

EXECUTIVE OFFICE

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EXECUTIVE OFFICE

EFSA EXECUTIVE DIRECTOR PROGRESS REPORT

Executive Summary

The present report refers to the period from 1st June to 30 September, 2012.

Science Strategy and Coordination (SCISTRAT): At the inaugural meeting on 23-24 July the renewed Scientific Committee elected Anthony Hardy as the new Chair, and Jan Alexander and Robert Luttik as Vice-Chairs. It also discussed the work programme for its three-year term. The short term activities of the SC include: the development of a generic assessment system for priority setting among botanicals; the provision of scientific support in the emerging risks identification process; a review of data requirements and guidance documents published by EFSA; uncertainty in risk assessment; and the development of a harmonised guidance on Environmental Risk Assessment (ERA).

The Emerging Risk Unit published two Technical reports on the emerging risks identification process developed at EFSA, and the media monitoring tool MediSys.

Strategic discussion with the Member States centred on the ongoing scientific cooperation activities, the medium-term planning, the developing multi-annual plan, and the report on EFSA's second external evaluation. The Focal Point meeting in June focussed on risk assessment training in Member States and the synergies between Focal Points and the Advisory Forum Communications Working Group.

In June EFSA organised a Scientific Colloquium on "Low dose response in toxicology and risk assessment" where discussion focused on possible health effects of low levels of certain chemicals (the "low-dose hypothesis") and current and future challenges that these pose for food and feed risk assessment.

In July and September EFSA welcomed delegations from China and provided them with information on EFSA's role within the EU risk assessment system and, more particularly, on EFSA's activities in the field of risk assessment of feed and feed ingredients.

Risk Assessment and Scientific Assistance (RASA): RASA adopted 5 Opinions and 7 Scientific reports. In addition, 3 Technical reports and 13 External scientific reports were finalised.

The Opinion on the use of animal-based measures to assess the welfare of broilers was adopted as part of a series of scientific Opinions to assess the welfare of farm species. A technical meeting on animal welfare was organised to present the methodological approach as laid down in these Opinions. In addition, the following Opinions were adopted: animal health risk mitigation treatments as regards imports of animal casings; risks to human and animal health related to the presence of ergot alkaloids in food and feed; emerging and novel brominated flame retardants in food; and the first of the Tospoviruses opinions addressing pest categorisation of the 23 Tospoviruses.

Among others, RASA issued Scientific and Technical reports on a rapid risk assessment on the multi-country outbreak of *Salmonella* Stanley infections (jointly with the European Centre for Disease Prevention and Control), the harmonised monitoring and reporting of methicillin-resistant *Staphylococcus aureus* (MRSA) transmitted through food, the harmonised epidemiological indicators for biological hazards to be covered by meat inspection of poultry, the update of the monitoring levels of dioxins and PCBs in food and feed, and dietary exposure to lead in the European population.

Scientific Evaluation of Regulated Products (REPRO): REPRO adopted five Guidance documents on: safety assessment of bacterial susceptibility to antimicrobials; submission of food additives; use of probabilistic methodology for modelling dietary exposure to pesticide residues; and the last two Guidance documents (in a series of six) on scientific requirements for health claims in specific areas (i.e. claims related to the function of the nervous system and related to physical performance). In addition, REPRO adopted 98 Opinions, two Scientific Statements, two Scientific Reports, five Technical reports, 34 Reasoned Opinions on MRL and 13 Conclusions on pesticide peer review. The Opinion on Dietary Reference Values (DRV) for energy was endorsed for public consultation.

mb 18 10 12 item 3 doc 2 – EFSA's Executive Director progress report

The re-evaluation of feed additives remains one of the main working areas of the FEEDAP Panel, with 85 Opinions to be adopted in the coming months. The re-evaluation of food additives is among the main priorities of the ANS Panel, with the public consultation on the draft Opinion on aspartame planned for December. The CEF Panel will focus on the re-evaluation of 405 flavouring substances, as well as the evaluation of active and intelligent packaging processes. The work on recycling processes is foreseen to be finished by the end of 2013. The GMO Panel will focus on the urgent request from the Commission to review the study "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" and assess whether this study contains new scientific elements that could lead EFSA to reconsider the outcome of its Opinions on NK603 maize. In addition, the GMO Panel will continue working on the EC mandate to assess new GMO techniques. Next to the claims and novel food applications the NDA Panel will focus on the establishment of DRVs for approximately 30 vitamins and minerals. The PRAS Unit will work on the remaining 51 MRL applications submitted, as well as the 343 MRL reviews which are on the agenda.

Communications (COMMS): EFSA has communicated widely on chemicals in food, innovation, nutrition and pesticides. To mark the occasion of the publication of EFSA's external evaluation report (5 Sept.), the Media Relations office organised a media breakfast in Brussels with the Executive Director and 10 journalists. Key agenda issues of the meeting of the Advisory Forum Communications Working Group (AFCWG) included: update on finalised version of the Risk Communications Guidelines and on Glossary of Food Safety Terminology, debate on respective areas of work for AFCWG Members, and Focal Points at national level. EFSA published eight press releases, 23 web-stories, eight videos of the series "Understanding Science", and the 10-year anniversary brochure "EFSA@10: The science that is helping to keep Europe's food safe" (in English, German, French and Italian) featuring stories on EFSA's key achievements over the last 10 years.

Budget and human resources: On 30 September, EUR 58.96 million or 75.32% of the EUR 78.28 million budget was committed. EUR 46.07 million or 61.13% of the EUR 75.38 payment appropriations were paid. 449 posts were occupied and 11 job offers have been sent to the selected candidates bringing the total to 460 posts filled out of the planned 494 posts.

