force for the statistical re-analysis of the 90-day rat feeding study.
108. AMU participated in the AHAW "TBC in deer" working group and an innovative methodology to combine data from systematic literature review with expert opinion (Bayesian meta-analysis) was developed and implemented.
109. The AMU supported the AFC Working Group in the evaluation of the FSA's publication on the effects of certain food colours on hyperactivity in children. The available information was reviewed, and a report was provided to support AFC in its initial assessment.
110. The AMU managed the Q10 experimental dataset and coordinated the statistical analysis underlying the Q10-FATE opinion adopted by the PPR panel in December. In addition, it collated information relating to acute toxicology data in birds and mammals from Draft Assessment Reports for pesticides. This information will be used in the PPR Guidance Document for birds and mammals.
111. On April 4, the AMU delivered a final report on the global epidemiological analysis of the 2006 BT virus outbreak investigating factors associated with introduction, establishment and spread of BTV-8 in north-western Europe. A review was completed to evaluate the epidemiological analysis and reporting of surveillance data on AI carried out under the responsibility of the CRL.



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This review proposed additional analyses to be made and provided suggestions on how to improve the collection, collation and analysis of surveillance data.

112. In collaboration with the Communications department, the unit organised three colloquia (Cumulative Risk Assessment of Pesticides to Human Health, Environmental Risk Assessment of Genetically Modified Plants, and Nutrient Profiling); from November 15 this responsibility was transferred to the Scientific Cooperation Unit.
113. The AMU Multiple Framework Contract for outsourcing of statistical tasks and data management was finalised.
114. Training on Data Collection and Analysis tools and methodologies in food risk assessment was provided for the Turkish and Croatian delegations during the Data Collection Workshop which took place on the 2-3 October and the programmes for two other seminars for these pre-accession countries were coordinated, as well as the programme of the Scientific Forum on 20-21 November.
115. The AMU also provided support to the Zoonoses team in baseline studies in broilers and turkeys, to GMO on an application for a transgenic glufosinate-tolerant soybean (A2704-12), to PRAPeR in the creation of a database to store ADI, ARfD and AOEL values, to DATEX in the collation and summary of measurements of PAH in food samples, and to the IT department in installing specific statistical software packages on server and on client computers. Methodological and statistical support was also provided in the form of short-term consultations to various units in Science, including the PLH unit (planning of upcoming modelling activities), SC/AF unit (review of a draft guidance on transparency), SCA department (contribution to the EFSA Data Collection Strategy document) and Risk Assessment department (contribution to the future animal health policy in EFSA document). The AMU provided scientific support to the FEEDAP unit on the evaluation of the genetic toxicology of feed additives. It analysed and commented on the draft SC/AF guidance document regarding the strategy for genotoxicity testing of botanical preparations, and compiled an overview of EFSA Risk Assessment Guidelines for the ESCO working group on harmonization of risk assessments.

### Pesticide Risk Assessment Peer Review

116. The main task of PRAPeR continued to be the review of all pesticides on the EU market since 1993. Following the completion of the second stage of the programme in 2006, EFSA progressed the peer review of the third stage which comprised 136 active substances (in two parts A and B) already used in plant protection products. In 2007, peer review was launched for all substances in part A. The conclusions were published on the EFSA website along with an extensive set of background documents. They provide the Commission and the authorities of the Member States with a scientific basis for determining whether the substances in question can continue to be used in the EU.



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117. In 2007, the activities related to Regulation No 396/2005 on maximum residue levels (MRLs) focussed on requests of the European Commission in the context of the establishment of the Annexes II, III and IV.

### Data Collection and Exposure

118. During 2007, the Data Collection and Exposure Unit (DATEX) grew from two to seven staff. Expertise has been acquired in food consumption survey design, database management and consumer research. The unit now has capacity to cover food and feed contaminants, food consumption and food composition as well as techniques for exposure assessments. The unit has mainly serviced the CONTAM Panel, the NDA Panel, the AFC Panel and responded directly to inquiries from the Commission as well.
119. The Unit contributed to the following opinions/requests: aflatoxins in nuts, nitrate in vegetables, cadmium and other heavy metals, marine biotoxins (CONTAM), and smoke flavourings (request from Commission).
120. Evaluation of the data on polycyclic aromatic hydrocarbons submitted by Member States was completed. A draft report was prepared and peer reviewed. The final report was submitted to the Commission and presented by EFSA to the Environmental and Industrial Contaminant Expert Group.
121. Calls for scientific data were issued and/or are currently running on furan in food and beverages, acrylamide in food and saponins from *Madhuca* sp., and gossypol, ricin and theobromine in feed.
122. The Datex Unit issued two calls for Article 36 activities, for assistance in the chemical occurrence data submissions and for improving knowledge of furan formation during food handling and preparation. The Unit also initiated the establishment of an Expert Group to assist in data standardization and design of EU chemical occurrence surveys.
123. In terms of food composition, the Unit is involved in collecting food composition data from official and commercial sources to assist the NDA Panel Working Group on health claims. Preliminary evaluations of official and commercial food composition data were carried out applying selection criteria suggested by the Working Group.
124. The EFSA food consumption network, the Expert Group on Food Consumption Data, met to discuss progress of the EU concise food consumption database and to plan future activities. Agreement was reached to publish summary tables for each Member State on the EFSA website. The contract was signed for the Article 36 project providing assistance to some Member States to finalise the collection of data for the concise food consumption database and a preliminary schedule for remaining activities settled.

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### Scientific Cooperation

125. Recruitment for the Scientific Cooperation Unit has progressed with a head of unit and secretary in place since September/November, one scientific staff member working since July, and two further scientists transferred internally. In addition, two new scientific staff members will join in early 2008.
126. Financial management of the Focal Point agreements with Member States and validation of the database of organisations approved to support EFSA under Article 36 started in 2007.
127. In March 2007, the Advisory Forum Steering Group on Cooperation (ESCO) agreed the setting up of an Expert Database to support EFSA's scientific work. An Expert Database Working Group, made up of experts appointed by Advisory Forum Members, and with the participation of DG RTD, was set up to address certain open aspects of the project, namely the eligibility criteria to include experts in the database, the strategy to populate the database and the data protection policy issues applicable to the database concept. The first meeting of the Working Group took place in December 2007 and testing will occur during January – March 2008.
128. The unit has taken over the secretariat of the ESCO Working Group on Food Fortification with Folic Acid. A first discussion with some experts from interested Member States took place and a first meeting of the Working Group is planned for early 2008.
129. The unit drafted a policy paper on the organization of Scientific Colloquia. A strategy paper was also drafted on how best to increase the visibility of scientific work in EFSA in the scientific community. In November 2007, the unit took over the scientific part of the coordination of scientific events, such as the Scientific Forum and Scientific Colloquia.
130. From June 2007, the Unit has coordinated the production of two special issues of scientific journals. The special issue dedicated to Foot-and-Mouth disease will be published in the Journal "Transboundary and Emerging Diseases", from Wiley-Blackwell, in January 2008. The second special issue is dedicated to the BT epidemic in Western Europe in 2006 and will be published in the Journal "Preventive Veterinary Medicine", from Elsevier, during the first quarter of 2008.

### Zoonoses (Data Collection)

131. The unit successfully coordinated the annual data reporting on zoonoses, antimicrobial resistance and food-borne outbreaks, for 2006. To this effect, a revised web reporting system and reporting manual were launched in March, and the national datasets were received by the end of May. Information was obtained from 24 Member States and 6 additional European countries. Both the quantity and the quality of the information provided were improved. This

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eased the data validation processed carried out by the unit. The European Centre for Disease Prevention and Control (ECDC) provided the data and analyses of zoonoses in humans.

132. The Community Summary Report on Zoonoses, Antimicrobial Resistance and food-borne outbreaks in 2006 was prepared in close collaboration with ECDC and EFSA's Zoonoses Collaboration Centre and, for the first time, statistical analyses of the trends in occurrence of zoonotic agents were included in the report. Another new element concerned the analyses of data compliance with the new Community microbiological criteria.
133. The harmonisation of the reporting and monitoring activities of the Member States was continued. Harmonised reporting schemes for antimicrobial resistance in *Salmonella* and *Campylobacter* isolates from animals as well as for food-borne outbreaks were issued by the Zoonoses Task Force during 2007. These schemes will substantially improve the quality and the subsequent analyses of the data collected.

## AFC

134. Draft guidelines, which are expected to be adopted in 2008, were developed for the recycling of plastics, for substances for use in active and intelligent food contact materials, and for submission of dossiers for food enzymes in view of the pending Regulations in this area.

## AHAW

135. The AHAW Panel adopted the opinion on the "Framework for EFSA AHAW risk assessment" which highlighted that, in the absence of international standards for animal welfare, clear guidelines for risk assessment evaluation are urgently needed in order to establish a solid scientific approach.
136. Two calls were launched for proposals under the framework of Article 36 relating to animal welfare (risk assessment guidelines on stunning and killing) and animal diseases (scientific reviews on 3 specific diseases and an evaluation of the distribution of arthropod vectors and their potential for transmitting exotic or emerging vector-borne animal diseases and zoonoses). The calls were evaluated and the final agreements signed in December 2007 for delivery in September/October 2008.

## BIOHAZ

137. The revised methodology on GBR was published by the BIOHAZ Panel and includes innovations and changes at different levels. It was submitted for public consultation in early 2007 and adopted later in the year after inclusion of feedback.
138. The BIOHAZ Panel adopted the opinion on the self-tasking mandate on microbiological criteria and targets based on risk analysis. EFSA and the BIOHAZ Panel took into consideration all the

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comments received during the public consultation which was held in 2006 and amended the opinion accordingly. In undertaking this self-tasking issue, the BIOHAZ Panel aimed to provide an overview of the different concepts and their use with special considerations on the applicability of microbiological criteria and targets in the food chain at EU-level based on risk analysis. Recognising that risk-based food safety management is still evolving, this document should be subject to periodic review.

### CONTAM

139. In the opinion on the public health impact of raising current maximum levels of aflatoxins in almonds, hazelnuts and pistachios from 4 µg/kg (EU maximum level) to 8 or 10 µg/kg, the CONTAM Panel used the Margin of Exposure (MOE) approach. The application of the MOE approach as a harmonised methodology for assessing the risks of genotoxic and carcinogenic substances in food and feed has recently been recommended by EFSA. For risk managers, this methodology offers a comparison of risks posed by different genotoxic and carcinogenic substances. The MOE approach has also been applied by the CONTAM Panel in its risk assessment related to the presence of ethyl carbamate and hydrocyanic acid in food and alcoholic beverages, in particular stone-fruit brandies.

### FEEDAP

140. Following the public consultation that took place in 2006, the FEEDAP Panel adopted an opinion on the “Development of an Approach for the Environmental Risk Assessment of Additives, Products or Substances used in Animal Feed” in March. The principles set out in the guidance document will be used as the basis for assessing the environmental risks associated with the use of feed additives. The document was submitted to the EC and incorporated into the new “Implementing Rules for the preparation and presentation of applications and the assessment and authorisation of feed additives” which were adopted in December by the Standing Committee on the Food Chain and Animal Health (SCFCAH) and will serve as the basis for the environmental risk assessment of feed additives.
141. In September, a working document was published which provided practical guidance for the extrapolation of efficacy and safety from major species to minor species when assessing feed additives within the framework of Regulation (EC) No 1831/2003. Another document entitled “Guidance for the Assessment of Compatibility of Zootechnical Microbial Additives with Antimicrobial Substances” was endorsed by the Panel and submitted to public consultation through the EFSA website. It is expected to be adopted by the Panel by the end of the year, after review. These documents have been prepared with the aim of informing and helping the applicants in the preparation of dossiers to be submitted to EFSA.
142. In addition, the Panel has started a self-tasking activity to examine the scientific basis for the existing functional groups within the category of zootechnical additives (according to Annex I of Regulation (EC) No 1831/2003) and propose the establishment of additional functional groups if necessary.

