

## EFSA PROGRESS REPORT

The present report refers to the period from the 1<sup>st</sup> of October to the 15<sup>th</sup> of November 2015.

### SCIENCE

#### Outputs produced in the reporting period

In the risk assessment area, EFSA adopted two guidance documents ('Assessment of products notified as foods for special medical purposes' and 'Reporting data on pesticide residues in food and feed according to Reg. (EC) 396/2005) and a total of 28 scientific opinions, 23 of which in the area of regulated products. Among them, to mention some, the opinion on insects as food and feed, isoflavones for peri- and post-menopausal women, and *Xylella fastidiosa*. The panels issued 3 statements (health claims related to meal replacements for weight control, maize MIR604 and maize GA21) and EFSA a statement (co-formulant POE-tallowamine). Four public consultations were launched, including that on the draft EFSA Strategy 2020. EFSA issued 3 scientific reports, 11 technical reports, 10 reasoned opinions, 7 peer review conclusions (including that on glyphosate), 5 external reports and 6 event reports.

#### Glyphosate: EFSA updates toxicological profile

EFSA and the EU Member States have finalised the re-assessment of glyphosate, a chemical that is used widely in pesticides. The report concludes that glyphosate is unlikely to pose a carcinogenic hazard to humans and proposes a new safety measure that will tighten the control of glyphosate residues in food.

EFSA also considered, at the request of the European Commission, the report published by the International Agency for Research on Cancer (IARC), which classified glyphosate as probably carcinogenic to humans. The evaluation considered a large body of evidence, including a number of studies not assessed by the IARC which is one of the reasons for reaching different conclusions.

As well as introducing the ARfD, the review proposed other toxicological safety thresholds to guide risk assessors: the acceptable operator exposure level (AOEL) was set at 0.1 mg/kg body weight per day and an acceptable daily intake (ADI) for consumers was set in line with the ARfD at 0.5 mg/kg body weight per day. EFSA will use the new toxicological values during its review of the maximum residue levels for glyphosate in food, which will be carried out in cooperation with Member States in 2016. EFSA's conclusion will be used by the European Commission in deciding whether or not to keep glyphosate on the EU list of approved active substances, and by EU Member States to re-assess the safety of pesticide products containing glyphosate that are used in their territories.

#### Insects as food and feed

EFSA has performed a risk profile that identifies the potential biological and chemical hazards as well as allergenicity and environmental hazards associated with the use of farmed insects as food and feed. The opinion also compares these potential hazards with those associated with mainstream sources of animal protein. The possible presence of biological and chemical hazards in food and feed products derived from insects would depend on the production methods, what the insects are fed on (substrate), the lifecycle stage at which the insects are harvested, the insect species, as well as the methods used for further processing. EFSA concluded that when non-processed insects are fed with currently permitted feed materials, the potential occurrence of microbiological hazards is expected to be similar to that associated with other non-processed sources of protein.

There are limited data available on the transfer of chemical contaminants from different types of substrate to the insects themselves.

### **Isoflavones**

A comprehensive review of the available scientific evidence has revealed no indication that isoflavones at levels typically found in food supplements cause harm to post-menopausal women. Isoflavones are naturally occurring substances which are found, among other sources, in soy, red clover and kudzu root. Their extracts are often used as ingredients in nutritional supplements. EFSA's experts also attempted to assess the possible risks for women during the transition period to menopause and for menopausal women with a history or family history of cancer. They found, however, that there is no data to assess the safety of these substances for these groups of women.

In line with EFSA's new "Promoting Methods for Evidence Use" approach, the ANS Panel captured the strategy for performing this risk assessment in a protocol that documents all the steps taken in reaching its final conclusions. This was the first EFSA opinion to pilot this new way of working, which enhances the robustness and transparency of the scientific process.

### **Xylella fastidiosa**

Following the opinion published in September, which concluded that hot water treatment is an effective safeguard against all strains of *X. fastidiosa* in grapevine planting material, EFSA has assessed the results of experiments carried out in Apulia on the susceptibility of grapevine (*Vitis*) to *X. fastidiosa* CoDiRO, the strain that has been spreading in southern Italy since 2013. EFSA concluded that grapevine cannot be ruled out as a potential host plant for the strain of *X. fastidiosa* that is attacking olive trees in southern Italy. *X. fastidiosa* is one of the most dangerous plant pathogens worldwide, damaging important crops including fruit trees, grapevine and ornamentals. Emergency measures have been in place in the EU since the first outbreak in the territory in 2013.

