



EXECUTIVE OFFICE

**Management Board
18 December 2014
Parma**

Meeting :	Management Board - Open session	
Subject :	EFSA progress report	
Document number:	mb 18 12 14 item 3 doc 2	
Confidentiality level :		Confidential
		For Restricted Use Only
	X	Public

EXECUTIVE OFFICE

EFSA PROGRESS REPORT

The present report refers to the period from the 1st of October to the 30th of November, 2014.

Highlights

- **Outputs produced in the reporting period**

In the risk assessment area, EFSA endorsed two Guidance documents on “Statistical reporting” and “Risk assessment of the renewal of GM plant products authorised under Regulation (EC) No 1829/2003”, the latter published for public consultation. A total of 42 scientific opinions were adopted in the reporting period, 26 of which in the area of regulated products. EFSA issued two scientific statements and two scientific reports, which also include the report on the risk of transmission of Ebola via the food chain. In addition, 23 technical reports, 12 reasoned opinions and 6 peer review conclusions were issued in the reporting period. EFSA issued 10 external reports.

In the risk communication area, EFSA issued 11 news stories, 1 feature story and 8 news in brief. Media coverage included approx. 1,100 articles and 95 media queries. Main areas of interest: Ebola virus, probiotics, sweeteners, pesticides and food contact materials. Twitter account +545 new followers. The Scientific Cooperation Roadmap 2014-2016 was published and two videos were shot at the joint EFSA and ANSES Conference on occupational exposure to pesticides.

- **Guidance document on statistical reporting**

The Scientific Committee endorsed the new Guidance on statistical reporting which will increase the usability of EFSA's scientific outputs making it easier to reproduce or repeat statistical analyses used in EFSA's scientific assessments. The guidance aims to support stakeholders (e.g. potential applicants) and scientists by improving the quality of study planning and reporting. The Guidance document benefitted from an open public consultation, as well as consultations with other EU agencies.

- **Ebola**

Scientific report on the risk of transmission of Ebola via the food chain: Ebola virus has been found in bushmeat, which is meat derived from wild animals native to African forests. The import of bushmeat into the EU is not authorised. EFSA's Network on Microbiological Risk Assessment, the Focal Points and the members of the International Microbiological Food Safety Liaison Group (IMFLSG) were contacted to provide information on transmission of the Ebola virus via the food chain, in particular the meat chain (such as risk study, persistence in meat, inactivation treatments). Representatives from the WHO participated as hearing experts in the working group. The ECDC provided comments to the report before its endorsement by the BIOHAZ Panel. EFSA's scientists conclude that the risk of transmission from bushmeat is low. However, experts identified several knowledge gaps in their risk assessment. For example, there is no information about consumption levels in the EU, or on how illegally imported bushmeat is handled, prepared and consumed in Europe. Scientists do not know for how long the virus survives in meat or animal products. Despite these uncertainties, EFSA experts concluded that the probability of a viable virus surviving transportation to Europe is higher in fresh or frozen meat after a short transport time and lower in dried or smoked meat exposed to higher temperatures during transport. They also said that thorough cooking (at 100°C) kills the virus.

Scientific report on the risk related to household pets in contact with Ebola cases in humans: The likelihood of a domestic dog or cat being exposed to the Ebola virus through contact with infected persons in Europe is very low, as affected persons are typically isolated promptly. This is one of the conclusions of an assessment carried out by experts from EFSA, the European Centre for Disease Prevention and Control (ECDC) and Member States on the risks of pets transmitting the Ebola virus to humans in Europe. Experts identify many knowledge gaps and lack of data in their

assessment. For example, there is no evidence that dogs can develop the disease and transmit the virus, nor that cats can become infected. Experts recommend that the public health and veterinary authorities assess the risk of pets becoming infected and transmitting the disease on a case-by-case basis. They also identify different precautionary measures for different scenarios. These include people's self-monitoring and isolation of pets.

- **Avian flu: urgent request for scientific advice**

The highly contagious avian influenza virus has recently been detected in three European countries: in a turkey holding in Germany; three chicken holdings in the Netherlands and in a duck breeding holding in the United Kingdom. To date, there are no recorded cases of humans contracting the H5N8 virus. EFSA is assessing the situation on the H5N8 avian influenza following an urgent request from the European Commission. Experts are focussing on the possible entry routes of the virus into Europe- in particular on the role of wild birds.

- **Release of the software for GMO analysis for comparative assessment**

The new software provides stakeholders with a tool for carrying out complex data analysis as part of the risk assessment of GM plants. The software, which can be downloaded free of charge from EFSA's website, allows stakeholders such as Member States and industry applicants to analyse field trial data with a single mouse click. EFSA, in collaboration with Wageningen University and Research Centre, in the Netherlands, has developed a software tool to perform the statistical analysis necessary for comparative assessment in a way that complies with EFSA guidelines and European Union legislation. The software conducts the simultaneous analysis of the GM plant compared to its control and non-GM reference varieties. An output-file listing all the significant differences and the respective equivalence categories is generated with a single click.

- **First call for proposals for thematic grants**

As laid down in the Scientific Cooperation Roadmap, on the 12th of November, EFSA launched its first call for proposals for thematic grants: 'New approaches in identifying and characterizing microbiological and chemical hazards'. Member States are invited to form consortia and submit proposals in the following two areas:

- 1) Molecular approaches for identifying and characterising microbial foodborne pathogens;
- 2) Developing and applying read across methodologies to the hazard assessment of chemicals in the food safety area.

Thematic grants stimulate proposals for innovative multiannual project on broad scientific themes. This call is the first of several new funding opportunities EFSA will provide to boost scientific cooperation between scientists and research organisations across Europe.

- **Meetings of the Executive Director with the ENVI Committee**

On the 3rd of December, the ED held the annual exchange with the European Parliament's ENVI Committee, where he had the opportunity to outline the work carried out by EFSA and the challenges ahead (among others: globalisation, climate change and greater complexities in the scientific risk assessment). Looking ahead, EFSA's ED outlined his vision for the Authority, which encompasses the priorities of cooperation, innovation and openness, with the aim of creating a more open EFSA. The ENVI MEPs addressed the ED with questions, among others, on independence and transparency, health claims, meetings with applicants, GM feeding trials, cloning and nanotechnology and whether EFSA is acting against the wishes of society. The ED explained how scientific independence is ensured at EFSA and agreed that EFSA should do more to improve communication with applicants. However he stressed that there will not be any face to face meetings with individual applicants. The ED said that EFSA's role is to give scientific advice and not ethical assessments, nor interfere in any debate about whether new technologies were acceptable or not. Concluding, he encouraged the Parliament to make more use of the Authority's work.

On the 10th of November, the heads of EFSA, EMA, ECHA, ECDC and EEA held an exchange with the ENVI MEPs. EFSA's ED presentation focussed on the role of the Authority in the EU risk assessment community, pooling scientific expertise and competences and where close cooperation with Member States is crucial. While confirming their support for EFSA's work, the ENVI MEPs expressed particular interest in the independence of EFSA's scientific expertise, the services provided to applicants and long-term effect studies for GMOs.

- **Meetings of the Executive Director with the Health and Food Safety Commissioner, Mr Vytenis Andriukaitis**

On the 11th of November, the ED met Commissioner Andriukaitis and had the opportunity to present EFSA's main tasks and organisation of work, whilst putting forward the main challenges and opportunities ahead. Commissioner

Andriukaitis confirmed his strong engagement towards risk and evidence-based legislation and reaffirmed his full support in EFSA's work. The Commissioner expressed his wish to visit EFSA as soon as his agenda would allow and provisionally indicated the dates around EFSA's Management Board meeting in March 2015.

