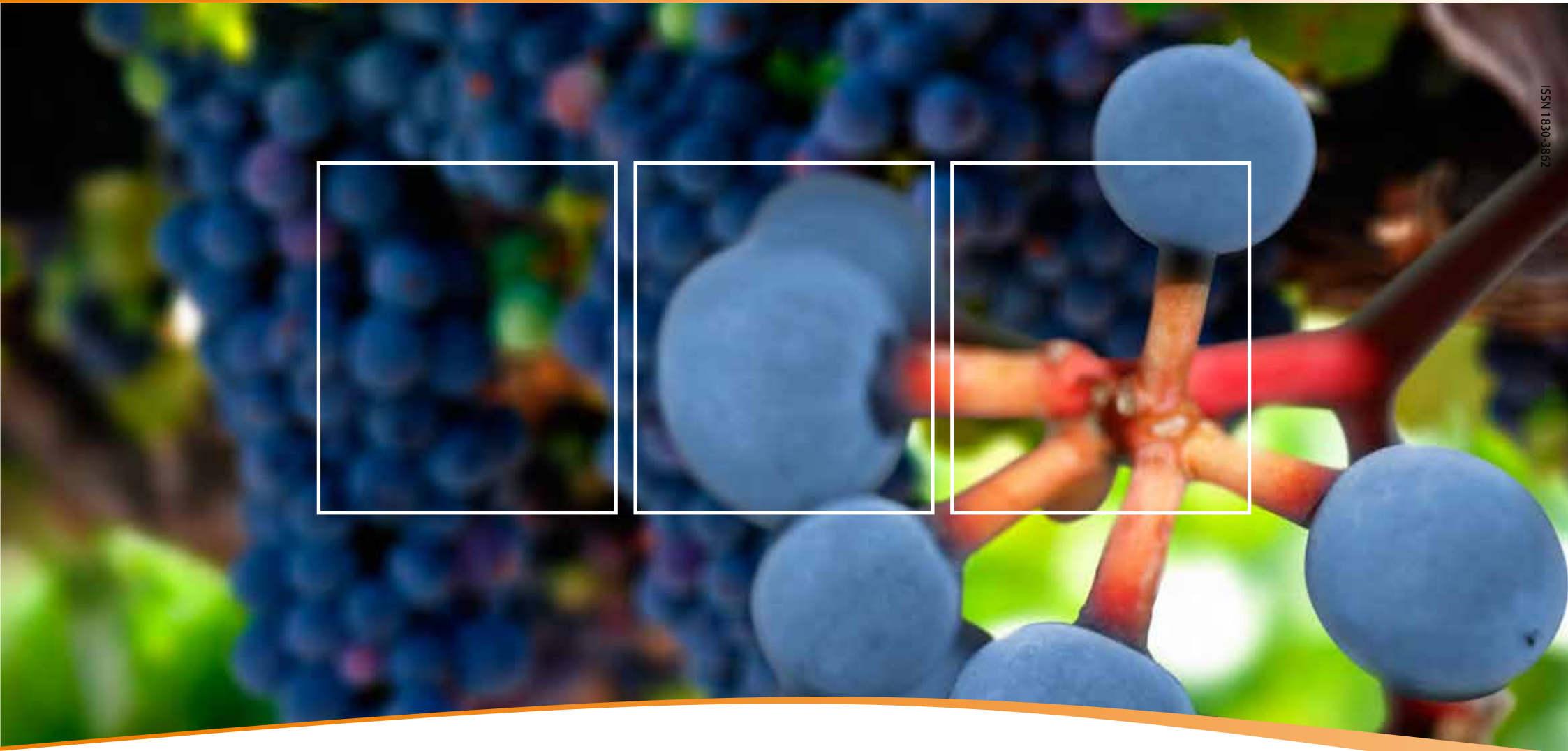


# Annual Report 2011

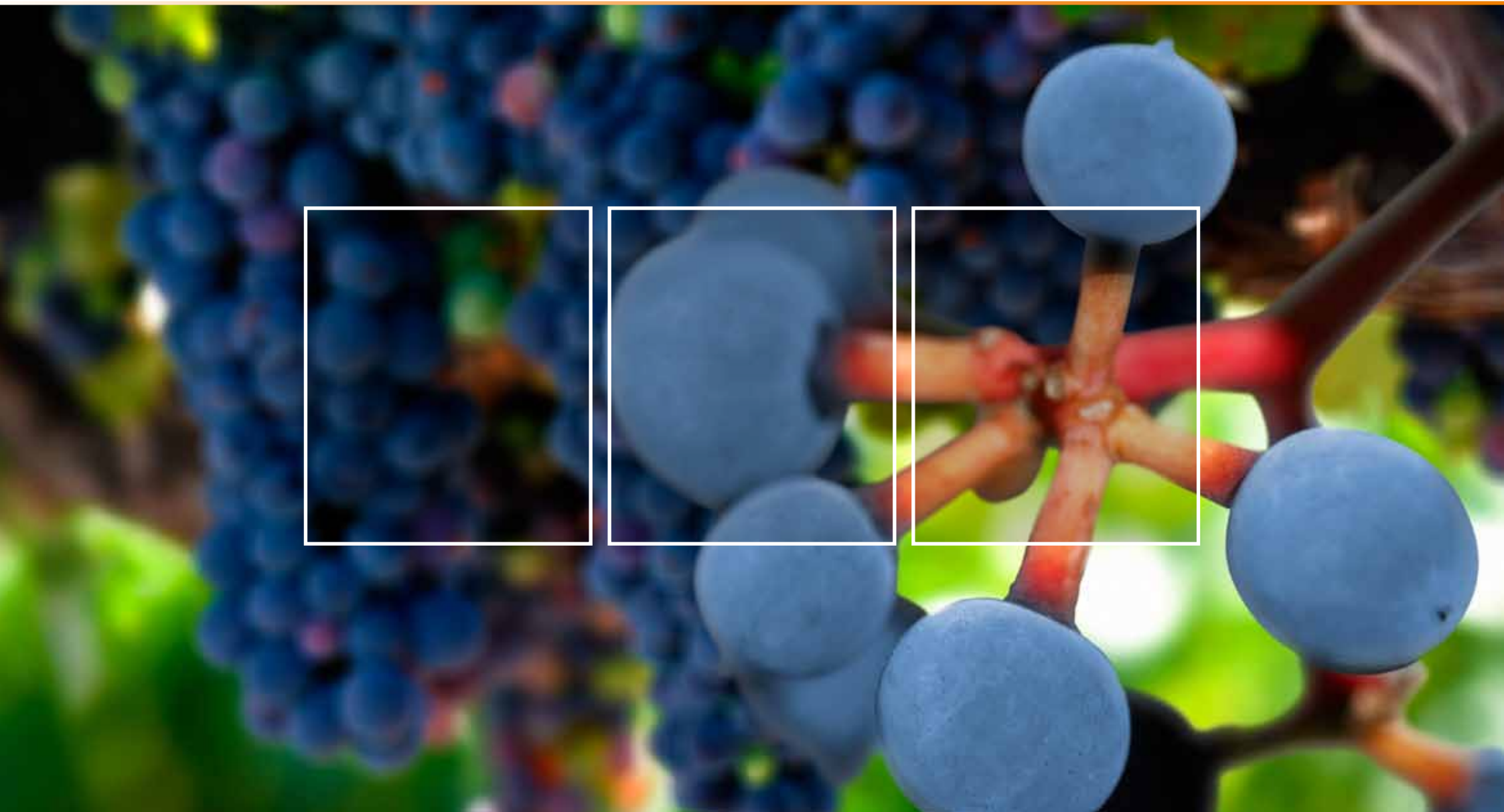


ISSN 1830-3862



Committed *since 2002* to ensuring that Europe's food is safe

# ANNUAL REPORT 2011



# CONTENTS

---

## **FOREWORDS**

Foreword by Jo Leinen	2
Foreword by John Dalli	3
Message from Catherine Geslain-Lanéelle	4

## **I. INTRODUCTION**

6

## **II. KEY ACHIEVEMENTS IN 2011**

10

1. Scientific opinions and advice	11
2. Evaluation of regulated products	15
3. Data collection	19
4. Crisis and emerging risks	24
5. Independence	27
6. Communications and dialogue	29
7. Governance and support	33

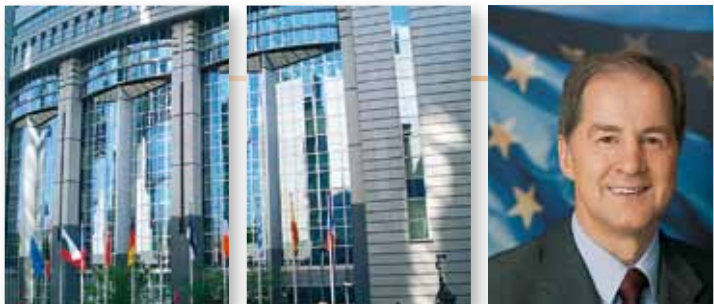
## **III. OUTLOOK**

36

## **IV. ANNEXES**

40

Annex I	Organisational structure on 01/06/2012	40
Annex II	Acronyms	42
Annex III	EFSA's scientific outputs and supporting publications 2011	44
Annex IV	Independence statistics 2011	46
Annex V	Financial report	48



## FOREWORD by Jo Leinen

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

The year 2011 showed once again that the role and position of the European Food Safety Authority (EFSA) in the area of food and nutrition safety is crucial. The work, research and risk assessment provided by EFSA, is the scientific basis for EU legislation that secures high standards and the quality of products within the food chain for all EU citizens.

I have witnessed lively debates in the European Parliament's Committee on the Environment, Public Health and Food Safety (ENVI) about the outcome of the work undertaken by EFSA scientists. Cooperation between the scientific world and the citizens' representatives allows for increased public awareness of EFSA's work. The issue of the *E. coli* epidemic, regulating chemicals and pesticides in foods, the placing on the market of foods derived from cloned animals, the discussion on food intended for infants or special purposes or the growing threat from non-communicable

diseases are just an illustration of the variety of topics which were debated or voted upon within the ENVI Committee in 2011.

Since its foundation in 2002, EFSA has developed into an important EU Agency with more than 400 staff members and 1,500 external experts cooperating in a network of more than 300 scientific institutions. Hundreds of scientific outputs are produced every year. EFSA is currently receiving around 800 applications a year for regulated products, in fields as varied as nutrition, food additives, nutrient sources, food contact materials, enzymes, flavourings, feed additives, genetically modified organisms and pesticides.

EFSA plays a significant role in the EU in not only controlling food and nutrition safety but also by being the watchdog for animal health as well as for plant protection and plant health. Assessment and communication on all risks

associated with the food chain is EFSA's vision for the globally recognised reference body for risk assessment in those fields. A vision that is resulting in highly protected and well informed consumers.

Europe faces new challenges related to global warming, overconsumption of natural resources and sustainability. Along the entire food chain, agriculture and food production are part of these problems. New technologies will be developed as we search for ways to cope with these challenges e.g. by improving crop yields or by making changes to the production of animal feed. In this area we also need to ensure that safety and health standards are duly taken into account. ■

*Jo Leinen  
Chair of the EP Committee on the Environment, Public Health  
and Food Safety (August 2009-January 2012)*

# FOREWORD by John Dalli

EU COMMISSIONER FOR HEALTH AND CONSUMER POLICY



■ The creation of EFSA in 2002 resulted in a significant increase in the EU's resources devoted to food safety. I am glad to be able to acknowledge that these increased resources have paid handsome dividends in underpinning food safety in the EU. However, we must be conscious that past success is no guarantee for the future and we need to maintain vigilance to assure our considerable level of food safety for the future. I am also a strong believer that our agencies need to better demonstrate their scientific excellence in the conduct of their core tasks, and the further reinforcement of the policy guarding against conflict of interests is key.

I would like to refer to some of the highlights of 2011 in the food safety area to which the input of EFSA was crucial. The outbreaks of *E. coli* (STEC) in Germany and France are a reminder of the devastation that can result from food-borne illnesses. EFSA's involvement was critical in identifying the source of the contamination and bringing

an early resolution to the outbreak. Let me also point out EFSA's significant contribution to the EU's progressive annual decrease in the numbers of human *Salmonella* cases, which is indicative that we can make further progress in this area.

Dietary exposure to unintended chemicals in food is another area of risk for consumers and is a further example of where EFSA has an important role. The Authority's involvement is vital in evaluating the risks and providing feedback through analysing the monitoring results from the EU coordinated food control systems. In addition to the work on occurrence of chemicals in food, EFSA's cooperation with Member States has been invaluable in preparing the Comprehensive European Food Consumption database. These data are imperative for the EU's work in the increasingly important area of nutrition.

The European Commission looks forward to a continued cooperation with the Authority in

order to serve European citizens by ensuring that our food supply maintains and even improves its high standards in the future. ■

*John Dalli*  
EU Commissioner for Health and Consumer Policy



## MESSAGE from Catherine Geslain-Lanéelle

EFSA EXECUTIVE DIRECTOR

In the field of public health, 2011 will be remembered as the year in which an outbreak of Shiga toxin producing *E. coli* O104:H4 (STEC) had tragic consequences for consumers in Germany and France. The outbreak claimed the lives of 50 citizens and left many hundreds of others in permanent ill health. This was the first occasion on which the gravity of the situation required us to work alongside our counterparts in the national agencies and provide hands-on technical assistance. We were very pleased to contribute to the resolution of the crisis and help identify the likely source of the outbreak. The tragic events reminded us of the devastation that foodborne diseases can cause and the importance of cooperation in combating and bringing a quick resolution to outbreaks.

The evaluation of regulated products and health claims continued to be a prominent feature of EFSA's work programme in 2011; in particular, the completion of the evaluation of the final series of general function health claims represents a significant achievement for the organisation. Our efforts ensure that consumers are not misled and provide clarity to industry on the standards of evidence required to support claims. We continue to enhance the support we provide to applicants: in late 2011 an Applications Desk unit was formed which will provide support for stakeholders and centralise the management of applications within EFSA. One of its first tasks was to launch an online helpdesk which has already responded to a significant number of queries.

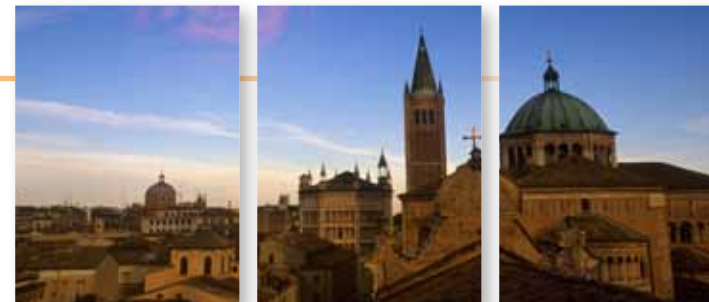
EFSA's Management Board adopted the Science Strategy 2012-2016 which lays out the vision of how EFSA will continue to support the European food safety system over the next five years. It also adopted EFSA's Policy on Independence and Scientific Decision-Making Processes which consolidates and strengthens all the measures EFSA has put in place to ensure the impartiality of its scientific advice. Both were built through a process of extensive consultation which is reflected in the final documents. The Implementing Rules of the Policy have recently been published; they continue to strengthen the procedures in place for screening and managing interests declared by all those involved in EFSA's activities.