On 12-13 November, scientists and other experts from around the world met to propose and discuss research initiatives that can further scientific understanding of the *Xylella fastidiosa* bacterium and help find solutions for its control.

As well as the two plenary meetings, four breakout sessions looked at:

- Surveillance and detection.
- The vectors: identity, biology, epidemiology and control.
- The plants: host range, breeding, resistance and certification.
- The pathogen: biology, genetics, control.

The workshop was held in collaboration with the European Commission's Directorates-General for Research and Innovation, Agriculture and Rural Development, and Health and Food Safety.

### **EFSA second scientific conference "Shaping the future of food safety together"**

EFSA's scientific conference has yielded a rich reservoir of ideas and inspiration that will help the Authority and the wider risk assessment community to meet the challenges of the coming years. That was the message with which Tony Hardy, Chair of EFSA's Scientific Committee, kicked off the final session of the conference in Milan.

Transparency, cooperation and the need to strengthen public engagement in risk assessment were the recurring themes of the conference, "Shaping the future of food safety, together", which was attended by 1100 people from 70 countries over three days. Hundreds more around the globe followed proceedings via live web streaming, which was available from every plenary session and breakout meeting.

Delegates examined pressing topics such as e.g. open data, weighing uncertainty in risk assessments, emerging issues in animal and plant health, nutrition, chemical and microbiological hazards, environmental risks, and developing expertise for the future. Video recordings of the conference are available on the EFSA website. The main discussions and conclusions will be published in a special edition of the EFSA Journal.

### **Antimicrobial resistance**

Antimicrobial resistance (AMR) is a major EU and global societal problem involving many different disciplines and sectors, which has been recognized by the Council, the European Parliament, as well as by the European Commission President Juncker and the EU Commissioner for Health and Food Safety Andriukaitis. AMR is a complex multi-factorial issue, which involves control of all the routes by which AMR bacteria can arise in the human patient and requires a response from all stakeholders. Given the importance for EFSA to ensure a high level of coordination within the numerous activities in the area of antimicrobial resistance, EFSA decided to establish an overarching project for the coordination of AMR activities that will require significant effort to support the EU risk managers in the fight against this major public health concern.

## **COMMUNICATIONS**

In the reporting period, media coverage counted approx. 4800 articles, representing a 20% increase compared to last quarter. This increase is related to the publication of the peer review of the active substance glyphosate. EFSA received 116 queries, representing a 10% increase on last quarter. A major part of these queries were on glyphosate. The latter was clearly the main focus of media activities regarding EFSA: in the first two days after publication (12-13 Nov.), EFSA counted 1,200 articles worldwide, 22 media requests, and 638 mentions on twitter.

A new Twitter account @EFSA\_Live was launched to cover events such as conferences, seminars, workshops and Twitter chats. EFSA increased its social media presence by covering the EXPO Scientific conference (Oct.) and the Xylella workshop (Nov.). Overall, EFSA published 7 news stories, 2 feature and event stories, 21 news-in-briefs and one plain-language summary. In addition to glyphosate, xylella and the EXPO Scientific conference, highlights included: isoflavones, insects and the public consultation on EFSA Strategy 2020. Videos on 'Open EFSA – engaging society in food safety' and on the EXPO Scientific conference were published.

The Agora project completed the implementation of new information architecture, rationalisation of content and visual design of EFSA's website. Management Board audio-on demand webcast will now be offered through SoundCloud service. Using this global online audio distribution platform will improve quality and usability of the webcast whilst reducing license and hosting costs.

EFSA received the visit of Marion Healy, deputy CEO and chief Scientist of Food Standards Australia and New Zealand (FSANZ), and Junshi Chen, senior research professor at the China National Center for Food Safety Risk Assessment. As well, EFSA met Stephen Ostroff, M.D., acting commissioner of Food and Drugs of the United States Food and Drug Administration (US FDA).