- **Occupational exposure to pesticides**

ANSES and EFSA jointly organised a conference on occupational exposure to pesticides. The two-day event, held on October 28 and 29, was an opportunity to take stock of scientific and technical developments on the issue of pesticides and to discuss the challenges and outlook for assessment, prevention and protection. During the seminar, the ANSES Opinion on the effectiveness of personal protective equipment for plant protection product applicators and the EFSA Guidance document on the assessment of risks linked to exposure to pesticides by operators and workers were presented. The conference ended with a round table for discussing the preventive actions to implement in light of the current state of knowledge and practices to minimise occupational exposure to plant protection products.

- **European Neighbourhood Food Safety Conference**

Sixty experts representing Algeria, Armenia, Azerbaijan, Belarus, Egypt, Georgia, Israel, Jordan, Lebanon, Moldova, Morocco, Palestine, Tunisia and Ukraine met EFSA from the 18th to the 20th of November. The overall objective of the conference was to gain knowledge on food safety in the EU focusing on EFSA's core tasks: risk assessment and risk communication. The conference also aimed to promote networking between EFSA and ENP Countries. 46 speakers from the European Commission, International organisations, the EU Member States, the ENP Countries and EFSA presented the work, methodologies and practice from their respective institutions working in the food safety areas.

- **EFSA Open Doors**

On the 22nd of November, EFSA held the third edition of the "Open Doors" since its move to the new premises inviting the citizens of Parma and surroundings to visit the Agency's headquarter and dialogue with the experts around the activities it carries out. The event had the patronage of Parma's City Council and EXPO 2015, and saw the active participation of the University of Parma, the European College of Parma and the School for Europe of Parma. The visitors had the opportunity to interact with the experts, who provided short info-sessions on, among others, GMOs, pesticides, health claims, bio-hazards and bee health. Didactic activities were organised to entertain the children. Media activities on the day included the Executive Director interview with German TV ARD, an encounter with local media and 11 articles (+83% compared to last year). The initiative encountered the strong support of Parma's local institutions, as well as the favour of many citizens. It was estimated that the number of visitors was around 1,500.

- **Changes in EFSA's organisational structure**

As of the 1st of November, the Communications Department is re-organised in two new Units: External Relations and Risk Communication. The External Relations Unit functions include the secretariat of the Stakeholders Consultative Platform, relations with other stakeholders (NGOs, civil society, etc.), relations with the EU Parliament, relations with media and EFSA internal communication. It also provides the secretariat to the Advisory Forum Communications Working Group. The Risk Communication Unit provides advice on communication approaches based on EFSA's strategy and objectives. In addition, it supports and partners EFSA scientists by explaining and contextualising food-related risks to both multi-disciplinary and non-scientific audiences. Following the resignation of Per Bergman as Head of the Assessment of Regulated Product Department (REPRO), as of the 1st of December Juliane Kleiner covers the role of ad-interim Head of REPRO. Her position as Head of the Science Strategy and Coordination Department (SCISTRAT) is covered ad-interim by Tobin Robinson, Head of the Scientific Committee and Emerging Risk Unit (SCER).

SCIENCE STRATEGY AND COORDINATION (SCISTRAT)	
Scientific Committee and Emerging Risks	<p><u>Scientific Committee (SC)</u></p> <ul style="list-style-type: none"> ○ Endorsement of the Guidance document on statistical reporting. ○ Discussion of the draft statement on the risk and benefit of fish/seafood consumption as regard the presence of methyl mercury. The statement will be adopted in December. <p><u>SCER Unit</u></p> <ul style="list-style-type: none"> ○ Publication of the Annual report of the Emerging Risks Exchange Network 2013. ○ Assignment of contract for four new advanced training courses targeting Scientific Panel members and EFSA network members: The training programme will start in spring 2015 and will last for 3 years. ○ A crisis training workshop was held with Member States and EC representatives.
Advisory Forum and Scientific Cooperation	<ul style="list-style-type: none"> ○ Advisory Forum (AF) meeting (10-11 Dec.). Among others, the agenda includes a discussion around the future way of working of the AF. A survey was conducted in order to further develop the format of the meetings and role of members to meet the needs of both EFSA and the Member States. ○ Focal Point (FP) meeting (8-9 October). Key issues: implementation of the new FP Agreements as of 2015 and the current developments of EFSA's Data Warehouse Access Rules and Data Roadmap. ○ The first thematic grant was launched: "New approaches in identifying and characterizing microbiological and chemical hazards". ○ External review of the impact of scientific grant and procurement projects on delivering EFSA's tasks. ○ European Neighbourhood Food Safety Conference (Parma, 18-20 Nov.).
Stakeholders	<ul style="list-style-type: none"> ○ Meeting of the Stakeholder Consultative Platform. Among others, the Platform discussed topics such as allergenic foods, the future of open plenary meetings and exchanged views on how to best deal with emerging risks and methodological approaches in risk assessment. ○ Meetings with COPA-COGECA, BEUC, Industrial Federations, Générations Futures and Inf'OGM. ○ The Platform actively contributed to the public consultation on the discussion paper "Open EFSA".
International relations	<ul style="list-style-type: none"> ○ Participation in the 1st meeting of the WHO's Chemical Risk Assessment Network to discuss current activities, share information and experiences and plan future collaborative activities. EFSA chaired the breakout session on 'Gaps and knowledge in internationally harmonised methodologies' and presented its activities in the area of combined exposures. ○ Participation in the WTO Workshop on Risk Analysis. The objective of the workshop was to define risk assessment by today's standards using scientific experts with specific examples from various sectors and discuss responding to challenges such as dealing with uncertainty, data availability, and qualitative vs. quantitative risk assessment.

	<ul style="list-style-type: none"> ○ EFSA-FSCJ meeting took place in Japan to discuss the renewal of cooperation agreement and to provide an update on subjects of mutual interest (among others: TSE/BSE, allergenicity, flavourings, acrylamide, bisphenol A, glycidol fatty acid esters and glycidol). EFSA presented its work on risk communication in the Risk Communication workshop organised by FSCJ. ○ Visit of Dr Leigh Henderson from the Food Standards Australia New Zealand (FSANZ). He discussed with EFSA staff around novel foods, allergen exemptions, food enzymes, emerging issues and contaminants.
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RISK ASSESSMENT AND SCIENTIFIC ASSISTANCE (RASA)

Animal health and plant health	<p><u>Panel on Animal health and welfare (AHAW)</u></p> <ul style="list-style-type: none"> ○ Opinions on “Porcine Epidemic Diarrhoea and emerging pig Deltacoronavirus” and “Sheep pox and goat pox” <p><u>Panel on Plant health (PLH)</u></p> <ul style="list-style-type: none"> ○ Opinions on the pest categorisation for “Aonidiella citrina”, “Rhagoletis ribicola”, “Scirtothrips dorsalis”, “Xylophilus ampelinus”, “Erwinia amylovora”, “Clavibacter michiganensis”, “Citrus tristeza virus”, “Potato stolbur mycoplasma”, “Spiroplasma citri”, “Atropellis”, “Verticillium albo-atrum” and “Verticillium dahlia”. <p><u>ALPHA Unit</u></p> <ul style="list-style-type: none"> ○ EFSA Scientific report on the assessment of Echinococcus multilocularis surveillance performed in some EU member states in 2014. ○ Joint EFSA-ECDC Scientific report on risk related to pets and Ebola virus. ○ Technical report on “Inventory of recent and on-going relevant activities at animal-human interface”. ○ External reports on: “Data quality on pest occurrence and distribution in the EU and its influence on uncertainty”, “The development of probabilistic models for quantitative pathway analysis of plant pests introduction for the EU territory” and for the development of an Opinion on the “Main welfare risks related to the farming of sheep for wool, meat and milk production”. ○ Plant health surveys for the EU territory: an analysis of data quality and methodologies and the resulting uncertainties for pest risk assessment (PERSEUS).
Biological hazards and contaminants	<p><u>Panel on Biological hazards (BIOHAZ)</u></p> <ul style="list-style-type: none"> ○ Endorsement of the Scientific report of EFSA on “An update on the risk of transmission of Ebola virus (EBOV) via the food chain”. <p><u>Panel on Contaminants in the food chain (CONTAM)</u></p> <ul style="list-style-type: none"> ○ Opinions on: “Presence of chloramphenicol in feed and food” and “Risks for animal and public health related to the presence of metabolites and



