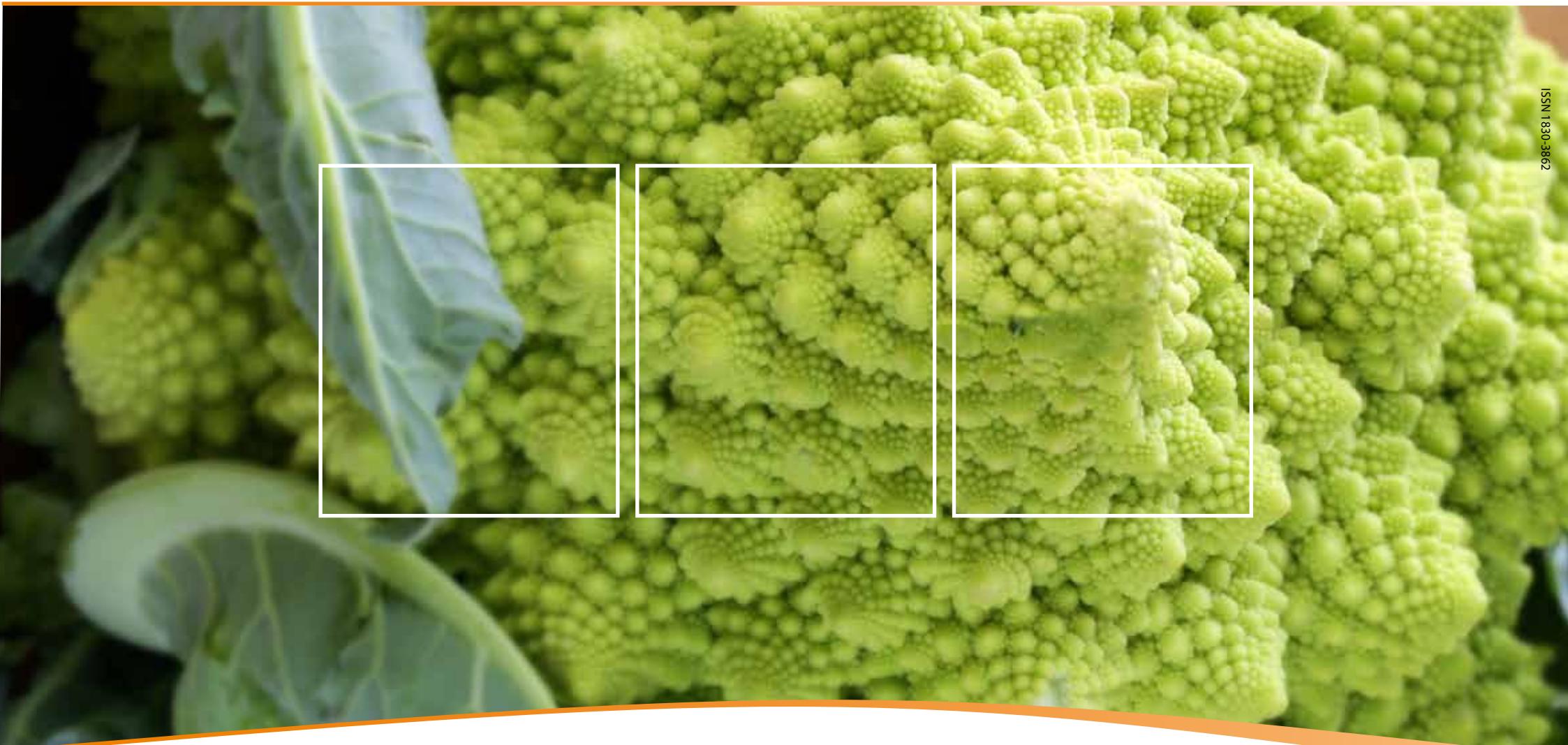
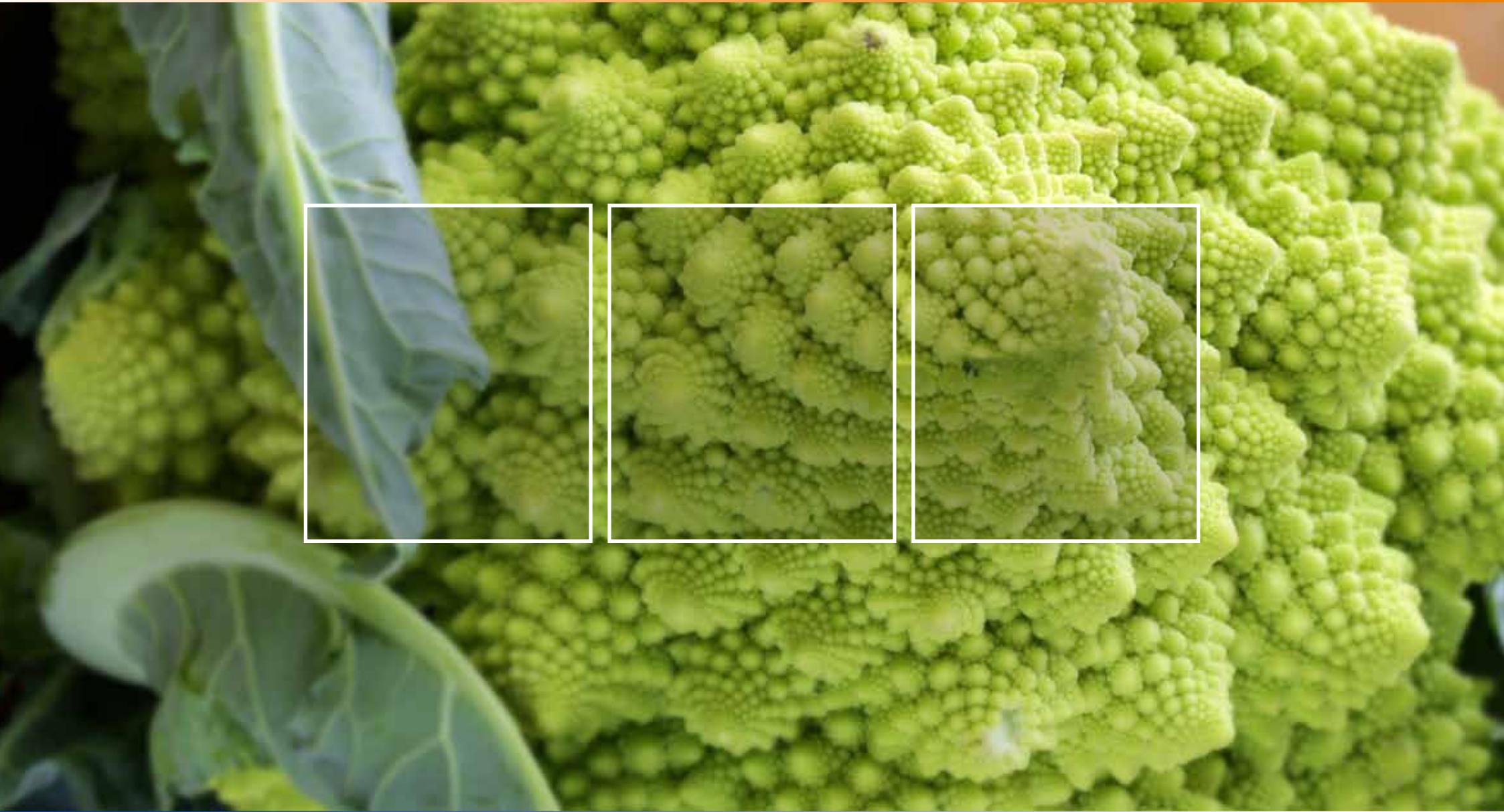


Annual Report 2012



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FOREWORD by Paola Testori-Coggi

DIRECTOR GENERAL FOR HEALTH AND CONSUMERS, EUROPEAN COMMISSION

The value of EFSA's scientific advice was demonstrated throughout 2012 when the agency delivered scientific opinions on food safety issues which lie at the heart of public health and consumer protection. The Commission called on the Authority to address complex and challenging questions across the range of disciplines within its remit. As in previous years, urgent advice featured regularly in EFSA's work and its rapid responses to emerging situations such as the Schmallenberg virus (SBV) and *Salmonella* Stanley enabled the European Commission to take timely decisions on how to best protect our citizens.

EFSA's scientific advice has impacted not just on food safety but also on environmental aspects, and the opinions delivered on subjects such as pesticides continue to build the evidence base for the Union's drive for sustainable food production.

EFSA continues to work on the evaluation of regulated products; its advice has significant economic implications for areas as diverse as novel food, food and feed additives, nutrition claims and genetically modified organisms (GMOs) and provides valuable support to the Union's strategy of smart and sustainable innovation in the agri-food sector.

It is important that the Union maintains and develops its capacity to scientifically assess risks to the food chain and it is reassuring that EFSA is playing a central role in building an integrated European risk assessment community that will have the skills, knowledge and capacity to meet future demands. The renewal of eight of its 10 Scientific Panels and Scientific Committee in 2012 illustrated its ability to attract high-level scientists.

It is essential to underline that many aspects of EFSA's work are of considerable public interest and have tangible implications for citizens in the food they consume. Increasingly EFSA has to deal with complex and ethically challenging issues, such as the recent work on animal cloning and nanotechnology. These subjects frequently involve fast-evolving science, a situation which creates a real challenge in terms of communication, as stressed by the recent and overall favourable external report on EFSA.

In this respect, EFSA demonstrated its commitment to engaging stakeholders and to reviewing its advice in light of the latest scientific insights, as illustrated by its rapid response to a new study on genetically modified (GM) maize NK603 and a glyphosate-containing herbicide. EFSA's commitment to openness and transparency is unquestionable and is central to building the trust of our citizens



in the regulatory process. Initiatives taken in 2012 such as the opening of scientific meetings to observers are testament to that commitment. A crucial issue for EFSA certainly remains the delicate balance between access to the best scientific expertise and the need to ensure independence and the prevention of conflicts of interest.

Of course, 2012 also provided the opportunity to reflect on the decade that has elapsed since the enactment of the General Food Law and the establishment of EFSA. While a high-level conference for institutional partners and stakeholders organised in Parma in November provided the opportunity to learn from previous experience, it wisely focused on the new realities in which European food safety finds itself. Undoubtedly, EFSA's operating environment has changed significantly over the past decade – driven by

diverse factors including technological and scientific advances, the economic crisis, societal changes etc. – and EFSA has worked hard to keep pace with the demands placed upon it. It continues to demonstrate that, despite its workload, it is adapting its working practices to meet those demands.

This was evident in 2012 in its ongoing structural adaptations of the organisation, its commitment to efficiency, the adoption and implementation of its new independence policy, and its effective and efficient use of the resources at its disposal.

The Commission looks forward to continued strong scientific and technical support from EFSA in 2013. ■

*Paola Testori-Coggi
Director General for Health and Consumers,
European Commission*



FOREWORD Catherine Geslain-Lanéelle

EXECUTIVE DIRECTOR, EFSA

As well as marking the tenth anniversary of the organisation, a number of important milestones in the development of EFSA were reached in 2012.

In September, the report on the second external evaluation was published and it provided an effective basis for the Management Board to chart the future direction of the organisation at the end of the year. The Board was supported in this task by the high-level institutional conference organised within the context of EFSA's tenth anniversary in Parma in November. It brought together representatives of the key institutional actors in European food safety to discuss the lessons learned from the previous decade and to explore the anticipated challenges and evolving demands on the organisation. The Board recommendations issued in December identified a number of directions which the organisation has already begun to address and the implementation of which is described in EFSA's multiannual work programme.

The roll-out of the Science Strategy 2012-2016 continued with the provision of advanced training in risk assessment for both external experts and staff and collaboration with the Commission on the Better Training for Safer Food programme. These initiatives were welcomed by the 600 or more scientists who attended the scientific conference organised in November to mark EFSA's 10th anniversary. The two-day event provided an effective platform for scientists from across a range of disciplines to discuss common risk assessment issues and address the future challenges. The conference was regarded as a very useful addition to the risk assessment calendar and EFSA is considering making it a regular event as part of its remit in developing European risk assessment.

Demand for EFSA's scientific advice showed no sign of diminishing in 2012 and the work programme continued to address issues of significant public health and environmental protection interest, as

well as responding to urgent requests for advice on issues such as *Salmonella Stanley*. Highlights included the re-evaluation of the safety of the sweetener aspartame. After the call for data and the literature search of 2011, the Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel) began its full re-evaluation of the sweetener in 2012 only to find that the data on one metabolite (Diketopiperazine, or DKP) were insufficient; hence a further call for data was launched and a final opinion is now scheduled for 2013. EFSA issued another call for data on bisphenol A (BPA), a food contact material that has also aroused public concern, and brought together national experts in Parma in October to exchange information and views; an opinion on BPA is also scheduled in 2013. EFSA has been active in ensuring healthy bee stocks in Europe for a number of years and in December conclusions were issued on three neonicotinoid pesticides (published in January 2013) linked with the decline in bee numbers; these will guide the



European Commission's recommendations on their continued usage. In the regulated products area, EFSA continued the process of enhancing its services to applicants via the Applications Desk unit, established in 2011. A Helpdesk function was launched on EFSA's website which provides structured guidance to applicants and enables them to submit questions on the application process.