## **SCIENTIFIC COOPERATION**

The Advisory Forum and Focal Points joint meeting in October mainly focussed on EFSA's draft strategy and vision on the way forward, along with a case-study session on practical examples aiming to facilitate the interaction between AF and FP members. Among others, at the subsequent meeting held in November, the Focal Points discussed around their role in supporting EFSA to manage the scientific networks, new procedures for designating Article 36 organisations, and devoted half-day to a training on grants & procurement.

Scientific cooperation activities with and between Member States include: the further development of SGL's IMPRORISK model, which could be an add-on for the food

consumption data collection to perform exposure assessment, in particular for the small Member States with low capacity on this area; the organisation, with the Cypriot National Food Safety Council, of a workshop on 'Food risk analysis framework'; cooperation with Croatia in the framework of EFSA's new pre-accession programme, notably in the area of food consumption and data collection; exchange of views with the Food Safety Authority of Ireland on future projects of scientific cooperation; and the participation of Portuguese organisations in the project led by Spain on Ciguatoxin.

EFSA hosted the Global Summit on Regulatory Science 2015 (GSRS15) 'Workshop on the physico-chemical characterisation of nanomaterials' and on 'Regulatory Bioinformatics'.

EFSA and the Food Safety Commission of Japan signed a memorandum of cooperation.

## **EXTERNAL RELATIONS**

EFSA met with the Director-General of SANTE, Xavier Prats-Monné and exchanged views on EC-EFSA future work planning, antimicrobial resistance, plant health, glyphosate, and long-term scientific sustainability of EFSA. The meeting with the JRC Director-General, Vladimír Šucha, focussed on EFSA-JRC scientific cooperation, planning of priorities and communities of knowledge.

EFSA received the visit of a delegation from the Greens/EFA European Parliament group, who received information on EFSA's activities in the fields of GMOs and pesticides. EFSA met with MEPs Derek Vaughan, Tomas Deutsch and Jasenko Selimovic, who are the rapporteurs for the 2014 discharge for the European Parliament, the CONT Committee and the ENVI Committee respectively. EFSA exchanged views with the ENVI Committee on glyphosate.

EFSA participated at the conference "Science vs. Lobbying. A conference on the uses and misuses of scientific evidence" organised by Corporate Europe Observatory (CEO) and the European Parliament's intergroup on integrity, transparency, anti-corruption and organised crime.

EFSA's Executive Director paid courtesy visits to various stakeholder organisations in Brussels (i.e. European Crop Protection Association, European Environmental Bureau, and Friends of the Earth) to hear from them how to best build basis for constructive stakeholder engagement.

EFSA has added webinars to its list of communication tools with applicants. The webinars will enable direct interaction between EFSA and interested parties through presentations and live question-and-answer sessions. Webinars can host up to 500 participants, and are therefore an effective way to reach large audiences, eliminating the usual logistical barriers. The first webinar took place on 19 November and presented practical scenarios using the calculation tool annexed to the pesticides guidance document on non-dietary exposure of workers and bystanders to pesticides.