	<p>masked or bound forms of certain mycotoxins in food and feed”</p> <p><u>BIOCONTAM Unit</u></p> <ul style="list-style-type: none"> External report on “Combined toxicokinetic and in vivo genotoxicity study on Alternaria toxins”.
Assessment and methodological support	<p><u>AMU Unit</u></p> <ul style="list-style-type: none"> Methodological support to the Scientific Committee (Guidance on statistical reporting), PRAS (Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products), GMO (Use of existing environmental surveillance networks to support the post-market environmental monitoring of GM plants) and ALPHA (“Sheep pox and goat pox” and “Echinococcus multilocularis surveillance”).
Evidence management	<p><u>DATA Unit</u></p> <ul style="list-style-type: none"> Support to BIOCONTAM for opinions on “Chloramphenicol in feed and food”, “Metabolites and masked or bound forms of certain mycotoxins in food and feed” and “Perchlorate in food, in particular fruit and vegetables”. External reports on: “Post-market monitoring of food additives”, “Molecular typing of Salmonella”, Molecular typing of Escherichia coli” and “Molecular typing of Listeria monocytogenes” from food, feed and animal samples.

SCIENTIFIC EVALUATION OF REGULATED PRODUCTS (REPRO)

Additives and products or substances used in animal feed	<p><u>Panel on Additives and products or substances used in animal feed (FEEDAP)</u></p> <ul style="list-style-type: none"> Opinions on feed additives: technological (6), nutritional (1), zootechnical (4); coccidiostats and histomonostats (1). Six of these opinions were a re-evaluation of feed additives already on the market.
Food ingredients and packaging	<p><u>Panel on Food contact materials, enzymes, flavourings and processing aids (CEF)</u></p> <ul style="list-style-type: none"> Opinions on: Flavouring substances (3), food contact materials (1) and recycling processes (2). <p><u>FIP Unit</u></p> <ul style="list-style-type: none"> Update of a technical report on “Guidance of the CEF Scientific Panel on the submission of a dossier on Food Enzymes” based on comments received during an info session organised on food enzymes. Statement of EFSA related to “Refined exposure assessments for food colours with possible excess of ADI – curcumin (E100)”.



	<ul style="list-style-type: none"> ○ Meeting of the FIP Network: discussion around risk assessment activities, approaches and challenges in the area of non-plastic food contact materials and proposals for future activities/follow-up meetings.
<p>Genetically modified organisms</p>	<p><u>Panel on Genetically modified organisms</u></p> <ul style="list-style-type: none"> ○ Opinions on: “Identification of existing monitoring networks suitable to provide datasets to support post market environmental monitoring (PMEM) of GMOs” and “Notification for the risk assessment of the genetically modified carnation line SHD-27531-4”. ○ Endorsement of the Guidance document for the “Risk assessment of the renewal of GM plant products authorised under Regulation (EC) No 1829/2003” for public consultation. <p><u>GMO Unit</u></p> <ul style="list-style-type: none"> ○ EFSA statement on “Explanatory note to the Guidance of the EFSA Scientific Committee for 90-day study on whole food/feed in rodents”. ○ Release of the software for GMO analysis for comparative assessment. ○ Info Session GMO on applications: technical meeting with applicants.
<p>Dietetic products, nutrition and allergies</p>	<p><u>Panel on Dietetic products, nutrition and allergies (NDA)</u></p> <ul style="list-style-type: none"> ○ Opinions on Health Claims: Art. 14 (4). ○ Opinion on Dietary Reference Values (DRVs) for Folate. ○ Opinion on the “Evaluation of allergenic foods and food ingredients for labelling purposes”. <p><u>NUTRI Unit</u></p> <ul style="list-style-type: none"> ○ Technical reports resulting from public consultations on DRVs for Folate, Selenium, Chromium and Zinc. ○ Technical report resulting from the public consultation on the evaluation of allergenic foods and food ingredients for labelling purposes. ○ External reports related to preparatory work for the setting of DRVs.
<p>Pesticides and plant protection products and their residues</p>	<p><u>Panel on Plant protection products and their residues (PPR)</u></p> <ul style="list-style-type: none"> ○ Publication of the EFSA Guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products and of the technical report on its public consultation. <p><u>PRAS Unit</u></p> <ul style="list-style-type: none"> ○ Technical reports: two on basic substance applications in accordance with Article 23 of Regulation (EC) No 1107/2009 and six to finalise the reporting table on confirmatory data. ○ Nine Reasoned opinions covering 12 questions. ○ Launch of the Member States consultation on the 2012 Annual Report on Pesticides Residues. ○ Six Conclusions on pesticides peer review.



Application Desk	<p><u>APDESK Unit</u></p> <ul style="list-style-type: none"> ○ Receipt of 41 applications and 29 requests via web form. ○ Support to the organisation of the “Technical meeting with GMO applicants” and “Technical meeting with Stakeholders on agronomic and phenotypic characterisation of genetically modified plants”. ○ Finalisation of the report on the stakeholders’ satisfaction survey.
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COMMUNICATIONS (COMMS)

- Content overview: 11 news stories, 1 feature story and 8 news in briefs were published, 14 of which were related to scientific topics and 6 to corporate issues. To be highlighted:
 - World Mycotoxins forum 2014 (WMF): A newsletter and an expert interview summarised EFSA's expert scientific contribution to mycotoxins risk assessment. Messages focused on the need for EU-wide projects and improved methods for data collection on toxicity, combined toxicity and exposure.
 - Scientific Cooperation Roadmap: Two news stories raised awareness among key stakeholders of the Roadmap launch and the first call for thematic grants.
 - Ebola: The web story explained EFSA’s report conclusions as well as knowledge gaps. Proactive media relations were done, which resulted in factual media coverage.
- Media: Coverage in approx. 1,100 articles and 95 media queries. Main areas of interest: Ebola virus, probiotics, sweeteners, pesticides and food contact materials. Twitter account +545 new followers. EFSA took part in its first Twitter chat in cooperation with DG SANCO, ECDC, EMA and WHO marking the European Antimicrobial Awareness Day. EFSA posted 19 tweets during the Twitter chat which generated 182 interactions (re-tweets, replies, mentions). The Twitter chat resulted in an increase of EFSA applause rate (# of retweets vs. tweets posted) from 5.19 reporting period average to 8.25.
- EXPO 2015: The microsite was launched on the 1st of Dec. together with the official announcement. The microsite aims at supporting the organisation (registration and call for abstracts) and promotion of EFSA’s second scientific conference “Shaping the future of food safety together”.
- Publications & Multimedia: Scientific Cooperation Roadmap 2014-2016 was published in October; Two videos were shot at joint EFSA and ANSES Conference on occupational exposure to pesticides.