The renewal of eight Scientific Panels and Scientific Committee represented an important milestone for the organisation in 2012 and presented the first opportunity to apply the new implementing rules of the Policy on Independence and Scientific Decision Making Processes. The rules were launched with a stakeholder information session in Brussels in March and entered fully into force in July. A related initiative introduced by EFSA in early 2012 was the participation of observers at selected scientific meetings. After the terms of reference were established, a pilot programme was launched

with the first plenary meeting hosting observers in March. This pilot is due to run until mid-2013 when it will be evaluated and decisions taken on the possible expansion of the programme.

In the area of risk communication, EFSA continued to enhance its portfolio with the addition of significant new multimedia and social media functionalities. The publication of the multilingual Risk Communications Guidelines represented the culmination of the joint efforts of EFSA and the Advisory Forum Working Group on Communications (AFCWG) and this living document will serve as an essential reference for Member States and the Authority for the coordination of their communication activities in the coming years.

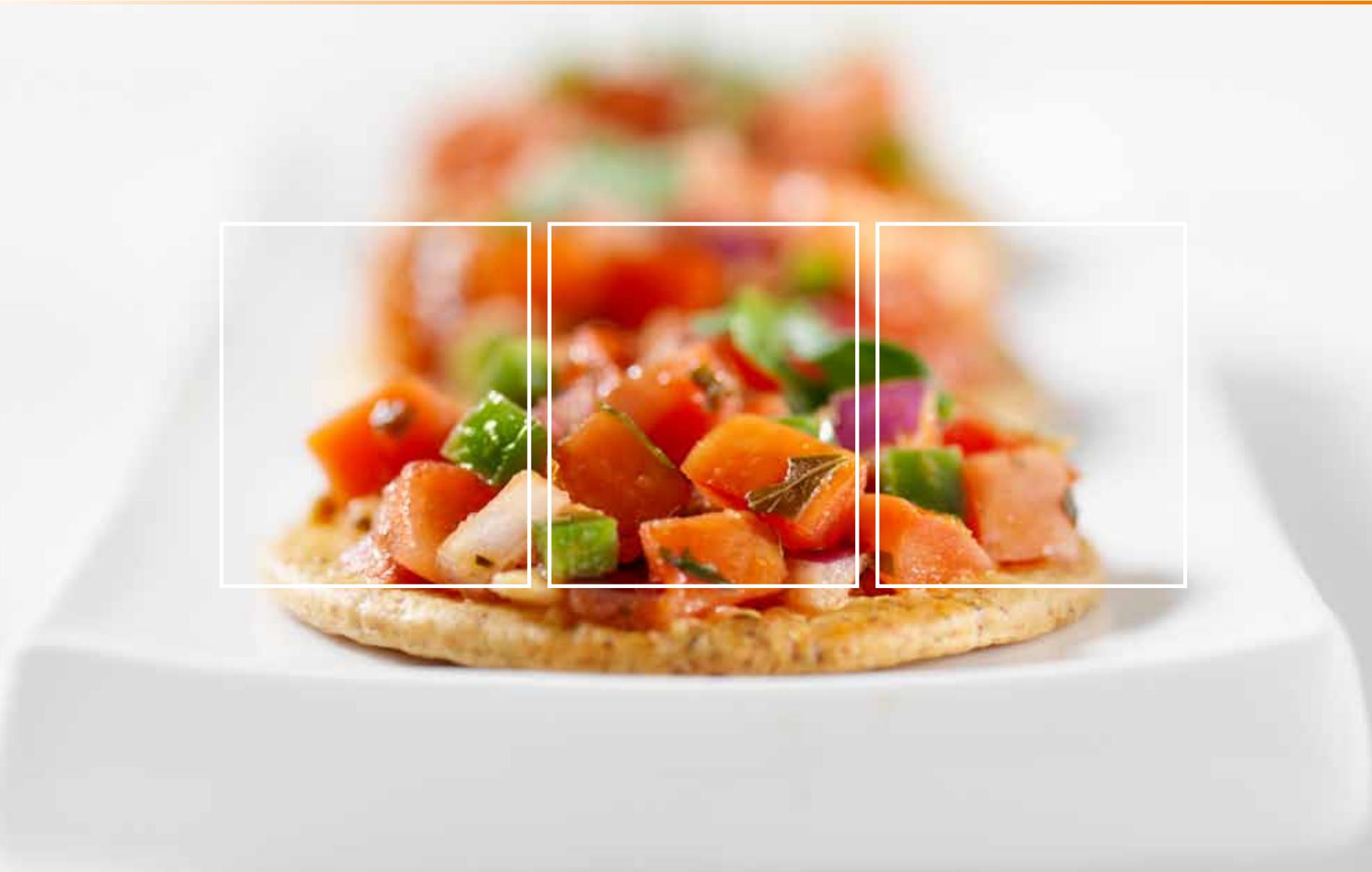
From an organisational perspective, EFSA continued to build an integrated management system. The centralisation of the planning and monitoring function within directorates was

completed and has contributed to more efficient financial management: budget execution in 2012 is the best recorded for the organisation (99.3% committed, 88% paid and a carry forward of 12%). Personnel engaged in governance and support activities have been reduced by 4% as a result of efficiency gains and €3.94 m of savings were achieved in 2012, on top of the €1.98 achieved in 2011. These savings have been redeployed in scientific cooperation and IT development.

I would like to thank all those who contributed to EFSA's work – scientific experts, partner European Union (EU) institutions, Member State bodies, stakeholders, scientific organisations and networks, and EFSA staff – without whose support we could not have delivered our ambitious work programme in 2012. ■

*Catherine Geslain-Lanéelle,
Executive Director, EFSA*

I. INTRODUCTION





Maintaining scientific excellence

EFSA celebrated its 10th anniversary in 2012, an occasion it marked with a number of events and publications highlighting the Authority's integral role in the European food safety system and the main achievements of its first decade. The organisation also looked to the future and took a number of steps that will mean it continues to play a central part in ensuring the safety of the food chain across Europe. Foremost among these was the publication of the Science Strategy for 2012-2016, which lays out the vision for its scientific development for the next five years by setting four key objectives:

- To further develop the excellence of EFSA's scientific advice;
- To optimise the use of risk assessment capacity in the European Union (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 lays out how EFSA, together with risk assessment partners in Member States, will ensure that it 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 reviewed regularly 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 multiannual work programme and annual management plans.

The renewal of eight of EFSA's Panels and the Scientific Committee was another key milestone in 2012. In June a list of members and reserve members was adopted by the Management Board, the culmination of more than 12 months' preparatory work and the engagement of external expertise and observers to ensure the highest standards of transparency and effectiveness. The 2012 renewal process meant that the contribution of almost half the previous Panel members ended as they reached the end of their third term. The incorporation of the new members and the transition from old Panels to new was effectively managed and the Panels have continued to meet their targets. It also

represented the first time that EFSA's new Policy on Independence and Scientific Decision-Making and its implementing rules were applied (see page 8).

In 2012 members of EFSA's Management Board elected a new chair and two vice-chairs. In addition, four new members joined the Management Board after being appointed by the Council of the European Union; three others were reappointed. The appointments were made following an open call for expressions of interest and were based on a list of candidates submitted by the European Commission following consultation with the European Parliament.

EFSA, 10 years on

EFSA's anniversary programme culminated in two corporate events held in Parma in November which focused on the key future scientific and institutional challenges facing the organisation. The scientific event, "Challenging boundaries in risk assessment – sharing experiences", attracted nearly 600 leading experts in risk assessment from Europe and further afield and provided a stimulating platform for scientists from a range of disciplines relevant to EFSA's work. It produced a wealth of



ideas for strengthening Europe's risk assessment capacity, as a result of which EFSA is considering making such a conference a regular event.

The discussions at the high-level institutional conference, organised jointly with the European Commission's Directorate General for Health and Consumers (DG SANCO), looked both at EFSA's achievements over the past 10 years and also at the challenges that lie ahead. Ladislav Miko, Deputy Director General for the Food Chain at DG SANCO, said in his introductory address to representatives of the European Commission, the European Parliament, non-governmental organisations (NGOs) and industry bodies: "EFSA's cluster of scientific knowledge is without parallel in the world and the Authority is a crucial partner for the Commission. Its work impacts on the daily lives of European citizens."

The 10th anniversary was also marked with a special issue of the EFSA Journal which, since December 2009, has been established as an open-access online scientific journal and is referenced in leading bibliographic databases

relevant to EFSA's work. The EFSA Journal is now by far the most visited section of EFSA's website.

The view from outside

Much of the discussion at the institutional conference centred on the results of the second external evaluation of EFSA, which were published in September. The evaluation, the second to be carried out since EFSA was established, was conducted by international auditors Ernst & Young and covered the Authority's performance from January 2006 to December 2010. The report noted the high quality of EFSA's scientific outputs and risk communication activities and highlighted the Authority's culture of transparency and robust systems to ensure the impartiality of its scientific advice. It also recommended that EFSA: enhance transparency in some decision-making processes; build better links with the risk assessment authorities of Member States; increase its planning and prioritisation capacity; improve the clarity of its communications; and further develop its data collection practices.

The results of the evaluation, as well as the valuable input from the institutional conference, were considered by EFSA's Management Board when it met at the end of the year to formulate recommendations for the future strategic direction of the organisation. The recommendations form a roadmap for EFSA in the coming years and will be described in EFSA's multiannual work programme.

Proudly independent and transparent

EFSA's working processes are designed to ensure that European consumers are protected by the highest quality of scientific expertise and that outputs are free from any undue influence. Reinforcing this independence continued to be a major theme for EFSA in 2012. In February, the Authority adopted updated rules for the implementation of its Policy on Independence and Scientific Decision-Making Processes with respect to Declarations of Interest (Dols). The rules strengthen the procedures in place for screening and managing interests declared by those involved in EFSA's activities, in particular

those submitted by the Authority's scientific experts and other individuals and organisations involved in EFSA's scientific work. They provide a definition of what EFSA considers to be a conflict of interest and also a clear and transparent set of definitions and general principles for the declaration of interests applicable to all those involved in EFSA's work. The implementing rules were presented to a representative cross-section of stakeholders and interested parties at a dedicated information session in Brussels in March, at which EFSA explained their application using practical examples.

In October, the European Court of Auditors (ECA) reported on the systems in place to prevent and manage conflicts of interest at four EU agencies, including EFSA, and, in addition, the European Parliament made a series of recommendations related to independence in its deliberations on the discharge of EFSA's 2010 budget. ECA concluded that EFSA is applying some of the most advanced policies and procedures for declaring, assessing and managing potential conflicts of interest and made a number of

recommendations for making the system even more effective. Many useful suggestions were gleaned from both the parliamentary and ECA inputs and all are being addressed.

EFSA's work in this area was acknowledged by the national competent food authorities in Europe, which issued a joint declaration through the Authority's Advisory Forum to mark EFSA's 10th anniversary and to recognise its achievements over the past decade. The authorities reaffirmed their endorsement of the valuable work EFSA has carried out to improve consumer safety since 2002, and re-stated their commitment to safeguarding the role of EFSA's scientific experts and partner organisations as trusted, independent sources of advice.

Another major initiative aimed at improving accountability and transparency was the launch in March of a pilot project allowing observers to attend some meetings of the Authority's Scientific Committee and its Scientific Panels. The pilot was extended in October.



Health and Consumer Policy Commissioner Tonio Borg and EFSA's Executive Director Catherine Geslain-Lanéelle

Service and support

EFSA continued to build its stakeholder engagement with the renewal and strengthening of the Stakeholder Consultative Platform (SHP), and the development of the Applications Desk Unit, which was set up in 2011 as a one-stop shop for those with questions about applications for the authorisation of regulated products, substances and processes, as well as the validation of claims about food.

In November, Catherine Geslain-Lanéelle, EFSA's Executive Director, welcomed representatives of the EU, the European Parliament, the European Commission, the Italian Minister of Health and the Mayor of Parma to the official inauguration of EFSA's new purpose-built headquarters in Parma. The Authority moved into the building in January 2012. ■

II. KEY ACHIEVEMENTS IN 2012



1. SCIENTIFIC OPINIONS AND ADVICE

EFSA continued to take a more multidisciplinary approach to emerging issues related to food safety, such as low-dose effects, endocrine active substances, bee health and chemical mixtures, and to work towards the harmonisation of risk assessment practices. In 2012 the Authority also continued its major work on the modernisation of meat inspection processes and responded to requests for urgent input on Schmallenberg virus (SBV) and *Salmonella* Stanley and to assess a long-term feeding study of genetically modified (GM) maize NK603 and glyphosate.