---

EFSA continued to develop its working practices and organisational structure in 2011 guided by the outcomes of the efficiency review programme that was initiated in 2010. This culminated in May with the launch of a new organisational chart that reflects the future challenges and demands on the Authority. From an organisational performance perspective, EFSA continued to make good use of the resources at its disposal, delivering 658 scientific outputs, with an end-of-year budget commitment approaching 99%. Focus increased on the core scientific tasks and deliverables, with savings of €1.98 m implemented in areas such as translation, publications and meeting organisation.

I would like to take this opportunity to thank EFSA's staff, scientific experts, partners and stakeholders for delivering our ambitious work programme in 2011. ■

*Catherine Geslain-Lanéelle*  
EFSA Executive Director



# I. INTRODUCTION





### Committed to scientific excellence

The year 2011 was a watershed for EFSA. As the Authority approached its 10<sup>th</sup> anniversary, it took a number of decisions and implemented measures that reflected its growth from a fledgling EU agency in 2002 to a mature lead actor on the European food safety stage by 2011. A commitment to its core activity of thorough science-based risk assessment of food and feed remained at the heart of all its work and EFSA is now globally recognised as a European reference point in this respect.

Since 2002 the advice provided by EFSA's scientific experts has played a central role in protecting European consumers against potential threats in the food chain. EFSA has put in place the necessary scientific infrastructure – in the form of its Scientific Committee, Scientific Panels and supporting scientific Units – to enable it to deliver opinions and advice in response to requests from national and EU-level risk managers.

In 2011, cooperation with EU Member States continued to be firmly embedded in the Authority's operations. EFSA's Advisory Forum was at the

heart of its collaborative approach to working with Member States and the network provided essential support in the area of information and data exchange and in advising EFSA on its work programme and priorities. The Forum has developed and strengthened over time and has an increasingly important role to play in helping EFSA to effectively implement its dual mandate in risk assessment and risk communications.

In 2011, EFSA took stock of the changing context in which it operates, particularly in relation to advances in science and technology, changes in the demands of EFSA's stakeholders and an evolving EU legislative framework.

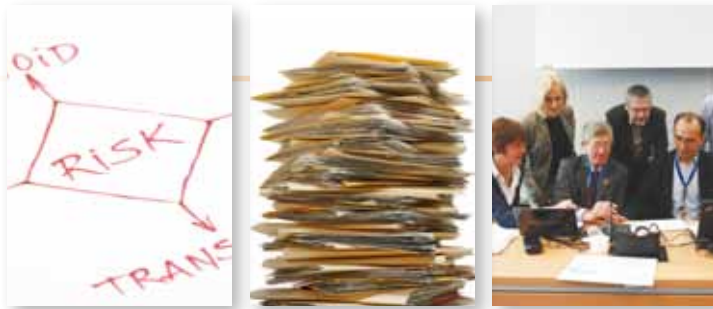
In recent times, the environment in which EFSA works has also been affected by broader issues such as climate change, the evolving demographics of the European population, and the growth and diversification of international trade, which has led to an increase in imports from emerging markets of primary goods, food products and ingredients. In addition, the EU has highlighted the importance of innovation as a means of increasing the competitiveness of Europe; the necessity of ensuring food security

both within Europe and internationally; the importance of environmental, social and economic sustainability; and addressing the needs of an ageing population.

### Changing priorities

All these factors are reflected in EFSA's scientific work programme, the emphasis of which has moved in recent years towards the safety assessment of regulated products submitted for market authorisation in the EU, the assessment of environmental risk and the post-market monitoring of authorised products. The resources committed to the evaluation of regulated products alone have more than doubled over the past four years and about two-thirds of EFSA's annual scientific outputs now relate to this area of the Authority's work.

EFSA's work on the evaluation of regulated substances is likely to continue to grow; a large number of new applications, for example for feed additives, food enzymes and flavourings, are expected in the coming years. In 2011, the Authority took a major step towards building the capacity necessary to meet this growing demand



by setting up an Applications Desk Unit to provide a streamlined service to applicants and other interested parties in this changing environment.

While the emphasis on regulated products has increased, the workload in the area of public health risks has also expanded with major mandates such as that on meat inspection methods, which covers microbiological and chemical food safety as well as animal health and welfare aspects for various animal species. This mandate will result in a number of opinions, the first of which was published in 2011.

As the volume of work has grown, so has the nature and complexity of the scientific advice requested of EFSA. Innovation in scientific knowledge has not only resulted in new food and feed products and production processes but has created a need for EFSA to develop and validate new risk assessment methods. The agri-food sector is increasingly innovative in the way it uses novel technologies, and the assessment of the risk they may carry is accordingly more complex. Furthermore, there is an increasing trend for risk assessments to include evaluation of issues that require a broadening of the scientific

discourse, such as environmental and health impacts or the efficacy of certain substances.

### A strategy for the future

EFSA spent much of 2011 considering how best to address the key challenges and demands facing the organisation over the coming years. Following a process of extensive consultation with its Scientific Committee, Advisory Forum and Management Board and with its various stakeholders, the Authority adopted a Science Strategy for 2012-2016 which focuses on four key objectives:

- To further develop EFSA's scientific excellence.
- To optimise the use of risk assessment capacity in the EU.
- To develop and harmonise methodologies and approaches to assessing risks associated with the food chain.
- To strengthen the scientific basis for risk assessment and risk monitoring.

This ambitious strategy will ensure that EFSA can continue to support the European food safety system in the coming years with up-to-date science-based risk assessments. The strategy will be regularly reviewed to take account of changes in the working environment. Progress in implementation will be assessed annually against EFSA's corporate key performance indicators, and any remedial actions will be included in the multi-annual work programme and annual management plans.

### Improving engagement with EFSA's stakeholders

Dialogue and consultation are central to the work of EFSA, and in 2011 the Authority took a number of measures aimed at developing its service to, and interaction with, its stakeholders. In May, a directorate – Scientific Evaluation of Regulated Products – was created to focus on regulated products, and later in the year the Applications Desk Unit was established to assist stakeholders who are applying to have regulated substances, products or claims approved in the EU. Another new directorate,



Scientific Strategy and Coordination, was given responsibility for maintaining and improving international stakeholder relations.

A working group of the Stakeholder Consultative Platform – one of the mechanisms by which EFSA engages interested parties in its work – drafted a paper laying out proposals for improving EFSA’s interaction with its stakeholders, which was adopted. These included: giving Platform members a greater opportunity to provide input about their work and strategic plans, thus allowing EFSA to benefit from shared information on stakeholder priorities as it draws up its own work plan; allowing Platform members to suggest subjects for technical meetings and to nominate organisations with relevant skills and expertise that could be invited to technical meetings; organising breakout meetings at Platform plenary meetings where topics of relevance to large groups of members could be discussed; and the creation of an extranet for the exchange of information among members.

Another suggestion was for increased openness in the risk assessment process. To this end, a pilot project is being initiated in early 2012 under which observers can express interest

in attending a limited number of meetings of the Scientific Committee and Panels.

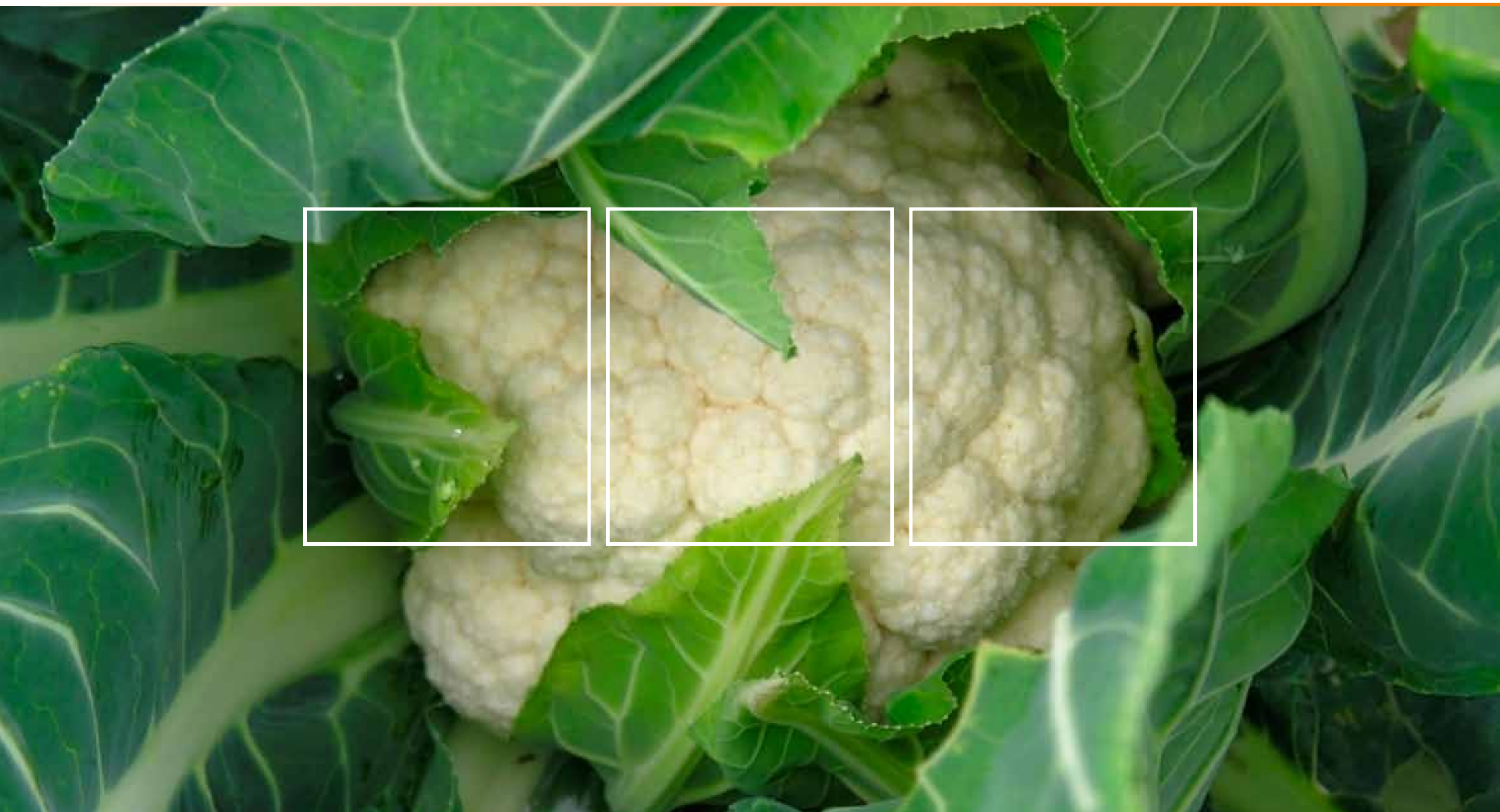
### **Safeguarding EFSA’s independence**

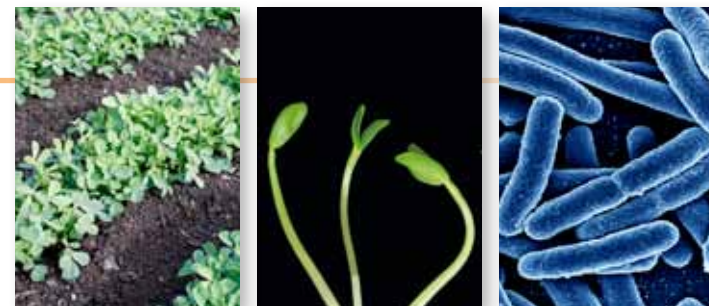
In October 2011, EFSA held a major stakeholder workshop in Brussels, attended by 150 delegates, to discuss a draft Policy on Independence and Scientific Decision-Making Processes. The Management Board subsequently adopted the policy, which incorporates and further strengthens all the steps that EFSA has taken since 2002 to ensure the implementation of its core values of independence, scientific excellence, transparency, and openness. The final policy incorporated comments received during the extensive public consultation, including those raised at the stakeholder workshop.

The policy identified areas for improvement such as: simplifying and clarifying the rules on identifying and handling conflicts of interest; increasing information on how decisions on conflicts of interest are reached by outlining admissible and incompatible interests in a transparent manner; strengthening procedures

concerning breach of trust; and amending the definition of conflict of interest to better reflect guidelines of the Organisation for Economic Co-operation and Development (OECD). These were subsequently addressed in the implementing rules for the policy, which were adopted at the beginning of 2012. (See also page 27.) ■

## II. KEY ACHIEVEMENTS IN 2011





## 1. PROVIDING THE SCIENCE TO PROTECT CONSUMERS

**From a public health point of view, 2011 was dominated by the outbreaks of Shiga toxin-producing *E. coli* 0104:H4 (STEC) in Germany and France which claimed more than 50 lives (see also page 24). In addition to its emergency response to the STEC outbreaks, EFSA continued with its planned work programme and adopted 658 scientific outputs in 2011.**

EFSA was at the core of the Europe-wide effort to deal with the STEC outbreaks of 2011. Working closely with the national authorities and with the European Centre for Disease Prevention and Control (ECDC), the Authority provided urgent scientific advice and technical assistance to support the German and French authorities. EFSA staff worked alongside colleagues in the German agencies to help trace the source of the outbreak, concluding that the outbreaks were probably caused by imported fenugreek seeds. During the crisis, EFSA released a number of urgent scientific outputs and made an important contribution to the “lessons learned” exercise organised by the European Commission. EFSA’s Panel on Biological Hazards subsequently produced an opinion, requested by the Commission, on the risks posed by STEC bacteria present in seeds and sprouted seeds.

### **Putting human health and animal health and welfare first**

EFSA’s Panel on Animal Health and Welfare (AHAW) delivered a major scientific opinion on

the welfare of animals during transport, which supplements the two reports delivered in 2002 and 2004. The Panel set out indicators that veterinary inspectors and transport workers can use in assessing the welfare of transported horses, pigs, sheep, goats, cattle, poultry and rabbits. The recommendations were based upon a thorough review of the most recent scientific literature and an assessment of the risks involved in all aspects of animal transport, particularly those related to the means of transport, transport practices and space requirements.

The Authority also worked on two important outputs in support of the EU Animal Welfare Strategy 2012-2015. Firstly, it developed pioneering guidelines laying out, for the first time, a standardised methodology for the risk assessment of animal welfare. The methodology is designed to be applicable to all animal species and all factors that affect animal welfare, including housing, transport, stunning and killing. The guidelines – which were due to be published in early 2012 and will be applied by the AHAW Panel to the future scientific advice it gives on risks associated with animal welfare – support EFSA’s commitment



to ensure that all its work on animal welfare is underpinned by a strong scientific approach.