## SCIENCE

<p><b>Scientific Committee and Emerging Risks</b></p>	<p><u>Scientific Committee</u></p> <ul style="list-style-type: none"> <li>Scientific opinions on: 'Risk profile related to production and consumption of insects as food and feed', 'Endangered species as non-target organisms in single-stressor environmental risk assessments', and 'Temporal and spatial recovery of non-target organisms for environmental risk assessments'.</li> </ul> <p><u>SCER Unit</u></p> <ul style="list-style-type: none"> <li>Scientific reports on 'Review of results published by Mesnage et al. (2015) in PLoS ONE and the laboratory findings communicated by Dr Samsel to Farm Wars' and 'Shaping the future of food safety, together'.</li> <li>External Report on 'Statistical analysis on the EPILOBEE dataset: explanatory variables related to honeybee colony mortality in EU during a 2-year survey'.</li> <li>EFSA crisis simulation training: it was the culmination of a 4 year training programme which covered areas such as principles of risk assessment, data collection and crisis communications. The training focused on the interaction between scientists and communicators, as well as national, regional and international cooperation during crisis periods with the objective to improve preparedness for potential crises.</li> </ul>
<p><b>Animal health and plant health</b></p>	<p><u>Panel on Plant health (PLH)</u></p> <ul style="list-style-type: none"> <li>Procurements on: 'Development of parameters for a database containing data and information on the diseases of apple fruit' and 'Collection of data and information with ELS approach for the EU-28 regarding EU pests and diseases of apple fruit'.</li> </ul> <p><u>ALPHA Unit</u></p> <ul style="list-style-type: none"> <li>Workshop to identify knowledge gaps and research priorities on Xylella Fastidiosa.</li> </ul>
<p><b>Biological hazards and contaminants</b></p>	<p><u>Panel on Biological hazards</u></p> <ul style="list-style-type: none"> <li>Opinions on: 'Risk to public and/or animal health of the treatment of dead-in-shell chicks to be used as raw material for the production of biogas or compost' and 'Continuous multiple-step catalytic hydro-treatment for the processing of rendered animal fat'.</li> </ul> <p><u>BIOCONTAM Unit</u></p> <ul style="list-style-type: none"> <li>Scientific reports on: 'Evaluation of the application of Denmark, Finland and Sweden to be recognised as having a negligible risk of classical scrapie' and 'Request for clarification on the maintenance of the cold chain during storage and transport of meat'.</li> </ul>

<b>Additives and products or substances used in animal feed</b>	<p><u>Panel on Additives and products or substances used in animal feed (FEEDAP)</u></p> <ul style="list-style-type: none"> <li>Opinions on feed additives: sensory (2), technological (1), nutritional (2) and zootechnical (5). In the context of re-evaluation, following the assessment of the data submitted by the applicant and other available relevant data, the Panel identified in a technological additive (Ethoxyquin) potential safety concerns related to the safety for the consumer, the target animals and the environment.</li> </ul>
<b>Food ingredients and packaging</b>	<p><u>Panel on Food Additives and Nutrient Sources added to Food (ANS)</u></p> <ul style="list-style-type: none"> <li>Opinions on: re-evaluation of food additives (3).</li> </ul> <p><u>Panel on Food contact materials, enzymes, flavourings and processing aids (CEF)</u></p> <ul style="list-style-type: none"> <li>Opinions on: flavourings (1); food contact materials (4).</li> </ul> <p><u>FIP Unit</u></p> <ul style="list-style-type: none"> <li>Organisation, in collaboration with APDESK, of a stakeholder info session on the principles of the tiered approach for refinement of exposure estimates for food enzymes.</li> </ul>
<b>Genetically modified organisms</b>	<p><u>Panel on Genetically modified organisms</u></p> <ul style="list-style-type: none"> <li>Opinions on: soybean MON 87769 × MON 89788; maize Bt11 × 59122 × MIR604 × 1507 × GA21; and revised PMEM report on GM maize MON 810.</li> <li>Statements on maize MIR604 and maize GA21.</li> </ul> <p><u>GMO Unit</u></p> <ul style="list-style-type: none"> <li>Scientific advice to EC on accumulating formaldehyde in GM soybeans.</li> <li>Technical reports on: Application of soybean MON 87769 × MON 89788 genetically modified to contain stearidonic acid and be tolerant to glyphosate; and Relevance of a new scientific publication on previous conclusions on Cry1Ab-expressing maize.</li> <li>Event report on the workshop with stakeholders for the collection of initial feedback on the development of supplementary GD on allergenicity assessment.</li> </ul>
<b>Dietetic products, nutrition and allergies</b>	<p><u>Panel on Dietetic products, nutrition and allergies (NDA)</u></p> <ul style="list-style-type: none"> <li>Opinions on: DRV (iron and copper); Health Claims Art. 14 (2); Art. 13.5 (1) and novel food (2).</li> <li>Guidance for the assessment of products notified as foods for special medical purposes.</li> <li>Statement providing scientific advice in relation to the opinion on the substantiation of health claims related to meal replacements for weight control.</li> </ul> <p><u>NUTRI Unit</u></p> <ul style="list-style-type: none"> <li>Technical reports on: Outcomes of the public consultations on DRV for iron and copper; and Food intended for sportspeople.</li> </ul>