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143. The FEEDAP Panel and its Secretariat participated in meetings organised by the Standing Committee on the Food Chain and Animal Health (SCFCAH), concerning in particular the discussion on the “Implementing Rules for the preparation and presentation of applications and the assessment and authorisation of feed additives”. In 2006, EFSA, via the FEEDAP Panel, presented to the EC a complete proposal for the assessment of feed additives, which now constitutes the “backbone” of the document that was adopted by the SCFCAH by qualified majority in December.
144. After adoption of the “Implementing Rules for the preparation and presentation of applications and the assessment and authorisation of feed additives”, EFSA will develop specific guidance documents aimed at providing detailed guidance to applicants seeking authorisation of feed additives. The work has already started with the development of a guidance document on flavouring substances, with the important contribution of industry representatives.

## GMO

145. In accordance with Regulation (EC) N° 1829/2003 on genetically modified food and feed, EFSA is tasked with publishing detailed guidance to assist applicants in the preparation and the presentation of applications for the placing on the market of GM food and/or feed. Following a website consultation, the GMO Panel finalized its guidance document for the risk assessment of GM plants containing stacked transformation events.
146. Following consideration of feedback received during the public consultation, the GMO Panel adopted its revised report on the safety and nutritional assessment of GM plants and derived food and feed – the role of animal feeding trials. The report was presented to risk assessors from MS during a special meeting of the Advisory Forum in November.
147. The GMO Panel adopted a draft guidance on the risk assessment of GM plants for non-food or non-feed purposes. Following feedback from the EC and the European Agency for the Evaluation of Medicinal Products (EMA) with respect to legal and risk management issues, the report will be published on the EFSA website for public consultation.
148. Within the self-task on new approaches for the assessment of allergenicity of GM food, specific subgroup meetings were organised to deal with specific issues such as the use of bioinformatics and the development of animal models. The WG on “Strategies for statistical analysis of data generated for the comparative food safety evaluation of GMOs” presented its interim report to the Panel.
149. In March, EFSA organized a scientific hearing with applicants in order to be informed about forthcoming developments in the area of plant biotechnology which may lead to further issues to be addressed in risk assessments (e.g. guidance documents and self-tasking activities).



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150. In May, EFSA participated in a joint scientific session at the 2nd Meeting of the European Advisory Committees on Biosafety on the deliberate release of GMOs which took place in Ljubljana, Slovenia. An EFSA Scientific Colloquium on Environmental Risk Assessment of Genetically Modified Plants took place in June.
151. In November, a special meeting of the EFSA Advisory Forum was held with GMO experts from national regulatory risk assessment bodies and the GMO Panel to discuss scientific GMO risk assessment approaches at national and European levels. EFSA assisted the Joint Research Centre in a workshop organized in November following a request of the European Parliament to discuss the overall strategy on tools to assess the potential, short, medium and long-term health issues related to GMOs.
152. In June, two proposals were launched in the framework of Article 36 scientific cooperation concerning (1) the expression of Cry proteins in microorganisms and plants and (2) the impact of herbicide tolerant GM plants on non-target organisms. A third call for scientific cooperation concerning guidance for the risk assessment of GM animals has been delayed until 2008.
153. The scope of 8 of the applications currently under assessment and submitted within the framework of the GM Food and Feed Regulation includes the cultivation of a GM crop. In such cases, a Member State is involved in the environmental risk assessment in accordance with Article 6.3(c) and 19.3(c) of Regulation (EC) 1829/2003. In this context, experts from France, Germany, Spain and the Netherlands met with members of the Panel in January 2007 to share experiences on the environmental risk assessments of these applications and to discuss the evaluation of data presented in the applications and the risk assessment of herbicide-tolerant and insect-resistant GM crops. Bilateral meetings took place with experts from Germany and The Netherlands.

## NDA

154. The NDA Panel issued scientific advice within the context of Regulation 1924/2006 on nutrition and health claims. In particular, the Panel adopted a guidance document for manufacturers for the preparation and presentation of individual applications for health claims. This guidance was adopted following web-based public consultation and a meeting with stakeholders.
155. The Panel also started to address the different tasks allocated to EFSA in the Regulation and in particular the scientific advice on nutrient profiles for foods bearing claims. To this end, the outcome of EFSA Scientific Colloquium N°9 on "Nutrient Profiling for foods bearing Nutrition and Health Claims" held on 11-12 October constitutes the basis for an opinion on the subject which will be adopted by January 2008.
156. As part of the task on nutrient intakes for Europeans, the Panel was also working on advice on the translation of nutrient-based recommendations into guidance on the contribution of different foods or categories of foods to healthy diets. The opinion is expected to be issued by mid-2008.



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### PLH

157. To ensure a transparent, objective and consistent approach to peer-review of pest risk assessments, the Panel initiated a self-mandate to develop guidelines for the evaluation of PRAs prepared by a third party for phytosanitary purposes.
158. Aimed at enhancing the quality and availability of scientific data needed for a comprehensive risk assessment, a call within the Article 36 framework was launched on an inventory of data sources for phytosanitary pest risk assessment in the European Community.

### PPR

159. Updating of the Guidance Document on the risk assessment of Birds and Mammals was progressed; a Workshop took place in May 2007 involving 22 Member States and 10 representatives from industry. A public web consultation on the new draft Guidance Document was carried out at the end of 2007 and adoption is expected in spring 2008.
160. Updating of the Guidance Document on persistence of pesticides in soil started at the end of 2007. The preparation of a new Guidance Document on pesticide exposure assessment for workers, operators, bystanders and residents also started at the end of 2007 with the outsourcing of the assessment on current approaches and knowledge in EU (via a grant under the Article 36 of Regulation 178/2002).
161. Using the outcome of the 7th EFSA colloquium held on 28-29 November 2006 on “cumulative risk assessment of pesticides to human health: the way forward”, an opinion is being prepared on the suitability of existing methodologies and the identification of new approaches to assess cumulative and synergic risks from pesticides to human health with a view to setting MRLs; it is anticipated that this opinion should be adopted in spring 2008. The PPR Panel has self-tasked another request for an opinion on the cumulative exposure assessment of triazole fungicides as an example of the main opinion.

## II.5 Scientific Outputs and Resources

Table 1. Scientific outputs of EFSA units in 2007.

	AFC	AHAW	BIO HAZ	CON TAM	FEE DAP	GMO	NDA	PLH	PPR	SC/ AF	PRA PeR	DAT EX	AMU	Zoonos es	Sci Coop
Opinions	68	15	23	14	34	6	26	5	10	1	2	0	0	0	0
Plenaries	6	7	8	5	9	8	4	6	7	6	4	0	0	4	0
WGs	9	8	21	11	22	8	5	5	7	11	0	1	0	9	1
WG meetings	44	130	63	48	54	50	25	40	51	52	29	21	0	20	1
Other reports/ documents	2	5	0	1	1	1	8	0	1	2	17	0	12	3	6
Public consultations	0	5	1	0	1	1	1	0	1	4	46	3	0	0	0

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Guidance documents	0	1	2	0	2	1	1	0	0	3	0	0	0	5	0
Data collection reports	0	0		0	0	0	0	0	0	1	0	1	0	4	0
Contracts/grants	0	3	2	0	1	2	0	1	2	1	0	2	1	9	18

Table 2. New applications and renewals in 2007.

	IN to end 2007	OUT to end 2007	In process 2007
AFC	Additives: 385 Flavourings: 1541 Supplements: 420 Food Contact Mats: 182 Total: 2528	1 1201  113 Total: 1315	1213
FEEDAP	186	139	47
GMO	91	30	61
NDA	Claims: 4 Infant form: 4 Novel Food: 17 Food allergy: 51 Total: 76	0 3 14 51 Total: 68	8
PRAPER	239	80	159

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Table 3. Human resource by Unit

Unit	Type of contracts					2007	2006
	TA		CA	END	AUX		
	AD	AST					
Directorate	1	1				2	2
RA Dir	1	1				2	-
AFC	8	5		1		14	10
AHAW	9	3	2	2	1	17	11
BIOHAZ	10	5				15	11
CONTAM	4	2				6	5
FEEDAP	8	3	2			13	10
GMO	9	3				12	11
NDA	4	2				6	5
PLH	3	2				5	3
PPR	6	3				9	5
	63	30	4	3	1	101	73
SCA Dir	1	1				2	-
Assess Meth	5	2				7	6
DATEX	4	3				7	3
Emerging Risks		1				1	-
PRAPeR	20	5	1			26	19
SCOOP		1		1		2	-
ZOONOSSES	5	2	1	2		10	9
	35	15	2	3	0	55	37

Table 4. Financial resource by Unit (TBC)  
Execution 2007

Budget 2007

Execution 2006

## III Communication

### III.1 Activity overview

162. In 2007, EFSA continued to implement its communications strategy with the following priorities: build visibility for EFSA's corporate mission and scientific expertise; enhance the clarity and relevance of EFSA risk communications; and promote coherence in risk communications across the Community. New communications platforms, such as the EFSA Fifth Anniversary, were used to reach a broader audience with clear and more targeted messages.
163. The expert Advisory Group on Risk Communications held two plenary meetings in Parma in 2007. New challenges in risk assessment and risk communications, such as nanotechnology, cloning and EFSA's role in nutrition, were discussed along with developments in GMOs, zoonoses, and aspartame. The final draft of the Annual Review on Risk Communications was delivered to EFSA for comment. Some of the members met at a one-day workshop with social science experts to discuss public perception of animal cloning. A report on consumer perceptions of food products from cloned animals was produced after the workshop in order to summarise the discussions and outline areas of consideration for EFSA in preparing for future communications and stakeholder dialogue, related to the risk assessment on cloning. Two ad-hoc meetings were also organised in Parma and Brussels to review lessons learnt from Eurobarometer 2005 and discuss the possibility of a future survey in collaboration with the EC (DG SANCO).
164. To follow-up the outcomes of the strategy paper "Building the visibility of EFSA's Scientific Work", a working group involving staff from both Communications and Science addressed methods of increasing awareness of EFSA's work in the scientific community and a paper was drawn up presenting the advantages and disadvantages of the various options, and the implications for resources and scheduling. Suggestions ranged from the indexing of EFSA outputs in databases and publication of supplements to the creation of an online scientific bulletin. These options will be evaluated for implementation in 2008.
165. With the evolution of EFSA's role and the increasing importance of its corporate image, there was a need to revise and update the initial branding and visual identity. In March 2007, EFSA presented its new logo which, deliberately, does not incorporate any visual element referring to food or feed themes since associations with any given image would inevitably produce an imbalanced representation of the Authority and its activities. This choice was also driven by the consideration that such a visual approach could infer and contribute to the misconception that EFSA plays a role in quality control. This update brought EFSA's approach into line with European institutional guidelines. EFSA is now developing a corporate identity manual which will be delivered in the course of 2008.