CORPORATE – RESOURCES AND SUPPORT

Institutional relations	<ul style="list-style-type: none"> ○ Meeting with the Heads of EU Agencies (17 Oct.): among others, the Head of Agencies discussed around the implementation of the EC Roadmap on the Common Approach aiming at undertaking initiatives and reforms of individual decentralised EU Agencies. ○ Meeting of EFSA, EMA, ECDC, ECHA and EEA with the ENVI Committee (10 Nov.). The Heads of these Agencies provided the MEPs with information on the role of their respective Agency, their achievements and challenges ahead. ○ Meeting with the Health and Food Safety Commissioner, Mr Vytenis Andriukaitis (11 Nov.). It was the first opportunity for the ED to present to the new Commissioner the functioning of EFSA, whilst highlighting the main challenges ahead. Commissioner Andriukaitis confirmed his willingness to strengthen EFSA and science's role as a basis for policy making, and his engagement to help finding ways to strengthen EFSA's reputation. ○ On 3 Dec., the ED intervened at the EP ENVI Committee for the annual exchange of views with ENVI MEPs. ○ The ED held bilateral meetings with MEPs (mainly from the CONT, AGRI and ENVI Committees) to address some specific issues in the area of EFSA's activities (e.g. novel foods, GMOs and scientific risk assessment decision making process). ○ Joint ANSES-EFSA conference on Occupational exposure to pesticides (28-29 Oct.). ○ Visit of the UK Food Standards Agency (25 Nov.). The delegation was composed of the FSA Chief Scientific Advisor, Prof. Guy Poppy, the FSA Director of Science and UK Advisory Forum member, Mr Penny Bramwell and the UK Focal Point, Mr Alisdair Wotherspoon.
Planning & Monitoring	<ul style="list-style-type: none"> ○ A baseline plan of activities, organized in terms of projects and processes and covering all EFSA's portfolio of activities, has been developed to prepare the 2015 annual work programme. ○ Further implementation of the project and resource management approach is planned with the application of a Project and Portfolio Management professional tool by the 1st of January 2015.
Quality	<ul style="list-style-type: none"> ○ Quality management <ul style="list-style-type: none"> ▪ The External Review Working Group (ERWG) has completed the fifth annual review of the quality of science of EFSA in areas covered by the Scientific Departments, and its Scientific Committee and Advisory Forum Unit. 15 scientific outputs and 20 third party technical reports were reviewed. The overall conclusion was that the scientific outputs and third party reports were of a very high standard. The overall recommendation is for the adoption of a quality management across the organisation extending to all activities. ▪ The customer feedback interviews with DG SANCO were held in October. The feedback was positive, delivered constructively and provides good input for EFSA to implement continuous improvement measures to better meet customer's needs. ▪ Agreement has been reached by the EFSA senior management to aim for certification against the ISO9001:2008 Quality Management Standard across the whole organisation by the end of 2016. A Framework Contract is in place to provide the necessary support.



	<ul style="list-style-type: none"> ○ Document management <ul style="list-style-type: none"> ▪ Around 4 million documents have been successfully migrated from previous document management system into the OpenText System. An extensive training course has been run for external experts and the system has been opened as a collaboration platform for all Panel, working group and network members as well as for selected contractors and other third parties.
Data protection	<ul style="list-style-type: none"> ○ Contribution on the data protection challenges related to the deployment of cloud computing solutions (e.g. Talent Management); ○ Interaction with the EDPS (European Data Protection Supervisor) on the newly adopted video surveillance policy of EFSA.
Court cases	<ul style="list-style-type: none"> ○ Case T-716/14 <i>Tweeddale v EFSA</i>: New action for annulment lodged by an individual, Mr Tweedale, against an EFSA decision refusing him access to two toxicological studies, studies from food business operators submitted to EFSA in the framework of the scientific risk assessment of glyphosate as a pesticide. The application is grounded on the alleged infringement of Regulations (EC) No 1049/2001 and No 1367/2006. The Case was served to EFSA on 22 October 2014 and EFSA is expected to lodge its Defence by the 1st of January 2015. ○ On 23 October 2014, EFSA attended a hearing before the General court of the European Union in case T-334/12 <i>Plantavis and NEM v. Commission and EFSA</i> concerning a challenge to the legality of the nutrition and health claim regulation in conjunction to Regulation (EC) No 432/2012. ○ On 10 November 2014, EFSA lodged a statement in intervention supporting the EMA in case T-213/13 P <i>European Medicines Agency v Drakeford</i> concerning an appeal against a ruling annulling the decision of the EMA not to renew a contract of employment of one of its temporary agents.
Ombudsman	<ul style="list-style-type: none"> ○ Own-initiative inquiry of the European Ombudsman (OI/4/2013/CK): On 27 October, EFSA informed the Ombudsman on the endorsement of the proactive disclosure of the names of the Selection Board Members described in the Good Practice guidelines that the Ombudsman issued upon the closure of the inquiry and addressed to all the EU Agencies. ○ Complaint 1493/2014/PMC: Brought by former seconded national expert related to the follow-up of the decision of the EFSA Staff Committee linked to the participation of the expert as an observer to the EFSA Staff Committee. The Ombudsman closed the case on 4 November, by finding that the arguments of EFSA are convincing and reasonable.
IT systems	<ul style="list-style-type: none"> ○ Windows 7 Migration completed on 98% of staff computers to improve performance and security. ○ Endorsed decision on modernisation of EFSA IT landscape toward 2020, mainly based on commercial off the shelf systems and open data technologies supporting the Roadmap on Open EFSA. ○ Awarded €25 million supply for EFSA’s large business transformation projects, in a framework of re-opening competition. The awarded services resulted in average capacity increase of approximately 25% for project delivery.



<p>Outreach and support services</p>	<ul style="list-style-type: none"> ○ Further to the flood suffered by part of the city of Parma in October, a refined risk strategy in terms of business continuity is being prepared with the aim of setting up a prioritisation plan of those IT structures that would need to be ‘rebuilt’ if such an event would affect EFSA. The outcome of this analysis is expected in June 2015. ○ The information sessions with GMO applicants and on risk assessment at the World Mycotoxin Forum in Vienna, and the Open Doors attended by approx. 1,500 among high school students and citizens were the outreach initiatives for which the satisfaction rate average expressed by the participants reached over 80%. 															
<p>Financial management</p>	<ul style="list-style-type: none"> ○ At the end of November, € 70.57 million or 88.5% of the € 79.70 million budget was committed (2% below the target), and € 57.66 million or 72.3% of the € 79.70 million payment appropriations were paid (9% below target). Detailed information on the 2014 budget execution is available in document “2014 budget execution and transfers” (mb 18 12 14 item 11 doc 6). 															
<p>Human resources</p>	<ul style="list-style-type: none"> ○ On 30th November, 447 posts were occupied out of the available 474 posts (all types, Officials, Temporary agents and Contract agents as well as Seconded National Experts). The average post occupancy rate (January – November 2014) for the Establishment Plan 2014 (Temporary Agents and Officials) is at 94.9%, while that for Contract Agents is at 92.4% (below the 2014 target of 95% due to a cumulated turnover rate at 4.2% and 13 internal staff being successful in external procedures). This gives an overall weighted average of 94.3%. <table border="1" data-bbox="846 778 1805 1078"> <thead> <tr> <th>Staff Categories</th> <th>Target 2014</th> <th>Total Contracted and accepted</th> </tr> </thead> <tbody> <tr> <td>Temporary Agents and Officials</td> <td>344</td> <td>331</td> </tr> <tr> <td>Contract Agents</td> <td>110</td> <td>100</td> </tr> <tr> <td>Seconded National Experts</td> <td>20</td> <td>16</td> </tr> <tr> <td>Total all staff categories</td> <td>474</td> <td>447</td> </tr> </tbody> </table>	Staff Categories	Target 2014	Total Contracted and accepted	Temporary Agents and Officials	344	331	Contract Agents	110	100	Seconded National Experts	20	16	Total all staff categories	474	447
Staff Categories	Target 2014	Total Contracted and accepted														
Temporary Agents and Officials	344	331														
Contract Agents	110	100														
Seconded National Experts	20	16														
Total all staff categories	474	447														