Corporate: EFSA closely collaborated with the European Parliament (EP) rapporteur for the discharge of EFSA's budget 2010, MEP Monica Macovei, and provided further information to the EP Committees ENVI and CONT, notably on the latest developments in the field of independence and the implementation of EFSA's Policy on Independence and Scientific Decision-Making Processes.

On 5 September EFSA published the External Evaluation report prepared by Ernst & Young and promoted a wide consultation with its key partners (Advisory Forum, Scientific Committee, Stakeholders, as well as its staff members) seeking their views on the outcomes of that report.

On 20 September EFSA's Executive Director had her annual hearing before the ENVI Committee in the European Parliament, where the outcomes of the report on EFSA's second external evaluation were presented. A constructive and open dialogue took place on a series of issues that are high on MEPs agendas, which included *inter alia* nutrient profiles, GMO risk assessment, endocrine disruptors and independence.

In August the Commission informed EFSA on the revised predicted activities for the coming years, and the update of the Medium Term Plan is being carried out.

EFSA is in the process of drafting the Multi Annual Plan (MAP) 2014-2016, which is expected to be presented to the Board in December with the aim of adopting it in March 2013. The two-year pilot phase on EFSA's Impact Indicators is coming to a conclusion. The final report with recommendations on the follow-up is being prepared and will be presented to the Board at the December meeting.

EFSA EXECUTIVE DIRECTOR PROGRESS REPORT

SCIENCE STRATEGY AND COORDINATION (SCISTRAT)

Scientific Committee (SCOM)

At the inaugural meeting on 23-24 July the renewed Scientific Committee (SC) elected the new Chair, Anthony Hardy, and Vice-Chairs, Jan Alexander and Robert Luttik. The SC discussed the work programme for its three-year term and agreed on the initiation of activities for the update of the compendium of botanicals; the development of a generic assessment system for priority settings among botanicals; the provision of scientific support in the emerging risks identification process; a review of data requirements and guidance documents published by EFSA; uncertainty in risk assessment; and the development of harmonised guidance on Environmental Risk Assessment (ERA).

A statement of EFSA giving an update on “Animal health and welfare and the environmental impact of animals derived from Somatic Cell Nuclear Transfer (SCNT) cloning and their offspring, and food safety of products obtained from those animals” was endorsed. The first meeting of EFSA's Scientific Network for the harmonisation of risk assessment methodologies was held on 7-8 June: The Network discussed its work-plan and activities, cooperation and information sharing.

A new mandate on the human health and environmental risks of endocrine disruptors has been discussed and terms of reference were considered during the September SC plenary. The Opinion is expected to be adopted in March 2013.

Emerging Risks Unit (EMRISK)

EMRISK has published two Technical reports: an overview of the emerging risks identification process developed at EFSA and the experience gained from its initial pilot phase, and the tailoring of the media monitoring tool MediSys, developed by the JRC, to the emerging risks needs of EFSA in areas of plant health, animal health, pesticides, biological hazards and genetically modified organisms.

In line with the recommendations published in the review of the emerging risks identification process, a new Standing Working Group of the Scientific Committee is being established to support this activity. A new internal mandate has been accepted to review the regulatory data requirements for risk assessment in order to identify inconsistencies between the regulations covering the different areas within EFSA's mandate.

Advisory Forum and Scientific Cooperation Unit (AFSCO)

Discussions at the Advisory Forum (AF) meetings centred on the medium-term planning and ongoing cooperation between EFSA and the Member States (MS), EFSA's management plan, the developing multi-annual plan, and the report on EFSA's second external evaluation. DG Research and Innovation provided information on the development of the Horizon 2020 Framework programme. AF members were informed about EFSA's policy on public access to documents.

The 14th Focal Point (FP) meeting in June focussed on training on risk assessment in MS and on the planning of the joint meeting between FPs and the AF Communications Working Group in October.

The 2011 Annual reports on Article 36 activities and on the Expert Database were published.

In June EFSA organised a Scientific Colloquium on low dose response in toxicology and risk assessment where discussion focused on possible health effects of low levels of certain chemicals (the “low-dose hypothesis”) and the current and future challenges that these pose for food and feed risk assessment.

With reference to the Pre-Accession programme, 30 experts participated in five EFSA meetings and EFSA's Scientific Colloquium on low doses, and 40 experts participated in a Pre-Accession workshop on data collection and analysis.

The EFSA Journal is now indexed in two further bibliographic databases (AGRIS, the FAO database, and Directory of Open Access Journals).

Cooperation with Stakeholders

The Stakeholder Consultative Platform (SCP) plenary meeting was held in Brussels on 19-20 June. EFSA updated the members, in particular, on the renewal of EFSA's Scientific Panels and on training activities in the area of food risk assessment. The Stakeholder Consultative Group on Emerging Risks contributed to EFSA's annual report on emerging risk identification.

International relations

On a regular basis EFSA exchanges information with the US Food and Drug Administration (FDA) involving the respective liaison officers. In two meetings with Korean delegations views were exchanged aiming to foster future cooperation with the Korean Food and Drug Administration (KFDA) and the National Institute of Food and Drug Safety Evaluation (NIFDS). In July EFSA welcomed a Chinese delegation of the National Panel of Feed and Feed Additive Experts. This mission was part

of a Chinese Government-funded programme to support effective implementation of the new Chinese Feed and Feed Additive Legislation, which was published in October 2011. On this occasion, EFSA provided Chinese counterparts with information about EFSA's risk assessment of feed and feed ingredients.

In September EFSA welcomed a high level delegation from China led by the Vice Minister of the Food Safety Commission Office of the State Council, which comprises high officials of the Chinese Ministries of Agriculture and Health. On this occasion EFSA provided the Chinese authorities with more detailed information on the EU risk assessment system.