The guidance was complemented by work on two opinions on the use of animal-based measures to assess the welfare of dairy cows and pigs. The use of animal-based measures to assess animal welfare is relatively new. Legislation on the protection of animals usually focuses on the assessment of factors that can have an impact on welfare rather than on the animal's response to these factors. Such factors may include the resources available to the animal in its environment, for example space or bedding material, or the practices used to manage the animal on the farm, such as how and when the farmer feeds the animal or the procedures in place for weaning. The opinions, which were also due to be published in early 2012, are the first two in a series that will eventually cover all farm species.

In 2011, EFSA also published the first results of its work on a major mandate from the EC to provide the scientific basis for the modernisation

of meat inspection in the EU. To fulfil this complex mandate, EFSA is drawing on its expertise in a wide range of fields within its scientific remit: animal health and welfare, chemical contaminants in the food chain, biological health hazards including zoonoses (animal diseases transmissible to humans), risk assessment methodologies and data collection. Specifically, EFSA must identify and rank public health hazards in meat and may recommend possible improvements or alternative methods for inspection of meat at the EU level, including revising current methods that may not be adequate in detecting risks or which are disproportionate to the risk involved. The first opinion, covering swine meat, will be followed by advice covering inspection of meat from poultry, cattle, sheep and goats and game.

#### **Noteworthy opinions and advice**

EFSA issued important scientific advice in 2011 related to norovirus in oysters. Often known as

the “winter vomiting bug”, norovirus is a major cause of acute gastroenteritis in Europe causing diarrhoea and vomiting. EFSA's Panel on Biological Hazards (BIOHAZ) evaluated detection methods and control options for norovirus in oysters and concluded that the most effective way to further reduce norovirus in oysters would be to focus on preventing initial contamination rather than attempting to remove the virus from contaminated foods. The Panel also recommended that risk managers consider establishing an acceptable limit for norovirus in oysters intended for harvesting or placing on the market in the EU.

The Authority carried out other important work in the area of contaminants in food and feed. EFSA's Panel on Contaminants in the Food Chain (CONTAM) delivered a series of opinions on: brominated flame retardants, man-made chemicals used in industrial and consumer products that persist in the environment; alkaloids, naturally occurring chemical contaminants produced by plants; and



mycotoxins, a type of fungal contaminant mainly associated with cereal crops.

### Working towards a common understanding in scientific risk assessment

EFSA devotes significant amounts of resources and expertise to providing guidance in areas where none is currently available and to developing harmonised approaches to risk assessment. In 2011, the Authority's Scientific Committee issued advice on subjects as diverse as nanoscience, repeated-dose 90-day oral toxicity studies in rodents and genotoxicity testing strategies.

The guidance on nanoscience was the first of its kind to give practical advice on the assessment of potential risks arising from applications of nanotechnologies in the food and feed chain. Nanotechnologies refer to the use of food ingredients at a molecular level. Nanotechnology products could have a substantial

impact on the food and feed sector in the future, potentially offering benefits for industry and the consumer, although possible risks need to be considered. Companies and institutes worldwide are researching and developing applications in fields such as the treatment of the mechanical and sensorial properties of food – for instance to achieve changed taste or texture – and modified nutritional value. The guidance covered risk assessments for food and feed applications including food additives, enzymes, flavourings, food contact materials, novel foods, feed additives and pesticides.

The general guidance for carrying out 90-day feeding studies on whole food and feed in rodents was the first guidance on the subject to be published by EFSA. It will support applicants in carrying out feeding trials related to applications for novel foods and food and feed derived from genetically modified organisms (GMOs). The objective of a 90-day feeding trial in animals is to detect any possible toxicological effects

of the test diet compared to the control diet. EFSA's guidance provides specific advice to applicants on how to design, conduct, analyse, report and interpret 90-day oral toxicity studies, such as those carried out to assess the safety of novel foods or food and feed derived from genetically modified organisms. It also includes directions for the preparation of appropriate test diets, statistical analysis and for further harmonised reporting of the results.

The opinion of the Scientific Committee on genotoxicity testing strategies for substances used in the food and feed chain will support the identification and safety assessment of substances that cause harm to the genetic material (DNA) of cells and which may contribute to the development of chronic afflictions such as cancer and heritable diseases. In the opinion, EFSA's experts reviewed the latest scientific knowledge on genotoxicity testing at European and international level. A wide range of aspects was taken into consideration, including: current



EFSA Scientific Committee

experience on combining tests which have different levels of sensitivity and predictivity; internationally accepted guidelines or protocols for tests; and guidance for the consideration of use of *in vivo* testing taking into account the need to avoid unnecessary animal testing.

EFSA also launched a public consultation on an important opinion evaluating the relevance and reliability of the Threshold of Toxicological Concern (TTC) approach for assessing human health risks from low levels of exposure to substances present in food and feed. The draft opinion deals with the relevance and reliability of the science underpinning TTC and the possible application of the approach in EFSA's scientific work not related to the evaluation of regulated products (where there is a legislative requirement for the submission of toxicological data). It concludes that the approach is a useful screening tool for substances with a known chemical structure, when limited or no relevant toxicity data exist but exposure is known to be low. EFSA's work on TTC will be pursued in 2012 in cooperation with other European and international organisations.

### Experts and the pursuit of scientific excellence

The key outcome of the efficiency review programme which started in 2010 was the reorganisation in May 2011 of some of EFSA's units and directorates with the aim of better addressing the challenges and demands on the organisation that lay ahead. The main changes included the creation of three scientific directorates – Science Strategy & Coordination Directorate, Scientific Evaluation of Regulated Products, and Risk Assessment and Scientific Assistance – the merger of some units with similar remits (such as the former ANS and CEF units, which had crossover in the area of food additives and in the area of pesticides, PPR and PRAPeR), the refocusing of human resources with an emphasis on developing the skills of staff and experts and the establishment of new units in business-critical areas such as applications.

EFSA's units exist to support the work of its external scientific experts, who are organised into panels that reflect the different areas of the Authority's

work. The experts deliver their advice in the form of scientific opinions and reports which are published in the *EFSA Journal*. Membership of the panels is renewed every three years, and in 2011 EFSA launched a call for experts to join its Scientific Committee and eight of its panels. New members were sought for the panels covering plant health and plant protection; GMOs; feedstuffs; animal health and welfare; contaminants in the food chain; pesticides; biological hazards; and dietetic products, allergies, novel foods and nutrition. Applicants had to demonstrate experience in carrying out scientific risk assessment and have proven scientific excellence in one, or preferably several, of the fields in EFSA's remit.

The current round of renewals will be the first to be carried out under EFSA's new Policy on Independence and Scientific Decision-Making Processes (see page 27). ■

## 2. EVALUATION OF PRODUCTS, SUBSTANCES AND CLAIMS SUBJECT TO AUTHORISATION

Of the 658 scientific outputs EFSA adopted in 2011, 58% were related to regulated products, an indicator of the high importance of this activity to EFSA. The completion of the evaluation of the final series of “general function” health claims represents a significant achievement for the organisation. It brings the total number of claims assessed by EFSA's Panel on Dietetic Products, Nutrition and Allergies (NDA) since 2008 to 2,758. Regarding flavourings, the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) adopted 55 opinions on applications, 33 of which related to new flavouring substances. Other figures to highlight from 2011 regarding regulated products include: 67 opinions by the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP) on feed additives; and 9 opinions by the Panel on Genetically Modified Organisms (GMO) on GMO applications.

The year 2011 was also significant for EFSA in that it saw the establishment of the Applications Desk Unit. This Unit will provide greater support and guidance for applicants seeking the safety assessment of regulated products submitted for market authorisation in the EU.



### Claims: a landmark year

EFSA's nutrition experts reached a major milestone in 2011 by completing the evaluation of the final series of general function health claims. These are claims made for products that relate to growth, development and the functions of the body; psychological and behavioural functions; and slimming and weight control. The publication of the final series of 35 evaluations in 2011 represented the culmination of more than three years' work by EFSA's experts and staff. They will provide the scientific basis for the authorised list of claims for food in the EU which is in the process of being established by the European Commission and Member States.

The outcomes of evaluations were favourable when there was sufficient evidence to support the claims. This was the case for about one in five claims reviewed by the NDA Panel which related to areas such as: vitamins and minerals; specific dietary fibres related to blood glucose control, blood cholesterol, or weight management;



live yoghurt cultures and lactose digestion; antioxidant effects of polyphenols in olive oil; walnuts and improved function of blood vessels; fatty acids and function of the heart; carbohydrate-electrolyte drinks/creatine and sports performance.

Experts issued unfavourable opinions in cases where the information provided did not allow a relationship between the food and the claimed effect to be established. Reasons included: lack of information to identify the substance for which the claim was being made; lack of evidence that the claimed effect is indeed beneficial to the maintenance or improvement of the functions of the body; lack of precision regarding the health claim being made; lack of human studies with reliable measures of the claimed health benefit; claims referring to food categories, such as “fruits and vegetables” and “dairy products”, which were considered to be too broad to be linked to specific effects.

EFSA adopted a phased approach because of the large number of claims received and the

requirement to publish opinions soon after adoption to ensure transparency. EFSA also combined similar claims – for example, by substance and/or benefit – to facilitate the risk assessment process and ensure a consistent approach.

In addition, EFSA continued to produce guidance documents to support applicants with their submissions. In 2011 the NDA Panel adopted guidance on the scientific requirements for claims related to gut and immune function, and for those related to antioxidants, oxidative damage and cardiovascular health. The Authority also carried out public consultations on draft guidance for claims related to bone joints and oral health; weight management; and neurological and psychological function.

### Applications Desk

EFSA’s Applications Desk Unit was launched in November 2011 to support applicants from industry seeking safety assessment of regulated

products submitted for market authorisation and to increase the efficiency of the application process. The unit will serve a dual purpose: as a “front office” and support desk for applicants, Member States and other stakeholders; and as a “back office” within EFSA for centralising and processing the initial administrative steps of all applications (including reception, registration and verifying completeness, from an administrative point of view, of the information in the submitted application). This will be a critical aspect of the new unit’s work given the complex legislative framework within which EFSA operates: there are 34 different legislative frameworks and almost 40 workflows for applications assessed by EFSA.

The Communications Directorate played a key role in this initiative by setting up an online helpdesk on EFSA’s website offering comprehensive advice and guidance on applications. This section also contains answers to frequently asked questions related to the different categories of regulated products as well as links to guidance documents and application forms. This will be of critical assistance in the



new unit's work given the complex legislative framework within which EFSA operates.

### EFSA's advice in areas of public concern

In May, EFSA was asked by the European Commission to bring forward to 2012 the full re-evaluation of the safety of the sweetener aspartame (E 951). Previously planned for completion by 2020 along with all sweeteners, the risk assessment of aspartame is part of the systematic re-evaluation of all food additives authorised in the EU prior to 20 January 2009. EFSA accepted this mandate and launched a public call for scientific data as well as a thorough literature review which gave it access to a large number of both published and unpublished scientific studies and datasets. Reaffirming its commitment to openness and transparency, the Authority published the full list of these scientific studies and also made publicly available previously unpublished scientific data, including the 112 original documents on aspartame which were submitted to support the request

for authorisation of aspartame in Europe in the early 1980s. The Panel on Food Additives and Nutrient Sources (ANS) is due to start its risk assessment of aspartame in early 2012.

EFSA released a statement on the safety of bisphenol A (BPA) following a report by the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) on the health effects of the chemical. BPA is used in plastic packaging such as re-usable drinking bottles, infant feeding bottles and storage containers. The Authority's Panel on Food Contact Materials, Enzymes and Flavourings (CEF) considered that the ANSES report – which was limited to hazard identification – did not change the views expressed by the panel in its 2010 opinion on the safety of BPA. In late 2011, EFSA established a working group of experts to evaluate new scientific studies and data on BPA as they become available. EFSA will review all the available data and scientific studies on dietary exposure published since its 2006 opinion on BPA and also take into consideration the contribution of non-dietary sources to overall exposure to BPA. The Authority will also liaise with scientific

experts in the Member States and in the United States on risk assessment reports and large-scale studies that are currently in progress. The CEF Panel will reconsider its 2010 opinion following further evaluation of new studies and after new data from low-dose studies being conducted in the United States become available in 2012.

### Environmental monitoring

Environmental issues have become a priority for EFSA in recent years and in 2011 the Authority took its work in this area to the next level. The previous year the Authority had published two landmark documents: an updated version of its guidance on the environmental risk assessment (ERA) of GM plants; and, from the Panel on Plant Protection Products and their Residues, an opinion on the ERA of pesticides. In 2011, EFSA built on its work in the area of GM plants with a guidance document on post-market environmental monitoring (PMEM). PMEM is a key feature of the legislative framework on GM plants and a crucial part of the cycle of measures – alongside pre-market environmental



risk assessment and risk management – in place to detect and limit possible adverse effects, including those that may occur over a long period of time.

Under EU legislation, applications for the cultivation of GM plants must contain a detailed PMEM plan demonstrating how the plant will be monitored for possible adverse effects on human health and the environment. Through the updated guidance on the PMEM of GM plants, the Authority will further strengthen the requirements placed upon applicants to carry out environmental monitoring of GM plants that have been authorised for the EU market. The guidance also made recommendations for risk managers to improve the way PMEM data are collected and reported in the EU. As with all EFSA guidance documents on GMOs, the Authority engaged in consultation at different stages during its development with Member States and a broad range of stakeholders.

The updated guidance was discussed at a meeting with environmental and consumer

non-governmental organisations, which was held at EFSA's headquarters in Parma. EFSA's Scientific Network for Risk Assessment of GMOs, which consists of nationally-appointed EU Member State organisations, also made a valuable contribution during a dedicated session at its second meeting in June.

In October, the Authority published a scientific opinion on the PMEM report for the cultivation of maize MON810, its first opinion on a PMEM report. The report was submitted by the producer and assessed by EFSA's GMO Panel. The panel concluded that maize MON810 cultivation for the 2009 growing season had no adverse effects on human and animal health or the environment, in line with the findings of the previous EFSA risk assessment of MON810.

Another important aspect of EFSA's work in the area of GMOs (although not directly linked to environmental monitoring) was its guidance on the risk assessment of food and feed derived from

genetically modified animals, including aspects of animal health and welfare. The document, a joint effort by the GMO and AHAW Panels, was launched for public consultation in the summer. In addition to providing guidelines for the risk assessment methodology for food and feed derived from GM animals, it also outlines the approach for the comparative assessment of health and welfare aspects of GM animals should such applications be submitted for market authorisation in the EU in the future. In 2012, EFSA will provide guidance on the environmental risk assessment of GM animals. ■

### 3. DATA COLLECTION, SCIENTIFIC COOPERATION AND NETWORKING

As EFSA's workload has continued to increase, particularly in the area of regulated products and claims submitted for authorisation in the EU, so has the importance of its cooperation with Member States. This collaboration takes place at all levels – from national competent authorities to scientific organisations and individual experts – and provides EFSA with valuable data, research and expertise that help the Authority to maintain and strengthen a rigorous system of risk assessment. Cooperation is at the heart of EFSA's Science Strategy 2012-2016 and its importance was clearly highlighted in 2011 during the STEC outbreaks in Germany and France (see also page 24).