Glossary

ADoI – Annual Declaration of Interest
AF – EFSA's Advisory Forum
AFCWG – Advisory Forum Communications Working Group
AFSCO – EFSA Unit on Advisory Forum and Scientific Cooperation
ALPHA – EFSA Unit on Animal health and plant health
AHAW – EFSA Panel on Animal health and welfare
AMU – EFSA Unit on Assessment and methodological support
ANS – EFSA Panel on Food additives and nutrient sources added to food
BIOCONTAM – EFSA Biological hazard and contaminants Unit
BIOHAZ – EFSA Panel on Biological hazards
BPA – bisphenol A
CEF – EFSA Panel on Food contact materials, enzymes, flavourings and processing aids
COMMS – EFSA Department of Communications
CONTAM – EFSA Panel on Contaminants
DATA – EFSA Unit on Evidence management
DG SANCO – Directorate General for Health and Consumers
DoI – Declaration of Interest
DPO – EFSA Data Protection Officer
EC – European Commission
ECA – European Court of Auditors
ECDC – European Centre for Disease Prevention and Control
ED – EFSA Executive Director
EP – European Parliament
ERA – Environmental risk assessment
ERWG – EFSA's External Review Working Group
EU – European Union
EXO – EFSA's Executive Office Unit
FAQ – Frequently asked questions
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
GMO – EFSA Panel/Unit on Genetically modified organism
HUCAP – EFSA Unit on Human capital and knowledge management
IEP – Information exchange platform
IFCSLG – International Food Chemical Safety Liaison Group
MAP – Multi-Annual Plan
MEP – Member of the European Parliament
MRL – Maximum residue levels
MS – EU Member States
PRAS – EFSA Unit on Pesticides
PPR – EFSA Panel on Plant protection products and their residues
QPS – Qualified Presumption of Safety
RASA – EFSA Department of Risk assessment and scientific assistance
RASFF – Rapid Alert System for Food and Feed
REPRO – EFSA Department of Scientific evaluation of regulated products
RESU – EFSA Department of Resources and Support

SC – EFSA Scientific Committee

SCER – EFSA Scientific Committee and Emerging Risk Unit

SCISTRAT – EFSA Department of Scientific strategy and coordination

SCP – Stakeholders Consultative Platform

SOP – EFSA's Standard Operational Procedure

WG – Working group

EXECUTIVE OFFICE

Progress Indicators Executive Summary

This document includes: progress of key corporate indicators vs. the monthly target (figure 1), details on scientific outputs and supporting publications (figures 2 to 4), analysis of ongoing questions by status and their monthly evolution (figures 5 and 6), indicators on Communication (figures 7 and 8). All figures and data refer to the period 1/1/14 - 30/11/14.

Overall, in the first 11 months of 2014, 390 scientific outputs (73% of the target for 2014) have been adopted.

While for Activity 1 (Scientific advice and risk assessment), scientific outputs are on track, for Activity 2 (Evaluation of regulated products) EFSA will not meet the yearly target, mainly due to deviations within the Pesticide Unit. For the Conclusions on pesticides active substances this underperformance is mainly due to unforeseen requirements for additional information and delays in receiving the assessments from the rapporteur Member States. For MRL Reasoned Opinions main reasons are an overstated target and a reprioritization towards other activities as requested by the European Commission. (See figure 2). For Activity 3 (Data collection, scientific cooperation and networking) the target will not be met as a number of Scientific Reports originally foreseen under this Activity were delivered as Technical Reports, which are included under Supporting Publications.

At the end of November, 159 supporting publications have been adopted, i.e. well above the yearly target of 147.

Adoption timeliness indicator is affected by the late adoption of MRL Reasoned Opinions. Without the Reasoned Opinions, the timeliness indicator is 84% for all scientific Activities -against a yearly target of 90% - and 80% for Activity 2. Main deviations, apart from MRL, are due to the late adoption of opinions by FEED, where the stock of overdue questions has been significantly reduced.

Communication activities are on track.

Financial performance at the end of November is - at global level - 2% below the monthly target for commitments and 9% below the monthly target for payments. Commitments for Scientific Cooperation are 7% below target. (For further details on financial performance, please refer to document mb 18 12 14 item 11 doc 6 - 2014 Budget Execution & Transfers).

Progress Indicators 1/1-30/11/2014 - overview

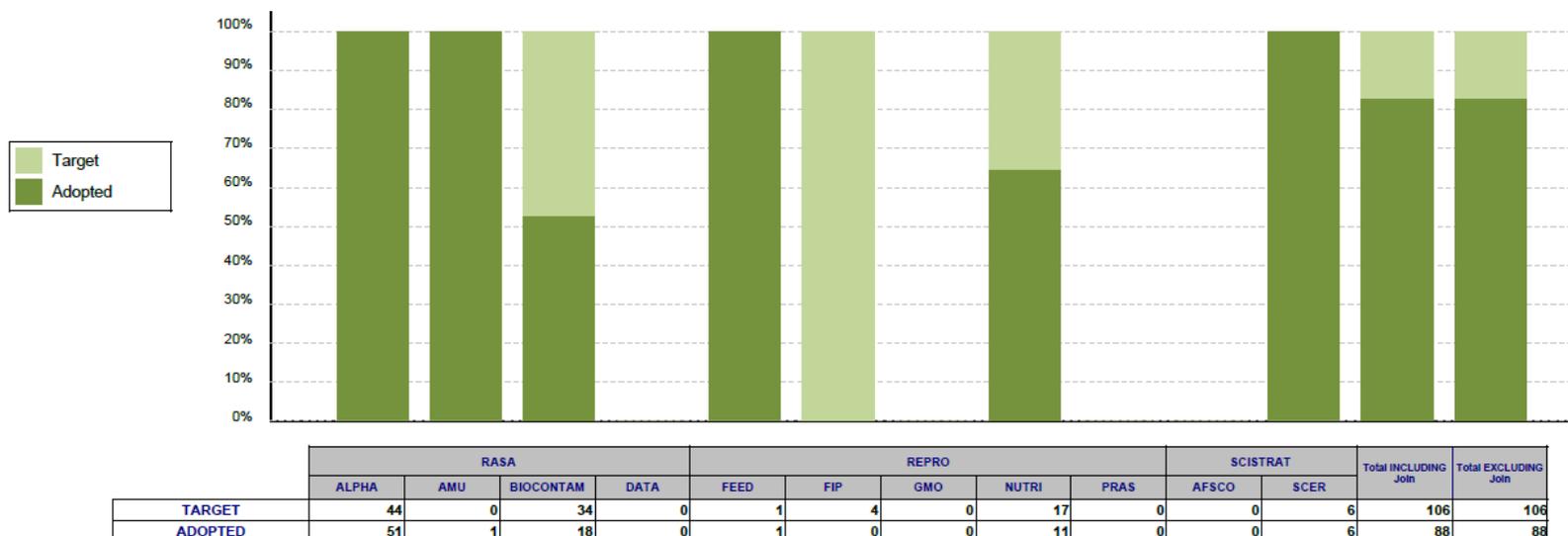
INDICATOR	TRAFFIC LIGHT	COMMENTS
1. Scientific outputs adopted under Activity 1 (Scientific advice and risk assessment)		By November 2014 the number of outputs adopted compared with the yearly target is at 82% for Activity 1 (88 vs. 106), 72% for Activity 2 (292 vs. 404) and 50% for Activity 3 (10 vs. 20). For details and comparison with annual targets see Fig. 1, 2 and 3.
2. Scientific outputs adopted under Activity 2 (Evaluation of regulated products)		
3. Scientific outputs adopted under Activity 3 (Data collection, scientific cooperation and networking)		The total amount of on-going questions (1247) as well as its monthly evolution is available at Fig. 5 and Fig. 6.
4. Supporting publications adopted		Actual number of output is above the monthly and yearly target (for details see Fig. 4)
5. Global commitment rate		For detailed information, please refer to document mb 18 12 14 item 11 doc 6 – 2014 Budget Execution & Transfers.
6. Global payment rate		For detailed information, please refer to document mb 18 12 14 item 11 doc 6 – 2014 Budget Execution & Transfers.
7. Commitment level for scientific cooperation programme		Commitments related to scientific cooperation were 7% below target (EUR 7.4 vs. 8.0 million). For detailed information, please refer to document mb 18 12 14 item 11 doc 6 – 2014 Budget Execution & Transfers.
8. Payment level for scientific cooperation programme		Payments related to scientific cooperation were 25% below target (EUR 5.8 vs. 7.7 million). For detailed information, please refer to document mb 18 12 14 item 11 doc 6 – 2014 Budget Execution & Transfers.
9. Tele-expert-days		Number of tele-expert-days vs. total expert-days above the monthly target (20% vs.15% for RASA, 17% vs. 15% for REPRO and 10% vs. 8% for SCISTRAT).
10.DOI processes without exceptions		Actual number of DOI processed with no exceptions vs. total DOI in line with 100% target.
11.Scientific outputs under Activity 1 adopted on time		Actual number of outputs adopted on time vs. total number of scientific outputs adopted (97%) in line with target.
12.Scientific outputs under Activity 2 adopted on time (*)		Timeliness indicator for Activity 2 - excluding MRLs - is below target at 80% mainly due to delayed opinion adoptions in the FEED area where in the period the stock of overdue questions was reduced by 38.
13.Scientific outputs under Activity 3 adopted on time		Timeliness indicator for Activity 3 (79%) is below the monthly target. The result is determined by the late adoption of two scientific reports of EFSA (one by SCER and one by AMU) out of the 10 adopted.
14.Outputs published on time		At the end of November the percentage of all outputs (including supporting publications) published within 15 working days from adoption is 87%. In particular 57 outputs out of 454 were published in more than 15 working days (48 within 6 weeks from adoption and 9 within 8 weeks from adoption). The indicator including only scientific outputs is 89% (AMP target 90%).
15.Outputs accompanied by press releases and web stories on time		Actual number of outputs accompanied by press releases and web stories published within 20 working days from adoption vs. total number of outputs accompanied by press releases and web stories published (92%) is in line with target.
16.Web visits		Total number of visits to the EFSA web site is around 2.6 million, in line with target (for monthly evolution see Fig. 7)
17.Number of subscribers to online products and newsletters		Total number of subscribers to online products and newsletters is around 33,743 in line with target (for details see Fig. 8)
18.Statutory Staff occupancy rate		The occupancy rate at end November was 94.9%, in line with the 95% target. The average rate for 2014 is 94%, slightly below target.
19.Exchange Staff: Volume of END present in EFSA		Year to date number of END is 16 in line with target.