RISK ASSESSMENT AND SCIENTIFIC ASSISTANCE (RASA)

Panel on animal health and welfare (AHAW)

The AHAW Panel adopted two Opinions on: animal health risk mitigation treatments as regards imports of animal casings, and the use of animal-based measures to assess welfare of broilers.

An External scientific report was published on the contribution of meat inspection to animal health surveillance in poultry.

A technical meeting on animal welfare was organised in July to present the methodological approach as laid down in the Opinions of the AHAW Panel on the use of animal-based measures for dairy cows, pigs and broilers.

The Panel is finalising Opinions on the use of a gamma interferon test for the diagnosis of bovine tuberculosis, and on infectious salmon anaemia. Work continues, in collaboration with the BIOHAZ Panel and the BIOMO Unit, on the meat inspection of cattle, small ruminants, farmed game and solipeds, the opinions of which are due for adoption in 2013.

New mandates have been received in relation to maintaining technical assistance on the possible risks for animal health caused by the Schmallenberg virus and for scientific and technical assistance on *Echinococcus multilocularis* infection in animals.

Panel on biological hazards (BIOHAZ)

EFSA collaborated with the European Centre for Disease Prevention and Control (ECDC) on a joint rapid risk assessment on the multi-country outbreak of *Salmonella* Stanley infections, which resulted in the publication of a Scientific report with the involvement of BIOHAZ and BIOMO Units.

A Technical report has been published reporting on the solution of the scientific divergence with Germany on EFSA's Opinion on "Assessment of the human and animal BSE risk posed by tallow with respect to residual BSE risk" published in September 2005.

An External scientific report (including a user manual) on the development of a user-friendly interface version of the *Salmonella* source-attribution model was published.

In the coming months the BIOHAZ Panel will focus on mandates such as: risk posed by pathogens in food of non-animal origin; and a self-task mandate on the maintenance of the list of QPS recommended biological agents intentionally added to food or feed. New mandates have been received for: the scrapie situation in the EU after 10 years of monitoring and control in sheep and goats; the risk of transmission of TSEs via *in vivo* derived embryo transfer in ovine animals; an application for a revision of the annual monitoring programme for BSE from Norway; and scientific and technical assistance on the provisional results of the study on genetic resistance to scrapie in goats in Cyprus. Moreover a new mandate was received about the assessment of the public health risks related to the different types of mechanically separated meat and the parameters, their values and their measure to distinguish between these.

Contracts were signed for two procurement projects relating to "VTEC-seropathotype concept and scientific criteria regarding pathogenicity assessment" and "TSE infectivity level in animal tissues".

Panel on contaminants in the food chain (CONTAM)

The CONTAM Panel adopted two Opinions on the risks to human and animal health related to the presence of ergot alkaloids in food and feed, and the emerging and novel brominated flame retardants in food.

One External scientific report has been approved by EFSA in the context of a procurement contract providing literature data on toxicity of mercury in experimental animals and humans.

In the coming months the Panel will work on mycotoxins and plant toxicants (sterigmatocystin, nivalenol, tropane alkaloids); mercury and methylmercury; dioxins in food for children; meat inspection of bovine, domestic sheep and goats, farmed game and domestic solipeds; reference points for action; and on the recent mandate on the health risks of ammonium released from water filters.

Panel on plant health (PLH)

The PLH Panel adopted an Opinion on the pest categorisation of the Tospoviruses. Three External scientific reports were published: Review of the quantitative assessment of risk reduction options applied in the EFSA outputs on biological hazards; Climest project (Service Level Agreement with JRC) which developed models to be used to predict EU climatic

suitability for the establishment of organisms harmful to plants and plant products; and Prima phacie Art. 36 project on comparison of pest risk assessment methods through case studies. The Technical report on the public consultation on the Guidance document on Risk reduction options was also published.

In the coming months, the PLH Panel will complete the work on the following mandates: pest risk assessment of *Tomato Spotted Wilt virus*; the risk to plant health for the EU territory of *Bemisia tabaci*; the risk to plant health in the EU territory for a number of plant pests and pathogens; a reply to the Portuguese comments on *Pinus pinea* as host plant of pine wood nematode. A new mandate has been received to provide an Opinion on the risk to plant health of other 13 regulated harmful organisms, for the EU territory.

Scientific assessment support Unit (SAS)

One Scientific report on "Schmallenberg" virus (Analysis of the epidemiological data and assessment of impact) and one External report on Commodity based hazard identification protocol for emerging diseases in plants and animals were published.

The SAS Unit has provided hands-on methodological and modelling support to FIP and PESTICIDES.

The SAS Unit will continue the activities on the Guidance document for statistical reporting in dossiers submitted to EFSA and start to work on a new mandate for the identification of existing monitoring networks suitable to provide datasets to support post-market environmental monitoring (PMEM) of GMOs.

The SAS and AHAW Units will continue collecting epidemiological data in Members States with regard to the "Schmallenberg" virus (SBV).

Dietary and chemical monitoring Unit (DCM)

The DCM Unit provided assistance regarding data collection and/or data analysis to CONTAM, BIOHAZ, GMO and FIP.

Three Scientific reports and one Technical report were published: an update of the monitoring of levels of dioxins and polychlorinated biphenyls (PCBs) in food and feed; lead dietary exposure in the European population; perfluoroalkylated substances (PFASs) substances in food: occurrence and dietary exposure; and the effect on dietary exposure of an increase of the maximum levels for aflatoxins for dried figs.

Four External scientific reports were also published: two reports on electronic transmission of chemical occurrence data, in Belgium and Ireland respectively; a European tool for usual intake (ETUI) distribution estimation in relation to data collection by EFSA; and a comparison by simulation of different methods to estimate the usual intake distribution for episodically consumed foods.