<b>Pesticides and plant protection products and their residues</b>	<p><u>PRAS Unit</u></p> <ul style="list-style-type: none"> <li>○ 7 Peer-review conclusions.</li> <li>○ Guidance of EFSA on 'Reporting data on pesticide residues in food and feed according to Regulation (EC) No 396/2005' (2014 data collection).</li> <li>○ 10 Reasoned opinions.</li> <li>○ Scientific report on the assessment of the quality and scientific relevance of dermal absorption studies submitted to EFSA.</li> <li>○ Statement of EFSA on co-formulant POE-tallowamine.</li> <li>○ Technical reports on: assessment of endocrine disrupting properties (1); confirmatory data (2); basic substance applications (2).</li> <li>○ Technical briefing on Glyphosate including a summary explaining the EFSA assessment for carcinogenicity and the differences with the IARC assessment.</li> </ul>
<b>Assessment and methodological support</b>	<p><u>AMU Unit</u></p> <ul style="list-style-type: none"> <li>○ External report on "Logistic Models: Separation Issues and Possible Solutions"</li> <li>○ Methodological support to GMO (evaluation of farmer questionnaires), NUTRI (statistical analysis of data on iron excretion), ALPHA (<i>Xylella fastidiosa</i>), FIP (peri- and post-menopausal women taking food supplements containing isolated isoflavones), BIOCONTAM (analysis of the Listeria baseline survey) and SCER (2015 crisis exercise).</li> </ul>
<b>Evidence management</b>	<p><u>DATA Unit</u></p> <ul style="list-style-type: none"> <li>○ Support to: FIP (peri- and post-menopausal women taking food supplements containing isolated isoflavones, re-evaluation of food colours - E120 Cochineal, Carminic acid, Carmines and E311 Octyl Gallate) and NUTRI (DRV for iron and copper).</li> <li>○ External reports on: 'Electronic transmission of chemical occurrence data in SSD format' from UK, Norway and Lithuania and 'Support for the collection of national food consumption data in the view of a pan-European dietary survey' from Spain.</li> </ul>
<b>Application Desk</b>	<p><u>APDESK Unit</u></p> <ul style="list-style-type: none"> <li>○ Receipt of 99 applications and 50 requests via web form.</li> <li>○ Organisation of webinar (online information session) on the calculation tool annexed to the pesticides guidance on the assessment of exposure of operators, workers, residents and bystanders in risk assessment for plant protection products.</li> </ul>
<b>Quality Management</b>	<ul style="list-style-type: none"> <li>○ Customer feedback exercise with DG SANTE: Improvement as follow up from the 2014 exercise is noticeable in recent outputs and EFSA scientific outputs are recognised for their excellent science at an international level. Areas for improvement have been also identified and are being followed.</li> </ul>

<b>Quality Management</b>	<ul style="list-style-type: none"> <li>Outcomes of the independent assessment of EFSA’s quality management system (QMS): EFSA’s QMS is firmly established in the units, there is adequate awareness of QMS principles and commitment clearly to be seen. Remaining gaps can be addressed by the first half of 2016.</li> </ul>
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## COMMUNICATION