(*) For what refers to the reasoned opinions on MRLs, nearly all outputs adopted in 2014 were late as related to a stock of overdue questions which the PRAS Unit is engaged to reduce progressively, while at the same time handling the new evaluation requests received. In the first 11 months of the year the stock of overdue questions related to the MRL evaluations has been reduced by around 3% (277 vs. 286).

Progress indicators: details by activity / unit

SCIENTIFIC ACTIVITIES

Fig. 1. Provision of scientific opinions and advice & risk assessment approaches (Activity 1) 01.01.2014 – 30.11.2014 vs. Annual Target



Activity 1: 88 outputs adopted as of November 2014 (82% of the total target for 2014):

- 76 Opinions of Scientific Committee/Scientific Panels
- 1 Guidance document
- 9 Scientific Report of EFSA
- 2 Statements of EFSA

ALPHA exceeded its yearly target and expects to adopt 8 outputs currently in progress by the end of December 2014.

BIOCONTAM: targets in terms of outputs will not be reached as some planned requests have not been sent in 2014 by the European Commission and on-going tasks have been extended to 2015. To be noted that 4 more outputs are expected to be adopted by the end of the year.

Fig. 2. Evaluation of products, substances and claims subject to authorisation (Activity 2), 01.01.2014 – 30.11.2014 vs. Annual Target



Activity 2: 292 outputs adopted as of November 2014 (72% of the total target for 2014):

- 33 Conclusions on Pesticide Peer Review
- 4 Guidance documents
- 171 Opinions of Scientific Committee/Scientific Panels (1 RASA)
- 72 Reasoned Opinions
- 2 Scientific Reports of EFSA
- 7 Statements of EFSA
- 3 Statement of Scientific Committee/Scientific Panel

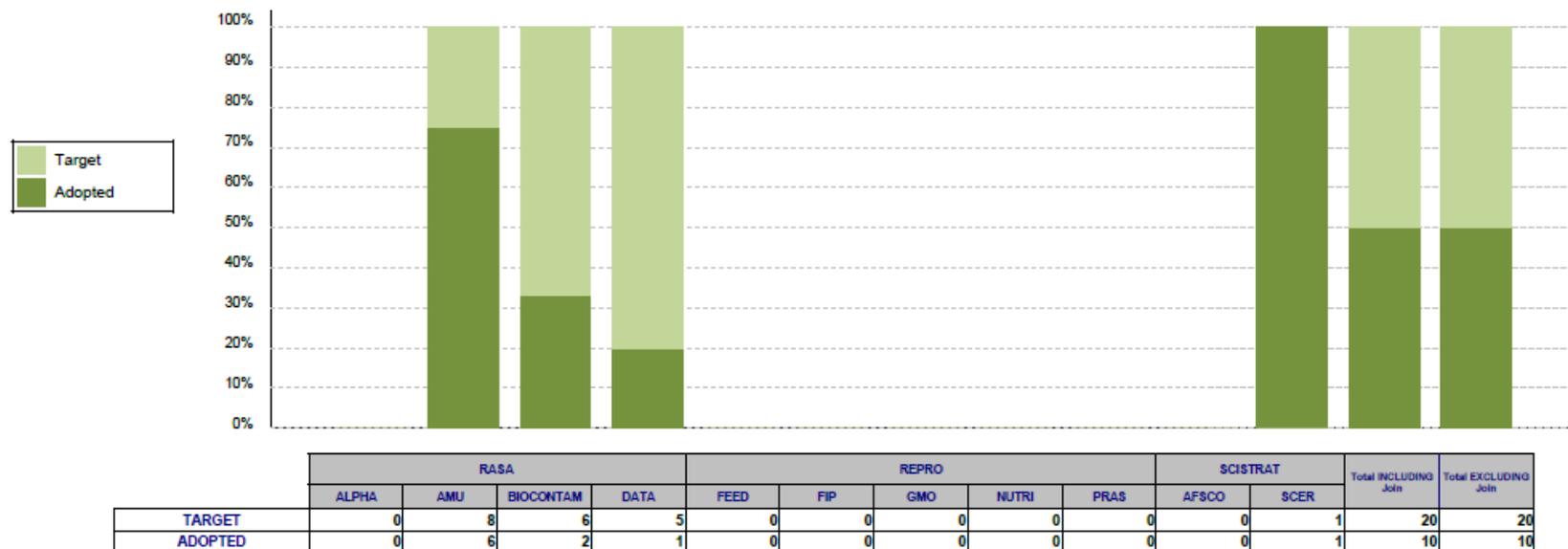
BIOCONTAM and DATA will not meet the target for outputs for 2014 as some planned request have not been received.

GMO will not meet the target for Panel outputs because several applications close to finalisation were withdrawn by the applicants or are delayed due to high complexity (stacked events including all sub-combinations). In addition, fewer requests related to panel outputs were received from the Commission (e.g. safeguard clauses were addressed as EFSA statements). To be noted that several “other outputs” (e.g. analysis of 4 NGO reports by Testbiotech and GIET were produced in the reporting period).

PRAS will not meet the target for outputs in 2014:

- Conclusions on pesticides active substances are below target due to requirements for additional information (clock stops) and delays in receiving the assessments from the rapporteur Member States, postponing the starting of the EFSA process and moving the deadline for the EFSA conclusion to 2015. It should be noted that the Unit has produced about 30 unplanned Technical reports on pesticide active substances.
- The number of Reasoned Opinions - MRL is significantly behind the 2014 annual plan mainly due to an overstated target and the reprioritization of other activities in the MRL area following the request from the European Commission. In this sense it is important to mention the significant improvements regarding the Annual Report on Pesticide Monitoring, with the annual reports for 2011 and 2012 published during 2014 and absorbing the delay in order to allow the publication of the 2013 report according to the legal deadline. In addition, some applications have been grouped in a single output for gaining efficiency.