In the coming months, work will continue on: monitoring acrylamide levels in food; monitoring of veterinary medicinal product residues; European data collection of chemical occurrence in food and feed. In addition, work will continue on the development of a Raw Agricultural Commodity database, and the extension of the Standard Sample Description to include biological samples and food additives, as well as on the implementation of the new food classification system FoodEx2.

The Unit will further co-ordinate activities within the framework of the pan-European Food Consumption Survey "What's on the Menu in Europe?" (EU Menu project) including two ongoing pilot studies on tools and procedures for food consumption data collection, and will continue ongoing work on food consumption and chemical occurrence data collection activities.

Biological monitoring Unit (BIOMO)

The BIOMO Unit issued two Scientific reports: on harmonised epidemiological indicators for biological hazards to be covered by meat inspection of poultry, which supported the corresponding opinion on poultry meat inspection; and on technical specifications on harmonised monitoring and reporting of methicillin-resistant *Staphylococcus aureus* (MRSA) transmitted through food. In addition, two External scientific reports were published related to analyses of antimicrobial resistance in isolate based data collected from volunteer Member States and to case studies implementing the epidemiological indicators for poultry slaughter.

The meeting of the Task Force on zoonoses data collection took place in June.

The BIOMO Unit is analysing the data for the EU Summary reports on zoonoses, food-borne outbreaks and antimicrobial resistance in 2011, which will be issued at the beginning of 2013. In addition, the analyses of the EU wide baseline survey on *Listeria monocytogenes* in ready-to-eat foods have started. The Unit received a new mandate on setting up a data collection for molecular typing information related to food-borne bacteria from food and animals.

SCIENTIFIC EVALUATION OF REGULATED PRODUCTS (REPRO)

Panel on additives and products or substances used in animal feed (FEEDAP)

The FEEDAP Panel adopted 36 scientific Opinions on the authorisation of feed additives, belonging to the following categories: technological (12), sensory (3), nutritional (12) and zootechnical (9). Twenty four were applications for re-

evaluation, and nearly half were combined with a request for a new use (mainly in water). Additionally, the Guidance on the safety assessment of bacterial susceptibility to antimicrobials was adopted.

The re-evaluation of feed additives remains one of the main working areas of the FEEDAP Panel. In the coming months the Panel will follow up on 85 Opinions, which include mandates related with trace elements, flavourings, silage, antioxidants, vitamins and colourings.

Food ingredients and packaging (FIP)

The ANS Panel adopted the Guidance on the submission of food additives, one Statement on Butylated Hydroxyanisole E320 (BHA) and three Opinions on Patent Blue, Chromium (III) lactate tri-hydrate and Carnauba Wax.

The CEF Panel has adopted 19 Opinions: two on Smoke Flavourings (re-evaluation of Smokez Enviro 23 and Smokez C-10), eight on Flavourings (FGE.08Rev5, FGE.226, FGE.09Rev4, FGE.07Rev4, FGE.63Rev1, FGE.99, FGE.205, FGE.304) and nine on Food Contact Materials (including 4 opinions on plastic recycling processes).

The FIP Unit issued a Technical report on the public consultation on the Guidance for submission for food additive evaluations. A stakeholder workshop on "Guidance for food additives evaluations" was held in September.

In the coming months, the ANS Panel will focus mainly on the re-evaluation of food additives in line with Regulation (EU) No 257/2010. In addition, it will continue assessing the safety of new food additive applications, and the safety assessment of nutrient sources, including the fortifications of food that are subject to national derogations. The public consultation on the draft Opinion on aspartame is planned for December, and the adoption of the Opinion is foreseen by May 2013.

The CEF Panel will focus on the re-evaluation of flavouring substances, mainly based on submission of genotoxicity data (405 substances). The work on recycling processes is foreseen to be finished by the end of 2013. The evaluation of active and intelligent packaging processes (23 applications under evaluation) will also continue. The CEF Panel will work on a self-mandate to update the risk assessment of bisphenol A (BPA) by May 2013. The Panel organised two working group meetings focusing on toxicology of BPA and exposure (including non food sources).

Panel on genetically modified organisms (GMO)

The GMO Panel adopted one Opinion on oilseed rape Ms8, Rf3 and Ms8 x Rf3 under Regulation (EC) 1829/2003. In the context of safeguard clauses, the Panel adopted four Opinions on: maize MON810 (from Greece), two on oilseed rape GT73 and oilseed rape Ms8, Rf3 and Ms8 x Rf3 (from Austria), and on GM potato EH93-527-1 (from Luxembourg).

The GMO Unit published four Technical reports related to adopted application opinions, one Event report on a technical Meeting on GM potato EH92-527-1 (Amflora), and one External report on a database on non-target arthropods.

The GMO Unit received an urgent request from the Commission to review the study "Long term toxicity of a Roundup herbicide and a Roundup-tolerant genetically modified maize" and assess whether this study contains new scientific elements that could lead EFSA to reconsider the outcome of its Opinions on NK603 maize. The GMO Unit also received two new applications on GM plants, a request to assess the 2011 PMEM report on Amflora potato and three requests to collect all scientific information available on three GM events previously assessed (maize MON810, Bt11 and 1507). The GMO Panel will continue working on the EC mandate to assess new GMO techniques.

A scientific workshop on effects of Bt -proteins from Bt- crops on terrestrial non-target arthropods is being prepared together with the Netherlands Commission on Genetic Modification, as well as the annual meeting with applicants: both to take place in November.

Panel on dietetic products, nutrition and allergies (NDA)

With reference to the health claims applications, the NDA Panel adopted 15 Opinions related to Art 13.5; one Opinion related to Art 14; and 12 Opinions covering 73 claims related to Article 13, which were eligible for reassessment.