Modernising meat inspection

EFSA, together with the European Centre for Disease Prevention and Control (ECDC), is engaged in a major scientific project aimed at introducing a risk-based approach to meat inspection, at all relevant stages of the meat production chain. 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, risk assessment methodologies and data collection.

In 2011, EFSA published the first of six opinions on public hazards linked to meat inspection, which was accompanied by a scientific report proposing epidemiological indicators. The second opinion on inspection of poultry meat was published in June 2012. The latter suggests that traditional poultry meat inspection may not suffice to fully address the most relevant biological hazards to public health such as *Campylobacter* and *Salmonella*. EFSA's opinion will have far-reaching implications for European meat inspection practices and



public health. It proposes a shift to risk-based interventions coupled with the improved use of information shared between farms and abattoirs, suggesting that such information would also play an important role in identifying animal health and welfare issues. Chemical substances found in poultry meat are unlikely to pose an immediate or acute health threat to consumers.

Raising awareness of animal welfare

The Authority also published a number of 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 published in January 2012 – 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 three opinions regarding the use of animal-based measures to assess the welfare of dairy cows, pigs and broilers. 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 are the first in a series that will eventually cover all farm species.

The Panel on Animal Health and Welfare (AHAW Panel) also issued a statement on the use of animal-based measures, providing a general framework for future scientific opinions and for a wider range of animal species. In particular, the statement highlighted the potential importance of validated animal-based measures in developing quantitative risk assessment.

EFSA's animal welfare experts presented their work on animal welfare risk assessment at an international conference in Brussels at the end of February. The conference, organised by the European Commission, was entitled: "Implementing animal welfare through the new EU strategy: consumer empowerment and market opportunities".

Ready to respond

Throughout 2012 EFSA published a number of reports and updates on SBV, following an urgent request for assistance from the European Commission. The data was shared with the Commission and Member States, providing them with the state of play on the latest scientific information on SBV and assisting them with the risk management approaches that may be taken. The results of the initial reports were shared at a scientific seminar held in Brussels, organised by the Commission's DG SANCO.

Subsequent updates reported on the spread of SBV – which can affect domestic and wild ruminants, leading in some cases to birth defects – across the European Union (EU).

EFSA and ECDC provided joint advice on an outbreak of a rare type of *Salmonella*. The *Salmonella* Stanley infection involving more than 150 confirmed and over 250 probable cases was reported in Austria, Belgium, Czech Republic, Germany, Hungary and Poland. Food and veterinary investigations conducted in these Member States suggested a likely connection between the turkey production chain and the outbreak. The two agencies were asked to provide advice given the rarity of the *Salmonella* type, but stressed the importance of putting this incident into the context of the 100,000 human cases of salmonellosis reported in the EU each year.

Another urgent request dealt with by EFSA concerned the safety of genetically modified organisms (GMOs). The Authority set up a multi-



disciplinary task force in response to a request from the European Commission to evaluate a scientific study and assess whether its findings could lead EFSA to reconsider its previous opinion on maize NK603. The two-year study, by Professor Gilles-Eric Séralini and others, suggested that consumption of the GM maize and a herbicide containing glyphosate at levels below safe limits are linked to a reported increase in incidence of tumours in rats. EFSA set up a task force, drawn from its Panel on Genetically Modified Organisms (GMO Panel) and its Pesticides and Scientific Assessment Units, to consider the Séralini study, and concluded in its initial statement that the design, reporting and analysis were inadequate and the study's findings were, therefore, not scientifically sound. These conclusions were confirmed in a final review carried out by the task force and by assessments by five Member States – Belgium, Denmark, France, Germany and the Netherlands. On the basis of this scientific consensus, EFSA decided that there was no need to re-examine its previous safety evaluations of maize NK603.

A multidisciplinary approach

In cooperation with its European partners, EFSA is playing a central role in addressing emerging issues related to food safety, such as low-dose effects, endocrine active substances and chemical mixtures. Such challenging, complex issues require a multidisciplinary approach and fall within the remit of the Authority's Scientific Committee.

At the request of the European Commission, EFSA began preparing a scientific opinion on the human health and environmental risks associated with the possible presence of endocrine active substances in the food chain. In co-operation with other European scientific advisory bodies, the Scientific Committee carried out a review of all the current scientific information on these substances, with a view to evaluating possible approaches for their identification and methods to assess the hazards they may pose. The opinion would also feed into EFSA's ongoing and future scientific work in such areas as food contact materials,

pesticides and contaminants in food and feed, and help to inform the decisions of risk managers with regard to endocrine active substances.

The opinion, which was published in March 2013, was based on an evaluation of existing information, current insights and scientific work on endocrine active substances, including ongoing work by the Organisation for Economic Co-operation and Development (OECD), the European Commission's 2012 report *State of the Art Assessment of Endocrine Disruptors* and the proceedings from EFSA's June 2012 Scientific Colloquium on low-dose response in toxicology and risk assessment.

EFSA's Panels are increasingly confronted with tasks that require them to address the risks of combined exposures to multiple chemicals ("mixtures") through the diet, in some cases also from multiple sources. This is acknowledged in the Science Strategy 2012-2016, which identifies the risk assessment of chemical mixtures as a priority issue over the coming years. An important



EFSA's Scientific Committee

step towards achieving a harmonised approach to the scientific evaluation of chemical mixtures was the establishment of an internal task force, which is charged with reviewing frameworks already in place internationally. The task force continued this work in 2012, taking into account EFSA's work in areas such as cumulative risk assessment of pesticides, and low-dose toxicology. The task force is scheduled to publish its report on international frameworks in 2013.

Plan bee: protecting our pollinators

Also in line with EFSA's desire to consider risk assessments holistically, and in response to growing concerns about the worldwide decline in bee numbers, the Authority set up a multidisciplinary task force to provide an overview of its work related to bee health. The primary aim is to identify areas which would benefit from a more integrated approach in assessing the risks to bees and the services they provide to humans. The task force – consisting

of experts in the areas of emerging risks, GMOs, pesticides, plant health, animal health and welfare, and data collection and modelling – delivered its first report in November, in the form of an inventory of relevant work being carried out by EFSA in the area of bee health. The inventory identified 355 scientific outputs relevant to bees, the majority of them related to applications for approval of regulated products such as pesticides and GMOs. The work will continue in 2013 with a Scientific Colloquium focusing on multiple stressors in bees and a second report from the task force looking at risk assessment related to bees conducted outside EFSA.

The work of the task force complemented that of EFSA's pesticides experts, who in 2012 delivered an opinion on the science behind the development of guidance for the risk assessment of plant protection products with respect to bees as well as a statement on two innovative behavioural studies which suggested a link between neonicotinoid pesticides and declining bee numbers.

Guidance in a changing world

The development of guidance for risk assessors as well as for applicants seeking approval of regulated products remains an important part of EFSA's work (see also "Evaluation of products, substances and claims subject to authorisation"). The Scientific Committee took this forward in 2012 by establishing a standing working group on the review of guidance for risk assessment that will continue in 2013 and 2014. The mandate of this working group is to establish priorities for the review of existing guidance documents and the preparation of new ones. It will also assist in the implementation and further use of guidance documents across EFSA.

To help build greater understanding of risk assessment principles and methodologies with particular emphasis on general, cross-cutting approaches to risk assessment, the Scientific Committee also initiated a dedicated network on the harmonisation of risk assessment methodologies with the aim of:



- Facilitating harmonisation of risk assessment practices and methodologies;
- Enhancing exchange of information and data between EFSA and Member States;
- Achieving synergies in risk assessment methodology.

The network held its first meeting in June 2012 when members committed to examining the extent to which EFSA's methodological guidance documents are being implemented by the relevant national competent authorities. The results of this analysis will assist EFSA in understanding the reasons behind any divergences and form the basis for further harmonisation in Europe.

Other noteworthy opinions and advice

In addition to its work on meat inspection, EFSA's Panel on Biological Hazards (BIOHAZ Panel) carried out the first scientific assessment

at European level on public health risks posed by pathogens that may contaminate food of non-animal origin. The scientific opinion, which was subsequently published in January 2013, compares the proportion of human cases reported in outbreaks of food-borne disease related to food of non-animal origin with those associated with food of animal origin in Europe. EFSA experts also identified and ranked combinations of foods and pathogens most often linked to food-borne illness from foods of non-animal origin. The opinion complemented previous advice of the BIOHAZ Panel published in October 2011, which assessed the risks posed by Shiga toxin-producing *Escherichia coli* (STEC) and other pathogenic bacteria that may contaminate seeds intended for consumption such as sprouting and sprouted seeds. EFSA's scientific advice was requested after the large STEC outbreak in the spring and summer of 2011. This was caused by a virulent, rare strain of STEC known as O104:H4. This incident highlighted that food of non-animal origin can cause significant outbreaks.

The Authority continued to carry out important work in the area of contaminants in food and feed. The Panel on Contaminants in the Food Chain (CONTAM Panel) adopted the last two of its series of six opinions on brominated flame retardants, man-made chemicals used in industrial and consumer products that persist in the environment; and the last two of three opinions on the re-evaluation of acceptable previous cargoes for edible fats and oils. In 2012, the CONTAM Panel also updated its advice on mercury and methylmercury in food, establishing tolerable weekly intakes intended to protect consumers from adverse health effects posed by the possible presence of mercury in food. Building on this work, EFSA received a new mandate from the European Commission for a scientific opinion on the risks and benefits of fish/seafood consumption as regards methylmercury. ■



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

Key scientific activities in 2012 included the start of EFSA's first full risk assessment of the sweetener aspartame. EFSA issued another call for data on bisphenol A (BPA), a food contact material that is arousing public concern, and brought together national experts in Parma to exchange information and views. In December, EFSA finalised conclusions on three neonicitinoid pesticides that some studies have suggested are linked to a decline in bee numbers in the EU; EFSA's conclusions will guide the European Commission's recommendations on their continued usage. EFSA's scientific work contributed to the publication by the Commission of lists of approved health claims and food flavourings.

Advice in areas of high public concern: from sweeteners to pesticides

In the area of chemical risk assessment, three issues stand out in 2012: BPA, aspartame, and neonicitinoid pesticides. As a result of EFSA's ongoing monitoring of scientific research on BPA, the Authority began a full risk assessment of this chemical commonly used in food contact materials, which has generated much public interest and has been banned by some national authorities. The new, self-tasked opinion, to be published in 2013, will complement earlier scientific advice provided at the request of the European Commission. 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. Experts on the Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF Panel) are further evaluating uncertainties about the possible relevance to human health of some BPA-related

effects observed in rodents at low dosage levels. New findings from studies on low-dose effects as well as on dietary and non-dietary exposure to BPA are being considered as they become available. EFSA also held a Scientific Colloquium of international experts to debate the most recent scientific evidence of low-dose effects in toxicology and the challenges this poses for risk assessment.

Two multidisciplinary working groups of experts were established to focus, respectively, on the hazard characterisation of BPA – concerning its toxicological effects – and on exposure to BPA – how and in what quantities BPA is absorbed by the human body. To enhance EU-wide cooperation, experts from national authorities undertaking related scientific work on BPA have also been invited to contribute to the working groups.

Regarding aspartame, the European Commission extended the deadline for the full re-evaluation of this sweetener (E 951) to 2013. This was to give sufficient time to EFSA's scientific experts



to consider new data and complete their comprehensive risk assessment, as well as to publicly consult on their draft opinion prior to its final adoption. The review of this sweetener is part of the systematic re-evaluation of all food additives authorised in the European Union (EU) prior to 20 January 2009, as anticipated under Regulation EU 257/2010.

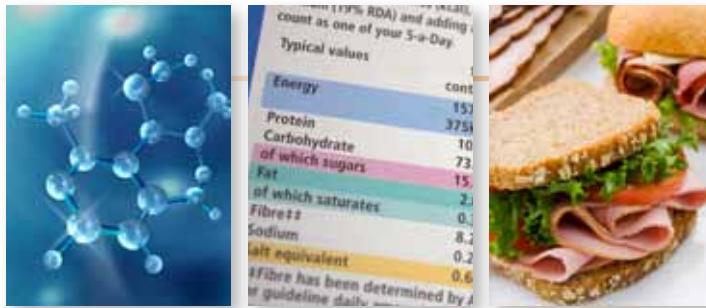
EFSA had been asked to carry out a full risk assessment by 2012 and launched a public call for scientific data, as well as a thorough literature review, enabling the Authority's Panel on Food Additives and Nutrient Sources Added to Food (ANS Panel) to start its risk assessment in early 2012. In the course of its deliberations, the ANS Panel found that there were insufficient data available on diketopiperazine (DKP) and other potential degradation products that can be formed from aspartame in food and beverages when stored under certain conditions. EFSA, therefore, issued an additional call for data and requested the deadline extension.

The public consultation was launched in January 2013 following a comprehensive review of the peer-reviewed scientific and other literature on aspartame and its breakdown products, including new human studies. The material reviewed included the 112 original documents on aspartame that were submitted to support the request for authorisation of aspartame in Europe in the early 1980s. In the interest of transparency and openness, EFSA published the full list of these scientific studies and also made publicly available previously unpublished scientific data.