<b>Media and social media</b>	<ul style="list-style-type: none"> <li>Media coverage counted approx. 4800 articles, representing a +20% increase compared to last quarter. This increase is likely to be explained by the publication of the peer review of the active substance glyphosate.</li> <li>EFSA received 116 queries, representing a 10% increase on last quarter. A major part of these queries were on glyphosate.</li> <li>Media focused especially on the peer review of glyphosate. In the first two days after publication, EFSA counted 1,200 articles worldwide, 22 media requests, and 638 mentions on twitter. Another issues discussed in media: risk profile on edible insects as food, feed and EFSA’s 2<sup>nd</sup> scientific conference and Xylella fastidiosa.</li> <li>EFSA organised a media visit to the conference in Milan, which resulted in 10 interviews. The ED gave three interviews (Nutraingredients, EU Food Law and Science) mainly focused on EFSA’s Strategy 2020.</li> <li>A new Twitter account @EFSA_Live was launched to cover events such as conferences, seminars, workshops, Twitter chats, etc.</li> <li>EFSA increased its Social Media presence by covering the EXPO Scientific Conference (Oct 2015) and the Xylella workshop (Nov 2015). During the EXPO Conference: Tweets posted by EFSA: 200, Tweet impressions: more than 80K over the 3 days, #EFSAExpo2015 hashtag mentions: almost 1,500.</li> </ul>
<b>Publications</b>	<p><u>Content overview</u></p> <ul style="list-style-type: none"> <li>7 news stories, 2 feature and event stories, 21 news in brief, 1 plain-language summary were published; 10 of which were science related and 21 were on corporate issues. Highlights included: glyphosate, Xylella, isoflavones, insects, EFSA Strategy 2020 public consultation and EFSA’s 2<sup>nd</sup> Scientific conference at EXPO.</li> <li>EFSA’s 2<sup>nd</sup> Scientific Conference took place in Milan on 14-16 October. More than 10 teaser stories were published in the weeks preceding the event. During the conference, 2 press releases and 3 news stories were published.</li> </ul> <p><u>Website</u></p> <ul style="list-style-type: none"> <li>Completion of all post-migration stabilization activities (including broken links fixing, now back to standard level).</li> <li>Implementation of Cookie notification, in compliance with EU cookie law.</li> <li>New website (Project Agora):             <ul style="list-style-type: none"> <li>Completed implementation of new information architecture and visual design.</li> <li>Completed major rationalisation of content in preparation for the launch of the new EFSA website.</li> </ul> </li> </ul>



## Publications

- Started final phase of fine-tuning and troubleshooting.
- Management Board audio-on demand webcast will now be offered through SoundCloud service. Using this global online audio distribution platform will improve quality and usability of the webcast whilst reducing license and hosting costs.

### EFSA Journal

- Procurement with publisher completed (John Wiley & Sons).
- Publication of supplement for Second EFSA Scientific Conference at EXPO 2015.
- Revised editorial guidance for EFSA scientific documents issued.

### Publications & Multimedia

- Video on 'Open EFSA – engaging society in food safety'.
- Videos on EFSA's scientific conference daily highlights.
- Programme leaflet, branding material, roll-up banner and several gadgets were produced for the EFSA stand at the scientific conference.

## Advisory Forum and scientific cooperation

### Advisory Forum

- Joint AF and FP meeting. Focus was mainly on EFSA's draft strategy and vision on the way forward, along with a case-study session on practical examples aiming to facilitate the interaction between AF and FP members.
- The 48<sup>th</sup> AFCWG meeting took place in Parma with a focus on exploring closer alignment of the group with the AF, defining topics for the EU Insights Project for 2016, reviewing achievements in 2015, and planning projects for 2016.

### Focal Point Network

- FPs submitted their technical reports describing the activities carried out and to be carried by year end.
- November meeting: Issues for discussion include the operational role of FPs on the management of EFSA's scientific networks, new procedures for designating Article 36 organisations, and half-day training on grants & procurement.

### Scientific cooperation with the Member States

- EFSA met with the National Food Safety Council (NFSC) at the Ministry of Health of Cyprus. EFSA agreed to support the further development of SGL's IMPRORISK model, which could be an interesting add-on for the food consumption data collection to be able to perform exposure assessment, in particular for the small MS, with low capacity on exposure assessment, and also to ENP countries.
- Workshop on "Food Risk Analysis Framework", co-organised by the NFSC and EFSA, took place in Larnaca, Cyprus. The aim of the workshop was to exchange knowledge and best practices in risk assessment and risk analysis work between the experts from National Food Authorities in Cyprus, EU Neighbourhood countries (ENP) and EFSA.
- EFSA met with the Croatian Food Agency (HAH) and the Minister of Health at the Ministry of Agriculture in Zagreb. Croatia's experience in food consumption data collection was highlighted and identified as an area for joint work through EFSA's new pre-accession programme.