The Panel also adopted the last two Guidance documents (in a series of six) on the scientific requirements for health claims in specific areas (claims related to the function of the nervous system and related to physical performance). Furthermore, the Panel adopted three Opinions on novel food applications, (dihydrocapsiate, bovine lactoferrin and zeaxanthin), and three Opinions related to: Tolerable Upper Intake Levels for omega-3 long chain polyunsaturated fatty acids (DHA, EPA, DPA), Calcium; and Vitamin D. The Opinion on Dietary Reference Values (DRV) for energy was endorsed for public consultation (open until 28 September). A revised DRV Opinion on energy, taking into account the inputs of the public consultation, is expected to be adopted at the November meeting.

To date EFSA has received 385 health claims applications, for which the NDA Panel has adopted 152 opinions covering 161 applications. The assessment of 16 applications is in progress, whilst 150 applications have been withdrawn.

The Panel is currently evaluating five novel food applications and is working on Dietary Reference Values (DRV) for energy and 29 micronutrients, as well as on an Opinion on the evaluation of allergenic foods for labelling purposes. Next to the claims and novel food applications, the Panel will also focus on the establishment of DRVs for approximately 30 vitamins and minerals.

Panel on plant protection products and their residues (PPR) and Pesticide Unit (PRAS)

The PPR Panel adopted a Guidance document on the use of Probabilistic methodology for modelling dietary exposure to pesticide residues, and an Opinion on the evaluation of the toxicological relevance of metabolites and degradates of pesticide active substances for dietary risk assessment.

The PRAS Unit issued 13 pesticide peer review Conclusions and an EFSA Statement concerning the assessment of scientific information from the Italian project 'APENET' investigating effects on honeybees of coated maize seeds with some neonicotinoid substances and fipronil.

On MRL applications, 23 Reasoned Opinions in response to 34 MRL applications and 11 Reasoned Opinions reviewing the existing MRLs were published. In addition, one Scientific report was published which covered 27 questions.

New mandates have been received to deliver EFSA Conclusions on the risk to bees for three neonicotinoid substances and fipronil. The peer review programme will continue for both the new active substances and the remaining 21 active substances of the review programme.

The PRAS Unit will continue working on the remaining 51 MRL applications submitted so far, as well as the 343 MRL reviews which are currently on the agenda. In addition, the 2010 Annual Report on Pesticide Residues will be finalised, and the work for the 2011 and 2012 Annual Report on Pesticide Residues will continue.

Application Desk (APDESK)

The APDESK Unit is centralising and processing the initial administrative steps of all applications received by EFSA for the REPRO Directorate (FEED, FIP/ANS, FIP/CEF, GMO, NUTRITION and PRAS): 47 applications have been received during the reporting period. A call for tender has been published in order to map EFSA's stakeholders and their needs in relation to APDESK services, with a special focus on small and medium enterprises (SME). The Unit received 44 written requests via the online web form. All questions were registered and answered individually within an estimated timeframe of 15 working days.

In the following months APDESK will support EFSA's Units in organising dedicated meetings with stakeholders on Flavourings (14 Nov.) and GMO (29-30 Nov.).

COMMUNICATIONS ACTIVITIES / MAIN HIGHLIGHTS

10th ANNIVERSARY:

The 10-year anniversary brochure "EFSA@10: The science that is helping to keep Europe's food safe", featuring stories on EFSA's key achievements over the last 10 years, was issued in July in four languages (English, German, French, Italian) and was published on the EFSA website. The upcoming scientific and institutional conferences planned in November in Parma were promoted through online announcements and media relations activities.

EFSA highlighted its role in the context of the 10th anniversary of the EU food safety system, taking part in a joint event on new methodologies in the field of risk assessment and risk communication, organised with the Italian Ministry of Health in Rome on 21st September.

External Evaluation of EFSA:

EFSA published a press release and web news story on the external evaluation of the Authority conducted by Ernst and Young. The release included a summary of the report main findings and a link to a comment by Sue Davies, Chair of the External Evaluation Steering Committee and Management Board Vice-Chair. EFSA also coordinated a media breakfast briefing by Catherine Geslain-Lanéelle held in Brussels.

THEMATIC:

Chemicals in food – An 'Understanding Science' video was published in June and accompanied by an 'In focus' campaign in support of EFSA's scientific Colloquium on low dose effects. Three new subtopics related to food contact materials were published, a much expanded topic on dioxins and PCBs, and important updates to the topics on food additives and aspartame. Eight press releases/news stories were published including those on the Threshold of Toxicological Concern guidance, the new food additives guidance, the Mineral oil hydrocarbons Opinion and the extension of the deadline for the re-evaluation of aspartame. "Chemicals in Food" remains a key area for communications and plans for Q4 include the recording of four new Understanding Science videos (safe levels of chemicals in food, endocrine active substances, feed materials, enzymes).

Innovation – In July there were a series of updates to the Applications helpdesk section of the web site; background information (including a series of downloadable tools for applicants) about the authorisation of regulated products, and the

mb 18 10 12 item 3 doc 2 – EFSA's Executive Director progress report

roles of the REPRO Directorate as well as the APDESK Unit were published on the website. An Understanding Science video was also recorded and published as part of this programme.

Nutrition – News stories were published in support of the opinions on the safety assessment of long-chain omega-3 fatty acids, and the review of upper intake levels for vitamin D and calcium. A news story was published covering the publication of two more guidance documents on health claims and on EFSA's further assessment of Article 13 claims. This story was further supported (in early August) by an In Focus homepage "block" on health claims.