In late 2012 EFSA finalised opinions on three neonicitinoid pesticides, which identified a number of risks to bee health. The Authority was asked by the European Commission to assess the risks associated with the use of clothianidin, imidacloprid and thiamethoxam as seed treatment or as granules, with particular regard to: their acute and chronic effects on bee colony survival and development; their effects on bee larvae and bee behaviour; and the risks posed by sub-lethal doses of the three substances.

The risk assessments focused on three main routes of exposure: exposure from residues in nectar and pollen in the flowers of treated plants; exposure from dust produced during the sowing of treated seeds or application of granules; and exposure from residues in guttation fluid produced by treated plants. In reaching their conclusions, EFSA's scientists evaluated data previously submitted for the approval of the active substances at EU level and in support of product authorisations at Member State level, as well as relevant literature and monitoring data. They also considered new developments in the assessment of risks to pollinators from plant protection products, in particular recommendations contained in the EFSA Scientific Opinion on the science behind the development of a guidance document on the risk assessment of plant protection products with respect to bees, which was published in May.

EFSA adopted its first three scientific opinions on the safety of processes to recycle polyethylene terephthalate (PET) for use in food contact materials. These opinions are the first of a series on



recycled plastic materials for food use. Once this series is completed, EFSA's opinions will inform the decisions of EU risk managers regarding their authorisation. After that, most recycled plastics used in food packaging, food containers and other food contact materials should only be obtained from processes which have been assessed for safety by EFSA and authorised by risk managers.

EFSA also played a significant role in the landmark publication of a list of food flavourings authorised for use in the EU. About 2,500 flavouring substances were included in the list, which came into force on 22 October 2012 and followed the publication by EFSA of 170 scientific opinions evaluating the safety of thousands of flavouring substances. This significant programme of scientific work, which began in 2003 and is ongoing, has played and continues to play a critical role in ensuring that flavouring substances used in foods are of no safety concern for consumers. In November the Authority held a technical meeting with stakeholders to exchange views on the administrative and scientific challenges

related to the preparation, submission and risk assessment of applications for flavourings.

Assisting applicants

The renewal of the Scientific Panels and Scientific Committee represented an important milestone for EFSA, but one of the other key achievements in the regulated products arena was the ongoing development of the Applications Desk Unit. The unit was established in 2011, and in 2012 staffing was completed and the harmonisation of administrative procedures began. The Helpdesk function was launched on EFSA's website to provide structured guidance to applicants and enable them to submit questions on the application process. The unit answered hundreds of queries and organised four information sessions on pesticides, food additives, genetically modified organisms (GMOs) and flavourings to ensure that commercial operators and other stakeholders were fully informed of the application process.

Health claims: a landmark year

2012 was a landmark year for EFSA in the area of health claims as the European Commission published a list of 222 general function claims that are approved for use in the EU. The list is based on scientific advice that EFSA's nutrition experts have been providing since 2008. General function claims are those made for food 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 list means that claims that are not supported by science will be removed from the market and consumers will be able to make more informed choices about the food they buy.

Although EFSA finalised its evaluations of general function claims in 2011 – publishing a total of 341 opinions covering 2,758 claims – the European Commission and the Member States agreed that a limited number would be eligible for further assessment following the submission of additional data. These included 74 claims



related to microorganisms, which the Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) initially considered to be not sufficiently characterised, and 17 claims for which the Panel concluded in its initial assessment that there was insufficient evidence to establish a cause and effect relationship between the consumption of the food and the claimed effect. After these 91 claims were further assessed in 2012, two were considered to be substantiated: these were those covering prunes and normal bowel function; and alpha-cyclodextrin and a lower rise in blood glucose after meals.

Because of the scientific and technical complexity inherent in the assessment of the scientific substantiation for health claims, EFSA has devoted considerable effort to the development of guidance to support industry in submitting applications to the Authority. In 2007 it published guidance on the preparation and presentation of applications, followed two years later by guidance on the general principles employed by the NDA Panel in assessing scientific substantiation for

health claims. There followed a series of specific guidance documents on gut and immune function; antioxidants and cardiovascular health; weight management; and bone, joints and oral health. Two more specific guidance documents were published in 2012 – on the scientific requirements for the substantiation of health claims related to functions of the nervous system, including psychological functions, and those related to physical performance.

Setting scientific standards for applicants

In addition to health claims, EFSA continued to issue guidance to assist applicants in other important sectors. For example, the ANS Panel published new guidance on the risk assessment of food additives, reflecting advances in science and the latest risk assessment principles. In the EU, the safety of food additives is assessed by EFSA prior to their consideration by the European Commission and Member States for market authorisation. Applicants seeking such an

authorisation are required to provide the necessary information and data supporting the safety of the food additive, according to EFSA's requirements.

The advice adopted by the ANS Panel in June 2012 replaced guidance originally established in 2001 by the European Commission's former Scientific Committee on Food. New guidance was deemed necessary to reflect both advances in science and 10 years' experience in applying the existing guidance. Important changes were introduced to the requirements for genotoxicity, toxicity, carcinogenicity and reproductive toxicity testing. An exposure assessment tool was developed by EFSA to support the calculation by the applicant of estimates of exposure to the food additive and its by-products and to harmonise the submission of the related data.

Another important guidance document published in 2012 covered the risk assessment of food and feed derived from genetically modified (GM) animals. The document outlines specific data requirements and the methodology to be



followed for risk assessment should applications for food and feed derived from GM animals be submitted for market authorisation in the EU. The risk assessment approach compares GM animals and derived food and feed with their respective conventional counterparts, integrating food and feed safety as well as animal health and welfare aspects.

At present, no applications for market approval of food and feed derived from GM animals have been submitted in the EU. However, the technology has advanced rapidly in recent years and in some countries outside the EU regulators are already evaluating the safety of GM animal products developed for food and feed purposes. In anticipation of potential future applications, the European Commission requested EFSA to develop comprehensive guidance for the risk assessment of food and feed derived from GM animals and on related aspects of animal health and welfare.

Finally, the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP

Panel) developed pioneering guidance for the safety assessment of one of the most common probiotics used in animal feed, *Enterococcus faecium*. The guidance provides a new methodology for distinguishing between safe and potentially harmful strains of *E. faecium* in animal nutrition and is intended for use by feed additive producers submitting applications to EFSA for safety assessment. Enterococci are well-known bacteria and are found in abundance in the gastrointestinal tract of both animals and humans. They are often used in the production of feed additives as a probiotic to prevent diarrhoea or to improve growth in animals.

Assessing risks to the environment

EFSA continued to build on its work in environmental risk assessment in 2012. In 2011 the Panel on Genetically Modified Organisms (GMO Panel) published a guidance document on post-market environmental monitoring (PMEM) and issued its first scientific opinion on

a PMEM report, for maize MON810. The GMO Panel published a second opinion for MON810 in 2012, which covered the growing season in 2010. It concluded that cultivation in 2010 had no adverse effects on human and animal health or the environment. Opinions were also published on the Post-market environmental monitoring (PMEM) reports for potato Amflora (planting seasons 2010 and 2011), which made recommendations on improving data collection, analysis and reporting.

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 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.



The Panel on Plant Protection Products and their Residues (PPR Panel) carried out two important pieces of work in the area of environmental risk. A guidance document was drafted on assessment of the risk to aquatic organisms from plant protection products. The guidance, which will be adopted in 2013, outlines a tiered assessment procedure and proposals on how to link effects to exposure evaluations for aquatic organisms living in edge-of-field surface waters.

The Panel also published a scientific opinion on the science behind the development of guidance on the risks posed by pesticides to bees. This opinion was the precursor to the development of specific guidance for the assessment of possible risks to bees from the use of plant protection products. The guidance, to be published in 2013, will provide up-to-date advice to those involved in the evaluation of plant protection products and their active substances, including industry and public authorities. It forms the

centrepiece of EFSA's full programme for 2013 of scientific projects related to bee health.

In addition to these projects, EFSA's pesticides experts continued with their ongoing work in peer reviewing risk assessments of active substances used in pesticides. These substances can be authorised only if they have no harmful effects on human and animal health and do not have unacceptable effects on the environment, considering in particular the contamination of water and the possible impact on non-target organisms (such as birds, mammals, aquatic organisms, bees, arthropods, soil organisms, flora). The environmental risk assessment (ERA) of pesticides assesses the impact that the use of pesticides has on non-target living organisms and on soil, water, and air. Twelve external scientific reports were published in support of current or future activities of the PPR Panel. These reports focused on human dietary and non-dietary cumulative exposure to pesticides and on

various aspects of environmental risk assessment (sediment-dwelling organisms, population of vulnerable species, bees, amphibians, multiple stresses on aquatic organisms, non-target arthropod communities, microbial organisms and marine and estuarine organisms).

The Authority's GMO experts published draft guidance for the ERA of GM animals, to be published in 2013. The document, which focuses on GM fish, insects, mammals and birds, outlines the specific data requirements and methodology for the ERA of GM animals should applications be submitted for market authorisation in the EU in the future. The risk assessment is based on a comparative approach between GM and non-GM animals. ■



3. DATA COLLECTION, SCIENTIFIC COOPERATION AND NETWORKING

One of the key objectives of the Science Strategy 2012-2016 is to optimise the use of European risk assessment capacity across the European Union (EU). With constant developments in science and technology, it is crucial that our ability to assess and mitigate risks keeps pace. Central to this endeavour are EFSA's Advisory Forum of national food safety representatives; the networks for exchanging information and sharing expertise across the EU, which support the Authority's scientific units; and its Focal Points, which act as interfaces between EFSA and the Member States.

Maintaining and improving risk assessment expertise

The availability of high-quality risk assessment expertise is crucial at both national and European levels. Maintaining and developing this expertise is identified as a priority in EFSA's Science Strategy, which explicitly calls for greater coordination with organisations in the Member States, the sharing of work programmes and the use of joint initiatives in order to make the best use of available capacity and resources throughout Europe.

Cooperation activities were central to EFSA's continued ability to proactively identify and assess emerging issues in 2012. A standing working group of the Scientific Committee dedicated to implementing the process of emerging risk identification was set up, supported by a Stakeholder Consultative Platform (SHP) Working Group on Emerging Risks and the Member State network on emerging risks. Sixteen issues were discussed in detail with the Member State

network, some of which were discussed with the dedicated stakeholder group. Two of these were followed up on: the use of data from the EU's REACH programme for the identification of priority emerging chemical risks in the food chain, and a recommendation for carrying out research in the area of emerging indigenous ciguatera toxin production in European waters, which was sent for consideration by the European Commission's DG Research and Innovation. The SHP working group also contributed to EFSA's Annual Report on Emerging Risk Identification.

The Science Strategy 2012-2016 also cites the need for training and other initiatives to develop expertise in risk assessment both within and outside EFSA. The Authority began to address this requirement by developing a continuing professional development programme for external experts and EFSA staff and collaborating with the European Commission on basic training in risk assessment through its Better Training for Safer Food programme.



Engaging stakeholders

EFSA strengthened its dialogue with sectoral organisations engaged in the Authority's areas of work, with groups directly representing industry interests and with non-governmental organisation (NGOs), when it renewed the membership of the SHP in June 2012. Throughout the year, EFSA provided SHP members with information on its activities and increased the interaction with stakeholders to reinforce their scientific engagement. EFSA sought the views of the Platform on corporate documents such as the 2013 work programme and the second external evaluation of the organisation.

The SHP is not the only way EFSA engaged with stakeholders; in March 2012 the Authority organised an information session on the implementing rules of its independence policy to provide a detailed description and practical illustrations of the factors EFSA considers when screening declarations of interest. A number of technical meetings were organised on specific scientific issues, including the annual meeting with

NGOs on methodologies and procedures applied in the field of genetically modified organisms (GMOs) and environmental risk assessment. At the meeting with NGOs, EFSA provided information on its activities on the risk assessment of herbicide-tolerant genetically modified (GM) plants and related herbicides and gave a presentation on its draft environmental risk guidance on GM animals, as well as an overview of the comments received earlier this year as part of the public consultation on the document. Each presentation was followed by an exchange of views with NGO representatives.

Forum for cooperation

The Advisory Forum continued to address key strategic issues at the four meetings it held in 2012. The Forum emphasised its support for EFSA's contribution to the progress of EU food safety over the past decade in a statement of support published by all Member States. Scientific cooperation with Member States, EEA/EFTA countries and candidate countries also continued to be promoted by the Focal Points. One of the

three Focal Point meetings was organised back-to-back with a joint meeting with the Advisory Forum Working Group on Communications (AFCWG), the aim of which was to optimise risk communication activities at national level.