#### Building risk assessment capacity

One of the key objectives of the Science Strategy 2012-2016 is to optimise the use of European risk assessment capacity across the EU. Central to this endeavour is: EFSA's Advisory Forum of national food safety representatives; its networks for exchanging information and sharing expertise across the EU, which support the Authority's scientific units; and its network of Focal Points, which act as interfaces between EFSA and the Member States. All of these bodies made significant contributions to EFSA's work in 2011.

At its four meetings in 2011, the Advisory Forum addressed strategic topics and EFSA's work in different scientific areas. As well as setting priorities for the Focal Points and agreeing on further development of the Information Exchange Platform (IEP), the focus was on development of the Science Strategy. In March, the Forum met with the EFSA Management Board in a joint meeting addressing cooperation in risk



#### Information Exchange Platform (IEP)

##### About the IEP

The IEP is an online site that promotes scientific cooperation and networking in Europe by enabling countries to share information on risk assessment activities in food and feed safety.

assessment and risk communication. The Focal Points played an essential role in sharing data and information between Member States and EFSA, for example through the IEP or by disseminating information at the three Focal Point meetings, and throughout the year by email. The IEP was actively promoted, with all EFSA Panels and Networks being updated on how to use the tool.

Another important tool for cooperation is the Article 36 list of organisations, which assist EFSA in its tasks, for example in the area of data collection or in preparatory work for scientific opinions. This now comprises 416 designated organisations. In 2011, EFSA committed €7.1 million to scientific cooperation resulting in the successful launch of five grant and 75 procurement calls. The Expert Database further grew with 3,000 scientific experts included by the end of the year. A total of 1,700 scientific experts, with whom EFSA has collaborated in recent years, were invited to participate in the second Scientific Expert Satisfactory Survey of EFSA, the outcome of which



helps EFSA to better understand the needs of its experts. The results of the survey were positive: 91% of the respondents were either satisfied or very satisfied with the overall support provided by EFSA. Specifically, 93% were satisfied or very satisfied with the level of administrative support, 89% were satisfied or very satisfied with the scientific support provided, and 85% were satisfied or very satisfied with the level of communication support. On the basis of the responses, EFSA is planning a number of improvements to the service it provides to its experts.

A report published in 2011, *Scientific Cooperation between EFSA and Member States: Taking Stock and Looking Ahead*, summarised the Authority's cooperation activities and examined how they could be further developed. It concluded that the development of links with EU Member States has brought mutual benefits, such as: the ability to deal with an increasing workload; greater efficiency; a reduction of duplication of efforts; harmonisation of risk assessment requirements;

and standardised guidance for risk assessment. The report also outlined medium-term planning regarding risk assessment activities for EFSA and EU Member States. This is important to ensure coherence between European risk assessors and to avoid duplication of work.

There were a number of important developments in EFSA's relations with its stakeholders in 2011. In particular, the Stakeholder Consultative Platform adopted a paper on the engagement of stakeholders in EFSA's activities. The document was drafted by a working group chaired by EFSA and comprising nine stakeholder organisations. It reviewed the existing activities and tools for interaction between EFSA and its stakeholders, and looked at areas for improvement.

EFSA laid the groundwork for future cooperation activities by signing the new pre-accession programme contract for 2011-2013. EFSA's engagement focused on providing the Accessing, Candidate and Potential Candidate

countries with information on EU food safety via training seminars, study tours, conferences and participation of experts from the countries in EFSA meetings and networks as observers. A seminar took place in Ankara, Turkey, on Chemical Contaminants and Emerging Risks with 50 participants from eight beneficiary countries. In addition, study tours were organised to the Danish institutions on food safety (for 15 experts from the Potential Candidate countries) and to Croatia for five experts from Turkey. Experts from beneficiary countries continued to participate as observers in 18 EFSA networks meetings. EFSA also continued its activities in the context of the European Neighbourhood Policy (ENP) and helped to organise a seminar for 25 experts from eight of the Mediterranean ENP countries on animal health and welfare.

EFSA's Strategy for Cooperation and Networking and its Strategic Plan 2009-2013 both emphasise the importance of training, and in 2011 the Authority's Working Group on Training



Activities on Principles and Methods of Risk Assessment in Food Safety finalised technical specifications for training that have been used by the Commission in the development of its Better Training for Safer Food programme.

### How data collection helps protect consumers: zoonoses and antimicrobial resistance

As well as collecting data for individual risk assessments, EFSA collects data at EU level to establish, for example, how often foods are contaminated with bacteria or chemicals and at what levels. This information, combined with reliable information on food consumption in the Member States, makes it possible for risk assessors to assess consumer exposure to a certain hazard at both EU and national level. The assessments also allow scientists to make recommendations for the prevention, reduction, and monitoring of these hazards in the food chain.

Every year, EFSA examines data submitted by Member States on zoonoses, zoonotic agents, food-borne outbreaks and antimicrobial resistance and prepares Community Summary Reports in close collaboration with the European Centre for Disease Prevention and Control (ECDC). The *Summary Report on Zoonoses and Food-borne Outbreaks* published in 2011 revealed that cases of *Salmonella* in humans fell by 17% between 2008 and 2009. Taken together with figures from previous reports, human *Salmonella* cases have decreased by almost one-half over five years, a clear benefit of joint EU actions in this area. The reduction targets set by the European Commission – based on analysis of data carried out by EFSA – to reduce the spread of *Salmonella* in poultry, eggs and chicken meat are likely to be the main reasons for the reduction in the number of human cases. In 2009, 17 Member States met their *Salmonella* reduction targets for laying hens and the proportion of EU laying hen flocks infected with the targeted *Salmonella* types continued to fall (3.2% compared to 3.5% in 2008).

The EU *Summary Report on Antimicrobial Resistance*, the first to be prepared in collaboration with ECDC, revealed the presence of resistant bacteria in humans, food and animals. The report, based on 2009 data, shows that a high proportion of *Campylobacter* in humans is resistant to ciprofloxacin, which belongs to the fluoroquinolones group and is defined by the World Health Organization (WHO) as critically important for the treatment of serious human infections. In animals, a high or moderate proportion of *Salmonella* (in chickens), *Campylobacter* and non-disease-causing *E. coli* were also found to be resistant to this antibiotic. The report makes an important contribution to work being carried out at European level and the findings will be considered by the European Commission as it develops its proposals for fighting antimicrobial resistance.

EFSA also published its annual report on veterinary medicinal product residues and other substances in live animals and animal products.



A total of 736,806 samples were reported by the 27 Member States in 2010, including 418,081 targeted samples. Of the targeted samples, 1,373 or 0.33% were non-compliant, compared to 0.32% in 2009. In 2011, EFSA also produced a report based on data submitted by Member States on the presence of perfluoroalkylated substances (PFAS) in food. PFAS are a large group of compounds which are generally recognised as being persistent in the environment and associated with a large number of health effects. They are found in a variety of products, such as cleaning agents, paper, packaging and furniture, to name only a few. In analysing data provided by Member States, EFSA found that the highest contamination both in terms of frequency and mean level was found in meat and edible offal of game animals, fish and seafood, whereas meat and edible offal of farmed animals was less affected.

#### **Food consumption: new data on the table**

EFSA reached a number of significant milestones in 2011 in its development of data collections

related to dietary exposure assessments and food consumption. The Authority published its Comprehensive Food Consumption Database, a new source of information on food consumption in the European Union, containing detailed data from a total of 32 dietary surveys carried out in 22 Member States. The new database will play a key role in the evaluation of the risks related to possible hazards in food and will allow more precise estimates of consumers' exposure to such hazards, a fundamental step in EFSA's risk assessment work.

The database, which has been developed in close cooperation with EU Member States, will also be relevant in future for other fields of EFSA's work, such as the assessment of nutrient intakes of the EU population. The overview includes guidance on how summary statistics in the database can be used by food safety and public health experts at national and EU level.

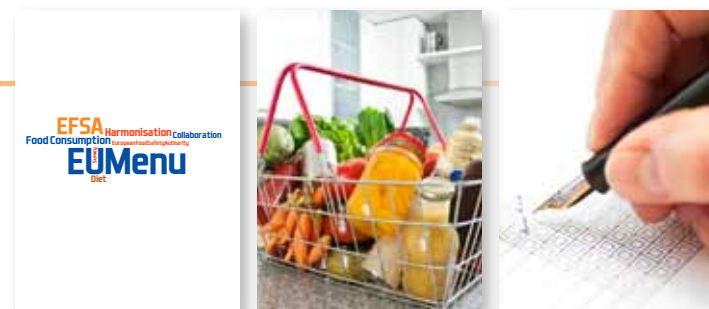
The database was put to practical use in 2011 for two EFSA reports on the food-related contaminants acrylamide and furan. In addition to

providing analysis on data about the occurrence of acrylamide and furan in food, both reports included an exposure assessment to estimate intake of these chemicals for different age groups of European consumers. The exposure assessments also showed which foodstuffs were the major contributors to acrylamide and furan exposure in the diets of European consumers.

In parallel with the development of the food consumption database, the EU Menu project – which is intended to establish fully harmonised food consumption surveys across Europe – continued to progress with pilot studies carried out in France and Estonia for children, adolescents, adults and the elderly.

Although national dietary surveys are already conducted in many European countries, it is not currently possible to carry out EU-wide analysis or country-to-country comparisons on food consumption because of differences in how information is collected. The EU Menu, which is coordinated by EFSA in cooperation with all Member States, aims to provide standardised

## II. KEY ACHIEVEMENTS IN 2011



information on what people eat in all countries and regions across the EU. It will allow more efficient and accurate exposure assessment and support risk managers in their decision-making on food safety.

The work on food consumption was complemented by joint guidance published in 2011 by EFSA, the Food and Agriculture Organization of the United Nations (FAO) and WHO on harmonisation of the Total Diet Study (TDS) approach. The organisations concluded that, combined with other dietary surveillance and food consumption programmes, TDS is an effective tool for estimating population dietary exposure to both harmful chemicals (such as pesticide residues and contaminants) and beneficial chemicals (such as nutrients) across the overall diet. The guidance proposes general principles for harmonising TDS methods, which would provide comparable data.

A TDS consists of selecting and collecting foods representing the overall diet of a population, which are prepared as they are consumed and pooled into representative food groups before the levels of contaminants or nutrients

in the foods are analysed. Combined with food consumption data, the results allow scientists to calculate the amount of each chemical substance that is being consumed by a specific population as part of their typical diet. ■



## 4. ANTICIPATING RISKS AND RESPONDING TO CRISES

As well as providing scientific advice in response to non-urgent requests from third parties, EFSA has comprehensive measures in place governing how it should deal with requests for urgent advice and respond to food safety crises. In 2011, these procedures were tested to the full when the Commission asked the Authority for immediate scientific assistance in the face of two *E. coli* outbreaks that struck Germany and France.

### The 2011 STEC outbreaks

Between the beginning of May and the end of July 2011, there was an outbreak of Shiga-toxin producing *Escherichia coli* (STEC) in Germany. On 24 June 2011, the French authorities also reported an outbreak in the region of Bordeaux. Across the EU more than 3,100 cases of bloody diarrhoea and more than 850 of haemolytic uremic syndrome (HUS), a serious condition that can lead to kidney failure, were reported; there were 53 confirmed deaths. It was the biggest food-borne bacterial outbreak in Germany for 60 years. Initially the outbreak of *E. coli* O104:H4, a rare strain, was linked through epidemiological investigations to the consumption of fresh salad vegetables. Further investigations identified seed sprouts as the likeliest source.

Upon request from the Commission, EFSA liaised with German risk managers and assessors and the European Centre for Disease Prevention and Control (ECDC), issuing a joint statement with ECDC that provided information on STEC infection and transmission modes and advice on how to

avoid infection. The Authority sent senior scientific staff to Germany to provide assistance on data collection and epidemiological analysis, the first time EFSA has sent staff to a Member State to assist in resolving a crisis. The exchange of information between Member States was facilitated by EFSA through its Advisory Forum and network of Focal Points.

EFSA issued a number of important outputs during the crisis. At the beginning of June it published a fast-track risk assessment on the risks to public health from the consumption of raw vegetables and provided advice on options to mitigate the risks of food contamination and human infection. On the same day, EFSA published a technical report with ECDC on the prevalence and incidence of STEC in humans, food and animals. After the French outbreak was reported, EFSA jointly prepared with ECDC a rapid risk assessment of the two outbreaks which concluded that fenugreek sprouts were the most likely connection and, in response to an urgent request from the Commission, it set up a Task Force to trace back the implicated seeds through the EU supply and distribution chain.



The Task Force, which included specialists from Member States and the Commission and scientists from ECDC, the World Health Organization (WHO) and the Food and Agriculture Organization (FAO), delivered its report on 5 July, concluding that one lot of fenugreek seeds imported from Egypt and used to produce sprouts was the likely link between the two outbreaks.

After the crisis had subsided, the Commission asked EFSA to deliver a scientific opinion on the risks posed from seeds and sprouted seeds intended for human consumption, which was published in November. EFSA's Panel on Biological Hazards (BIOHAZ) concluded that pathogenic bacteria can contaminate seeds and grow during sprouting, and highlighted the importance of preventing initial contamination during production, storage and distribution of seeds. EFSA also attended a "lessons learnt" meeting in Brussels on 18 November which was attended by representatives from the Commission, ECDC and the relevant competent authorities in Germany, Sweden, France and Spain.

Ten EFSA units as well as individuals seconded from other units were involved in the Authority's response to the crisis.

### How it was made possible

Cooperation with Member States, particularly in the area of data collection, was of great importance to EFSA during the outbreak. This was made possible through the processes built up and experience gained from data collection in recent years in the area of zoonoses and on exposure to chemical contaminants and residues in food. The work of the Biological Monitoring (BIOMO) and Dietary and Chemical Monitoring (DCM) units in this area means that EFSA has both the tools and the experience to collect and analyse data from Member States. Furthermore, the Member States are accustomed to, and confident about, sharing information with EFSA.

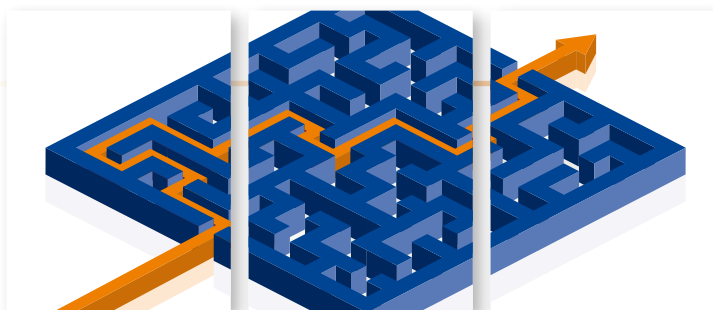
The data gathered through zoonoses monitoring enabled, in collaboration with ECDC, the rapid

compilation of an overview of STEC in humans, food and animals in the EU, so providing useful background information. EFSA and ECDC collaborated closely during the outbreak, supporting the European Commission and providing coherent advice to consumers on issues related to both food-safety and human health respectively.