## EXECUTIVE DIRECTORATE

The ring of stars that forms the main graphical element recalls our European dimension without simply duplicating the conventional EU flag. It also captures the spirit of a network, introducing an idea of cooperation with our institutional and stakeholder partners.

The EU flag is included as a reference to the fact that EFSA belongs to the EU institutional framework.

The phased orange colour of the stars and the blue in the main body of the logo allow for continuity with EFSA's original corporate colours while bringing EFSA's image up to date.

Lower case is used in the main body of the logo to capture the spirit of a young, dynamic and accessible organisation.

166. From the perspective of the Communications Directorate, 2007 was a year of major initiatives and events, many co-organised with European Institutions and MS. The events provided the opportunity to present EFSA as an institution – its role, work and achievements in its first five years of activity – to a wide range of target audiences, increase cooperation with MS, and increase the Authority's visibility in the Parma region. A wide range of events was organised in Parma and Brussels and, in line with the Authority's priority of enhanced cooperation and networking in Europe, a number of joint events were held in MS, in cooperation with the national food safety authorities. Further details of the events are given in section V.3.

### III.2 Media relations

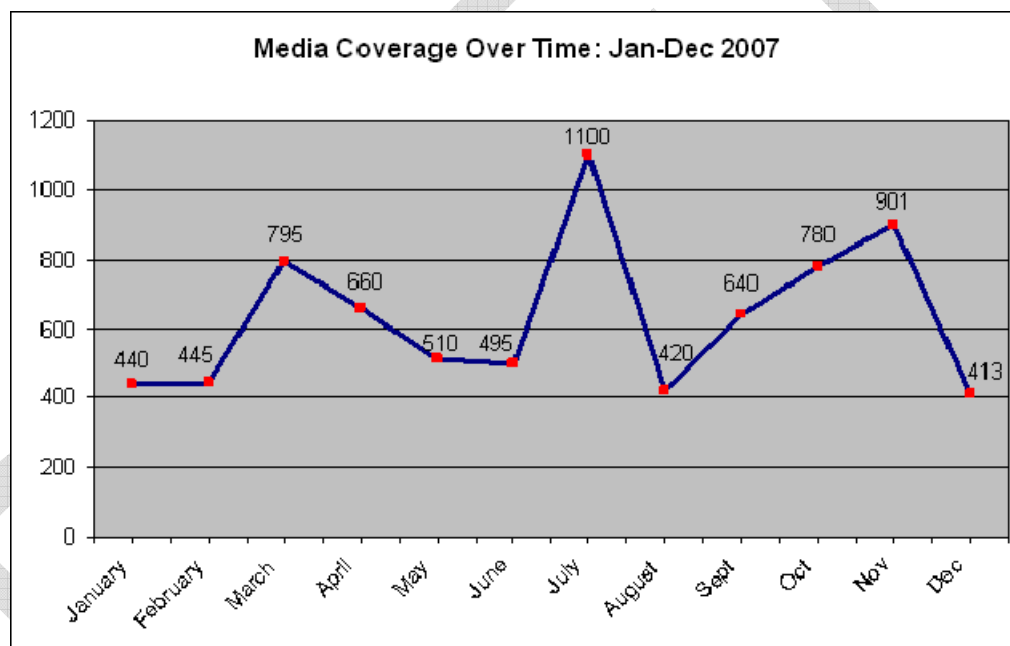
## EXECUTIVE DIRECTORATE

167. In 2007, EFSA's press office implemented a targeted communications approach using appropriate channels, tools and processes to reach the media - one of the Authority's key target audiences. We organised 8 press conferences which were attended by a total of 147 journalists. In addition, the following media materials were issued, highlighting the results of risk assessments as well as reporting on key decisions and meetings:
- 25 press releases and statements
  - 32 web news stories
  - 37 news alerts
  - Frequently Asked Questions on Bisphenol A
168. In total, 20 press releases and 5 press statements were issued covering both corporate developments (transparency policy, declarations of interest; Fifth Anniversary; and EFSA's meeting with representatives of the Genetic Rights Foundation and Coalizione Italia-Europa "Liberi da OGM") and scientific activities. With respect to the latter, EFSA made public announcements on topics such as: the safety of bisphenol A; evaluation of a study on citrus canker disease; risk of rabies introduction into the UK, Ireland, Sweden and Malta; EU Maximum Residue Levels for pesticides; EU-wide survey on Salmonella levels in broiler meat flocks; BSE infectivity in specified risk material from cattle at different age groups; nutrition and health claims (guidance to applicants); smoke flavouring Primary Product FF-B; genetically modified maize MON 863; food colours (Red 2G; evaluation of study on colours and hyperactivity); hormone residues in beef; EFSA-ECDC annual report on animal infections transmissible to humans; and animal welfare aspects of different methods of killing and skinning of seals.
169. EFSA also produced 32 web news stories on key corporate and scientific developments and activities, including GMOs; TSEs (e.g. update on TSE risks of feeding ruminants with fishmeal, quantitative risk assessment on residual BSE risk in sheep); FSA-EFSA workshop on emerging risks; aflatoxins in food; animal cloning; killing and skinning of seals; pesticides; ragweed; Salmonella in pigs; fruit fly in imports from Egypt; food supplements; and the safety of reptile meat. Web stories were drafted to inform the public also on institutional matters, such as the launch of a call for new Management Board members, the re-launch of EFSA's website, scientific cooperation with the FDA, signing of new Focal Point agreements with Member States, and announcements related to EFSA's Fifth Anniversary.
170. Overall, 37 tailored news alerts were distributed to a selected list of journalists. They reported on issues such as meetings of the Advisory Forum, Management Board, the Advisory Forum Working Group on Communications, Parma Liaison Committee, the activities of EFSA's Stakeholder Consultative Platform, visits by European and international delegations, EFSA-FDA agreement, European meetings held in Parma, and EFSA's activities in the region, as well as scientific topics such as nutrient profiles and the future of plant pest risk assessment.



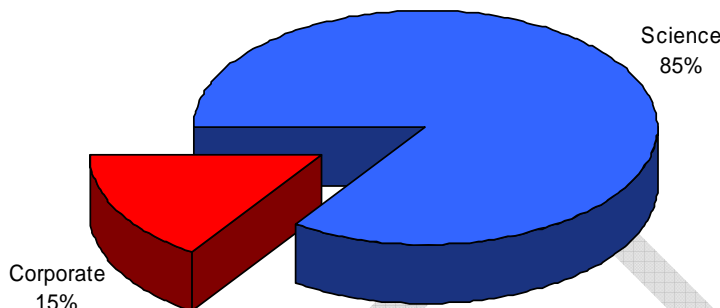
## EXECUTIVE DIRECTORATE

171. EFSA spokespeople gave 44 interviews over the year with selected media to illustrate, with practical examples, EFSA's work in specific areas of risk assessment. In addition to this, the EFSA press office received some 405 requests from European and international media.
172. Media monitoring is a key tool for EFSA's communications department that enables a constant review of performance. Through the use of professional media monitoring services, EFSA was able to expand the tracking of its media coverage, with around 7,760 articles and audiovisual coverage registered in 2007, representing a 60% increase in EFSA-related media coverage vs. 2006. Peaks in coverage occurred in March (cloning, bisphenol A, MON 863), July (MON 863, food colour Red 2G), and in November (food colours and GMO). Of note is the steady increase in the share of EFSA's media coverage dedicated to its scientific work: 85% of articles covered scientific issues in 2007 (15% for corporate) vs. 69% and 79%, respectively, for media coverage related to science in 2005 and 2006.



## EXECUTIVE DIRECTORATE

### Science vs. Corporate Coverage



### III.3 Fifth Anniversary

#### Parma Week, 1-7 October 2007

173. During the week 1-7 October, a range of activities to mark EFSA's Fifth Anniversary took place at different venues in Parma. The programme did much to increase visibility and awareness of EFSA in the Parma and greater Emilia Romagna area and represented a unique opportunity to present its work to decision makers, stakeholders and the general public. Activities included the following:
174. An EFSA exhibition and information stand on Piazza Garibaldi in central Parma was open to the public throughout the week. Visitors were offered: information material, poster exhibitions, educational games for children and adults, lectures, conferences and video shows. In total, 1,850 people visited the stand. EFSA organised lectures for more than 500 pupils from local schools who also visited the stand. EFSA held four small conferences on: Food safety and consumers; Animal welfare and consumer protection; EFSA in Parma: what has changed?; Food law and EFSA. Among the speakers were representatives from consumer associations, lawyers, local business and farmers. Italian journalists were also involved in the discussions. EFSA organised the launch of a book "Looking at Parma" in cooperation with the Province.
175. A ceremony in Palazzo Ducale was attended by about 150 representatives of European, national and local institutions; it was preceded by a press conference attended by 17 local and national media.
176. Porte Aperte - DUS: EFSA opened the doors of its headquarters to the public. EFSA's scientists and staff presented their work in 11 meetings. About 150 people attended including many students.

## EXECUTIVE DIRECTORATE

177. Porte Aperte - Palazzo Ducale: during the weekend, EFSA opened the doors of its official seat Palazzo Ducale, including the "Galleria Nobile". More than 600 people visited, in organised guided tours.
178. The Scientific Symposium on Food Safety, Nutrition and Nanotechnology was organised in cooperation with the University of Parma. The objective was to foster dialogue with the Italian scientific community and to increase awareness of EFSA's activities and its role in Europe. In total, 260 participants, mainly from Italian and European academia, attended.
179. The main Parma newspapers published daily articles on the events and a live interview with the Executive Director at the Palazzo Ducale was broadcast in the RAI 3 programme "Ambiente Italia". Nine local media attended the pre-Parma week press briefing; coverage was positive with all key messages conveyed. The EFSA web section dedicated to Parma week was updated daily, providing latest information and photos.

### Brussels Week 19-22 October 2007

180. EFSA used the week to explain its role, discuss future scientific challenges and demonstrate the value of its scientific work in support of EU and national decision-makers.
181. Inauguration of the EFSA exhibition in the European Parliament: Hans-Gert Pöttering, President of the European Parliament, and Robert Madelin, Director General SANCO, delivered keynote speeches together with Patrick Wall (Chair, EFSA Management Board), Vittorio Prodi (MEP) and EFSA's Executive Director. The cocktail buffet was sponsored by Europass and provided a selection of local specialities from Emilia Romagna.
182. Exhibition in the European Parliament: A poster exhibition in EFSA's four working languages explained EFSA's role and areas of operation. EFSA scientists and External Relations and Communications staff engaged in discussions with MEPs and stakeholders.
183. Information stands in the Berlaymont and Charlemagne buildings: EFSA staff provided information and distributed scientific and corporate publications.
184. Scientific Forum: More than 500 participants attended the Forum on 20 and 21 November. Various plenary sessions focused on future challenges in scientific risk assessment and 10 parallel sessions covered EFSA's main activities.
185. European Food Safety Summit: Jointly organised by EFSA, the Portuguese Presidency and the EC, it brought together high-level decision makers from MS, EU Institutions, International Organisations and non-EU partner countries. Speakers at the Summit included Commissioner Markos Kyprianou and three Ministers of the current and forthcoming Presidencies: Jaime Silva, Zofija Mazej Kukovič and Michel Barnier.