EFSA's scientific networks had a busy year once more. For example, several meetings of the Scientific Network on Risk Assessment in the field of Animal Health & Welfare were held addressing issues such as testing for bovine tuberculosis, the Schmallenberg virus (SBV) as an emerging disease, and surveillance options for *Ecchinococcus multilocularis*. A technical meeting of the network was also held on collaboration on non-food-borne zoonotic and potential zoonotic diseases, with participation of the European Centre for Disease Prevention and Control (ECDC) and European Commission representatives. The meeting participants concluded that EFSA and ECDC should proceed with establishing a joint animal health/human health network on non-food-borne zoonotic and potentially zoonotic diseases that should be flanked with an IT information exchange platform. The GMO network held its third annual



meeting in 2012, welcoming 49 scientific experts from Member States and Candidate Countries to discuss issues such as the environmental risk assessment of GM plants; allergenicity of GM food and feed; and EFSA's draft guidance on GM animals.

The Information Exchange Platform (IEP) continued to develop as a key food safety data and information exchange mechanism with 254 documents from 22 different countries uploaded in 2012, a 20% increase over 2011. EFSA's Expert Database grew to 4,000 with important improvements in its functionality.

In 2012 EFSA committed more than EUR 9 million to scientific cooperation through grants and procurement calls. The Authority also issued new guidelines on the management of the list of Article 36 organisation, to ensure that it is kept up-to-date and functional and that it covers the required expertise. A comprehensive review of the list was launched for organisations to update their profiles and for Member States to re-assess their nominated organisations in the light of the new guidelines.

Data collection

As well as collecting data for individual risk assessments, EFSA collects data at EU level to measure, for example, the occurrence of biological or chemical contaminants in the food chain. This information, combined with reliable information on food consumption in the Member States, makes it possible for risk assessors to estimate consumer exposure to a certain hazard at both EU and national level. The assessments also allow scientists to make recommendations for the monitoring, reduction and prevention 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 EU Summary Reports in close collaboration with the ECDC. The *Summary Report on Zoonoses and Food-borne Outbreaks* published in 2012 revealed that cases of *Salmonella* in humans fell by almost 9% in 2010, marking a decrease for the sixth consecutive year. *Salmonella*, which usually causes fever, diarrhoea and

abdominal cramps, accounted for 99,020 reported human cases in 2010 compared to 108,618 in 2009. *Salmonella* was found most often in chicken and turkey meat. However, a total of 212,064 *Campylobacter* cases in humans were reported, an increase for the fifth consecutive year with 7% more cases compared to 2009. In foodstuffs, *Campylobacter*, which can cause diarrhoea and fever, was mostly found in raw poultry meat. To combat *Campylobacter*, the European Commission has carried out a cost-benefit analysis of the control measures for the bacteria at different stages of the food chain. EFSA has supported this work by, among other things, analysing an EU-wide baseline survey on the prevalence of *Campylobacter* in chicken and providing a quantitative risk assessment on possible reduction measures.

EFSA and ECDC also published the second joint EU *Summary Report on Antimicrobial Resistance*. The report, based on data collected from EU Member States for 2010, showed that resistance to several antimicrobials was commonly detected in zoonotic bacteria such as *Salmonella* and *Campylobacter*, which are the main causes of reported food-borne



infections in the EU. The occurrence of resistance in animals and food remained similar to that of previous years. EFSA and ECDC were among the key actors participating in a conference to discuss joint actions in combating antimicrobial resistance organised in March by the Danish Presidency of the European Union. EFSA's Biological Monitoring Unit (BIOMO Unit) issued three reports in 2012 aimed at harmonising the monitoring and reporting of data on antimicrobial resistance in animals and food. A major step forward was the implementation of the automatic reporting tools for most of the annual reporting; half of the reporting countries used these in 2012 for at least some data sets.

EFSA drafted the *Annual Report on Pesticide Residues* for 2010. The report – published in 2013 – summarises the results of more than 77,000 samples of approximately 300 different types of food which were analysed in the 27 Member States and two EEA/EFTA countries (Norway and Iceland). Based on the results submitted, EFSA calculated the actual consumer exposure to pesticide residues from food and identified potential risks related to certain pesticide/crop combinations containing

critical concentrations of residues. As part of the analysis, EFSA tested an innovative approach to dietary exposure known as cumulative risk assessment. In contrast to established techniques that evaluate pesticide residues individually, this approach considers the potential effects of combined exposure to a number of chemicals that have similar toxicological properties.

EFSA's Dietary and Chemical Monitoring Unit (DCM Unit) published a new report on levels of dioxins and polychlorinated biphenyls (PCBs) in food and feed. Dioxins and PCBs are persistent environmental pollutants which can accumulate in the food chain. These toxic substances can over time have adverse effects on human health and may cause cancer. The report revealed a general decrease in dietary exposure to dioxins and dioxin-like PCBs, comparing the period 2008–2010 with 2002–2004. The average decrease was 46% for the general population, with a similar decrease for children. Exposure to non-dioxin-like PCBs, a sub-set of PCBs with different toxicological properties, also decreased. The

report is based on 33,000 samples collected by 26 European countries between 1995 and 2010.

The DCM Unit also published its annual update report on acrylamide levels in food in 25 European countries. The report covered the monitoring period 2007–2010 and did not reveal any considerable change in acrylamide levels in food from the previous report for the majority of the food categories assessed. Acrylamide is a chemical compound that typically forms in starchy food products such as potato crisps, French fries, bread, biscuits and coffee, during high-temperature processing, including frying, baking and roasting. An EFSA statement in 2005 noted that there may be a potential health concern with acrylamide, which is known to be both carcinogenic and genotoxic. Member States are requested to perform yearly monitoring of acrylamide levels and EFSA assesses these data for compilation in an annual report. In 2013 EFSA will update its European exposure assessment – last carried out in 2011 – based on more recent data on acrylamide levels in food, as well as new food consumption data. ■



4. COMMUNICATIONS AND DIALOGUE

A number of developments made 2012 a significant year for communications at EFSA, including the 10-year anniversary activities, the implementation of a thematic approach to communicating, the publication of Risk Communications Guidelines in cooperation with the Advisory Forum Working Group on Communications (AFCWG), and the launch of EFSA's Twitter account. The number of press releases and web stories rose from 80 in 2011 to 85 in 2012.

Cooperation breeds coherence

Cooperation with Member States on communication issues remained crucial in 2012 as EFSA continued to fulfil one of its key core functions: ensuring coherence and consistency of message among the EU's risk assessment community. The AFCWG continued to play an important role in meeting this remit. The AFCWG provides a mechanism for exchange of information and experiences between EFSA and the Member States, enabling tailoring of risk communications messages to the specific needs of European Member States and regions. The highlight of the group's ambitious 2012 work programme was the launch of its Risk Communications Guidelines, which have been translated into 17 EU languages. The guidelines, entitled *When Food Is Cooking Up a Storm – Proven Recipes for Risk Communications*, were initiated to promote the dissemination of best practices in risk communications between risk assessors in Member States and EFSA. The

AFCWG will revise the guidelines annually, adding best practice case studies when appropriate.

The AFCWG held discussions on the use of social media in risk communications and organised a training session on the subject. EFSA also provided communications support to two training courses under the European Commission's Better Training for Safer Food programme addressing microbiological and chemical risk assessment in food with particular emphasis on risk communication issues.

Adding context

In 2012 the Communications Directorate fully implemented the thematic approach outlined in the Communications Strategy 2010-2013. EFSA continued to communicate on individual scientific outputs but also started to take a more holistic approach to addressing and communicating



public health issues in key thematic areas, such as zoonoses, pesticides, chemicals in food, and nutrition. This thematic approach was clearly visible in the launch of the In Focus "campaign" slot on the homepage of the EFSA website. This was used to contextualise and reinforce the broader messages behind the outputs of the Authority's various Scientific Panels. For instance, communications on the outputs of the Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) concerning evaluations of health claims were packaged alongside the topic on nutrition and health claims, answers to frequently asked questions (FAQ), and previous news and feature stories related to the subject. The In Focus slot gains added visibility on the website from the inclusion of an Understanding Science video relevant to the featured subject. These "whiteboard" videos were launched in 2012 and take the form of EFSA scientific experts explaining in an accessible manner some of the scientific concepts that underpin EFSA's work. Subjects

covered so far include data collection, chemical contaminants in the food chain, pesticides, genetically modified organisms, zoonotic diseases, risk communication, and EFSA's independence. The videos have proved to be popular; the 25 published in 2012 had been viewed more than 40,000 times by the end of the year, both on the EFSA website and on the dedicated EFSA Channel on YouTube, which was also launched in 2012.

10th anniversary activities

The Communications Directorate was central to the activities organised in 2012 to mark EFSA's 10th anniversary. At the beginning of the year the directorate developed a discrete section on the website showcasing a series of feature articles looking at the key achievements of the Authority's first 10 years. This content was later included alongside additional material in a brochure entitled *EFSA@10: The science*

that is helping to keep Europe's food safe, which demonstrated the contribution that EFSA's work has made to protecting consumers, animals and the environment. As well as revisiting landmark projects related to, amongst others, *Salmonella*, *E. coli*, animal health, food consumption data and meat inspection, the brochure looked ahead to the challenges that EFSA will face in the future.

EFSA held a number of joint events with stakeholders and Member States, and the anniversary activities culminated in two major events at the end of the year. *Challenging boundaries in risk assessment – sharing experiences* was the title of a two-day event held in Parma that was attended by just under 600 people. Risk assessment specialists from across the EU discussed issues such as: identifying and characterising hazards; environmental risk assessment; dietary exposure in risk assessment; risk characterisation and efficacy assessment in food and feed. This was followed by a high-level



conference held jointly with DG SANCO, entitled *Ready for the Challenges of Tomorrow*, which was attended by 120 people and was webcast live. Delegates focused on the continuing importance to Europe of a strong relationship between risk assessors and risk managers. Other future challenges that were identified included: how, in times of austerity, to ensure the Authority receives sufficient funding to carry out its tasks; a need to better understand the public's perception of risk and make communications more accessible, particularly given the rise of social media and "viral" web stories; the importance of ensuring continued access to the best scientific experts; and building risk assessment capacity in the European Union (EU). As with the other meetings, the two conferences were promoted through a variety of outlets including press releases, media visits, tweets and announcements on the EFSA website and in the weekly *EFSA Highlights* newsletter.

Reaching out

EFSA continued to innovate and add to its box of media tools throughout the year. A Twitter account was launched to boost awareness of key outputs and events, and by the end of the year the Authority had more than 2,000 followers. Improvements to the website search engine and changes to other areas of the site architecture, carried out in response to user feedback, helped to increase the number of visits to the website by 27%. Other innovations focused on the provision of dedicated subscriber services. These included the launch of email alerts, which allow interested parties to tailor EFSA's web content to their needs, and *EFSA Highlights*, which replaced the printed *EFSA News* and *EFSA In Focus* newsletters; the e-newsletter has been developed so that it can be received on mobile platforms. EFSA also revamped its "shop window" with the creation of a new corporate brochure and video. Both products provide a concise overview of the Authority's

role in the EU food safety system, explaining how Europe's food chain is continually evolving and how, in turn, EFSA's remit has evolved to cover an increasingly complex number of areas.

One of the key priorities of EFSA's Communications Strategy is to raise visibility and awareness of the Authority, and to this end EFSA devotes great attention to developing relations with the media. In 2012 EFSA was mentioned in 9,194 articles and the Media Relations team organised 111 interviews and responded to 893 media enquiries. The vast majority of the articles were neutral in tone, with the negative coverage concentrated largely on issues related to the independence of EFSA's work, the European Parliament's budgetary discharge debate and the assessment of genetically modified organisms (GMOs). Seventy percent of EFSA-related reporting was accounted for by five countries – France, Germany, Spain, the UK, and Italy – as well as pan-EU media; the rest was shared among other EU Member States

and some non-Member States. The analysis of media message penetration is feeding into the work of the Media Relations and Editorial teams as a means of gauging the types of messages that are picked up and where further simplification is required. An increase in key message penetration was evident during 2012 compared to 2011.

EFSA and the wider European community

As well as its regular meetings and interactions with stakeholders through public consultations, technical meetings and meetings of the Advisory Forum and the Stakeholder Consultative Platform (SHP), EFSA also maintains relations with its broader community of partners through ad hoc meetings and visits. In 2012 the Authority continued to ensure effective working relations with the European Commission, the European Parliament and the Council of EU Ministers. A delegation from the European Parliament's

Environment, Public Health and Food Safety (ENVI) Committee led by its Chair Matthias Groote and liaison Member of the European Parliament (MEP) for EFSA Pilar Ayuso, visited EFSA in May. Topics discussed included working practices as well as EFSA's extensive scientific work programme with a focus on nutrition, new technologies, GMOs, pesticides and animal health and welfare. In addition, EFSA's Executive Director Catherine Geslain-Lanéelle had regular bilateral meetings with MEPs and welcomed Monica Macovei from the Budgetary Control Committee to Parma. Ms Geslain-Lanéelle's annual hearing before the ENVI Committee in the European Parliament took place in September and a number of MEPs attended the high-level conference organised by EFSA in Parma to mark its 10th anniversary.