In conclusion, EFSA's work throughout the crisis played an important role in supporting risk managers in the European Commission and in Germany and France, particularly in helping to identify the source of the outbreak. This was possible thanks to the long-standing cooperation that pre-dated the crisis.

### Staying one step ahead

The Authority was well placed to respond effectively to the STEC crisis as earlier in the year it had carried out, under the auspices of the Emerging Risks Unit, its seventh crisis simulation



exercise with the European Commission, ECDC, and members of its Advisory Forum and Focal Points. The exercise was designed specifically for those units involved in assessing biological risks as, until then, no urgent request concerning this type of hazard had been received by EFSA. The theme was data exchange with Member States, which proved to be critical for the trace-back operation EFSA was called upon to coordinate during the STEC outbreaks. The subsequent report, drawn up by an external contractor, concluded that all those who participated in the exercise had a good awareness of the EFSA procedures and understood their role and that of other units in EFSA's response.

The Emerging Risks Unit is responsible for supporting EFSA's mission, as specified in its Founding Regulation, to "undertake action to identify and characterise emerging risks" in the field of food and feed safety. In 2011, the unit set up a working group to evaluate and further develop a transparent and sustainable framework for identifying emerging risks.

The working group proposed a revised, simplified framework that comprises three main steps: preliminary identification of priority emerging issues; identification of appropriate data sources and data collection; and final evaluation and identification. It concluded that priority emerging issues should be identified through expert consultations and via exchange of information with qualified organisations (such as sister agencies and other competent organisations). In this respect, the role of the unit's two networks – the Emerging Risks Exchange Network and the Stakeholder Consultative Group on Emerging Risks – is expected to grow in importance. The working group also provided recommendations on how to improve the efficiency and transparency of the collection of information, the formalisation of outputs and follow-up actions.

In 2011, the Emerging Risks Unit started work on creating a chemical hazards database. This will make the data contained in EFSA's opinions on

chemical hazard risk assessment more readily accessible for any interested party. By consulting with other international organisations, the database has been aligned with related databases to ensure an easy exchange of information, internationally and across disciplines. ■

## 5. INDEPENDENCE

**EFSA's Founding Regulation stipulates that the Authority has to be a point of reference for risk assessment in the food chain by virtue of the scientific and technical quality of the outputs it issues, its independence, the information it disseminates, the transparency of its procedures and processes, and its diligence in performing its tasks. People working for, or on behalf of, EFSA are obliged to act independently in the public interest.**

Since its creation, EFSA has put in place a range of initiatives to safeguard its core values and build trust in its work. EFSA recognises that public trust is fundamental to the value of the scientific advice it produces. According to the Eurobarometer report on perceptions of food-related risk (2010), EU citizens have a high level of trust in scientists (73%) and national and European food safety agencies (64%) as sources of information on food risks. Nonetheless, less than half of EU citizens (47%) think that scientific advice on food-related risks is independent of commercial or political interests. In fact, as shown in another Eurobarometer report, on science and technology (2010), public concerns on the objectivity of scientific advice are widespread: on controversial scientific issues, 58% of Europeans have little confidence in scientists and scientific research because of the work they do with industry. Neither are regulators operating in the domains of life sciences and food safety immune from criticism, most frequently in relation to GMOs or chemicals used in foods such as food additives.



Independence, objectivity and high standards of professional conduct by all those involved in the activities of EFSA are crucial and so is the possibility that interested parties and the public at large are able to scrutinise what we do. EFSA strives to be transparent at all times, seeking to build better understanding of its work and opening up the organisation to public scrutiny.

EFSA's approach to safeguarding independence and integrity in its work can be seen in the related actions and decisions it took in 2011. In total, the Authority screened more than 8,000 Declarations of Interest from external experts and EFSA staff and scrutinised more than 40,000 specific declarations linked to agenda items. By doing so it prevented 356 potential conflicts of interest. EFSA also initiated two "breach of trust" procedures.

While the majority of respondents to a 2010 survey on attitudes towards EFSA among key partners and stakeholders viewed EFSA as an



organisation with “as much independence as can reasonably be expected” and with a “focus on avoiding conflicts of interest working very well”, the Authority is committed to further improving the way it implements its core values in order to continue to build trust in the independence of EFSA’s scientific advice.

All these considerations were instrumental in EFSA’s decision in 2011 to adopt a new Policy on Independence and Scientific Decision-Making Processes. The policy integrates in one document the wide range of initiatives EFSA has put in place to uphold its core values of scientific excellence, openness, independence, transparency and responsiveness. It identifies areas of improvement which include: simplifying and clarifying rules on identifying and handling conflicts of interest; increasing information on how decisions on conflicts of interest are reached by outlining admissible and incompatible interests in a transparent manner; strengthening procedures concerning breach of

trust; and amending the definition of conflict of interest to better reflect OECD guidelines. As well as issues related to interests and independence, the policy sets out the internal mechanisms and processes which EFSA follows to ensure good governance within the organisation. The policy was subject to a public consultation and was also discussed with stakeholders and interested parties at a meeting in Brussels in October 2011 before being adopted by EFSA’s Management Board in December.

On the basis of feedback received during the consultation on the policy, the Authority agreed that in 2012 observers should be invited to some Panel meetings on a trial basis. ■

## 6. COMMUNICATIONS AND DIALOGUE

The Communications Strategy 2010-2013 was fully implemented last year, following its adoption in 2010. In line with the strategy's focus on a thematic approach to communications, the directorate rolled-out a suite of outputs to support its work in the area of zoonoses. An integrated approach to communications on independence was also initiated as well as further work in the area of GMOs.

### Working to a strategy

EFSA's communications remit was reaffirmed in the Authority's Strategic Plan 2009-2013, which confirmed as a key priority the need "... to reinforce confidence and trust in EFSA and the EU food safety system through effective risk communications and dialogue with partners and stakeholders". The Communications Strategy 2010-2013 subsequently identified five key priorities: to increase relevance and understanding of EFSA communications for key target audiences and informed lay audiences, in cooperation with Member States (**simplicity**); to deliver proactive communications on the **independence** of EFSA's risk assessment advice; to raise **visibility** and awareness of EFSA and its role and work as a risk assessor; to further increase the **coherence** of risk communications across the EU and beyond; and to enhance **dialogue** with stakeholders and increase audience interactivity.

In 2011, EFSA focussed on embedding these priorities in its everyday communications practice. One important example of this is the Authority's approach to communicating on a thematic basis. The thematic approach is a way of organising



communications content across broad subject areas such as zoonoses, chemicals in food or independence. The aim is to give context and further meaning to the Authority's scientific work.

The implementation of EFSA's Communications Strategy 2010-2013 was also supported by the re-organisation of the Communications Directorate into two units – Communications Channels and Editorial and Media Relations. The former unit is dedicated to optimising the use of existing tools and rolling out new mechanisms, such as the *Understanding Science* video series and social media and developing an email alert system for implementation in early 2012; and the latter unit is responsible for developing consistent, harmonised content. The Editorial team significantly expanded the bank of "Topic" sections on the EFSA website as well as implementing the thematic approach to communications in specific areas, for example with zoonoses and independence.

### Communicating on a theme: zoonoses

Food-borne zoonotic diseases are a significant and widespread public health threat, with more than



320,000 confirmed human cases in the European Union each year. EFSA's work in data collection, reporting and monitoring plays a key role in the EU's strategy for combatting these diseases, and is thus an important focus for the Authority's communications activities. In October 2011, EFSA joined forces with the European Centre for Disease Prevention and Control (ECDC) and the Directorate-General for Health & Consumers (DG SANCO) to hold a meeting at the European Parliament in Brussels. The event, *Animal-to-human diseases: How does Europe protect its citizens*, hosted by Dagmar Roth-Behrendt, a former Vice-President of the European Parliament, provided an overview of the integrated approach to food safety taken in the EU to combat food-borne zoonoses. To coincide with the event, the Authority produced a range of zoonoses-related communications tools, including factsheets on the theme *EFSA Explains Zoonotic Diseases* and comprehensive content on its website.

### Coherence

EFSA's Advisory Forum Communications Working

Group (AFCWG) is at the heart of EFSA's collaborative approach to working with the EU Member States and the work that it has done over the last 10 years has contributed a great deal to ensuring coherence in risk communications on issues related to food safety. In 2011, EFSA progressed the work on its joint risk communications guidelines initiative with the AFCWG. The document is designed to improve understanding within EFSA and national food safety bodies about how to handle risk perception and risk communications issues related to food safety.

The AFCWG also provided valuable input into the creation of EFSA's Social Media Strategy, providing a platform for the launch of a Twitter site in 2012. The Authority has also issued guidelines for staff, scientific experts and other members of the EFSA community who use social media such as Twitter and Facebook.

EFSA's Stakeholder Consultative Platform, composed of EU-wide stakeholder organisations working in areas related to the food chain, is another EFSA network with an important contribution to make in the area of risk communications. By listening

to Platform members, EFSA forms a greater understanding of the views and concerns of its stakeholders. This, in turn, allows the Authority to communicate in a coherent, relevant way taking into account the needs of its various audiences. During the course of the year, three plenary meetings of the Platform were held and, with a dedicated session on risk communications, a new format was piloted that allowed for breakout groups on specific topics such as pesticides, health claims and zoonoses. In addition, a number of technical meetings with stakeholders on key topics were organised by EFSA scientific units throughout the year including one on GMOs with environmental NGOs in November.

### Visibility and outreach

In line with one of the key priorities of the Communications Strategy 2010-2013, to raise visibility and awareness of EFSA and its work, the Authority invests considerable time and effort in its relations with the media. In 2011, this resulted in a large amount of media coverage, 9,397 articles



The Advisory Forum Communications Working Group

in total, mentioning EFSA and its work. In total, 35% of EFSA's scientific outputs were supported by press releases or web news stories. The most popular topics covered by the media were *E. Coli*, nutrition, health claims, zoonoses, GMOs and food additives. The top five countries to report on EFSA in 2011 were France, Spain, Germany, the UK and Italy, representing 54% of coverage.

Another major communications initiative carried out in 2011 to increase EFSA's visibility and outreach was a series of videos entitled *Understanding Science*, developed for launch in 2012 on the EFSA website. *Understanding Science* is EFSA's scientific "white board" series of videos in which EFSA staff or experts explain the scientific concepts that underpin risk assessment of food and feed. The focus is on the science, rather than on EFSA's role, EFSA's position or current events and the subjects chosen correspond to the thematic areas of EFSA's communications work such as chemicals in food, pesticides, zoonoses, contaminants and GMOs. Due to be published in 2012, the videos will play a prominent part in further promoting the Authority's outputs in the key thematic areas.

EFSA also organised 13 events including: one Scientific Colloquium on emerging risks in plant health; two consultative workshops with stakeholders; a joint EFSA / European Commission / ECDC event on zoonoses; and a local community event, Festa dell'Europa. The Authority also participated in an EU Agencies exhibit at the European Parliament.

### Communicating in a crisis

Effective and timely communication was at the heart of EFSA's response to the outbreaks of the STEC outbreaks that affected the EU in the summer of 2011.

On 27 May 2011, EFSA issued a brief statement announcing that it was monitoring the German outbreak. The Authority issued a further seven news stories in the following five weeks addressing public health advice, the results of its urgent scientific advice as well as the role of the European Task Force. Public health advice was issued jointly with ECDC to ensure that the European agencies were speaking with a common voice.

EFSA coordinated its communication efforts with other organisations and liaised with its Focal Point network and the AFCWG. The Authority also kept the EU Health & Security Committee's communicators' network informed of its activities. Recognising the variety of advice that was being given in Member States, EFSA set up a system to monitor the types of communication that were being issued across the EU. This proved a useful tool for both risk communicators and risk managers.

The outbreaks highlighted the importance of EFSA's risk communications mandate and the need to coordinate communication between risk managers and risk assessors. This is reflected in the increased number of media enquiries and visitors to the Authority's website between the end of May and early July.

EFSA will use the Advisory Forum Communications Working Group to discuss with member States ways of improving information exchange in future crises.



### International and institutional relations

During 2011, EFSA continued to ensure effective working relations with the European Commission, the European Parliament and the Council of EU Ministers. Herman Van Rompuy, the President of the European Council, and Antonio Tajani, the Vice-President of the European Commission, visited EFSA during the course of the year. Catherine Geslain-Lanéelle, EFSA's Executive Director, met John Dalli, the Commissioner for Health and Consumer Policy, to discuss EFSA's main priorities for 2011. Ladislav Miko, Deputy Director General of the Directorate-General Health and Consumers (DG SANCO), visited EFSA to discuss work priorities.

EFSA continued to support the work of the European Parliament and build awareness of the Authority's role and ongoing work in the EU food safety system. Ms Geslain-Lanéelle had regular bilateral meetings with MEPs and Julie Girling, member of the Committee on Environment, Public Health and Food Safety (ENVI), visited EFSA's headquarters in Parma.

In addition, a joint EFSA/ECDC/DG SANCO seminar entitled *Animal-to-human diseases: how does Europe*

*protect its citizens* was organised in the European Parliament in October to brief MEPs on joint EU actions to combat food-borne zoonotic diseases.

During 2011, EFSA visited its counterparts in Member States including the Belgian Federal Public Service for Health, Food Chain Safety and Environment, the Belgian Food Safety Agency (AFSCA), the Food Safety Authority of Ireland (FSAI), the Bulgarian Food Safety Agency (BFSA) and Risk Assessment Centre (RAC), and the Food and Consumer Product Safety Authority of the Netherlands (VWA). EFSA received delegations from the French Agency for Food, Environmental and Occupational Health and Safety (ANSES), the Spanish Agency for Food Safety and Nutrition (AESAN), the German Federal Ministry for Food, Agriculture and Consumer Protection (BMELV), and the Swedish National Food Agency.

EFSA received international delegations from South Korea, China, Australia, the USA, Colombia, Kazakhstan, Kyrgyzstan, Uzbekistan and Japan. The agreement between EFSA and the FDA to exchange staff was renewed in June and will be subject to annual evaluation.

EFSA liaised closely with the two six-month EU Presidencies of Hungary and Poland in 2011 and held meetings of its Management Board and Advisory Forum in Budapest, Warsaw and Krakow. A meeting of the Advisory Forum Communications Working Group also took place in Lodz.