Pesticides – A press release was published in support of the statement on recent studies linking neonicotinoid pesticides to bee decline. The release also flagged up the mandate received from the Commission to provide an in-depth review of the effects on bees of the neonicotinoid active substances thiamethoxam, clothianidin, imidacloprid, acetamiprid and thiacycloprid.

COOPERATION AND OUTREACH:

MEMBER STATES

Advisory Forum Communications Working Group (AFCWG) – 4-5 July, Paris. Key agenda items of this meeting included: update on finalised version of the Risk Communications Guidelines and on Glossary of Food Safety Terminology, debate on respective areas of work for AFCWG Members, and Focal Points at national level. Members also discussed on possible approaches to joint media activities, as well as sharing experience on the use of social media.

As part of a joint initiative with national food safety agencies, EFSA has published new Risk Communications Guidelines: "When Food Is Cooking Up a Storm – Proven Recipes for Risk Communications".

INTERNATIONAL SCIENTIFIC CONFERENCES

The Communication Directorate supported EFSA's participation in three major international scientific conferences. Communications activities included dedicated event newsletters, publications, scientific posters and facilities for external communication and networking activities:

- The 48th **Congress of the European Society of Toxicology** (EUROTOX) was held in Stockholm on 17-20 June. Chemical risk assessment was the focus of presentations by EFSA scientists in Continuing Education Courses, Workshop and Symposium. An exhibition space enabled to promote EFSA's activities and networking among scientists.
- In the framework of the **International Symposium on Veterinary Epidemiology and Economics (ISVEE 13)** in Maastricht on 20-24 August, the COMMS Directorate supported the organisation of a networking side event to promote and inform on the expert database, calls for trainees, SNE's (seconded national experts) and NEPT's (national experts in professional training) as well as EFSA's procurement and grant calls policy.
- EFSA participated in the **FOOD MICRO international symposium** in Istanbul (3-7 September 2012), the corporate stand in the event served as central point to raise awareness on EFSA's work and to enable networking within the scientific community.

OTHER MEDIA RELATIONS

Media activities – To mark the occasion of the publication of EFSA's external evaluation report (5 Sept.), the Media Relations office organised a media breakfast in Brussels with the Executive Director and 10 journalists. Media included Brussels-based correspondents for: pan-EU newswires (e.g Agence Europe, Europolitics); national newswires (e.g. Austria Presse Agentur, ANSA); national publications (e.g Suddeutsche Zeitung, La Libre Belgique) and specialist publications (EU Food Policy, Agra Alimentation). The Executive Director introduced the evaluation report and answered questions on a range of subjects, including independence and transparency, GMOs and pesticides. There was resulting media coverage in most publications that attended the breakfast.

EFSA's Twitter – Tweets were sent out regularly during the period on the basis of relevant news and/or new features on EFSA's website. The number of users following EFSA's Twitter account is increasing steadily and reached over 1,400 at the end of August.

ONLINE COMMUNICATIONS

Improvements to the website search functions (including EFSA Journal) were implemented. A new search engine allows full indexing of web pages in real time, resulting in more precise results and a better display of multilingual results.

In the area of multimedia, a YouTube channel was created and procedures to manage and monitor the channel were put in place. All Understanding Science videos and the corporate video on risk assessment are now hosted on this platform. This initiative further expands outreach and helps in growing awareness about EFSA and its role amongst interested parties,

including the general public. A revamped video gallery on the EFSA website was launched in September, providing better access to Understanding Science videos on the website.

COMMUNICATIONS OUTPUTS

In the reporting period were issued eight press releases, 25 web news stories, eight multimedia science videos and nine key corporate publications such as Annual Report 2011, Science Strategy 2012-2016 and Risk Communications Guidelines.

CORPORATE – RESOURCES AND SUPPORT

On 5 September EFSA published the External Evaluation report prepared by Ernst & Young and promoted a wide consultation with its key partners (Advisory Forum, Scientific Committee, Stakeholders, as well as its staff members) seeking their views on the outcomes of the report.

Institutional relations

EFSA closely collaborated with the European Parliament (EP) rapporteur for the discharge of EFSA's budget 2010, MEP Monica Macovei, and provided further information to the EP Committees ENVI and CONT, notably on the latest developments in the field of independence and the implementation of EFSA's Policy on Independence and Scientific Decision-Making Processes.

On 20 September EFSA's Executive Director had her annual hearing before the ENVI Committee in the European Parliament, where the outcomes of the report on EFSA's second external evaluation were presented. A constructive and open dialogue took place on a series of issues which are high on MEPs agendas, which included *inter alia* nutrient profiles, GMO risk assessment, endocrine disruptors and independence.

Quality

Quality Management System: EFSA's Standard Operational Procedures (SOPs) have been revised. They have been made available to EFSA staff and a training programme initiated. A project called "Quality Circle" has been launched which, promoting the development of a quality culture and driving continuous improvement, aims to develop and share best practice.

External Review: The second meeting of the External Review Working Group (ERWG) has taken place in June and included training of the new members in the evaluation criteria. A meeting has been promoted between the Chair of the ERWG and the Editorial Board of the EFSA Journal to look at opportunities of closer cooperation. The transformation of the external review activity into an annual process has gone well: the outputs for 2012 have been selected and the first review completed. The first discussion of the findings has taken place in September and the report is expected to be finalised by December this year.

Document Management: The transfer of the first Unit into the system started in August and the training to support the roll-out was delivered. Based on the lessons learnt, the system is being reconfigured to optimise performance to meet EFSA complex needs. The next stage of the roll-out is due to start in November.