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186. Networking Buffet Dinner in the Piazza of the Berlaymont: This was attended by over 300 participants of the Forum and Summit. Patrick Wall, Chair of the EFSA Management Board delivered the opening speech.
187. Scientific Forum Press Briefing: 23 journalists attended the press briefing prior to the Forum and 38 journalists from across the EU attended the Forum itself, the highest number of journalists recorded at an EFSA event. In addition, several interviews with the Executive Director, Management Board members and invited Forum speakers were arranged with 11 publications. A press point was organised following the Summit and more than 25 pieces of coverage had been gathered by 27 November.
188. EFSA's visual presence in Brussels: Three large banners were placed on the façade of the Berlaymont and Charlemagne buildings, providing high visibility for EFSA in the heart of EU institutions.
189. Webcast: The entire Forum and Summit were webcast live on the EFSA website. Well over 2000 viewing sessions from 38 countries were registered throughout the 3 days of the conferences, with further viewing sessions expected over the coming months through the video-on-demand facility.
190. Media relations activities: In total, 43 media from across the EU attended the Forum and Summit. Of these, 22 attended the press briefing that took place prior to the opening of the Forum on 20 November and 4 attended the press point with the Executive Director on 22 November. Several interviews, mainly with the Executive Director but also with Director of Science (Herman Koeter), the Chair of the Scientific Committee (Vittorio Silano), Management Board members and speakers at the Forum, were arranged with 12 different EU media. On the evening of 22 November, the Executive Director was invited by German-speaking journalists for an informal background meeting in Brussels. About 10 Brussels-based EU correspondents from leading media attended, including *Reuters*, the German radio *ARD*, *WDR*, *NDR*, *Südwestpresse*, *Dow Jones*, *Basler Zeitung*, the Austrian news agency *APA* and the Swiss news agency *SDA*. The Executive Director explained EFSA's role and mission and answered questions over two hours on topics such as GMOs, health claims, food colours, flavourings, BT and EFSA's independence.

### Joint events with Member States

191. In line with EFSA's priority of enhancing cooperation with MS, the following events were jointly organised with the national authorities in MS:
192. The joint Food Standards Agency (UK)/EFSA workshop on "*Food incident prevention and horizon scanning to identify emerging risks*" took place on March 5-6 in London. EFSA scientists contributed by sharing their experiences in this field and a joint announcement of the event was published on the websites of both agencies.

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193. *"EFSA and food safety in the EU: achievements and challenges"* took place on June 7 in cooperation with the Italian Ministry of Health. The event included three roundtables on the following themes: "Harmonisation and transparency in risk assessment"; "Communicating food risks and benefits: a strategy for Europe"; and "What do different institutions and stakeholders expect from EFSA, and what does EFSA expect from them". This event was widely reported on Italian newswires where specific interviews were published.
194. *"Committed to the safety of Europe's food"* took place in Bratislava on 28 June in cooperation with the Slovak Ministry of Agriculture. The press conference was attended by 25 Slovak journalists. One-to-one interviews with the Executive Director were given to media after the press conference, which led to substantial coverage in the Slovak press.
195. *"Working Together Towards Safer Food in Europe"* took place on 10 September in Bucharest in cooperation with the Romanian National Sanitary Veterinary and Food Safety Authority, prior to the Management Board meeting. About 180 stakeholders attended the event. The press conference was attended by 33 Romanian journalists from press agencies, print and broadcast press and was followed by a series of one-to-one interviews.
196. *"Joining forces for safer food in Europe: the EU food safety system"* took place on 19 September in Lisbon in cooperation with the Portuguese Food Safety Authority (ASAE), prior to the Advisory Forum meeting. Among the 80 participants were representatives from the Ministry of Economy and Innovation; ASAE and other governmental institutions, as well as from trade, industrial and consumer associations; agricultural federations; universities and institutes. There was a joint press conference opened by the Portuguese Minister of Economy and Innovation, Manuel Pinho, and attended by 16 media from Portuguese and foreign media. In attendance were press agencies, 2 of the most important national dailies, regional newspapers, as well as weekly publications, online and audiovisual media.
197. 2007 represented an important year for other national agencies that also celebrated their five-year anniversary:
  - On 7 November 2007, the Executive Director addressed the German Federal Institute for Risk Assessment (BfR) at the commemoration of the BfR's Fifth Anniversary. The BfR is one of EFSA's partner organisations among the EU Member States and has made a key contribution to building strong cooperation between EFSA and national food safety authorities.
  - *"Five years of VWA: together taking care of trust"* was the 5-year celebratory event of the Dutch Food and Consumer Product Safety Authority which took place on 6 December. The symposium, attended by EFSA's Executive Director, included participants from a wide range of stakeholder organisations representing consumers, regulatory bodies, academia and industry. The event concluded with the official signing of a Focal Point agreement between EFSA and VWA. The Deputy Head of Cabinet of Commissioner Kyprianou, Mrs Despina Spanou, represented the Commission.

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- The Executive Director addressed a meeting of the Spanish Agency for Food Safety and Nutrition (AESAN) in Santander on 13 September to mark the fifth anniversary of its inauguration.

### Publications

198. In March, an anniversary leaflet was published in the four official languages plus Spanish, Portuguese and Romanian. A brochure entitled “Five years with EFSA – taking stock, looking forward” was published in September for decision-makers and key partners, outlining the main achievements of the Authority over the last five years. A small leaflet answering simple questions on EFSA for the general public was also produced in 6 languages.

### III.4 Other conferences and events

199. The *Open Doors Day* is an initiative of European Institutions taking place annually to mark May 9 with the aim of present their activities to the general public. The 2007 event also provided the opportunity to celebrate the “50 Year Anniversary of the Treaty of Rome” and about 80,000 visitors, mainly European families living in the Brussels region, participated in the celebration. DG SANCO focused on the theme “Nutrition and Health” and invited EFSA to take part in the event. EFSA organised a stand, in the same area as DG SANCO, DG AGRI, and two other agencies (CPVO and ECDC). Staff from the Communication and Science directorates provided technical and scientific information.
200. The *JRC Open Day* is a 12-year tradition and this year, as for Brussels, May 9 celebrations were associated with the 50 Year Anniversary of the European Union. The event is widely known in the region of Varese and beyond, as an excellent opportunity – in particular for children – to learn about science and its practical applications. EFSA had a stand attended by staff from Communication and Science who organised educational activities for children. The event was attended by about 8,000 people.
201. *Identity and Safety of Mediterranean Food Products* is the first event co-organised with the International Centre for Advanced Mediterranean Agronomic Studies (CIHEAM). About 100 participants from public and private institutions (local and national authorities, professional organisations, universities, the industry, non-profit organizations as well as representatives from CIHEAM and EFSA) attended the conference in Palazzo Ducale. The key themes included: EFSA’s role within the European food safety network; and the importance of cooperation and dialogue between producers, consumers and distributors, and the European and national institutions. The programme included a series of presentations and discussions on the identification of food safety strategies for the Mediterranean Region.
202. The Communications Directorate provided logistical and administrative support in the organisation of events for other EFSA activities, and in particular for the Science Directorate, including:



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- A consultation workshop for a PPR Working Group on the revision of the guidance document on birds and mammals with industry and MS in Valencia on 8-11 May.
- EFSA's 8th Scientific Colloquium - Environmental Risk Assessment of Genetically Modified Plants - Challenges and Approaches in Tabiano on 20-21 June.
- Participation of the PRAPER and PPR Panels in the XIII Symposium in Pesticide Chemistry organised by the Institute of Agricultural and Environmental Chemistry of the Catholic University of Piacenza on 3-6 September.
- EFSA's 9th Scientific Colloquium - Nutrient Profiling for Foods Bearing Nutrition and Health Claims in Parma on 11-12 October.
- EFSA conference with stakeholders – Risk assessment of feed additives in the EU: present and future in Toulouse on 24-25 October.
- EFSA's 10th Scientific Colloquium - Pest risk assessment - Science in support of phytosanitary decision making in the European Community in Parma on 6-7 December.

### III.5 Website

203. On 4 September, EFSA launched a completely redesigned and rebuilt website to optimise usability for EFSA's online audiences. The re-launch is a first step in EFSA's new online communication strategy which aims to increase visibility significantly. Some of the website's new features include:

- Simpler navigation;
- Topic- and output-driven content;
- More graphics and more use of the colour palette;
- More user-friendly written content;
- Events and meetings calendar: all EFSA events and meetings listed in one place;
- All documents searchable by title, date and category;
- EFSA scientific opinions searchable by sub-category, date and title;
- EFSA staff searchable by name;
- All declarations of interest for panel and working group members searchable by name or group;
- Cross-linking throughout the site using the right-hand column linking feature.

204. The new EFSA website continued to be the Authority's main interface for communicating with outside parties and a key vehicle for transparency. In the last quarter of 2007, the site received over 120,000 visits per month on average, with over 440,000 visits in the fourth quarter (up 34% on the same quarter of 2006). Over 17,500 subscribers now receive EFSA's electronic highlights newsletter, compared with around 12,500 at the end of 2006.

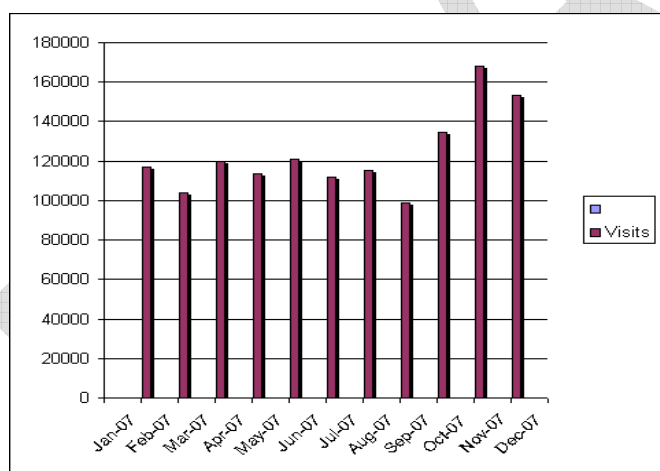
205. In the context of the redesign of the EFSA website, a number of new "key topic" sections was published to allow users easy access to information on topical issues, highlighting EFSA's work

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in this area with cross-links to opinions and other scientific outputs. These included subjects such as pesticides, food additives, BT and acrylamide.

206. EFSA continued to broadcast its Management Board meetings in 2007, with an average of over 1,500 viewing sessions (live and on-demand) registered for a single event. The Scientific Forum and Food Safety Summit in Brussels (20-22 November) were also broadcast live on the EFSA website and links to the video-on-demand uploaded shortly afterwards along with the set of presentations from speakers. The events attracted viewers from 38 countries with 2,368 unique viewing sessions registered during the live broadcast of the three days.
207. To support EFSA's fifth anniversary events, a dedicated section of the website was created and the website carried announcements, online subscriptions, animated banners and photos particularly for Parma week (1-7 October) and Brussels week (19-22 November).
208. Other new additions to the site in 2007 included the uploading of EFSA's new corporate video "5 years with EFSA" and four new landing pages for units of the Scientific Cooperation and Assistance department under "Scientific Panels and Units".