EFSA's Executive Director met both presidencies on a number of occasions, including at the Scientific Conference on Emerging Risks in Food Safety in Budapest and at a meeting with representatives of the Polish Chief Sanitary Inspectorate in Warsaw. The Executive Director met with Ringolds Arnitis, Director-General of the European and Mediterranean Plant Protection Organisation (EPPO), in July and on the occasion of the 2011 World Dairy Summit, EFSA welcomed a delegation of World Dairy Leaders to EFSA. ■



## 7. GOVERNANCE AND SUPPORT

### A new organisation

EFSA began rolling out its e<sup>3</sup> re-organisation programme in May, with the objective of making better use of its resources to reflect an ever increasing workload, strengthen efficiency and provide a higher-quality service to its clients. The re-structuring took place gradually throughout 2011 and was due to be completed by early 2012. Already in 2011, EFSA made structural savings of €1.98 million as a result of overall efficiency gains, particularly in specific areas such as interpretation, translation and meeting organisation.

The aim of the re-organisation was to address the growing demands on the Authority, particularly with regards to applications for the assessment of regulated substances and products. Resources have also been focussed on risk assessments related to general health and safety priorities in areas such as chemical and biological contaminants and animal health and welfare. In 2011, EFSA's approach to prioritising its scientific work over the medium term was agreed with the European Commission's

Directorate-General Health and Consumers. Towards the end of the year, the Authority set up an Applications Desk Unit to act as a first contact point for companies submitting applications for the evaluation of regulated substances, products and claims and to raise the level of service to other clients and partners such as Member States and stakeholders. The extra spotlight on applications also means EFSA will be prepared should EU institutions decide in the future to introduce a fee-based system.

EFSA is now made up of five directorates: three scientific directorates, which support the work of the Scientific Committee and EFSA's 10 scientific Panels; a reshaped Communications Directorate; and the Resources and Support Directorate.

The Risk Assessment and Scientific Assistance Directorate (RASA) includes risk assessment of animal health and welfare, contaminants and plant health as well as dietary and chemical monitoring and scientific assessment support. The Scientific Evaluation of Regulated Products Directorate (REPRO) supports EFSA's work related to the

risk assessment of substances, products and processes intended to be used in the food chain and related to the substantiation of claims made on foods in order to help protect public, plant and animal health as well as the environment. Its units focus on feed, food additives and nutrient sources, food contact materials, enzymes and flavourings, GMOs, nutrition and pesticides.

The Science Strategy and Coordination Directorate (SCISTRAT) coordinates the implementation of EFSA's science strategy and reinforces engagement and cooperation with stakeholders and international partners, in particular on broader horizontal scientific issues, for example, on risk assessment methodologies. The Directorate will also provide support to the Scientific Committee and Advisory Forum and focus on specific areas such as emerging risks in the food and feed chain.

The Communications Directorate is responsible for risk communication – a central part of EFSA's core business. As a result of the recent re-organisation, the Directorate has been



reshaped to include two new Units: Channels and Editorial and Media Relations. This restructuring will ensure greater efficiency in the way communications are developed to support EFSA's scientific and corporate work.

The Resources and Support Directorate (RESU) brings together a number of functions previously spread across the Authority, such as meeting organisational support, procurement and financial management. A new Human Capital and Knowledge Management Unit will develop strategies to encourage knowledge-sharing, training and best use of talent among EFSA staff and more than 1,500 external experts to help EFSA achieve its mission.

### A new home

The year 2011 was EFSA's last at its old, temporary headquarters in Parma. On 19 December 2011, EFSA, the Parma City Administration and the *Società di Trasformazione Urbana* (STU) – the company created by the Municipality of

Parma to manage the implementation of Parma's urban development and the settlement of EFSA in the town – signed the purchase agreement for the new EFSA seat. The construction works, including the final adaptation of the structure to EFSA's latest operational needs, enabled EFSA to move to the new premises during the Christmas break and start operating from its new seat as of 5 January 2012. All these activities were carried out successfully and according to schedule, without any disruption to EFSA's work. The Authority was fully operational from the first day, and meetings with scientific experts resumed smoothly in the first week of 2012.

The new seat is equipped with teleworking and video conferencing facilities to enhance networking with experts, generate quick response to emerging threats and guarantee business continuity under all foreseeable conditions, thus reinforcing EFSA's capacity for fulfilling its mission. Moreover, the remote participation in meetings will increase cost efficiency, help to strengthen transparency (in the form of audio/

video webcasting) and, importantly, reduce the carbon footprint of EFSA's activities.

### Getting fit for the future

As part of the e<sup>3</sup> programme the Authority also began a rationalisation of its work processes, focusing on scientific activities. The Management Team declared its ambition to have a Quality Management System (QMS) covering the Authority's scientific activities implemented by the end of 2013, with a fully integrated system for the whole organisation, with communications, human resources and information technology to follow by 2016.

At the core of the QMS will be an operating framework that brings together the standards, policy documents and procedures that govern the quality of EFSA's scientific activities. The Framework will thus be the reference point against which the quality of the Authority's operation can be assessed over a given period.



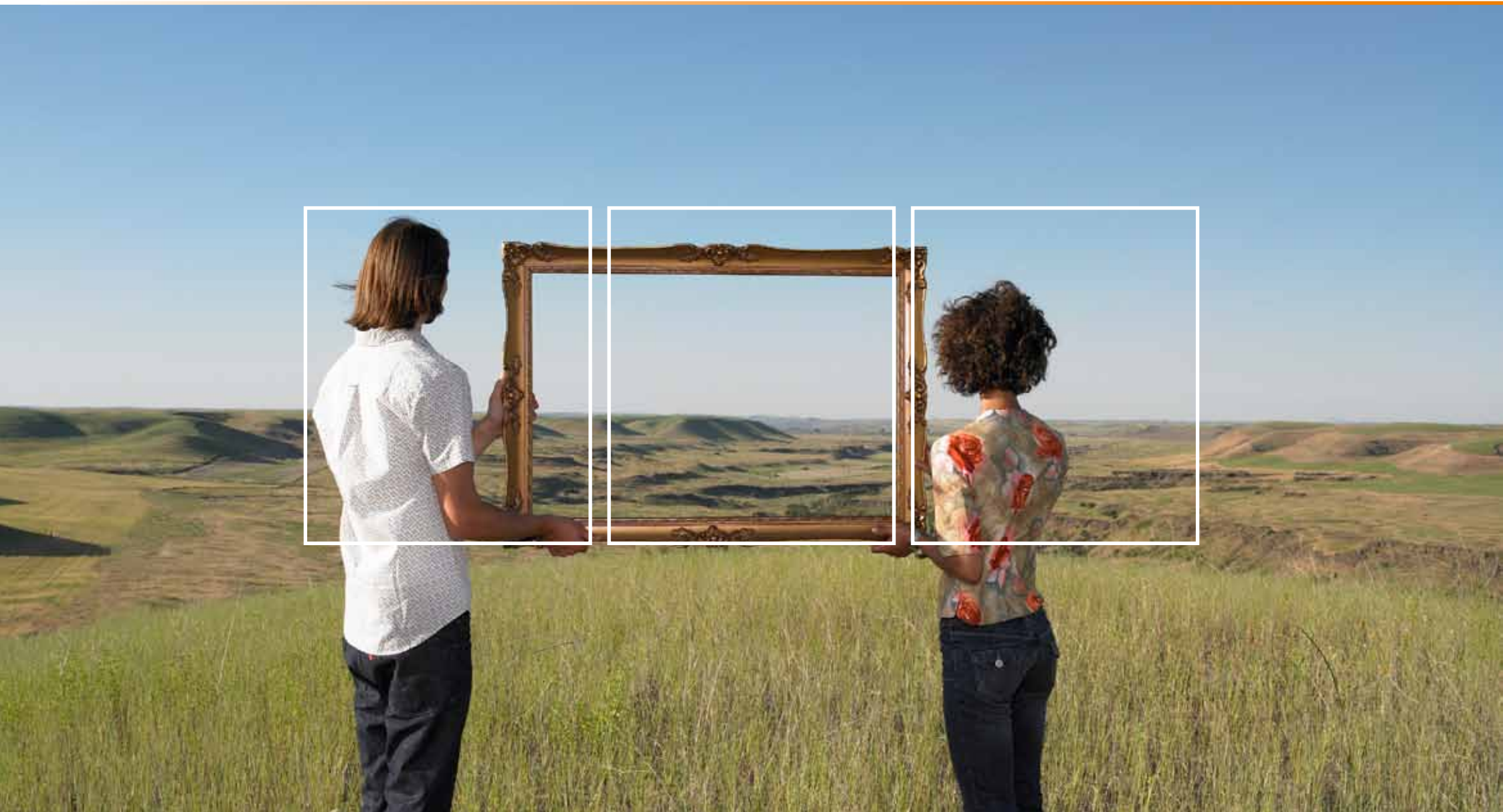
An important element in the drive to improve efficiency and quality management was the creation in 2011 of planning and monitoring teams for each of EFSA's directorates. The teams will help to expand internal coordination and long-term planning capabilities; increase efficiency of administrative processes through the centralisation of tasks related to finance, procurement, planning and monitoring; coordinate quality assurance regarding scientific processes and outputs; and relieve the burden on scientific units by giving responsibility for grants and procurement to the planning and monitoring teams.

### The view from outside

EFSA decided in 2007 to implement a review system to help improve the quality, clarity and consistency of the advice provided in its scientific outputs and to ensure that best scientific practice is followed. The first external review was carried out in 2009 and the second in 2011. For the second review, a total of 49 scientific outputs, generated by 16 science units – randomly selected by the

Authority – were reviewed. Each output was assessed independently by two reviewers according to a clear set of parameters aligned with EFSA's core values and guidance given on the criteria for the scoring. According to the review, a high proportion of the outputs were well constructed, transparent and easily understood, reflecting the high quality that generally exists in EFSA outputs. ■

### III. OUTLOOK





**From its new building EFSA will continue to pursue its risk assessment work to support EU decision-making in key areas for public health. Central to the Authority's work over the coming year will be the implementation of the Science Strategy 2012-2016, which highlights how the Authority has grown into its pivotal position within the European food safety system and lays out the vision for its scientific development for the next five years.**

The Applications Desk Unit will be at the heart of the Authority's work in evaluating regulated products and dialogue with stakeholders will also be enhanced through the continued strengthening of the Stakeholder Consultative Platform. The Policy on Independence and Scientific Decision-Making Processes will be embedded in the Authority's work culture with the adoption of the Implementing Rules on Declarations of Interest.

**A more efficient EFSA**

At an organisational level, EFSA will pursue its efficiency drive, concentrating in 2012 on optimising its information technology and science and support activities and establishing a Human Capital and Knowledge Management Unit. EFSA will submit to its Management Board a preliminary rolling multi-annual plan for 2013-2015 outlining the main challenges and deliverables and integrating the support activities critical to its development

(information technology, human capital development and knowledge management).

The Authority will also benefit from the new organisational model put in place in 2011 to strengthen efficiency and provide a higher quality service to its clients. A "scorecard" system will be introduced in 2012 to monitor performance and a quality management system is to be implemented, the first stage of which will cover EFSA's scientific outputs and is expected to be completed by December 2013.

Results of the ongoing external evaluation of the agency – due to be completed in June 2012 – will help to inform discussions on the future of EFSA's Panel system and the balance between internal and external expertise. EFSA will take stock of the external evaluation, helping to pave the way for the update of its five-year strategic plan. Membership of eight of EFSA's Scientific Panels and its Scientific Committee will be re-established over



the coming year and the Management Board will be partially renewed.

### **Risk assessment in the foreground**

EFSA will continue to harmonise its risk assessment approaches and to share best practices internally among its Panels and externally with other risk assessment bodies. The Scientific Committee will provide guidance on issues such as the risk assessment of chemical mixtures (the “cocktail effect”) and endocrine active substances and the harmonisation of methodologies for environmental risk assessment. Key areas of the Authority’s risk assessment work will include the development of animal welfare indicators; advice covering all the major farmed species will be delivered by the end of 2012.

EFSA will also continue to assist the European Commission in the modernisation of meat inspection practices by providing the scientific

basis for a risk-based approach at all stages of the production chain. Following their work on swine meat in 2011, the Authority’s experts will turn their attention to poultry in 2012. The Authority’s pesticides experts will prioritise the cumulative risk assessment of pesticide residues and an assessment of the risks to bees and other pollinators from pesticides.

### **Ready to help**

The Applications Desk Unit will become fully operational in 2012 and, in line with EFSA’s Science Strategy 2012-2016, staff within scientific units will be more involved in the scientific evaluation of applications. More preparatory work will be outsourced, much of it through national competent authorities in Member States, while core scientific work remains with the panels. Workshops, technical meetings and other forms of consultation will continue to be prioritised. EFSA has a full programme of evaluations or

re-evaluations of products and processes over the coming year. These include: feed additives; food additives, with the highest priority given to the re-evaluation of aspartame; food contact materials, such as bisphenol A; and flavourings.

### **Cooperation and collaboration**

EFSA will continue to strengthen its cooperation with national food safety agencies and scientific organisations in the Member States in order to pool risk assessment resources more effectively across the EU. This will be particularly important as the difficult economic climate will restrict budgets at both national and EU level. The Authority will allocate grants and contracts worth €9.2 million to Member State organisations, an increase of €1 million over 2011.

In addition to its Advisory Forum, the Authority will continue to strengthen cooperation and networking with Member States through its Focal



Point network and specific networks in areas such as animal health and welfare, genetically modified organisms and plant health. Collaboration will be strengthened through improvements to electronic tools such as the Information Exchange Platform and dialogue with stakeholders will continue through workshops and technical meetings.

The existing composition of EFSA's Stakeholder Consultative Platform, a network of EU-wide organisations working in areas related to the food chain, will expire in June 2012. The Authority will launch a public call for expressions of interest for organisations who wish to be considered for membership.