During 2012, EFSA visited its counterparts in Member States and participated in a variety of fora to discuss key food safety issues. The Authority received delegations from the



Delegation from the European Parliament's ENVI Committee

Republic of Korea, China, Thailand, Canada and Chile, and an EFSA delegation visited Japan and South Korea to lay the groundwork for future collaboration. EFSA liaised closely with the two rotating six-month EU Presidencies of Denmark and Cyprus and held meetings of its AF in Copenhagen and Paphos. EFSA met both presidencies on a number of occasions and held discussions with its counterparts and related organisations in the USA and international organisations such as the Organisation for Economic Co-operation and Development (OECD), the latter in relation to governance issues. ■



5. GOVERNANCE AND SUPPORT

EFSA moved into its new premises at the beginning of 2012, with no loss of business continuity, a transfer that brought financial efficiencies to the organisation. A number of important steps were taken to further strengthen EFSA's independence policy and related implementing rules, and improve planning and monitoring of the Authority's work.

Building on solid foundations

EFSA's move to new purpose-built premises in Parma was an apt metaphor for the building blocks that the agency has been putting in place over recent years to reinforce the integrity of its scientific work and corporate processes. In 2011 EFSA reorganised into five directorates and established an Applications Desk Unit. The aims of the reorganisation were to make better use of resources to reflect a growing and diversifying workload, to increase efficiency and to provide an improved service to clients. Having put the necessary working structures in place, EFSA moved to address its work practices.

An important initiative in this respect was the launch of the Project and Resource Management Approach (PARMA) Project, the aim of which is to harmonise working practices at EFSA, and at the same time improve efficiency and transparency by rolling out a project management approach to the Authority's scientific work. During October and December 2012, the PARMA Project team developed a model for a project management approach tailored to the needs of EFSA. This followed a pilot phase involving four

units that provided valuable insights. By the end of the year the team had drawn up a draft implementation plan that was subsequently approved by the Management Team.

The launch of the PARMA Project was complemented by the development of two other major shifts in EFSA's work practice. In 2011 the Authority created a system of planning and monitoring teams aimed at improving internal coordination and long-term planning in the organisation and also easing the burden on scientific units by transferring responsibility for grants and procurement to the new teams. In 2012 these teams became firmly embedded at EFSA, helping to improve efficiency and accountability. In particular, the Balanced Scorecard system for evaluating performance was fully implemented, thus providing an effective basis for monitoring organisational performance and setting priorities. Quarterly progress reports were presented to the Management Board along with key performance indicators.

Alongside the expansion of the planning and monitoring function, EFSA also made progress on the implementation of an ISO 9001 quality



management system. The External Review Working Group – made up of independent scientists who assess EFSA's compliance with its rules and operating procedures – was strengthened and renewed, and the organisation's progress towards developing an ISO 9001 system for its scientific activities was assessed by an internationally recognised certification body. The Authority remained on course to have all scientific outputs covered by the system by the end of 2013.

EFSA also continued to improve the efficiency of its logistical services by starting to centralise tasks such as meeting organisation and liaison with scientific experts within the Corporate Services Unit. A successful pilot project was carried out in the second half of the year, during which a number of efficiencies were identified, such as enhanced budget monitoring and better allocation of financial resources; and more structured and standardised communication with experts.

The Authority continued to make optimum use of the resources at its disposal, achieving several efficiency gains: 99.3% of the annual budget was committed, with 88% paid. Personnel engaged in

governance and support activities were reduced by 4% and, in addition to the EUR 1.98 million of savings in 2011, a further EUR 3.94 million was saved in 2012; these savings have been redeployed in scientific cooperation and IT development.

The Human Capital and Knowledge Management Unit, set up in 2012, developed a staffing and resource planning model which relies more on internal competencies and, where possible, less on external recruitment. To assist this process, a career development model was designed with the aim of enhancing internal mobility and career opportunities. To reinforce the link between EFSA's strategic needs and its learning activities, an assessment of knowledge management and development was performed in consultation with directors and operational managers. This led to the drafting of an EFSA Learning Framework 2013-2016, which identifies three key targets for EFSA's learning activities:

- To create a platform for the delivery of learning and development activities within and beyond the organisation – the EFSA Academy;

- To foster a continuous learning network that contributes to the enhancement of scientific excellence;
- To contribute to the evolution of the EFSA managerial culture through targeted development programmes.

Safeguarding independent science

In the first quarter of 2012, EFSA finalised the implementing rules of the Policy on Independence and Scientific Decision-Making Processes. Following the entry into force of the rules, the Authority ensured a coherent application and development of the concepts and principles enshrined in these rules. This applies first to the selection of members of EFSA's Scientific Committee and Scientific Panels, and subsequently to the daily operations of the Authority.

The efforts that EFSA has devoted to strengthening and safeguarding its independence were acknowledged by important independent bodies. ▀

III. OUTLOOK





For 2013 EFSA has a full programme of activities that address key public health priorities. To provide clarity and predictability on expected workloads and facilitate the involvement of national food safety agencies and other stakeholders in EFSA's work, a rolling multiannual work programme will be issued with input from the European Commission, Member States and other key stakeholders.

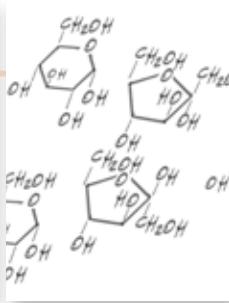
Risk assessment to the forefront

As EFSA proceeds with the implementation of its Science Strategy, it will continue to develop and harmonise its risk assessment approaches and to share best practices both internally between the Scientific Panels and externally with other risk assessment bodies. The Authority will consult its Scientific Committee on issues given high priority in the Science Strategy in relation to general risk assessment principles; the establishment of medium- and long-term planning of EFSA's activities in the areas of guidance development and the implementation of new risk assessment methodologies; and topics of a multisectoral nature.

Harmonised methodologies will be developed for environmental risk assessment, characterisation of uncertainties, and the risk assessment

of chemical mixtures. At the request of the European Commission, the Scientific Committee will also advise on the human health and environmental risks of endocrine disruptors.

EFSA will complete its major project on meat inspection in 2013. Scientific opinions were delivered on domestic swine and poultry in 2011 and 2012; the remaining species – solipeds, cattle, small ruminants, and farmed game species – will be covered next year. The Authority also has a full programme of evaluations or re-evaluations of products and processes over the coming year. These include: food additives, particularly the re-evaluation of aspartame; a comprehensive risk assessment of Bisphenol A (BPA); new applications for food enzymes; health claim applications and safety assessments of novel foods; the process contaminant acrylamide; and neonicotinoid active substances in pesticides.



In the area of nutrition, EFSA's work on setting dietary reference values will enter an important stage with opinions on the first batch of micronutrients, including vitamin C and fluoride.

Risk assessment work will continue to be supported by EFSA's specialists in data collection, monitoring of biological hazards, statistics, modelling and data management. They will, amongst other things, provide an assessment of the Schmallenberg virus (SBV) in Europe, and data for microbiological risk assessments. They will also assess dietary exposure to hazardous compounds using occurrence data for food and feed and information stored in the Comprehensive European Food Consumption Database.

Regulated products: the work goes on

The workload associated with the evaluation of regulated products and health claims will remain considerable in 2013. Although the overall number of scientific outputs is not expected to rise significantly – partly due to the uncertainty surrounding the evaluation of botanicals – the increasing complexity of evaluations in fields such as Genetically modified organism (GMOs) and pesticides coupled with the need to enhance stakeholder engagement means the workload will remain high.

The Helpdesk service for applicants will continue to enhance the dialogue and quality of the service provided to applicants, Member States, stakeholders and other interested parties and, in particular, will enhance interactions

with small and medium-sized enterprises. The Applications Desk Unit will also continue to streamline the registration and administrative procedures associated with applications. In line with the Science Strategy, efforts will be made to strengthen scientific cooperation and data exchange at European and international levels to better support applicants with updated guidance documents and risk assessment approaches based on the latest scientific developments. Colloquia, workshops, technical meetings and other forms of consultation will continue to be prioritised.

Cooperation remains the key to scientific excellence

Scientific cooperation and networking with Member States will remain a high priority in 2013.

A review of planning in scientific cooperation will be undertaken with a view to adopting a more multiannual approach in line with the Science Strategy. This medium-term planning process, along with a grants (Article 36) list revised to achieve its full potential, will make the network of stakeholders and partners even more effective in supporting EFSA. EFSA's data collection specialists will issue reports on selected contaminants, requested by the Commission, as well as the annual report on veterinary drug residues. The food classification system launched in 2010-2011 will be progressively implemented and made available to Member States. EFSA will promote and support planning and collection of harmonised occurrence and food consumption data, including post-market monitoring of food additives. Data collection for the European Union (EU) Menu project, the pan-European food consumption survey, will continue.

In the field of biological monitoring, EFSA will continue to produce the EU Summary Reports on zoonoses and food-borne outbreaks, and antimicrobial resistance, both in collaboration with the European Centre for Disease Prevention and Control (ECDC).

Spreading the message about EFSA

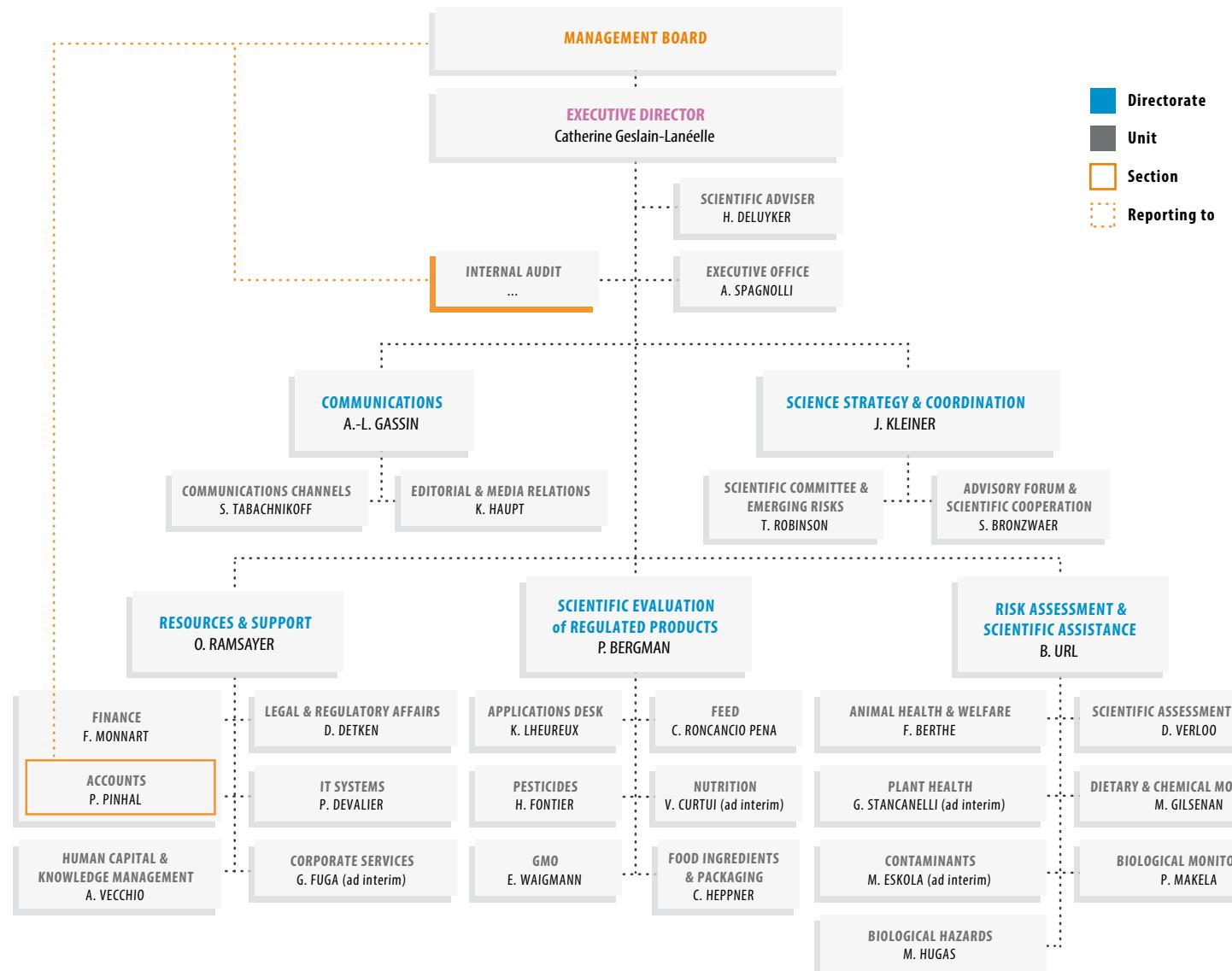
A priority for EFSA in 2013 will be to improve the effectiveness of its communications on independence and to widen understanding of EFSA's role in the EU regulatory system. The Policy on Independence and Scientific Decision-Making Processes and its implementing rules, which were introduced in 2012, significantly strengthened EFSA's systems for ensuring the independence of its science. But, as the final report of the second