### EFSA website - visits in 2007

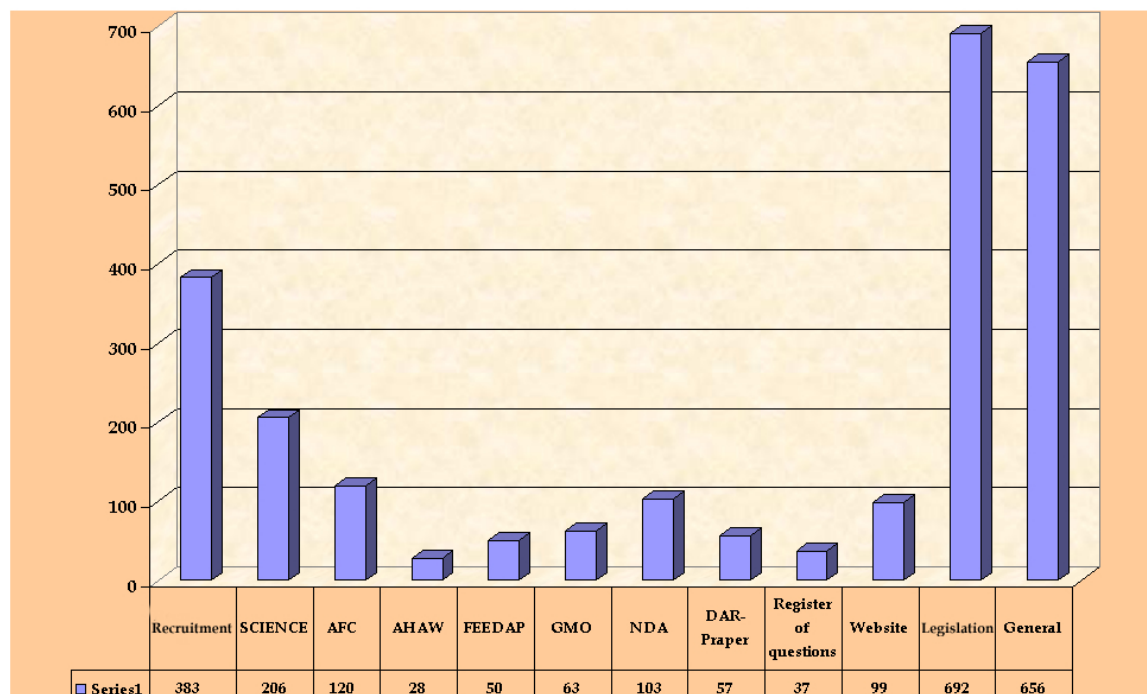


### Infobox

209. The Information mailbox ([info@efsa.europa.eu](mailto:info@efsa.europa.eu)) is the main contact point for the outside world to address requests for information to EFSA. In 2007, the number of requests for information received by e-mail has reached a total of 2,494. The chart below gives the breakdown by topic.

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### EFSA Infobox activities – breakdown by topic in 2007



### III.6 Publications

210. EFSA's corporate publications (Annual Report, Summary of the Annual Report, Management Plan and EFSAnews) were published in the four working languages. In addition, a new corporate brochure was produced in the four official languages as well as in Croatian, Bulgarian, Turkish and Romanian. As part of the support provided to applications developed by EFSA's services, the Public Information & Events (PIE) Unit supported the FEEDAP Panel with the publication of the user guide for the feed additives workspace in ScienceNet.
211. Three new Scientific Colloquium reports were published: "Cumulative risk assessment of pesticides to human health: the way forward" (7th Colloquium); "Risk-benefit analysis of foods: methods and approaches" (6th Colloquium) and "Development of food-based dietary guidelines" (5th Scientific Colloquium). The Community Summary report on trends and sources of zoonoses, zoonotic agents, antimicrobial resistance and foodborne outbreaks in the European Union in 2005 was published in May 2007. A brochure summarising this report and intended for the general public was published in Turkish and Croatian in addition to the four working languages.

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212. A CD-ROM compiling all the documents (opinions, guidance, statements) issued by the panels was also produced and distributed to the administrations/institutions of EFSA's scientific experts.
213. To increase visibility and understanding of EFSA's scientific work, the PIE Unit provided support in the production of posters on themes such as: QMRA of salmonella in pigs; EFSA scientific assessment on AI (H5/H7) vaccination carried out in zoos under Community approved programmes; and risk assessment of aflatoxins in almonds, hazelnuts and pistachios.
214. EFSA contributed to the 2007 edition of the EU Agencies' joint publication, part of a wider communication programme agreed by the Agencies' Heads of Communication and Information. The joint publication entitled "EU agencies – whatever you do, we work for you" is intended for the general public.

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Table 5. Human resource by Unit

Unit	Type of contracts					2007	2006
	TA		CA	END	AUX		
	AD	AST					
	1	2				3	2
PI&E	3	6	1			10	6
Press Office	4	5	2	1	1	13	9
Web	1	2	2			5	3
	9	15	5	1	1	31	20

Table 6. Financial resource by Unit (TBC)  
Execution 2007

Budget 2007

Execution 2006

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# IV Dialogue with Member States, EU Institutions, International Organisations and Stakeholders

## IV.1 Overview

215. EFSA continued to build dialogue with its institutional partners and to support their work in risk management. EFSA increased its activities with the risk managers in the MS and in the European Parliament as well as with the European Commission.
216. EFSA policy towards holding open dialogue with stakeholders was further enhanced with emphasis on contacts with consumer organisations.
217. 2007 saw EFSA further develop its policy towards collaboration with international and third country food safety organisations with the objective of sharing information, best practice and experience. EFSA assisted the European Commission with its work in Codex Alimentarius and forged greater contacts with key international partners to ensure that the risk assessments carried out by EFSA to support European food and feed law could become more and more globally recognised.

## IV.2 European institutions and agencies

218. In 2007 EFSA continued to implement the Recommendations of its Management Board with regards to the strengthening of its relationship with the EU institutions, international partners and stakeholders. Emphasis was placed on developing close dialogue with the European Commission on priorities and workload, with the European Parliament on advice to support their work and also furthering contacts and support to risk managers in the MS.
219. The overall objective were to:
  - build and ensure an appropriate interface between risk assessors and risk managers;
  - be informed about changes in policy and legislation which may have an impact on EFSA and ensure that decision makers are informed about the resource and other implications to EFSA;
  - for EFSA's role and activities to be understood and utilised to the full by risk managers;
  - ensure that EFSA is providing the appropriate advice and information to the key EU and national level decision makers; and
  - ensure appropriate contacts to assist with building coherence in risk communications activities with EFSA's institutional partners.
220. EFSA continued in 2007 to involve European Commission colleagues to the fullest extent possible in the scientific meetings of EFSA, in the Advisory Forum, Stakeholder Consultative Platform and through regular meetings at all levels.



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221. EFSA increased its presence in the European Parliament in 2007 to ensure that the requirements and needs for advice and support from EFSA were understood and known within EFSA. Also it was important to ensure that the remit work programmes and overall objectives of EFSA were appreciated and understood within the European Parliament.
222. EFSA welcomed the appointment of contact MEPs for the EU Agencies and welcomed the appointment of MEP Kartika Liotard as liaison MEP for EFSA. During the week of EFSA's 5th anniversary celebrations in Brussels in November 2007 MEP Liotard hosted a session of questions and answers with EFSA's Executive Director in the European Parliament.
223. Contacts were taken with MEPs with an interest in EFSA's activities and to forge greater dialogue. Equally, EFSA met EP rapporteurs on dossiers that affect EFSA, such as the food improvement agents package and plant protection products, in order to provide scientific and technical assistance on those dossiers.
224. In the context of the regular appearance of EFSA's Executive Director before the ENVI Committee, the Executive Director addressed the ENVI Committee twice in 2007 – in February and in October 2007 to present the work programmes for 2007 and 2008 respectively and to seek the views of the MEPs on EFSA's activities. Equally, EFSA's Executive Director appeared before the COBU and COCOBU Committees in January and June to discuss budgetary matters with MEPs.
225. EFSA's liaison officers with the European Parliament attended regularly the meetings of the ENVI Committee. In addition to participation at Committee meetings, EFSA increased its contacts with coordinators and key MEPs in the main Committees to further assist the discussions on scientific/technical matters.
226. EFSA's scientific officers attended also meetings of the ENVI Committee to further explain EFSA's activities in the area of GMOs and fish meal. On the latter and at the request of the EP, the EFSA Panel on biological hazards (BIOHAZ) issued an opinion on the assessment of the health risks of feeding of ruminants with fishmeal in relation to the risk of TSE. This opinion was presented before the ENVI Committee. Also upon request of the EP, an opinion of the BIOHAZ Panel was released on certain aspects related to the feeding of animal proteins to farm animals in 2007.
227. EFSA's Executive Director met with key MEPs during 2007 to explain EFSA's work and answer specific concerns raised by them.
228. During 2007, EFSA launched its first issue of *EFSA Information* to the European Parliament, which is aimed at informing MEPs regularly on EFSA's activities and forthcoming opinions.
229. On several occasions several occasions EFSA representatives attended EP hearings, including one dedicated to the new Commission Animal Health Strategy that proposes an action plan to provide a framework for animal health and welfare measures over the next six years. EFSA has

## EXECUTIVE DIRECTORATE

also been invited to take part to the EP Intergroup organised by the Eurogroup for Animal Welfare, chaired by MEP Neil Parish, chair of the EP Agriculture Committee. It is expected that EFSA's contribution will cover the animal welfare aspects of the laboratory testing of animal feedstuffs, in particular in connection with GM feed.

230. During 2007, EFSA increased its liaison with the EU Presidencies (German and Portuguese Presidencies). Equally, EFSA initiated preparatory work with the Troika and the upcoming EU Presidencies in 2008, Slovenia and France respectively.
231. As part of the regular visits that EFSA pays to the Member State holding the EU Presidency, the Executive Director met German Federal Minister Seehofer in Berlin and Portuguese Minister of Agriculture Silva in Lisbon at several occasions during the terms of their Presidencies.
232. At the invitation of the German and Portuguese Presidencies, EFSA participated in meetings of Council Working Parties, in particular at meetings of CVOs, COPHS and the Plant Protection Products Officers to explain EFSA's role in these areas and to provide technical and scientific assistance to Member State representatives.
233. At the invitation of the German Presidency and the German Federal Minister Seehofer, in June 2007 EFSA's Executive Director had the opportunity to address EU Ambassadors and to present EFSA's strategy for scientific cooperation and networking with MS.
234. EFSA's scientific officers participated at conferences organized by the EU Presidencies, and in particular to the Conference on nutrition organized by the German Presidency in February 2007, to a seminar on data collection systems organized in May 2007.

### Other EU Agencies

235. Another objective was to work closely with the other Community Agencies to ensure close synergistic working practices, avoid duplication of effort and fully utilise existing expertise.
236. EFSA has developed close working links with the EMEA on animal feed additives, botanicals and botanical preparations, nutrition and health claims, GMO and assessment of veterinary drug residues. During 2007, EFSA has developed joint working groups with the ECDC in relation to zoonoses and AI and joint activities include data sharing, scientific information and statistics, and preparation of the report on zoonoses.
237. EFSA continued to work with other EU Agencies through the Heads of EU Agencies meetings and in particular with EMEA, ECDC, ECHA and EEA on issues of common interest to ensure appropriate collaboration and exchanges. For example, one main output was the Community Summary Report on Trends and Sources of Zoonoses and Foodborne outbreaks in 2006

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prepared in collaboration with ECDC which provided the data and analyses of the human cases of zoonoses.