Fig. 3. Data Collection, Scientific Cooperation and Networking (Activity 3) 01.01.2014 – 30.11.2014 vs. Annual Target



Activity 3: 10 outputs adopted as of November 2014 (50% of the total target for 2014):

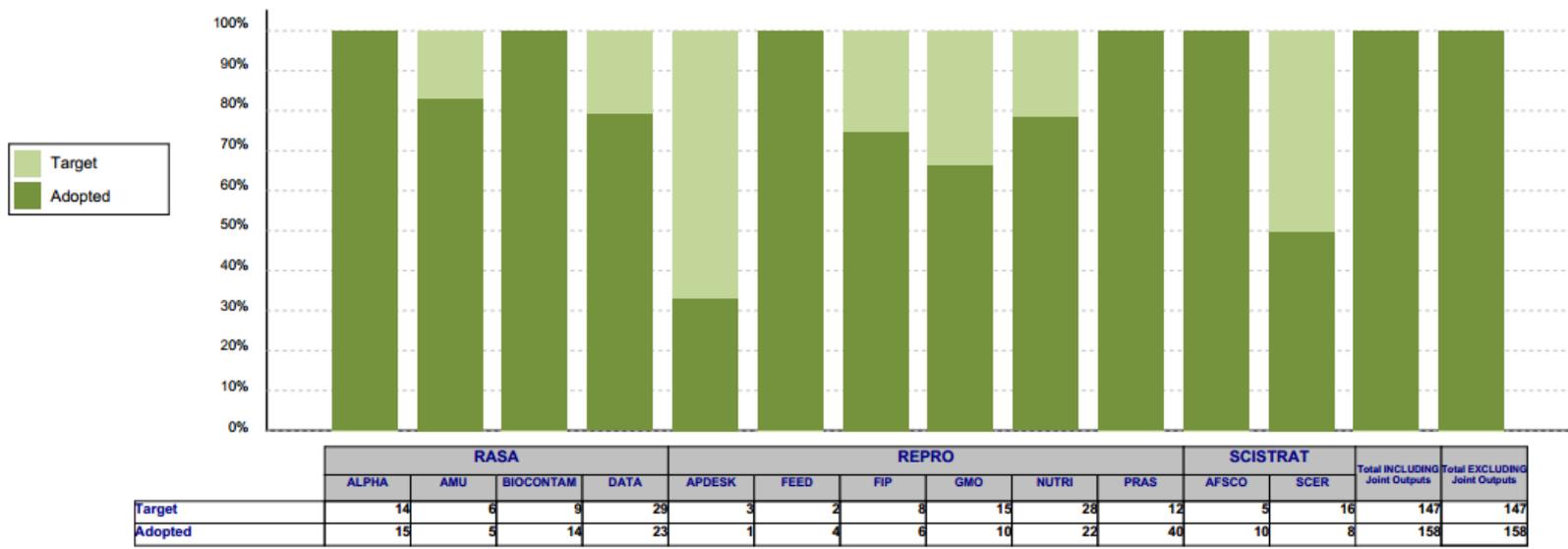
- 2 Guidance documents
- 8 Scientific Reports of EFSA

BIOCONTAM will exceed the target for 2014 under activity 3 as 5 originally foreseen Scientific Report of EFSA were delivered as Technical Reports (Supporting Publications).

DATA will not reach the target for 2014 under activity 3 as some requests planned to be sent by the Commission in 2014 with a deadline in the current year have not been received or the Terms of Reference have been extended, which requires postponement of the deadline to 2015.

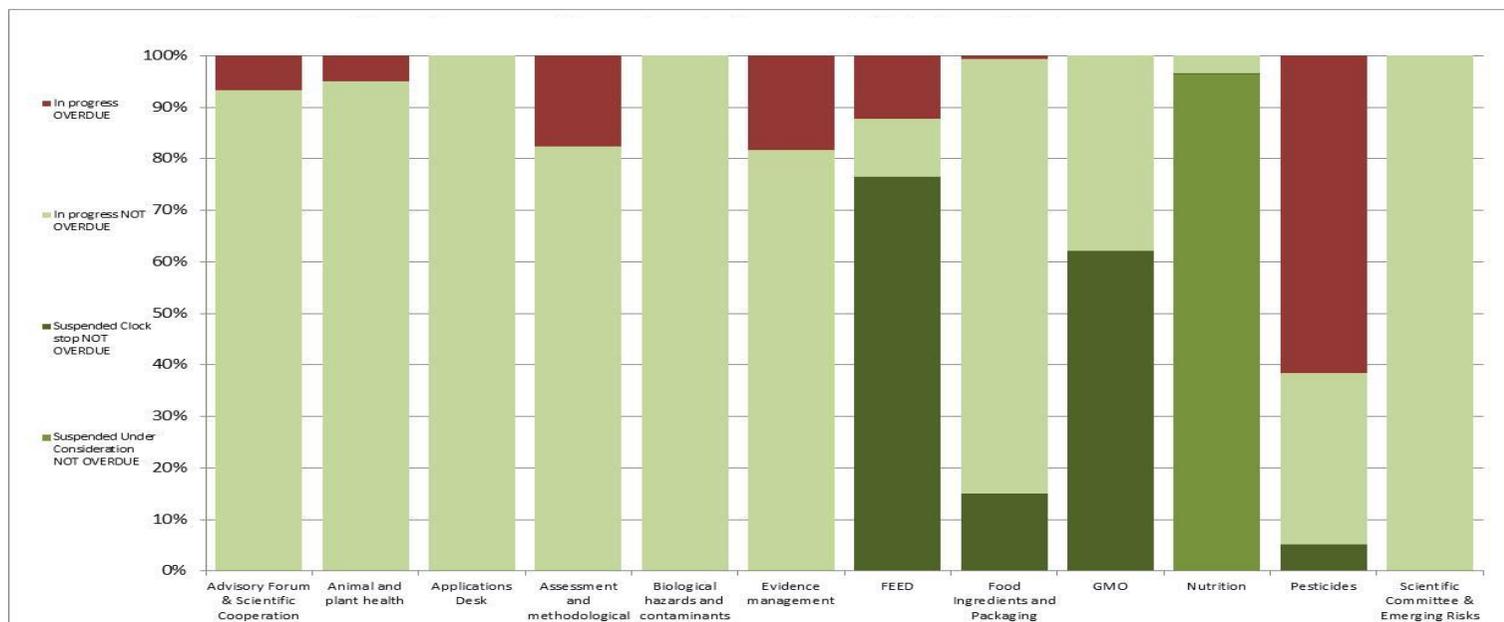
It has to be noted that two guidance documents on EU menu and Data Exchange are expected to be approved by the end of the year.

Fig. 4. Supporting publications, 01.01.2014 – 30.11.2014, vs. Annual Target



Supporting Publications: 158 outputs adopted as of November 2014 (107% of the total target for 2014).