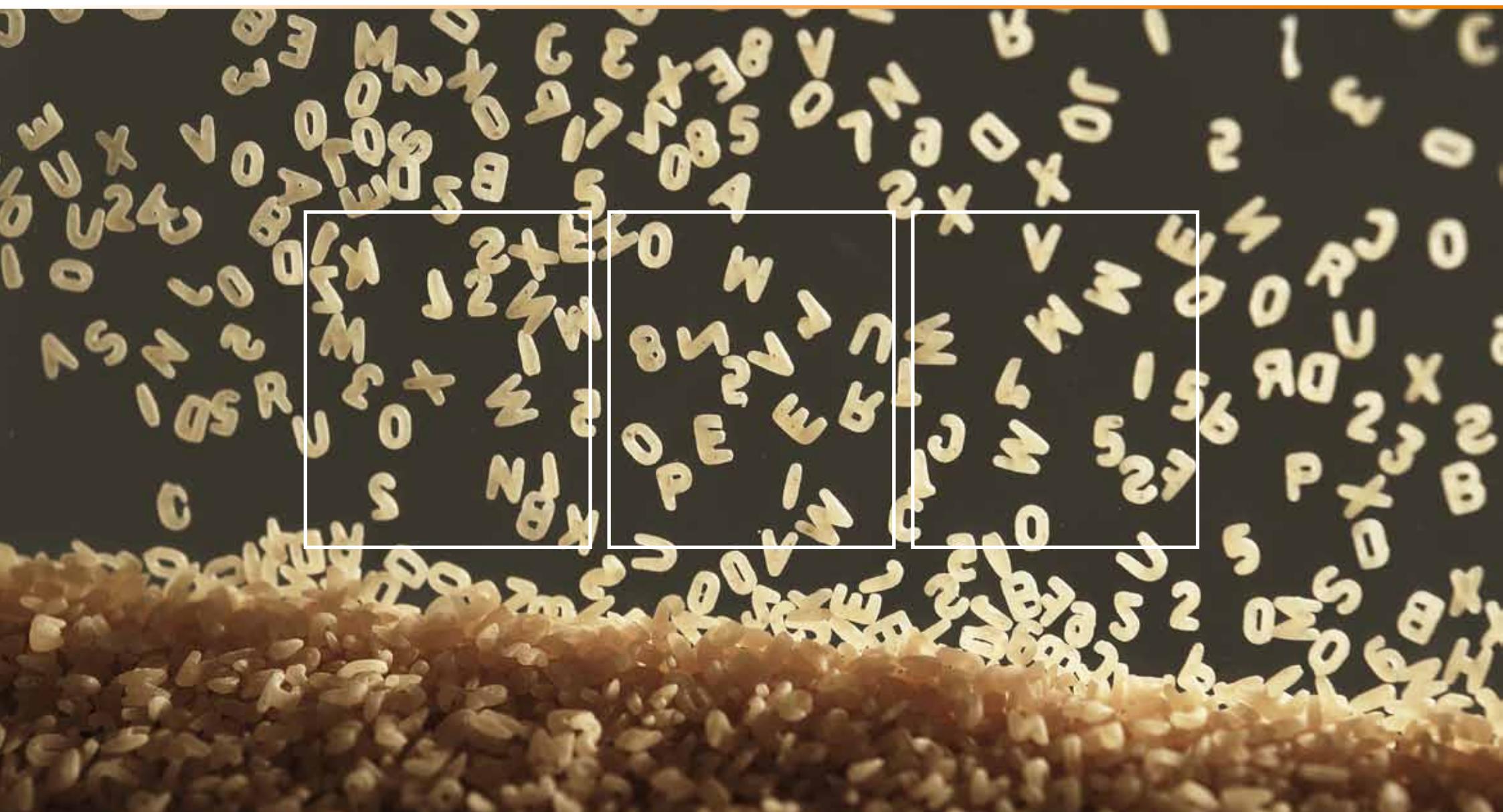
external evaluation pointed out, it is crucial that the robustness of the system is communicated effectively to all stakeholders. EFSA will also review its Communications Strategy 2010-2013, building on the outcomes of the external evaluation and the various meetings and conferences that were held with stakeholders in 2012. ■

ANNEX I – ORGANISATIONAL STRUCTURE ON 01/09/2012





ANNEX II – ACRONYMS



ANNEX II – ACRONYMS

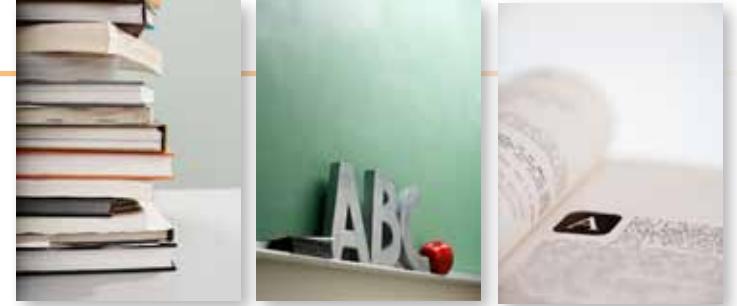
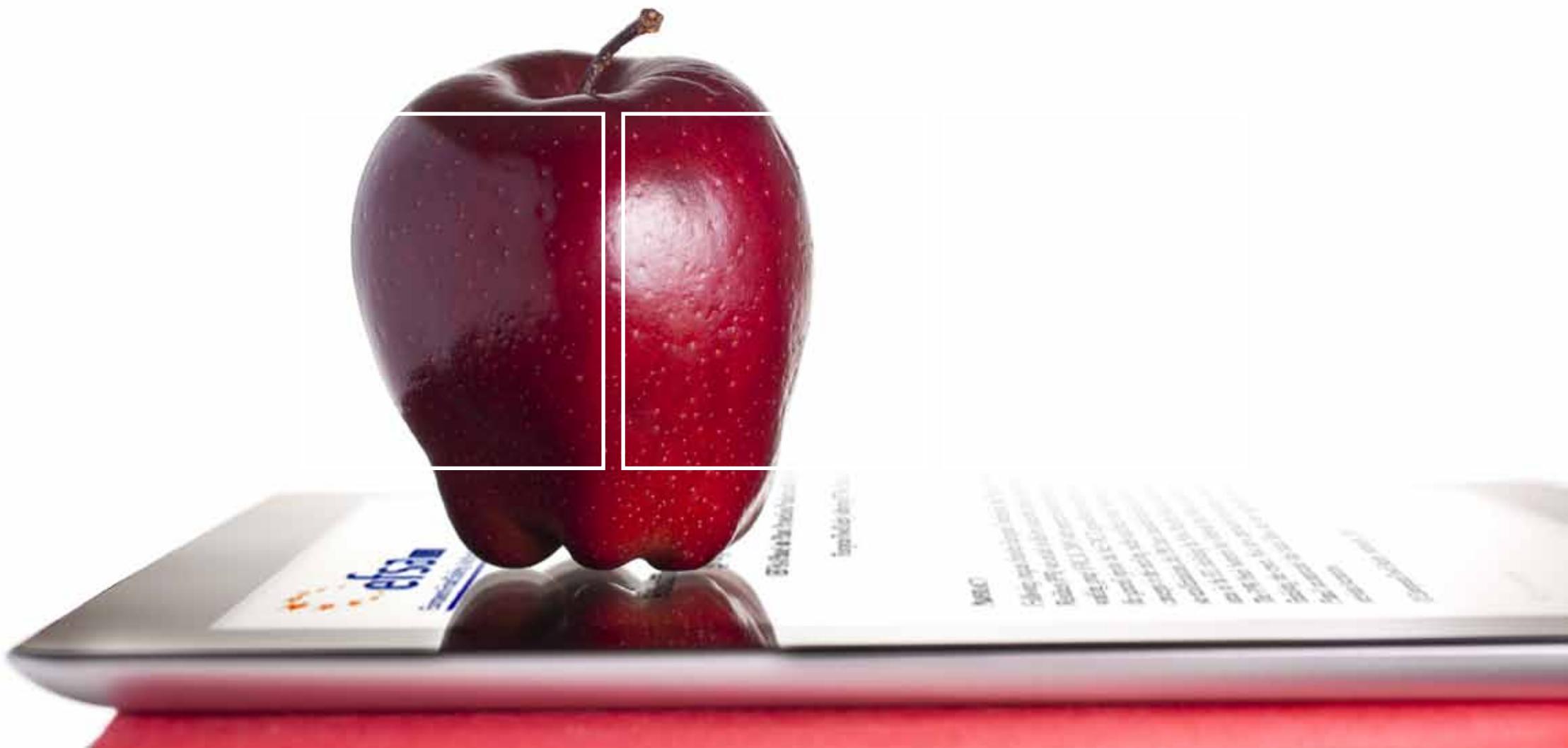


ABB	Activity Based Budgeting	DG SANCO	Directorate-General Health and Consumers of the European Commission	IEP	Information Exchange Platform
AFCWG	Advisory Forum Working Group on Communications	Dol	Declaration of interest	MEP	Member of the European Parliament
AHAW	Panel on Animal Health and Welfare	ECA	European Court of Auditors	NDA	Panel on Dietetic Products, Nutrition and Allergies
AMU	Assessment Methodology Unit	ECDC	European Centre for Disease Prevention and Control	NGO	Non-governmental organisation
ANS	Panel on Food Additives and Nutrient Sources Added to Food	ENVI	The European Parliament Committee for Environment, Public Health and Food Safety	OECD	Organisation for Economic Co-operation and Development
BIOHAZ	Panel on Biological Hazards	ERA	Environmental risk assessment	PARMA	Project and Resource Management Approach
BIOMO	Biological Monitoring Unit	EU	European Union	PCBs	Polychlorinated biphenyls
BPA	Bisphenol A	FAQ	Frequently asked questions	PET	Polyethylene terephthalate
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids	FEEDAP	Panel on Additives and Products or Substances Used in Animal Feed	PMEM	Post-market environmental monitoring
CoI	Conflict of interest	GM	Genetically modified	PPR	Panel on Plant Protection Products and their Residues
CONTAM	Panel on Contaminants in the Food Chain	GMO	Genetically modified organism (Panel on Genetically Modified Organisms)	SBV	Schmallenberg virus
DCM	Dietary & Chemical Monitoring Unit			SHP	Stakeholder Consultative Platform
DKP	Diketopiperazine			STEC	Shiga toxin-producing <i>Escherichia coli</i>

ANNEX III – EFSA'S SCIENTIFIC OUTPUTS AND SUPPORTING PUBLICATIONS 2012



Overview of EFSA's scientific outputs and supporting publications – 2012

All scientific outputs published by EFSA in 2012 can be found on the DVD attached to the back cover of the Annual Report.

	AFSCO	AHAW	APDESK	BIOHAZ	BIOMO	CONTAM	DCM	EMRISK	FEED	FIP	GMO	NUTRI	PLH	PRAS	SAS	SCOM	Total
Opinions of the Scientific Committee/Scientific Panel		10			14		10		87	54	25	71	10	4		2	287
Statements of the Scientific Committee/Scientific Panel		1								5	1	1	2				10
Guidance of the Scientific Committee/Scientific Panel									2	1		4	1	2		1	11
Statements of EFSA						1				2				4	2	1	10
Guidance of EFSA														1			1
Conclusions on Pesticides Peer Review														60			60
Reasoned Opinions														114			114
Scientific Reports of EFSA		1		3	7		5		1					1	3	2	23
Technical Reports	7	6		3	7		3	8	2	1	13	14	1	6	2	5	78
External Scientific Reports		14		4	5	4	19	1			1	6	5	11	3		73
Event Reports	4	1		4							2						11
Internal Report*	17	1	3	1	5		14	11	1	6	1	1			24		85
Total	28	34	3	29	24	15	41	20	92	70	43	97	19	203	34	11	763
Total outputs														763			

* Internal reports refer to scientific reports that are an integral part of the production of scientific opinions.

ANNEX IV – INDEPENDENCE STATISTICS 2012



In order to identify and prevent potential conflicts of interest (CoI) 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 interests related to the concrete agenda items of a meeting;
- oral Dol = Oral declaration of interests given before the beginning of a meeting.

Members of EFSA's Management Board must refrain from involving themselves or being involved in any activity that could result in a conflict of interest or is likely to provoke the perception of an existing conflict of interest by the general public. All Board members must provide an annual declaration of commitment and an aDol. Under its Code of Conduct,

members are obliged to inform the Chair and the Executive Director of the Authority without undue delay of any changes to their declared interests and update their aDol accordingly.

In addition, EFSA requires all its professional staff members to submit an annual declaration of interests. In parallel, staff members who leave the organisation are required to inform the Authority with respect to their future employment for a period of two years after the cessation of their employment in order that EFSA can consider whether any new position might lead to a conflict of interest.