### IV.3 Stakeholders

238. The Founding Regulation established EFSA as a transparent and open body, obliged to ensure good relations with consumers and other interested parties. In this respect, EFSA plays a significant part in developing good governance. To meet its key objective of playing its part in the development of consumer confidence in the safety of the food supply, the Authority continued to engage in dialogue and invite feedback from its stakeholders in order to ensure that its goals, priorities and outputs are in line with expectations.

239. Relationships and activities with stakeholder were intensified in the course of 2007, and in particular with the setting up of temporary working groups within the EFSA Stakeholder Consultative Platform to look at issues such as transparency in risk assessment and methodology for public consultation. But also, EFSA increased the number of public consultations and dedicated meetings with stakeholders all along the year.

240. EFSA carried out an external review of its activities with stakeholders in 2007 with the aim of taking stock of the current activities with stakeholder groups, its efficiency and added value, but also with the purpose of looking ahead and being provided with recommendations for the future. The results of the external review will serve as a basis for outlining EFSA's direction for the future in relation to its stakeholder activities, and most importantly, it will constitute the basis for a Stakeholder strategy that will be presented to EFSA's Management Board in the course of 2008. The main outcomes in 2007 were as follows:

- open consultation on scientific issues either via the web, scientific colloquia or technical meetings; nine public consultations were organised in 2007.
- regular consultations on EFSA's PRAPeR work where interested parties were consulted on draft assessment reports (DARs) on a regular basis and via the website.
- the ability for stakeholders to consult and review the register of scientific questions that is accessible from EFSA's website and that has been recently re-designed to provide a more complete and easy accessible set of information about the Questions and its status in the process.

241. The Stakeholder Consultative Platform further consolidated its activities, in particular with the setting up of two working groups that dealt with transparency in risk assessment and methodology for public consultation. The discussions within these two working groups were reported back in the Autumn Plenary of the Stakeholder Consultative Platform. The work programme of the Platform considered crucial issues for the development of EFSA's policy towards stakeholders, such as:

- criteria for public consultation and transparency in risk assessment
- emerging issues

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- EFSA's work programme for 2008
  - EFSA's activities in the area of nutrition, plant protection products, animal health and animal welfare, food additives, flavouring and related issues.
  - EFSA 's activities in new areas, such as cloning and nanotechnology.
242. The agendas and minutes of the Platform were published on EFSA's website. Equally all presentations made at each of the Platform meetings were posted on EFSA's website in a dedicated webpage to stakeholders and EFSA. EFSA 's new website was launched in September and the Stakeholders webpage was also re-designed as well to improve accessibility of information for all interested parties on stakeholder activities.
243. In line with EFSA's policy to further involve stakeholders in its work, EFSA organized dedicated meetings with stakeholder groups on particular topics during 2007. As part of its stakeholders' consultations dedicated meetings were held on the draft guidance on nutritional and health claims and on the risk assessment of feed additives. The latter was done in the context of a Conference that was open to interested parties and that took place in October 2007. Equally, the Stakeholder Platform was invited to take part in EFSA 's scientific colloquia held during 2007. Further meetings dedicated to stakeholders were agreed for 2008, including issues of particular interest to stakeholder groups: cloning, transparency in risk assessment, nanotechnology. These meetings involve representatives from stakeholder groups, experts from EFSA 's Scientific Committee/Panels and EFSA staff and facilitate further interaction among the various groups.
244. EFSA continued to ensure that interested parties could take part in meetings of the Stakeholder Consultative Platform and, to this end, announcements were published on EFSA's website before each meeting. Interested parties had the opportunity to register via the website and attend the meetings as observers. Around 15 participants were given that opportunity at each meeting. Of the groups that attended the meetings as observers, few associate-member organisations of the Platform were included.
245. EFSA had bilateral meetings with stakeholder organizations that have legitimate interests in the work of the Authority. EFSA participated in general assemblies of stakeholder groups – farmers, industry groups and consumer groups – during 2007.
246. EFSA increased its interactions with consumer groups and its representatives and the Authority's staff participated in meetings of consumer groups at the EU and international level. In particular, EFSA 's Executive Director addressed the Trans-Atlantic Consumer Dialogue (TACD) during their annual meeting in Brussels in March, and also the BEUC General Assembly in November 2007 to present the priorities and the challenges of the Authority for the coming year.
247. Furthermore, EFSA continued to cooperate with private initiatives, such as the European Food Safety Platform, in order to explain the work of the Authority and contribute to the discussions. As part of its overall objective to restore consumer confidence in the food chain, EFSA

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continued its practice of pre-notice and exchange of information with key interested parties on issues in which they have a legitimate interest and to allow concerned parties to prepare themselves and their constituencies. Conditions for these pre-notifications will continue to be considered on a case by case basis and based on mutual trust.

248. Stakeholder groups also participated at seminars on Stakeholder Relations organized by EFSA with Turkey and Croatia in the context of the Pre-Accession Programme that EFSA is co-ordinating with these two countries. At those meetings, stakeholder groups from these countries were invited to participate actively in the discussions. Equally, representatives from the two new MS – Romania and Bulgaria – were also invited to share the views of “new member states” and the lessons learnt in preparation for accession.

### IV.4 International cooperation

249. The overall objective of this activity was to:

- ensure that the Authority's scientific experts provide assistance to the European Commission's services in the international arena, i.e. Codex and OIE, when required in line with EFSA's mission and tasks.
- build close working relationships as appropriate with international and third country organizations with the objective of being able to exchange information and data and share best practices.
- build the visibility of EFSA internationally.
- prepare accession and pre-accession states for full participation in the activities of EFSA on accession to the EU.

250. EFSA increased in 2007 its participation in the delegations of the European Commission to Codex Alimentarius meetings. At the request of the Commission, EFSA participated in working groups preparing specific documents for Codex Alimentarius. EFSA assisted the European Commission by providing technical and scientific support in the Codex Ad Hoc Intergovernmental Task Force on Foods derived from Biotechnology, 7th session, Chiba, Japan, 24 – 28 September 2007.

251. EFSA collaborated with international organisations such as OIE (through AHAW), WHO and FAO on projects of mutual relevance and benefit in order to share information and experiences. Projects included data collection and the assessment of global scientific issues in the areas covered by EFSA.

252. EFSA continued to explore the possibilities of further utilising the outcomes of work already undertaken by JECFA, JMPR, JEMRA and other international scientific committees while ensuring that the quality of its opinions and scientific independence were uncompromised. EFSA also considered its input to calls for data from these committees and other methods of collaboration.



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253. EFSA continued to build collaboration with food agencies around the world including the Japanese Food Safety Commission, Australia and New Zealand Authorities, USA, and China.
254. EFSA received a delegation from the Japanese Food Safety Commission in early January. The visitors, among them the Director General and the Director for Risk Communication discussed future informal exchange of information with the Executive Director and the Director of Science and visited the EFSA BSE unit to learn about the Authority's work in this area, in particular the geographical classification of BSE risk (GBR).
255. On November 21 in Brussels, EFSA and the Food Safety Commission of Japan met to discuss the signing of confidentiality arrangements to facilitate the sharing of non-public information. Similar instruments are currently under discussion with Food Standards Australia New Zealand (FSANZ) and the New Zealand Food Safety Authority.
256. On July 2 in Brussels, EFSA and FDA signed the Statement on confidentiality arrangements to facilitate the sharing of non-public information. Following this agreement, EFSA and FDA held a technical meeting on November 12 in Parma. The agenda focused on scientific subjects common to both agencies, such as the Qualified Presumption of Safety (QPS) approach and general discussion on approaches to risk assessment, nanoscience and nanotechnologies, risk assessment of animal cloning and aspartame. There was also a discussion on future bilateral meetings and future issues for cooperation.
257. EFSA continued its practice of pre-notifying international and key third country authorities of its findings. This has proven mutually beneficial in dealing with sensitive matters and has thus promoted trust between EFSA and its international partners.

### EFSA's Enlargement Projects

258. As part of the EU programmes to integrate candidate and pre-accession countries into the work of EFSA and in line with the wider EU policies in these areas, EFSA participated and managed the Pre-accession Programme for Croatia and Turkey during 2007.

### Pre-Accession Programme for Turkey and Croatia 2006/2007

259. In this area, the main activities in 2007 were:

- To assist the food authorities in Turkey and Croatia to build their expertise in risk assessment and assist with their activities in this respect to prepare for future accession.
- To start cooperation with the most advanced neighbourhood countries based on the provision of training and exchange of information and their inclusion in EFSA's data collection activities where appropriate (e.g. in zoonoses).
- As food crises do not recognise national borders, collaboration at the European level was needed in order to establish an effective food safety system. That is why these key subjects play an



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important role in the accession negotiations.

260. Within this Programme, a total of 14 seminars and Project Steering Committee meetings with national authorities and stakeholders were organised with an average of 40 participants per meeting. Experts from Turkey and Croatia participated as observers in 60 EFSA meetings: Management Board (5), Advisory Forum (4) and Advisory Forum Working Groups on IT (4) and Communication (4), Stakeholders Consultative Platform (1), Scientific Panels (33) and Working Groups (2), Conferences (5), IT Web and Videoconferences (2).
261. As part of the programme for 2006 and 2007, the focus was put on in-depth workshops and seminars in the various areas of EFSA's expertise. The topics of the seminars were chosen after meetings between the EFSA Pre-accession Programme Steering Committee and (i) the Turkish authorities and stakeholders on 30-31 January in Ankara and (ii) the Croatian authorities and stakeholders on 13-14 February in Zagreb. EFSA experts from the External Relations Unit, Scientific Committee & Advisory Forum, Legal Affairs, Communication and Science were engaged in the implementation of the training seminars. Where relevant, speakers from MS also participated in order to inform the Turkish and Croatian experts on developments in their countries and to receive feedback on topics such as GMOs, relationships with stakeholders, the Advisory Forum, data collection and analysis, and managing food crises).
262. The projects implemented thus far have strengthened the efforts of competent authorities in beneficiary countries to understand the basic elements of the EU food safety system. By participating in relevant meetings organized by EFSA, representatives from Croatia and Turkey gained insight into the work of EFSA in order to integrate efficiently into its activities post-accession. Additional activities have to be implemented to help Candidate Countries adjust national legislation and regulations to the *Acquis Communautaire*.
263. Croatian and Turkish authorities and stakeholders have suggested several project activities (meetings, seminars, visits, study tours and training) for inclusion in the Pre-Accession Programme for 2008.

### External Programmes – The Pre-Accession countries and Neighbourhood countries

264. In this area the main objectives are:

- To assist the food authorities in the Pre-Accession countries and Neighbourhood countries to build their expertise in risk assessment, assist with their activities, and promote EFSA's activities.
- In order to assist the food authorities in Turkey, Croatia and Macedonia to build their expertise in risk assessment and assist with their activities, EFSA has applied for the Commission Regional Programme on Financing Preparatory Measures for the Participation of The Former Yugoslav Republic Of Macedonia, Croatia and Turkey in Certain Community Agencies. The contract between the Commission and EFSA for a one-year programme should be signed by the end of

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2007.

- The new legislation on the European Neighbourhood Policy came into force in January 2007 and it is foreseen that ENP countries implementing the EU Acquis on food and feed safety would be able to cooperate with EFSA in line with the cooperation EFSA has/will have with the Candidate and possible Candidate countries. Initial contacts with DG RELEX were made in 2007 regarding EFSA's possible participation in the ENP Programme and initial meetings with the relevant countries funded by the Commission.