Planning and monitoring

EXO is coordinating the finalisation of the Multi Annual Plan (MAP), which will be aligned with EFSA's strategies and the expected workload in the coming years (2014-2016). The draft will be presented to the Board in December with the aim of adopting it in March 2013. The two-year pilot phase on EFSA's Impact Indicators is coming to a conclusion. The proposed Indicators have been tested for their relevance and have been compiled by EXO in cooperation with other Units. The final report with recommendations on the follow-up is being prepared and will be presented to the Board at the December meeting. In August the Commission informed EFSA on the revised predicted activities for the coming years, and the update of the Medium Term Plan is being carried out. EFSA. The Commission agreed to update the Medium Term Plan twice a year. The Balanced Scorecard (BSC) project was initiated under the e³ – efficiency programme to develop and implement a strategic performance management tool. Following the six-month pilot phase, the indicators have been fine-tuned and the reporting structure stabilised. Efforts continue to move to an automatic production of the reports for all layers of the organisation.

Data protection (DP)

Data protection follow-up was pursued in several areas, including staff leave management and staff training policy, the end of employment procedure, procurement and grants management, and the video surveillance system installed at EFSA's final seat.

Court cases

EFSA has been active in case T-214/11, involving ClientEarth and PAN Europe/EFSA (Access to documents/Environmental information) in preparation of the forthcoming hearing in Luxembourg and has been taken to Court together with the Commission in a new complaint lodged by a German company (Plantavis) and an organisation representing medium-sized European companies producing and distributing food supplements and health products (NEM). This case, T-334/12, concerns an action for annulment pursuant to Article 263 of the Treaty on the Functioning of the European Union (TFEU), of inter alia the health claim Regulation (EC) No 1924/2006. EFSA and the Commission cooperate with regard to the defence.

Ombudsman

EFSA cooperated with the EU Ombudsman on three cases: the first concerned alleged conflicts of interests of the scientific experts involved in the Working Group of the Scientific Committee on the Threshold of Toxicological Concern (2522/2011/VIK); the second concerned alleged conflicts of interest of the former Chair of the Scientific Panel on GMOs, Mr Harry Kuiper (622/2012/ANA); and the third concerned an issue linked to allowances provided in the Staff Regulations (684/2012/JF).

IT and Operations

A number of new functionalities and improvements have been deployed to various IT tools aimed to support EFSA's scientific and operational activities. In particular: improvement of EFSA's Website Search Engine; upgrade of the Dol system in application of the new Policy on Independence and Scientific Decision Making Processes; automation of Experts Reimbursement after attending a meeting; extension of Contract Database to non-science contracts; extension of electronic workflow for non-compliance events; and non-financial exceptions.

Corporate Centralised Support Services

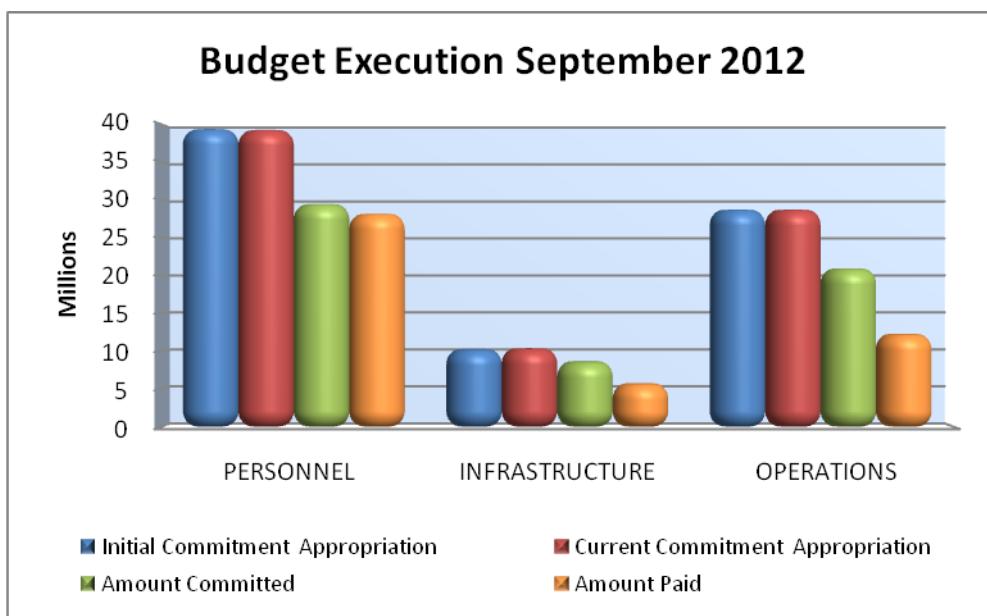
During summer the centralisation of logistic support to meeting organisation progressed with the definition of the organisational principles, pre-conditions and deployment strategy. This led to the implementation of a pilot phase, which started in September. The centralisation of meeting organisation will be gradually extended to other services by January 2013.

Financial management

As of 30 September 2012,

- EUR 58.96 million or 75.32% of the EUR 78.28 million budget was committed. This commitment level stands 10% below the target set for the month of September.
- Under Title I, commitments and payments levels are essentially driven by the staff expenditure, with 95% of the payments made to remunerate the staff.
- Under Title II Infrastructure, the budget is already at 83% committed in view of the quarterly pattern of the expenditures and higher than expected building start-up costs.
- Under Title III Operations, the execution rate reached 72% mainly triggered by scientific meetings (EUR 7.92 million), operational support (EUR 5.94 million) and scientific cooperation (EUR 5.87 million).
- EUR 46.07 million or 61.13% of the EUR 75.38 payment appropriations were paid, essentially corresponding to the staff and infrastructure expenditure and, under Title III, scientific meetings (EUR 5.49 million) and scientific cooperation (EUR 3.66 million). This overall payment level stands however 7% below the target for the month.