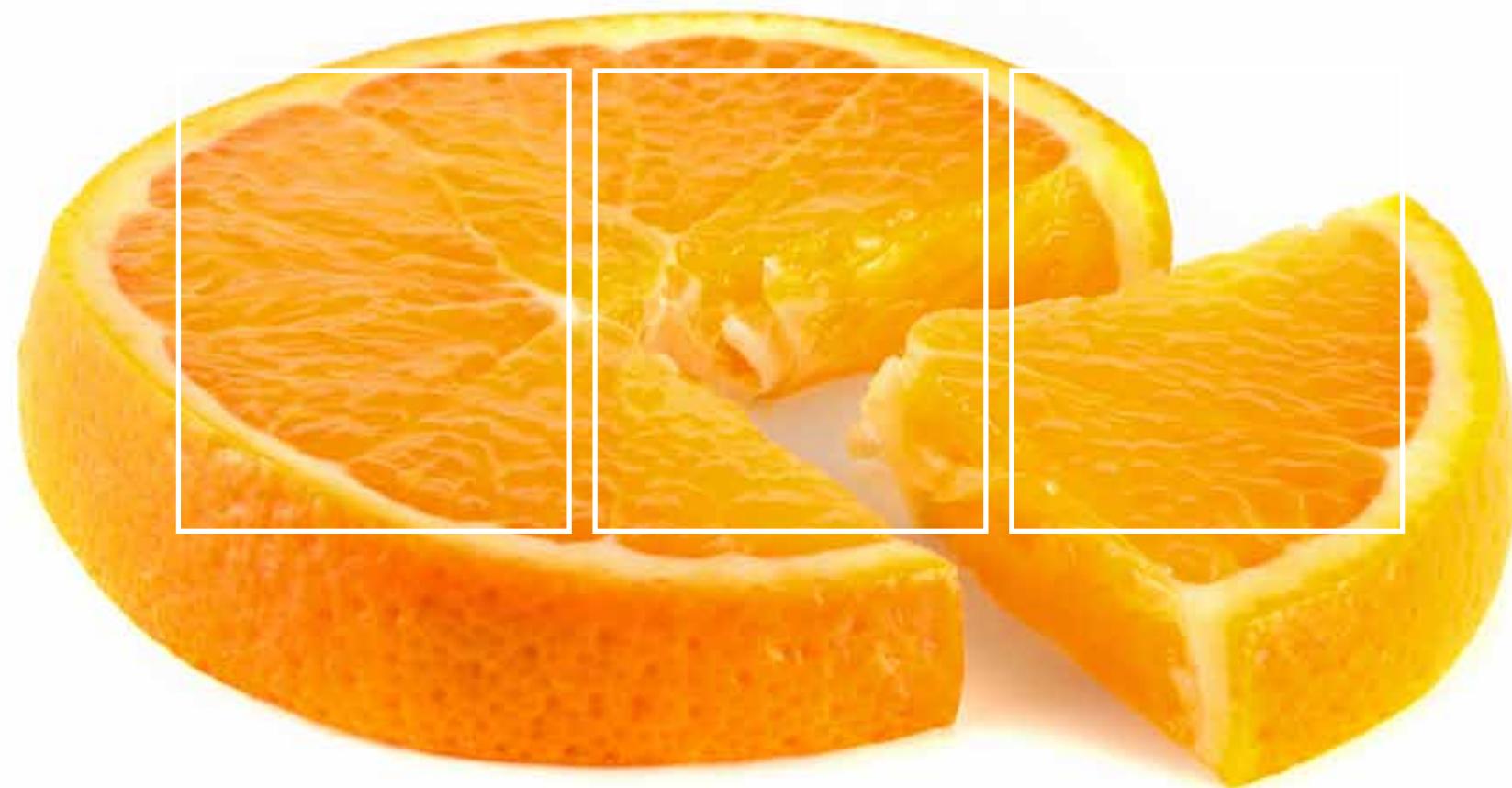
The table below shows some key statistics on the application of EFSA's independence system in 2012. From the screening of aDols and sDols, **272** potential conflicts of interests were prevented. Mitigation measures taken included exclusion of experts from working groups, meetings, meeting agenda items or other restrictions such as exclusion from drafting.

Total Dols screened	6,869
Meeting agenda items scrutinised	36,609
Potential conflicts prevented	272
Breach of trust procedures	1*
Staff members leaving EFSA	Total: 28 Private sector: 4** Restrictions: 0
Restrictions on members of other EFSA bodies	2

* The breach of trust procedure in 2012 involved an expert for whom EFSA became aware of a potential conflict of interest. On investigation, the expert confirmed an omission in the declaration of interest and EFSA has opened a breach of trust procedure which will conclude in early 2013. If the breach is confirmed, an audit of the scientific outputs to which the expert in question contributed will be undertaken. The expert was not considered in the Panel renewal exercise in 2012.

** Two to the chemical/pharmaceutical sector, one to a humanitarian non-profit organisation, and one self-employed in the mechanical components sector.

ANNEX V – FINANCIAL REPORT



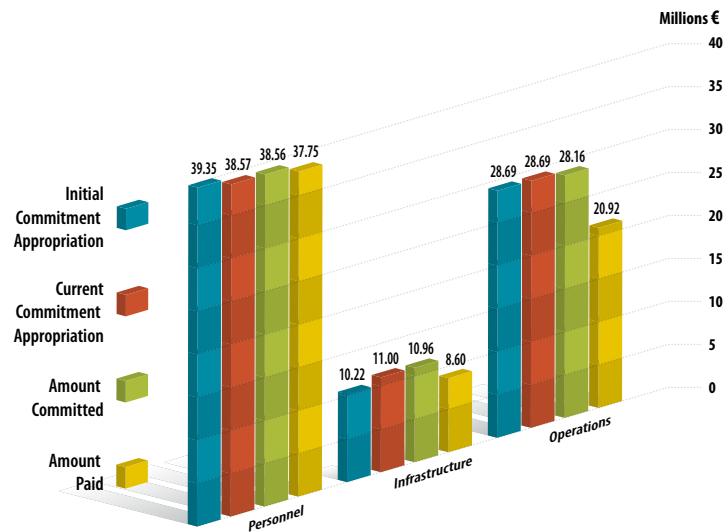
Budget Execution 2012

As of 31 December 2012:

- EUR 77.69 m or **99.3%** of the EUR 78.28 m budget was committed. This commitment level stands only 0.75% below the 100% target set for the year. The difference is mainly due to under-spending under Title III utilised at 98.1%. Transfers at year end amounting to EUR 0.5 m to infrastructure and EUR 0.8 m to IT support allowed optimising the budget execution. The infrastructure transfer relates to the non-decision by the Council on salary indexation leaving funds unutilised. The IT support transfer allowed anticipating foreseen investments in operational support.
- EUR 67.28 m or **88.0%** of the EUR 76.48 payment appropriations were paid. This global payment level stands however 7% below the EUR 72.61 m payment

target. This global target integrates two distinct targets for non-differentiated and differentiated payment credits:

- For non-differentiated payment credits, EUR 59.45 m was paid out of the initial EUR 69.08 m appropriation available. This payment level represents 91% of the EUR 65.20 m target for non-differentiated payment credits.
- For differentiated payment credits (SC coop), EUR 7.83 m was paid out of the EUR 7.41 m appropriation available including the EUR 1.1 m global transfer. This payment level represents 106% of the EUR 7.41 m target for differentiated payment credits.



Title	Initial Commitment Appropriation	Current Commitment Appropriation	Difference	Amount Committed	% Committed	Payment Appropriation	Amount Paid	% Paid
Personnel	39,359,000	38,573,067	-2.0%	38,563,788	100.0%	38,573,067	37,754,147	97.9%
Infrastructure	10,222,000	11,007,933	7.7%	10,966,034	99.6%	11,007,933	8,602,142	78.1%
Operations	28,698,000	28,698,000	0.0%	28,164,869	98.1%	26,905,090	20,922,308	77.8%
Total:	78,279,000	78,279,000	0.0%	77,694,691	99.3%	76,486,090	67,278,597	88.0%

Activity Based Budgeting (ABB) Execution 2012

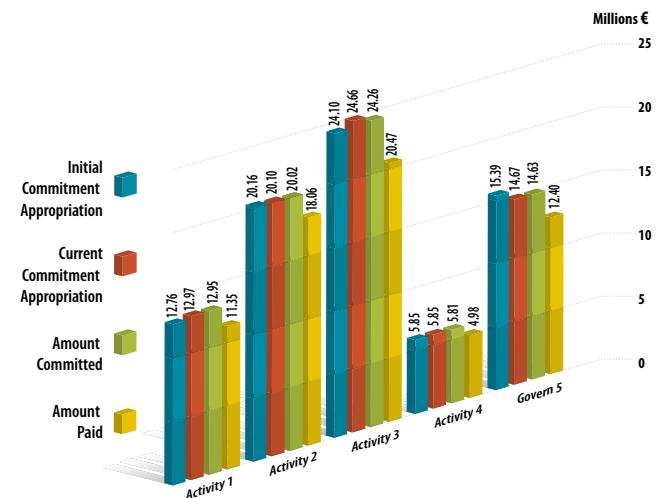
Activity 1 = Provision of scientific opinions and advice and risk assessment approaches

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



In EUR	Initial Commitment Appropriation	Current Commitment Appropriation	Difference	Amount Committed	% Committed	Payment Appropriation	Amount Paid	% Paid
Activity 1	12,762,762	12,979,554	1.70%	12,953,595	99.8%	13,049,966	11,354,948	87.0%
Activity 2	20,169,364	20,107,292	-0.31%	20,026,863	99.6%	20,155,422	18,062,624	89.6%
Activity 3	24,101,010	24,664,394	2.34%	24,263,404	98.4%	22,752,942	20,470,089	90.0%
Activity 4	5,854,240	5,852,267	-0.03%	5,811,301	99.3%	5,852,267	4,987,487	85.2%
Govern 5	15,391,434	14,675,493	-4.65%	14,639,719	99.8%	14,675,493	12,403,449	84.5%
Total	78,278,810	78,279,000	0.00%	77,694,882	99.3%	76,486,090	67,278,597	88.0%

ABB Appropriations 2012 (% at year end)

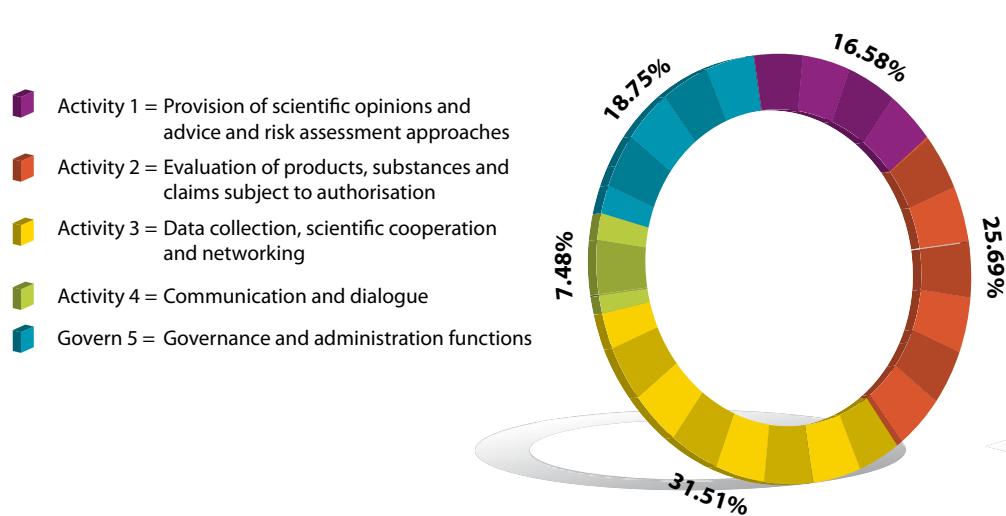
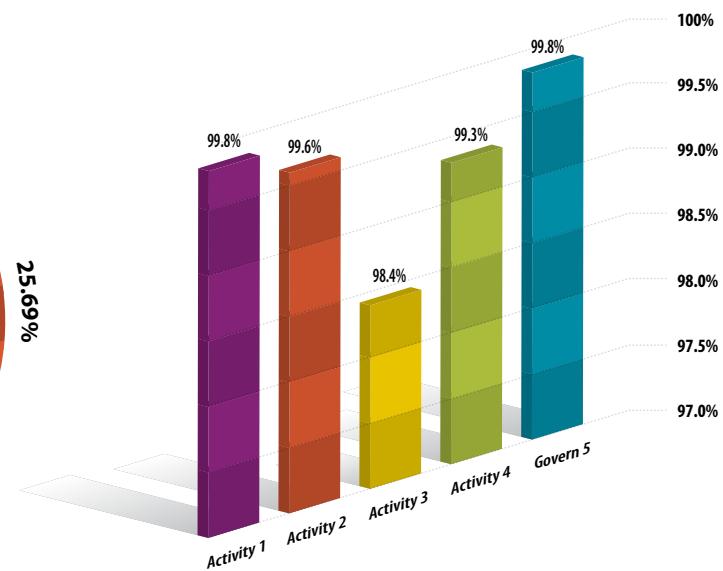


ABB Execution 2012 (% committed)





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