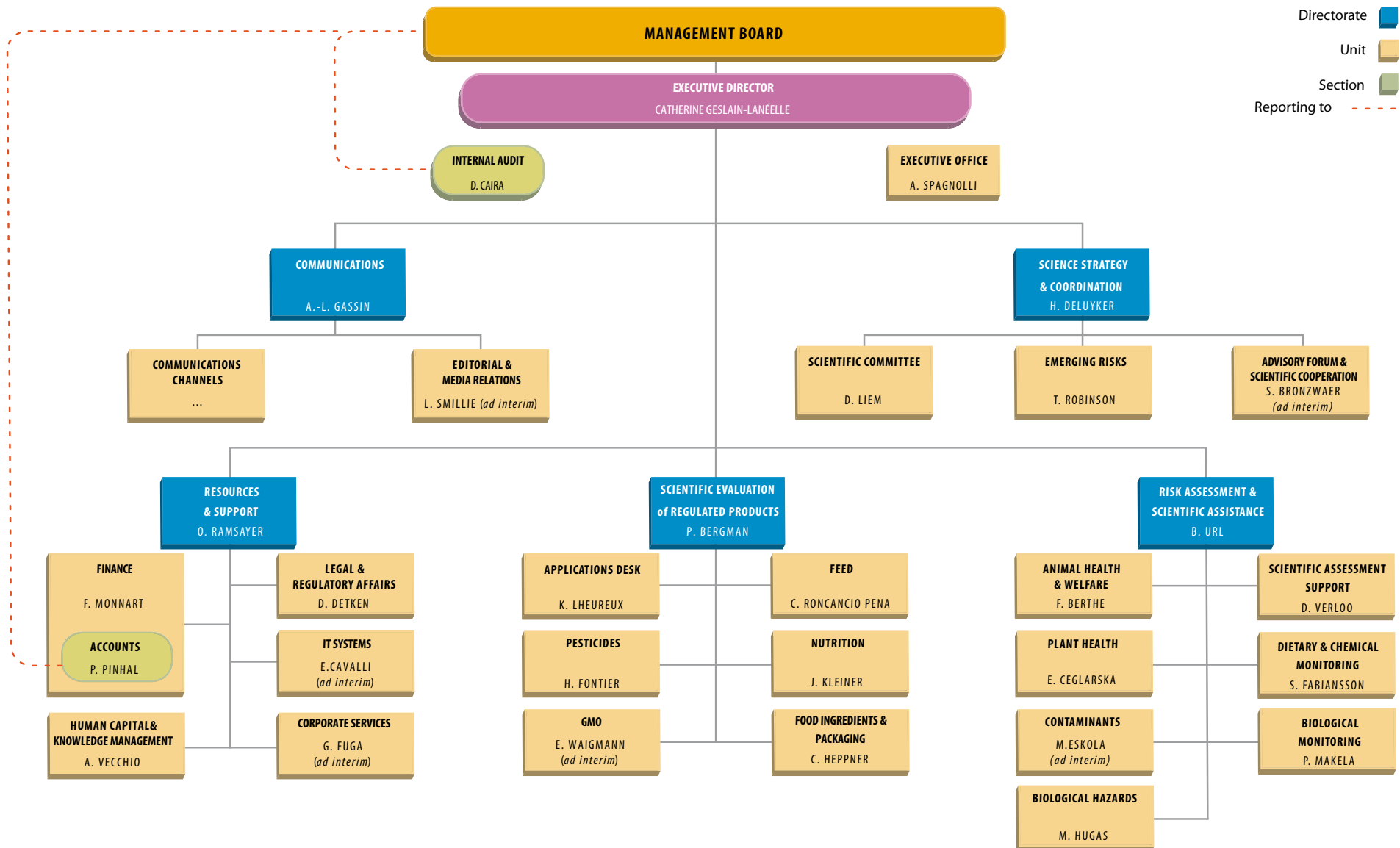
### Happy 10<sup>th</sup> birthday, EFSA

EFSA will use the occasion of its 10<sup>th</sup> anniversary to engage with a range of interested parties on the contribution the Authority makes to the European food safety system and also, in cooperation with its

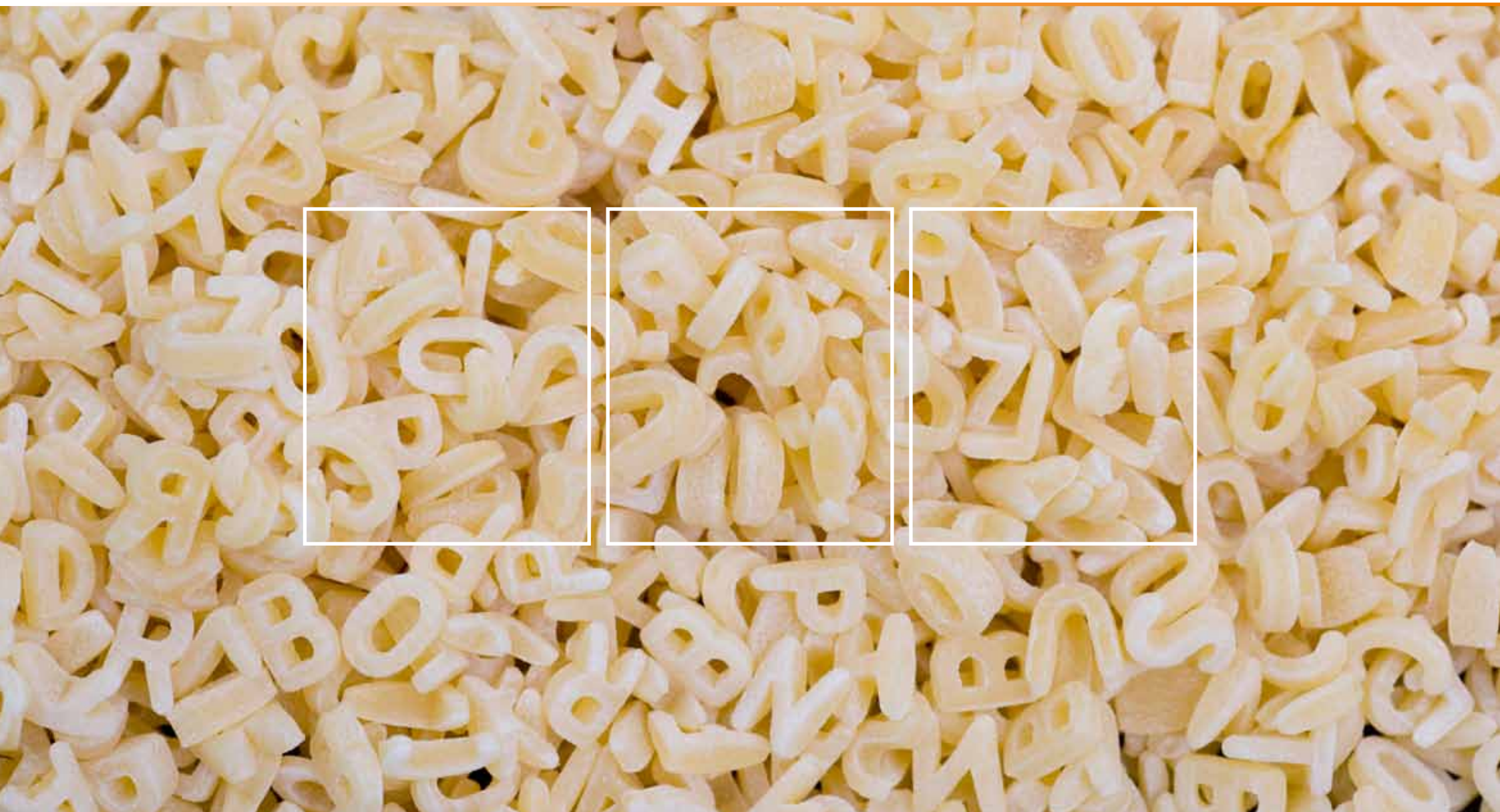
key partners at European and national levels, on opportunities to further enhance its impact. The year will culminate with a scientific conference in November and, in association with the European Commission, an event that will build on the results of EFSA's external evaluation, reflecting on EFSA's achievements over the past 10 years and looking forward to the challenges ahead. ■

# ANNEX I – ORGANISATIONAL STRUCTURE ON 01/06/2012





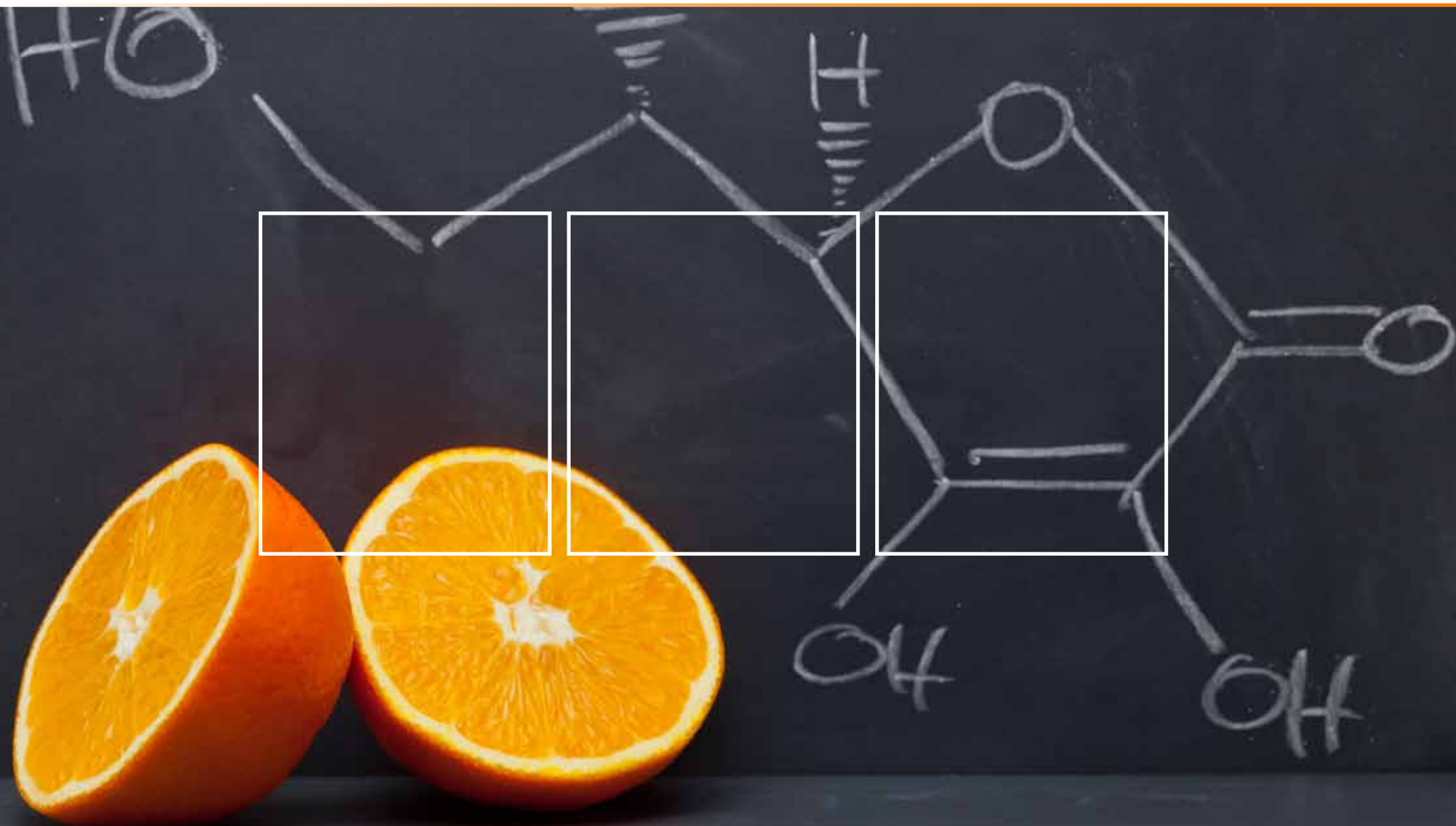
## ANNEX II – ACRONYMS





<b>ABB</b>	Activity Based Budgeting	<b>EMRISK</b>	Emerging Risks Unit	<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>AF</b>	Advisory Forum	<b>ENP</b>	European Neighbourhood Policy	<b>PFAS</b>	Perfluoroalkylated substances
<b>AFCWG</b>	Advisory Forum Communications Working Group	<b>ENVI</b>	The European Parliament Committee for Environment, Public Health and Food Safety	<b>PLH</b>	Panel on Plant Health
<b>AHAW</b>	Panel on Animal Health and Welfare	<b>EP</b>	European Parliament	<b>PMEM</b>	Post-market environmental monitoring
<b>AMU</b>	Assessment Methodology Unit	<b>ERA</b>	Environmental risk assessment	<b>PPR</b>	Panel on Plant Protection Products and their Residues
<b>ANS</b>	Panel on Food Additives and Nutrient Sources Added to Food	<b>EU</b>	European Union	<b>PRAPeR</b>	Pesticides Risk Assessment Peer Review Unit
<b>ANSES</b>	French Agency for Food, Environmental and Occupational Health & Safety	<b>FAO</b>	Food and Agriculture Organization of the United Nations	<b>QMS</b>	Quality management system
<b>BIOHAZ</b>	Panel on Biological Hazards	<b>FDA</b>	U.S. Food and Drug Administration	<b>RASA</b>	Risk Assessment and Scientific Assistance Directorate
<b>BIOMO</b>	Biological Monitoring Unit	<b>FEEDAP</b>	Panel on Additives and Products or Substances Used in Animal Feed	<b>REPRO</b>	Scientific Evaluation of Regulated Products Directorate
<b>BPA</b>	Bisphenol A	<b>FIP</b>	Food Ingredients & Packaging Unit	<b>RESU</b>	Resources and Support Directorate
<b>CEF</b>	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids	<b>GM</b>	Genetically modified	<b>SAS</b>	Scientific Assessment Support Unit
<b>CoI</b>	Conflict of interest	<b>GMO</b>	Genetically modified organism (Panel on Genetically Modified Organisms)	<b>SC</b>	Scientific Committee
<b>CONTAM</b>	Panel on Contaminants in the Food Chain	<b>HUS</b>	Haemolytic uremic syndrome	<b>SCISTRAT</b>	Science Strategy and Coordination Directorate
<b>DATEX</b>	Data Collection and Exposure Unit	<b>IEP</b>	Information Exchange Platform	<b>SCO</b>	Scientific cooperation
<b>DCM</b>	Dietary & Chemical Monitoring Unit	<b>IT</b>	Information technology	<b>STEC</b>	Shiga toxin-producing <i>E. coli</i>
<b>DG-SANCO</b>	Directorate-General Health and Consumers of the European Commission	<b>MEP</b>	Member of the European Parliament	<b>TDS</b>	Total diet study
<b>DoI</b>	Declaration of interest	<b>NDA</b>	Panel on Dietetic Products, Nutrition and Allergies	<b>TTC</b>	Threshold of toxicological concern
<b>EC</b>	European Commission	<b>NGO</b>	Non-governmental organisation	<b>WHO</b>	World Health Organisation
<b>ECDC</b>	European Centre for Disease Prevention and Control				

# ANNEX III – EFSA'S SCIENTIFIC OUTPUTS AND SUPPORTING PUBLICATIONS 2011



## Overview of EFSA's scientific outputs and supporting publications – 2011

All scientific outputs published by EFSA in 2011 can be found on the DVD attached to the back cover of the Annual Report.