### IV.5 Italian authorities

265. EFSA has a productive relationship with the Italian authorities. EFSA continued to strengthen the excellent collaborative relations with the Authorities in Italy at local, regional, provincial and national level in 2007.
266. EFSA has been particularly active in collaborating with the Management Board of the European School and with the Italian Ministry of Education to facilitate the full recognition of the School in the European system. The School has been accredited by the European School system up to fifth grade and the procedure to obtain recognition of the Baccalaureate was started in 2007, with a view to achieving full status in 2008.
267. The Liaison Committee established in 2005 met in 2007 to discuss, among other issues, transport and EFSA's Fifth Anniversary. This committee – comprising representatives of the municipality, province, region, Ministry of Health from Rome, prefect, police and other local institutions – continued to develop close working relations with the overall objective of integrating EFSA into Parma. Regarding the airport, meetings were organised with the Director General of Parma Airport to provide the airport with EFSA flight statistics in order to enhance air links with Parma.
268. EFSA continued to liaise closely with the Europass office, which includes members from the region, provinces of Emilia Romagna, the Chamber of Commerce, the Regional Union of Chamber of Commerce in Emilia Romagna and Regional Universities, and which supports EFSA in developing close relationships within the territory. Building on last year's success with the Emilia Romagna Provinces with the series of conferences "Getting to know EFSA", EFSA launched a new cycle of conferences under the title "Shall we talk about food safety?" in 2007. The objective of the new conferences was to familiarise the local people with EFSA's work as part of the strategy for settlement in Italy. On a roundtable basis, topics such as animal health, nutrition, contaminants and mycotoxins were discussed among Italian scientists and EFSA experts at well attended meetings.

### IV.6 Crisis support

269. The objective was to ensure that EFSA is prepared to react and support the European Community during crises, and in particular the European Commission during emergencies or

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other urgent situations.

270. EFSA published a tender to review its in-house procedures and perform exercises with its staff and with the MS via the Advisory Forum. This tender was awarded in October 2007 and the consultant is in the process of updating EFSA's procedures and drafting a crisis manual for all staff.
271. The Crisis support work during 2007 has resulted in the preparation of a crisis exercise scheduled for early 2008.

### IV.7 Support of the Secretariat for Management Board

272. The EFSA Management Board ensures that the Authority functions effectively and efficiently, delivers its mandate as defined in the founding Regulation and meets the expectations of European and national institutions, stakeholders and the public. The Board's function and role have evolved since the Authority became operational in 2002, shifting from an initial focus on the adoption of rules and procedures to its current emphasis on evolving EFSA's strategy and future direction. In this respect the Board sought in 2007 to ensure that EFSA's priorities were in line with its mandate and key missions as expressed in the relevant food and feed legislation, within the resources available to it as established in the work programme of the Authority and ensuring appropriate financial management and accountability.
273. The key highlights from the work of the Board in 2007 were:
- Implementation of the six key recommendations of the independent evaluation undertaken during 2005;
  - Establishment of the budget and work programmes and monitoring their implementation;
  - Updating the internal rules of the Scientific Committee and the nine Scientific Panels to assist EFSA scientists and increase indemnities;
  - Adoption of the new Declarations of Interest forms aimed at giving further transparency to the professional backgrounds of the scientists on EFSA's Panels carrying out risk assessments as well as for EFSA staff.
274. During 2007, the Management Board met 5 times; in January, March, June, September, and December. In addition the Board met for the EFSA 5 year anniversary celebrations in Parma and Brussels where members actively participated as speakers and Chairs to the Scientific Forum and Summit.
275. At the Management Board Away Day of 26 March 2007, the Board met to discuss its conclusions from the Evaluation which had been carried out during the first part of 2006 and adopted and presented by the Board in June 2006. The Management Board formed a task force which had visited EFSA to interview scientists and meet with the Scientific Committee in early 2007 in order to gather information.

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- 276. The Board issued its findings at the June 2007 Board meeting and the recommended follow up actions were adopted by the Board at its September 2007 meeting.
- 277. During 2007, the Board lost one of its members and was replaced by Professor Pogačnik from Slovenia.
- 278. Elections held at the September Management Board meeting resulted in Bart Sangster being elected Vice-Chair to replace Dame Deirdre Hutton who remains a member of the Board. The Board now has two Vice-Chair's, Bart Sangster and Diána Bánáti.
- 279. In 2007, the Audit Committee, which consists of four Board members and the EFSA Executive Director met several times to monitor the financial activities of EFSA.
- 280. The Management Board is legally required to adopt the work programmes, the budget, the Establishment Plan, accounts and the Annual Activity Report. The Board adopted these within the legal deadlines. The Board also adopted several other key documents including the Annual Report, the updated Article 36 list, endorsed the Advisory Forum's strategic projects, focal points and adopted the new Declarations of Interest Policy document and forms.

## IV.8 Advisory Forum

- 281. In 2007, the activities of the Forum in 2007 were guided by the *Strategy for Cooperation and Networking between EU Member States and EFSA*, endorsed by the Management Board in December 2006. The Steering Group on Cooperation (SGC) was established following the plenary meeting in February when members of the Forum, the SC and other EFSA staff reviewed scientific cooperation in the framework of the *Strategy*. Three meetings were held during 2007 (March and May in Brussels; November in Berlin) to set priorities for and monitor the progress of the different ESCOs in accordance with the terms of reference and agreed timelines. A representative of the European Parliament was invited to Forum meetings in 2007.
- 282. At its five plenary meetings in 2007, discussions included: the implementation of the *Strategy for Cooperation and Networking between EU Member States and EFSA*; cooperation in communications; exchange of scientific information; the list of competent organisations under Article 36; terms of reference for EFSA Scientific Cooperation Projects (ESCO); the establishment of national focal points; the mandates and progress of ESCO projects; EFSA's draft Management Plan 2008; operation of the Forum; and the new policy, format and guidelines for Declaration of Interests.
- 283. Besides the plenary meetings, a special Forum meeting on GMO risk assessment in Europe was held in Brussels in November with participation of 60 national experts in GMO risk assessment.

### Cooperation in Communications

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284. The Advisory Forum Working Group on Communications (AFCWG) met four times in 2007 and continued its activities to strengthen communications network between EFSA, MS and the EC. The group used the opportunities provided by the development of EFSA's overall strategy for cooperation and networking with MS, and EFSA's 5th anniversary, to take stock and consider its role and remit. A review of its ways of working and Terms of Reference (ToR) was undertaken in 2007. Discussions were held at three meetings, informed by a questionnaire sent to all members. The aim for 2008 is to further strengthen the group and enhance the added value of its work for all members, through increased interaction and intelligence sharing, not just at formal WG meetings, but also outside of meetings, on areas of mutual interest.

285. Communications support for cooperation and networking between EFSA and MS has been central to the work of the group this year. A number of initiatives were undertaken to support this:

- "Moving together – News on European food safety co-operation" is a newsletter created to promote the Advisory Forum's cooperation and networking strategy, further to the request of the Forum working group on communications. The editorial board is composed of representatives from Belgium, Germany, Greece, Ireland, the Netherlands, Norway and EFSA. EFSA is also responsible for the coordination of the project. The focus of the newsletter is on scientific issues in the field of food and feed risk assessment, highlighting synergies and scientific cooperation among MS. The newsletter will be published twice per year in English, French, Italian and German. The first issue was published in December 2007 and MS can translate it into other languages for distribution;
- text was agreed for MS websites to explain the European food safety system, the role of MS, risk assessors, risk managers, EFSA and the European institutions. This is being used in a number of MS as a consistent and clear way of explaining the roles of the different actors in the system to stakeholders via websites;
- a total of 7 joint events with MS were held over the year, linked to EFSA's 5th anniversary and the anniversaries for a number of food authorities. These events, involving stakeholder engagement and media activity, have enabled EFSA and MS to work together to communicate our synergistic activities within the European food safety system.

286. The group has also focused on how members can support each other by sharing their experiences of dealing with significant communications challenges. A new agenda item has been added to every meeting where a member outlines a case history of dealing with a significant issue or incident, how it was handled and the lessons learnt from that. The aim is to share experience more systematically and build best practice. Similarly, during the year a taskforce of the WG has looked at the issue of so-called misinformation in the media and helped the group to address the best ways in which to best respond to inaccurate reporting around "food scares".

287. The WG has continued to provide a useful forum for intelligence sharing and forward planning, particularly on high-profile issues with potential communications opportunities and/or



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challenges, at European and MS level. The WG has been briefed by EFSA scientists and colleagues in MS on key emerging issues such as cloning and nanotechnology, which have helped shape thinking around the communications issues.

288. Finally the group has begun discussing how to increase the visibility of risk assessment work amongst the scientific community and will review opportunities and share experiences in this area in 2008.

### Cooperation in Information Technology

289. In 2007, the IT Working Group met 5 times, 3 meetings co-hosted by the Forum Member institutions in Sofia (March), Berlin (June) and Oslo (September) and 2 web-conferences organized in August and December. These meetings were instrumental in advancing the projects run by EFSA and the IT WG (AF Extranet, Audio/Web conferences, Data Collection Framework) and sharing IT best practices (key IT systems used by members and IT Governance in Food Safety organizations). In addition, these meetings helped consolidate the network of Heads of IT.
290. In terms of projects, the EFSA Extranet now meets the needs for collaboration and information sharing of many communities, including the Forum and its Working Groups, and EFSA panels and suppliers. The IT WG is considering ways of implementing the Strategy on Cooperation and Exchange of Scientific Data on the Extranet. EFSA invested €330 k this year on the Extranet, with an additional €400 k planned over the next 2 years.
291. The IT WG is also working on technologies that will facilitate scientific meetings with international experts and ease communications among members of the Forum during emerging food crises. To this end, EFSA is building capacity to enable high-quality video-conferencing with up to 40 sites and audio/web-conferencing with up to 100 participants. EFSA is building meeting rooms in which high-quality meetings can be conducted with remote participants. Although EFSA is currently offering audio- and web-conferencing with up to 100 participants and video-conferencing with up to 5 sites, full capacity will not be reached until the third quarter of 2008. EFSA is investing €350 k in this project.
292. Finally, the IT Working Group has been working on a framework for allowing scientists to quickly generate cost-effective and reliable data collection applications with minimal assistance from IT. This framework includes tools for helping scientists bridge data collections and could be configured to offer data collection as a web-based, self-service or to allow Forum members create their own data collection applications. To date, EFSA has produced a technical architecture, a process model for launching data collection campaigns and a prototype for Ad-Hoc Data Collection. EFSA's IT Unit has dedicated two project managers to this project, has invested €140 k and plans to invest an additional €350 k over the next 2 years.