Title	Initial Commitment Appropriation	Current Commitment Appropriation	Δ	Amount Committed	%	Payment Appropriation	Amount Paid	%
PERSONNEL	39.359.000	39.249.000	-0,28%	29.436.146	75,00%	39.249.000	28.152.892	71,73%
INFRASTRUCTURE	10.222.000	10.332.000	1,08%	8.606.696	83,30%	10.332.000	5.676.770	54,94%
OPERATIONS	28.698.000	28.698.000	0,00%	20.917.548	72,89%	25.780.590	12.237.458	47,47%
Total:	78.279.000	78.279.000	0,00%	58.960.389	75,32%	75.361.590	46.067.121	61,13%



Year on Year

Year on year, the commitments increased by EUR 1.43 million, or a 2.49% increase. Payments increased by EUR 4.34 million or 10.4% compared to last year. On commitment and payments the increase is mainly due to operations.

Title	Commitments September 2012	Commitments September 2011	Increase	Payments September 2012	Payments September 2011	Increase
PERSONNEL	29.436.146	31.273.576	-5,88%	28.152.892	26.614.127	5,78%
INFRASTRUCTURE	8.606.696	9.775.229	-11,95%	5.676.770	5.249.661	8,14%
OPERATIONS	20.917.548	16.481.632	26,91%	12.237.458	9.865.136	24,05%
Total:	58.960.389	57.530.437	2,49%	46.067.121	41.728.924	10,40%

Human Resources

Staff Categories	End 2011	Target 2012	Total Contracted and Offered
Temporary Agents and Officials			
<i>Managers & Officers (AD)</i>	199	225	205
<i>Assistants functions (AST)</i>	133	130	129
Total	332	355	334
Contract Agents			
<i>Officers functions (CA FG IV)</i>	40	60	52
<i>Assistants functions (CA FG I, II, III)</i>	50	50	51
Total	90	110	103
Seconded National Experts	14	29	23
Total all staff categories	436	494	460

On 30 September 2012, 449 posts were occupied and 11 job offers sent to the selected candidates bringing the total to 460 posts filled-in out of the planned 494 posts. The Recruitment execution rate for the Establishment Plan 2012 (Temporary Agents and Officials) is at 94%.

Glossary

AF – EFSA's Advisory Forum
AFCWG – Advisory Forum Communications Working Group
AFSCO – EFSA Unit on Advisory Forum and Scientific Cooperation
AHAW – EFSA Panel/Unit on Animal health and welfare
ANS – EFSA Panel on Food additives and nutrient sources added to food
BIOHAZ – Biological Hazard Panel/Unit of EFSA
BIOMO – EFSA Unit on Biological monitoring
BPA – bisphenol A
BSC – Balanced scorecards
BSE-TSE - Bovine and Transmissible Spongiform Encephalopathies
CEF – EFSA Panel on Food contact materials, enzymes, flavourings and processing aids
COGEM – Netherlands Commission on Genetic Modification
COMMS – EFSA Directorate of Communications
CONT Committee – Budgetary control committee at the European Parliament
CONTAM – EFSA Panel/Unit on Contaminants
DCM – EFSA Unit on Dietary and chemical monitoring
DG COMM – Directorate General for Communication
DG SANCO – Directorate General for Health and Consumers
DOI – Declaration of Interest
DPO – EFSA Data Protection Officer
EC – European Commission
ECDC – European Centre for Disease Prevention and Control
ED – EFSA Executive Director
EDB – EFSA Expert Database
EDPS – European Data Protection Supervisor
EMRISK – Emerging Risk Unit of EFSA
ENVI Committee – Environment, public health and food safety committee at the European Parliament
EP – European Parliament
ERA – Environmental risk assessment
ERWG – EFSA's External Review Working Group
ETUI – European tool for usual intake
EU – European Union
EUROTOX – European Society of Toxicology
EXO – EFSA's Executive Office Unit
FAQ – Frequently asked questions
FDA – US Food and Drug Administration
FEED – EFSA Unit on Feeds
FEEDAP – EFSA Panel on Additives and products or substances used in animal feed
FIP – EFSA Unit on Food ingredients and packaging
FP – EFSA Focal Points
FSCJ – Food Safety Commission of Japan
GMM – Genetically Modified Micro-organism
GMO – EFSA Panel/Unit on Genetically modified organism
HUCAP – EFSA Unit on Human capital and knowledge management
IEP – Information exchange platform
KFDA – Korean Food and Drug Administration
MAP – Multi-Annual Plan
MEP – Member of the European Parliament
MRL – Maximum residue levels
MS – EU Member States
NEPT – National expert in professional training
NIFDS – Korean National Institute of Food and Drug Safety Evaluation

PCB – polychlorinated biphenyl
PFAS – perfluoroalkylated substance
PLH – EFSA Panel/Unit on Plant health
PMEM – Post-market environmental monitoring
PRAS – EFSA Unit on Pesticides
PPR – EFSA Panel on Plant protection products and their residues
QPS – Qualified Presumption of Safety
RASA – EFSA Directorate of Risk assessment and scientific assistance
REPRO – EFSA Directorate of Scientific evaluation of regulated products
RESU – EFSA Directorate of Resources and Support
SAS – EFSA Unit on Scientific assessment support
SBV – “Schmallenberg” virus
SC – EFSA Scientific Committee
SCISTRAT – EFSA Directorate of Scientific strategy and coordination
SCNT: Somatic Cell Nuclear Transfer
SCOM – EFSA Unit on the Scientific Committee
SCP – Stakeholders Consultative Platform
SME – Small and medium enterprises
SNE – Seconded national expert
SOP – EFSA's Standard Operational Procedure
STEC – Shiga toxin-producing *Escherichia coli*
SVD – Swine vesicular disease
TTC – Threshold of toxicological concern
VTEC – Verotoxin-producing *E. coli*
WG – Working group