Fig. 5. Ongoing questions by status



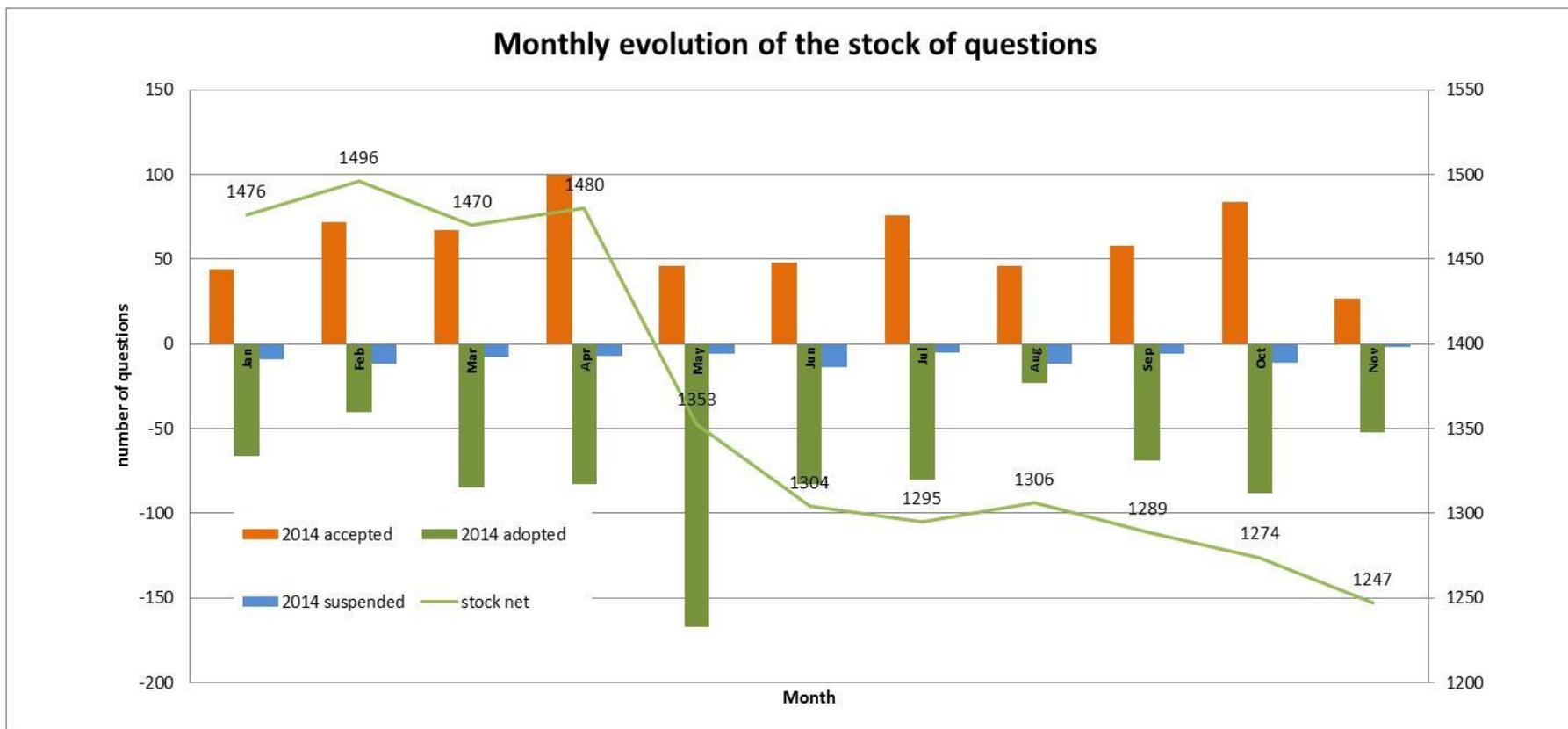
														Total
In progress	NOT OVERDUE	14	38	6	14	45	67	21	452	22	54	153	31	917
	OVERDUE	1	2		3		15	23	3			283		330
	Total in progress	15	40	6	17	45	82	44	455	22	54	436	31	1247
Suspended	Clock stop							143	81	36	3	24		287
	Under Consideration										1548			1548
Grand Total		15	40	6	17	45	82	187	536	58	1605	460	31	3082

In the Pesticides Unit the number of questions overdue is mainly related to request for reasoned opinions on the review of the existing maximum residue levels of pesticides (MRL) according to Article 12 of Regulation (EC) No 396/2005.

The 1548 questions under consideration refer to health claims pursuant to article 13 of Regulation 1924/2006 on nutrition and health claims made on food.

The questions in clock stop status (287 as of November) had an overall increase in the last two months (255 at the end of September). Main changes refer to FEED (increase from 109 to 143, mainly in the area of re-evaluation of feed additives applications under 1831/2003).

Fig. 6. Monthly evolution of the stock of questions



Requests accepted by EFSA until November generated 668 new accepted questions in the Register of Question system (RAW). In the same period, over 836 questions have been closed with adopted outputs and internal reports.

In the same period the stock of on-going questions excluding those suspended (clock stop and request without a deadline) was consequently reduced of around 170 questions (14% of the final stock of questions) not considering the 92 questions that have been put in a suspended status. The main impact on the reduction of the stock of question is related to the adoption by the CEF Panel of opinions on flavouring substances and in the area of Pesticides (Art 31 – Scientific and technical assistance - Reg. 396/2005 - Art. 43).

COMMUNICATIONS

Fig. 7 Total Web Visits

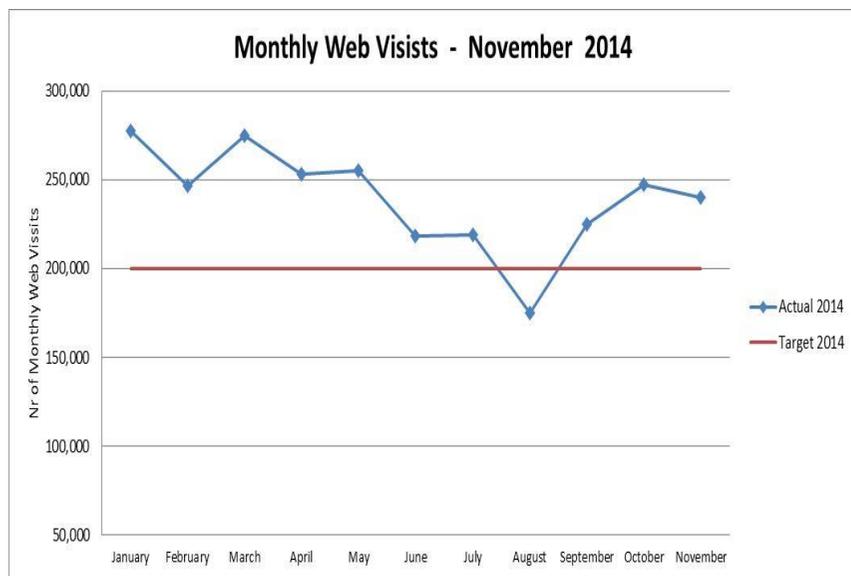
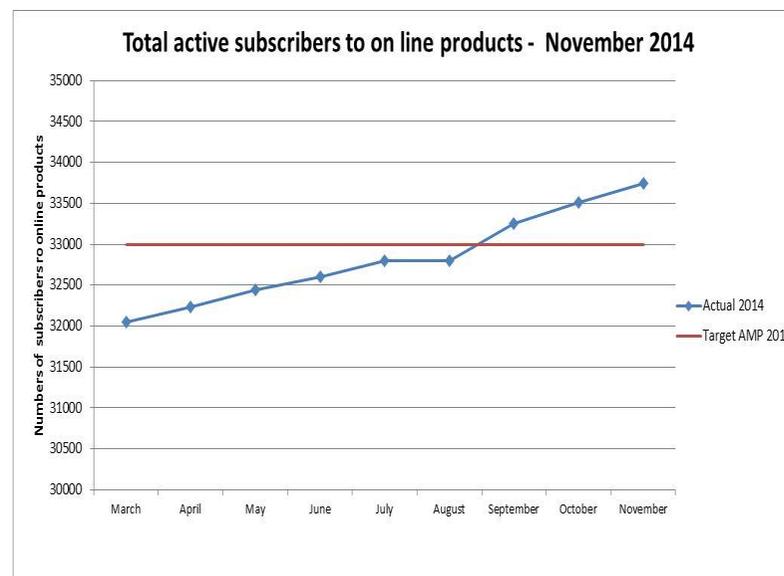


Fig. 8. Total newsletter subscribers



The number of visits to the EFSA Web Site has been above the monthly target for most of the year. The number of visits has start growing after the summer period.

For what refers to the active subscribers to on-line products, the number is above the target since September and a growing trend can be observed from March onwards.