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### V Administration

#### V.1 Human Resources

293. The success of EFSA lies in large part in its ability to attract and retain a high-quality and motivated workforce. In this context, the key objectives of the Human Resource Unit in 2007 were to actively contribute to the growth and consolidation of the Authority by completing an ambitious recruitment plan and to consolidate the establishment of a sound, stable and motivating work environment for staff.
294. Human Resources has significantly contributed to the growth and consolidation of EFSA in 2007. The execution rate of the establishment plan in 2007 is 91% compared with 69% at the end of 2006, while continuing to reduce turnover (4% in 2007 versus 8% in 2006). In addition, essential processes on which a stable and stimulating work environment are based (e.g. career development and promotion) have been launched.
295. 2007 has been a successful year for recruitment at EFSA. A net recruitment of 100 Temporary Agents was achieved, due to a restructuring of the recruitment team, better planning and follow-up, and the streamlining of procedures.
296. The Unit has also dedicated significant resources to completing the Staff Policy Plan which is being developed in close cooperation with Commission services and the agencies coordination group. In this context, EFSA will finalise a number of implementing decisions of the new Staff Regulations that include staff appraisal and career development and promotions.
297. The first appraisal exercise was undertaken in 2007 and will conclude in early 2008. Based on outcomes, the first promotion reclassification/exercise will be performed in early 2008. EFSA has been processing in 2007 the full range of implementing rules linked to Staff Regulations and the CEOS and will be able to trigger Procedure 110 in early 2008. The Staff Policy Plan 2009-2011 has been drafted and submitted to the Management Board for approval.
298. The assessment of existing competencies is linked to the outcome of the first career and development cycle. Based on it, training and personal development needs will be identified and training programmes established. EFSA has also introduced a review of its learning and development policy in 2007 that will serve the staff in the course of 2008.
299. In 2007 a new set of indicators has been created for the purposes of progress reporting to Management Board and internal review.

#### V.2 Facilities

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### Office buildings

300. During 2007 a new building (FRATTI building) near the original headquarters has been occupied with an increase of 3050 m<sup>2</sup> in office space (+ 40%); this new space accommodates 160 persons and provides meeting rooms for an additional 80 persons.
301. Regarding the final seat project, several meetings with architects and the Municipality have been organized to check the proposals and define the project according to EFSA needs and original budget. The definitive project is being developed by the architects and this version is expected in early 2008.

### Security, Health & Safety

302. Concerning security, the actions recommended in a security report have been completed, improving building security, infrastructure, systems and procedures and enhanced protection of EFSA staff and assets. The relationship with the local police forces has been consolidated and their support for the organization of EFSA events increased to ensure that security is covered.
303. Concerning safety, Facilities has worked on the establishment of an EFSA Health & Safety Committee and on the production of a Health & Safety action in collaboration with Human Resources.

### Equipment & furniture

304. The move to the new Fratti building has meant major seating reorganizations in the DUS buildings, and a significant number of moves were performed during the year (more than 300 individual moves). The development of the office and increasing staff numbers have resulted in increased logistical support for meetings (welcome desk, configuration and re-configuration of meeting rooms), a growing volume of mail, office supply services, and support for newcomers.
305. Procedures for incoming and outgoing mail have been implemented.

### V.3 Legal Affairs

306. In 2007, the Legal Affairs Unit provided continuous legal advice and support in relation to the implementation of legal acts providing authorization procedures involving EFSA, with a special focus on the Feed Additives Regulation (Regulation (EC) No 1831/2003), the Genetically Modified Food and Feed Regulation (Regulation (EC) No 1829/2003) and the Health and Nutrition Claims Regulation (Regulation (EC) No 1924/2006). The support has resulted in the finalization of guidance documents and correspondence with the European Commission and stakeholders. The Unit has continued to follow-up on cases lodged before the Court of First Instance against EFSA. This activity of the unit has resulted in 6 favourable orders of the President of the Court in 2007.

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307. Over the course of the year, the Unit has also finalized the package on Declarations of Interest and, after its adoption by Management Board, has offered legal advice on its interpretation. In the context of a general revision of EFSA statutory texts, the Unit has also reviewed the rules of procedure for the Scientific Committee and Panels and for the Advisory Forum leading to their adoption by Management Board.
308. In relation to Procurement and Contract Management, the Unit provided assistance in further adjusting and refining procurement templates in line with the modifications to the Financial Regulation which came into force in spring 2007. Awareness raising, information sharing and training on procurement and contract matters were supported both on a day-to-day basis and during structured training. A workshop on procurement open to all staff was organized in February 2007. During 2007, EFSA completed 10 open calls for tender and 40 negotiated procedures. These procedures resulted in 59 new EFSA contracts signed during 2007.
309. According to Regulation 178/2002 and Regulation 2230/2004, the financial support for Article 36 networking of organizations takes the form of grants. The Legal Unit prepared all templates for calls for proposals for grants to be launched according to the annual work programme published at the beginning of the year. In total, 12 calls were launched. Dedicated training meetings were held to explain the main rules governing grants.
310. The Legal Unit also provided support for all questions related to the Final Seat. The hosting Commune is tendering all procedures aimed at the construction of the Final Seat (tender for the architects and building contractors). The Unit provided support for all related legal questions concerning procurement procedures, editing of agreements/letters with the Italian contracting authorities, and support to Administration for negotiations to comply with public procurement rules (EU and Italian as appropriate).
311. During 2007, the data protection officer (DPO) continued and further intensified the follow-up of data protection issues notably after an investigation by the European Data Protection Supervisor in spring 2007. As a result of this, besides completion of a mapping of data processing operations at EFSA, follow-up on notifications was intensified, i.e. in the Human Resources area. A prior checking notification was prepared for the CDAC (Carrier Development Appraisal Cycle).
312. The DPO attended 2 meetings of the DPO network of EU institutions and bodies during 2007. As regards public access to documents, EFSA continued to implement tools and procedures to ensure that requests for public access are processed in an efficient and lawful manner, in close cooperation with the Communications Directorate and various units of the Science Directorate. Close cooperation was maintained with external partners on this matter, mainly with Commission services (Secretariat General and DG SANCO) to ensure common understanding and views on best practice in this area. EFSA has also started reflecting on the impact of the implementation by the European Union of the Aarhus Convention on public access to environmental information.

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313. The total number of requests received in 2007 was 28. The majority of these requests was in the areas of Genetically Modified Organisms and Food Additives, Flavourings, Processing Aids and Materials in Contact with Food (AFC) which were handled by the Unit in close cooperation with the respective scientific units. A total of 27 of these requests led to access given to the requestor. In 5 of these requests, the complexity of the application and the need for third-party consultations required an extension of the deadline, in line with regulation 1049/2001, but the process had been concluded and access granted in 2007. One request was denied because the documents requested were not held by EFSA.

### V.4 Finance and Accounts

#### Finance

314. Five main objectives were identified in relation to financial activities.

##### *Improve the overall budget execution*

The overall budget execution was monthly reported on an ABB and budget basis to Management. Forecasts were also provided to the Management Board and follow-up made with the Authorising Officers together with analytical reporting.

##### *Optimise and document the workflows*

The catering, shuttles and missions workflows were put in production in order to gain efficiencies in these processes and allow for easier reporting and forecasting. The meeting and ABB workflows were either started or postponed to next year in view of limited development resources.

##### *Shorten the payments deadlines*

The payments deadlines were carefully monitored with monthly reports sent to the Authorising Officers. The reduction of carry over at year end will also be ensured by additional financial verification of carry over requests in early 2008.

##### *Implement the ABAC system*

In view of agenda constraints at the level of DG BUDG, the migration to ABAC was postponed to 2008. The preparation of this migration has already started with first training given by DG BUDG and on-going coordination by an internal task force.

##### *Improve the effectiveness of Internal Control Standards*

The workplan in the ICS area was implemented through the organisation of the High Level Risk Assessment workshop organised with EFSA management, the survey on the efficiency of Internal Control Standards organised at all levels in EFSA with the Self-assessment survey, and the follow-up of the ICS action plan.

#### Accounts

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- 315. The 2007 exercise has seen a new increase of about 30% of the transactions to be executed (i.e., around 17500 payments). The average execution time was 2.3 days.
- 316. This increase was also reflected in the management of new legal entity files and bank account files for suppliers, experts and other stakeholders. EFSA now has more than 4600 records in its third party (bank accounts) central database.
- 317. The EC services have decided to postpone the migration to ABAC in 2008.
- 318. Both legal and ad-hoc reporting have been improved in order to give more visibility and transparency to senior management.

### V.5 Information Technology

- 319. The IT Unit continued the production of the Zoonoses Community Report in which €285 k were invested in 2007. In addition, the IT Unit finalised the Food Consumption Database so that the DATEX unit was able to collect data for the concise version. The PAH database was also produced.
- 320. The IT Unit continued to develop the Data Collection Framework (DCF), a set of standards and technologies allowing scientists to quickly compose reliable and cost-effective data collection applications with minimal assistance from the IT Unit. DCF was used to generate a first version of data collection applications with a simple schema.
- 321. The Document Register is ongoing. A first phase was rolled out, including features for registering incoming and outgoing correspondence and for tracking exception requests. Most of the €131 k invested in 2007 will come to fruition in 2008 in the form of an end-to-end, corporate-wide electronic document workflow.
- 322. The IT Unit Produced the Mission Order Workflow, a system used to streamline the authorization and reimbursement of staff missions (€76 k). The Mission Reimbursement Workflow, which the IT Unit intended to build in 2007, was postponed to 2008.
- 323. The Intranet was delayed to the 4<sup>th</sup> quarter of 2007 so that the higher priority Scientific Extranet and AF Extranet could be produced on time. The Intranet Inception phase was completed and the priority functionalities related to collaboration and document sharing will be implemented first in 2008.
- 324. The IT Unit established Audio- and Web-conference capabilities for up to a 100+ participants and Video-conference capabilities for up to 5. The Project to establish quality video-conferences with up to 40 participants and build audio-visual meeting rooms for quality work sessions (and

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Communication Control Centre during food crisis) started in December, with a total budget of €350 k. It should be completed by the second quarter of 2008.

325. Website: The IT unit switched to a more stable and cost-effective web content management system. EFSA's new website, based on the new system, was launched in September 2007 (€353 k). New search features (€94 k) are now being rolled out.

ABB: A system for facilitating budget forecasting for activities to be rolled out in 2008.

Time Tracking: A system for tracking costs of activities to be rolled-out in December 2008

MB Extranet: An extranet space for Management Board members (meeting registration, secure document sharing), available for user testing in February 2008.

Register of Questions: a tool used for listing questions received by EFSA was upgraded and now includes a list of all EFSA Scientific output.

### V.6 Audit

326. A Forward Audit Plan (2008-2010) was prepared in 2007. The processes governing risk communication and the preparation of EFSA's scientific outputs will be the main areas to be audited in 2008 and 2009, respectively.
327. Follow-up of the recommendations issued by the Internal Audit Service (IAS) in 2006 was performed and a second audit from the IAS took place in 2007. As a result, 35 of the 36 recommendations were "closed" by the Auditors.



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Table 7. Human resource by Unit

Unit	Type of contracts					2007	2006
	TA		CA	END	AUX		
	AD	AST					
	1	1				2	-
Accounts	1	4				5	4
Facilities	1	11	2			7	9
Finance	3	12	2			17	13
IT	6	13	2			21	17
Legal&Po	10	5	2	2	2	38	18
Library&Archives		4	1			5	5
HR	4	11	3			18	20
	26	61	12	2	2	103	86

Table 8. Financial resource by Unit (TBC)  
Execution 2007

Budget 2007

Execution 2006

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## VI Annexes

Annex 1: List of Management Board Recommendations Implemented.

Annex 2: Budget Execution

Annex 3: Budget Allocation

Annex 4: Establishment Plan

Annex 5: Allocation of Staff by Unit and Directorate

Annex 6: Declaration of Assurance

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