	AHAW	BIOHAZ	BIOMO (former Zoonoses)	CONTAM	DCM (former DATEX)	EMRISK	FEEDAP	FIP (including ANS and CEF)	GMO	NDA	PLH	Pesticides (former PPR and PRAPeR)	SAS (former AMU)	SC	SCO and AF	Total
Opinions of the Scientific Committee/Scientific Panel	7	19		11			71	61	9	149	7	1		1		336
Statements of the Scientific Committee/Scientific Panel				2				5	4	2						13
Guidance of the Scientific Committee/Scientific Panel	2						11		5	4	1			3		26
Statements of EFSA		1						5								6
Guidance of EFSA					2		1		1				1			5
Conclusions on Pesticides Peer Review												54				54
Reasoned Opinions												88				88
Scientific Reports of EFSA		1	7		5	1	1		1			3	1			20
Technical reports	2	3	6		4	8	3	3	13	9	1	3	1	3	6	65
External Scientific Reports*	5	3	7	3	8	2		2			1	5		1		37
Event reports		1							4					1	2	8
<b>Total</b>	<b>16</b>	<b>28</b>	<b>20</b>	<b>16</b>	<b>19</b>	<b>11</b>	<b>87</b>	<b>76</b>	<b>37</b>	<b>164</b>	<b>10</b>	<b>154</b>	<b>3</b>	<b>9</b>	<b>8</b>	<b>658</b>
<b>Total outputs</b>	<b>658</b>															

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

# ANNEX IV – INDEPENDENCE STATISTICS 2011



In order to identify potential conflicts of interest (Col) and safeguard the independence of EFSA's scientific advice, experts working for EFSA's Scientific Committee, Panels and Working Groups are required to declare their interests at three levels:

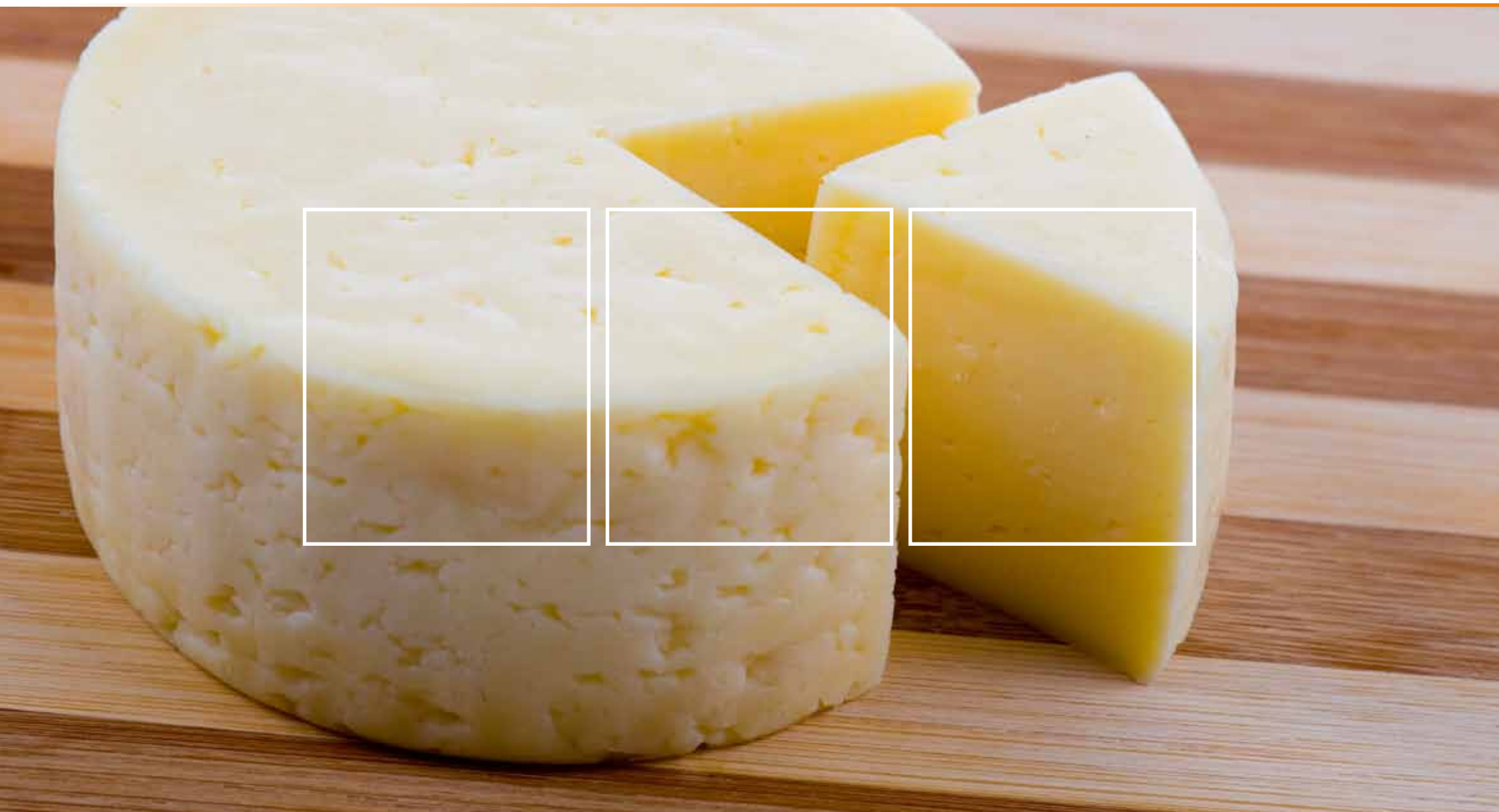
- ADol = Annual declaration of all interests;
- SDol = Specific declaration of interest related to the concrete agenda items of a meeting;
- Oral Dol = Oral declaration of interest given before the beginning of a meeting.

The table below shows the key statistics on the application of EFSA's Dol policy in 2011. From the screening of ADols and SDols, **356** potential conflicts of interests were prevented in 2011. Mitigation measures taken included exclusion of experts from working groups, meetings, meeting agenda items or other restrictions such as exclusion from drafting.

<b>Total Dols screened</b>	<b>8,526</b>
<b>Meeting agenda itmes scrutinised</b>	<b>39,500</b>
<b>Potential Cols prevented</b>	<b>356*</b>
<b>Breach of rules procedures initiated</b>	<b>2</b>

\* 356 represents the number of occasions, **not** the number of experts.

# ANNEX V – FINANCIAL REPORT



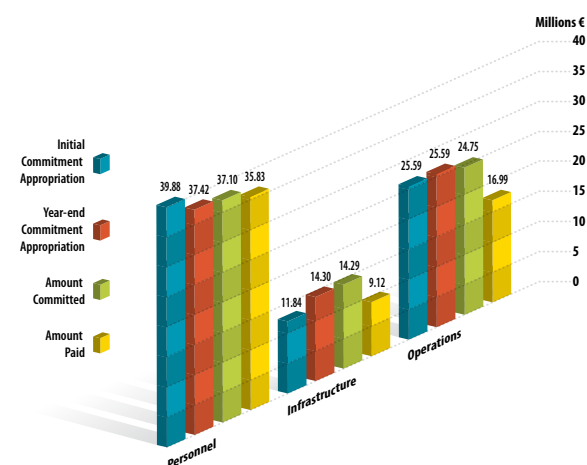
## Budget Execution 2011

As of 31 December 2011:

- EUR 76.13 million or **98.47 %** of the EUR 77.31 million budget was committed. This commitment level stands EUR 0.39 million or 0.5 % below the target set for the year (EUR 76.52 million):
  - This difference is essentially due to the December Council rejection of the Commission proposal on staff remuneration adjustment. This rejection triggers the non-utilisation of EUR 0.23 million foreseen for the remuneration adjustment. As a result, the budget was at 99.13 % committed under Title I Personnel.
  - Under Title II Infrastructure, the budget was at 99.93 % committed, in line with the objective.
  - Under Title III Operations, the execution rate reached 96.71 %. This 3.29 % under-utilisation (EUR 0.83 million) is explained by the lower

committed level achieved by the Scientific Cooperation programme with EUR 7.09 million committed, i.e. EUR 1.21 million below the initial objective (EUR 8.30 million). Part of this under-utilisation was reallocated to operational support activities, therefore limiting the underspend under Title III.

- The EUR 2.46 million transfer from Title I to Title II was utilised to finalise the foreseen investments related to the final seat and was made possible by the observed vacancy rate in the establishment plan posts (6.5% at year-end) as well as in the other staff categories.
- EUR 61.94 million or **82.05 %** of the EUR 75.50 million payment appropriations were paid. It is worth noting that EUR 1.46 million was returned in September



to the general budget of the EU in anticipation of the under-execution of running and to be launched Scientific Cooperation activities. The payment level achieved nonetheless stands EUR 3.90 million below the target (EUR 65.84 million) for reasons pertaining to delays in awarding the 2011 Scientific Cooperation programme and initiation of projects supporting the scientific activities late in the year, for which payments are carried out in 2012 instead of 2011.

Savings were generated in several areas for a total of EUR 1.98 million. More than 10 % of the expert participation to scientific meetings was done via tele-conference, with an ensuing saving estimated at EUR 0.75 million. Staff missions were less numerous as a result of the increased reliance on telecommunication technology, triggering a EUR 0.46 million saving. Costs of events and web-streaming were reduced by EUR 0.56 million. Translations, publications and archives accounted for savings of EUR 0.21 million.

Title	Initial Commitment Appropriation	Year-end Commitment Appropriation	Difference	Amount Committed	% Committed	Payment Appropriation	Amount Paid	% Paid
Personnel	39,882,000	37,424,532	-6.16%	37,097,113	99.13%	37,424,532	35,825,948	95.73%
Infrastructure	11,839,400	14,296,868	20.76%	14,286,533	99.93%	14,296,868	9,122,558	63.81%
Operations	25,588,400	25,588,400	0.00%	24,747,012	96.71%	23,776,900	16,994,131	71.47%
<b>Total:</b>	<b>77,309,800</b>	<b>77,309,800</b>	<b>0.00%</b>	<b>76,130,659</b>	<b>98.47%</b>	<b>75,498,300</b>	<b>61,942,637</b>	<b>82.05%</b>

## ABB Execution 2011

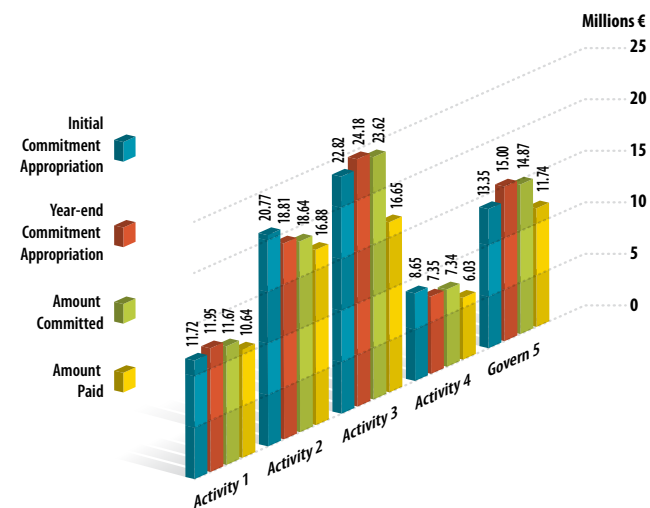
Activity 1 = Provision of scientific opinions and advice and risk assessment approaches

Activity 2 = Evaluation of products, substances and claims subject to authorisation

Activity 3 = Data collection, scientific cooperation and networking

Activity 4 = Communication and dialogue

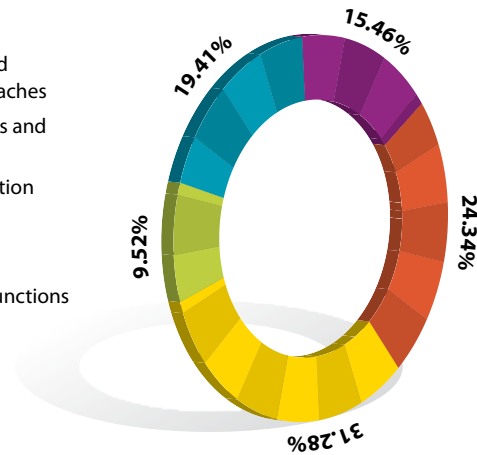
Govern 5 = Governance and administration functions



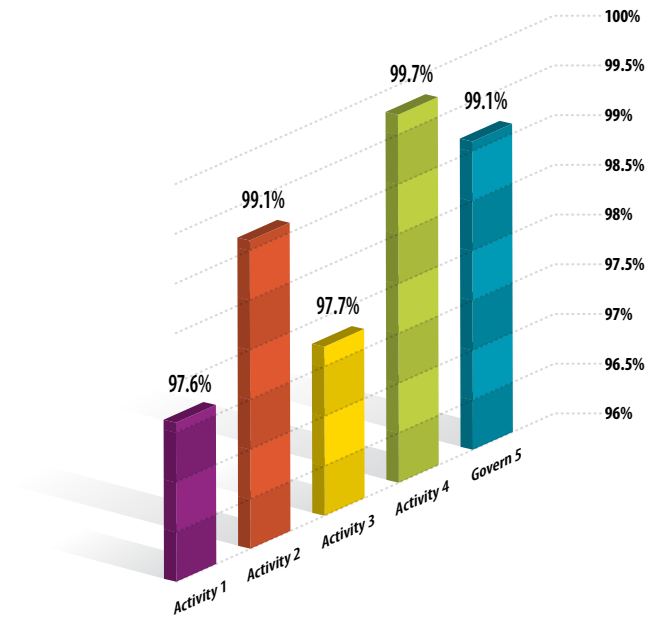
Activity as per ABB	Initial Commitment Appropriation	Year-end Commitment Appropriation	Difference	Amount Committed	% Committed	Payment Appropriation	Amount Paid	% Paid
Activity 1	11,723,805	11,953,599	1.96%	11,666,286	97.60%	11,863,083	10,642,163	89.71%
Activity 2	20,765,264	18,815,008	-9.39%	18,636,970	99.05%	18,803,356	16,882,094	89.78%
Activity 3	22,823,628	24,181,735	5.95%	23,622,711	97.69%	22,379,989	16,645,013	74.37%
Activity 4	8,648,597	7,356,986	-14.93%	7,336,707	99.72%	7,448,939	6,029,099	80.94%
Govern 5	13,348,506	15,002,473	12.39%	14,867,985	99.10%	15,002,934	11,744,267	78.28%
<b>Total</b>	<b>77,309,800</b>	<b>77,309,800</b>	<b>0.00%</b>	<b>76,130,659</b>	<b>98.47%</b>	<b>75,498,300</b>	<b>61,942,637</b>	<b>82.05%</b>

### ABB Appropriations 2011 (% at year end)

- Activity 1 = Provision of scientific opinions and advice and risk assessment approaches
- Activity 2 = Evaluation of products, substances and claims subject to authorisation
- Activity 3 = Data collection, scientific cooperation and networking
- Activity 4 = Communication and dialogue
- Govern 5 = Governance and administration functions



### ABB Execution 2011 (% committed)





---

© European Food Safety Authority, 2012

ISBN: 978-92-9199-424-3

doi: 10.2805/99403

Reproduction is authorised, except for commercial purposes, provided that the source is acknowledged.

The views or positions expressed in this Annual Report do not necessarily represent in legal terms the official position of the European Food Safety Authority.

The European Food Safety Authority assumes no responsibility or liability for any errors or inaccuracies that may appear.

Photo credits:

EFSA

Inmage

Getty Images

iStockphoto

Shutterstock

Jupiter Images

Science Photo Library

Visualphotos

European Centre for Disease Prevention and Control (ECDC)

World Health Organization

Food and Agriculture Organization

Thinkstock

Firebrand-Photography

Corbis

Lucio Rossi for EFSA - Studio Valle Progettazioni, Art & Build,

Manens - Tifs, Pool Engineering, Art Ambiente Risorse e Territorio