**Advisory Forum and scientific cooperation**

- EFSA met with the Food Safety Authority of Ireland (FSAI). EFSA and Ireland reiterated their commitment to continue working in partnership building on the good relationship already established, with some ideas for scientific cooperation and joint projects to be explored further.
- EFSA participated at the 7<sup>th</sup> meeting of the German EFSA Focal Point in Berlin, aimed at strengthening national and international networking. Main focus was on EFSA's data management, EFSA's outsourcing mechanisms, EFSA's risk communication strategy, EREN Network, and national and international cooperation in crisis situations.
- EFSA met the Portuguese Food and Economic Safety Authority (ASAE). Portugal is a key partner in joint projects like the Ciguatera project led by Spain. EFSA promoted the use of the guest scientist scheme and PhD exchange programme and agreed that Portugal could play an active role in the new EFSA's ENP programme with Morocco and the other Mediterranean countries.

Pre-accession Programme and European Neighbourhood Policy Programme

- EFSA signed the contract with DG NEAR (IPA) to implement the Action "Preparatory measures for the participation of the Candidate Countries and the Potential Candidate Countries in EFSA". Beneficiaries are national food authorities in seven Pre-Accession countries, including five Candidate Countries: Albania, the Former Yugoslav Republic of Macedonia, Montenegro, Serbia and Turkey, and two Potential Candidate Countries: Bosnia and Herzegovina and Kosovo.
- EFSA signed the agreements for the assistant coordinators in FYR of Macedonia, Serbia and Turkey.

**Stakeholders**

- EFSA progressed in its efforts to share best practices and experience in the area of stakeholder relations with other EU or national agencies by hosting a workshop with colleagues from the communication department of the French Agency ANSES.
- EFSA participated at the conference "Science vs. Lobbying. A conference on the uses and misuses of scientific evidence" organised by Corporate Europe Observatory (CEO) and the European Parliament's intergroup on integrity, transparency, anti-corruption and organised crime.
- Ms Astrid Bjerås, Communications Director at the Norwegian Vitenskapskomiteen for mattrygghet (VKM) significantly contributed to the External Relations' work on the stakeholder engagement approach during her two-week stay in the framework of the guest scientist scheme initiative.

**Institutional and international relations**

European Commission

- Meeting with SANTE Director-General, Xavier Prats-Monné: EC-EFSA future work planning, antimicrobial resistance, plant health, glyphosate, long-term scientific sustainability of EFSA.
- Meeting with the JRC Director-General, Vladimír Šucha: EFSA-JRC scientific cooperation, planning of priorities, communities of knowledge.
- Meeting with DG Research Director for Bioeconomy, John Bell: agenda Horizon 2020 and food/feed risk assessment needs, Horizon 2020 investments on science and capacity building in Europe.

- Meeting EFSA-DG SANTE-EuropaBio: tripartite meetings at request of EuropaBio to discuss risk assessment of GMOs, dialogue with applicants, development of guidance documents, data requirements, risk management meetings with Member States and EC authorisation process.

#### European Parliament

- Meeting with MEP Derek Vaughan (EP rapporteur discharge 2014), MEP Tomas Deutsch (CONT rapporteur discharge 2014) and MEP Jasenko Selimovic (ENVI rapporteur discharge 2014).
- Visit of delegation from the Greens/EFA European Parliament group: exchange of information in the areas of GMOs and pesticides.
- Intervention of EFSA at European Parliament EPP workshop on GMOs.
- Exchange of views with the ENVI Committee on glyphosate.

#### EU Agencies

- A videoconference EFSA-EEA took place to discuss EEA involvement on EFSA proposal for a long-term project aiming to develop methodologies for landscape risk assessment applicable in the regulatory context.
- EFSA visited JRC and identified several point of common interests regarding JRC-EFSA long term project on developing methodologies for landscape risk assessment.
- EFSA participated in the ECHA/EFSA topical scientific workshop on soil risk assessment in Helsinki, to develop new or improved scientific approaches in support of risk assessment within the European regulations.
- EU ANSA meeting took place in Dublin, at EUROFOUND. Update from the EC on the activities carried out by the non-food scientific committees (DG SANTE), the scientific advice mechanism for policy-making (DG R&I) and the communities of knowledge (JRC). EU ANSA working groups updated on the progress on peer review, open data, research needs, uncertainty and access to EUROSTAT data.

#### International relations

- EFSA participated in the workshop of the Asian Pacific Economic Cooperation in Chile, to strengthen EFSA's contacts with South America and the APEC countries.
- Marion Healy, deputy CEO and chief Scientist of Food Standards Australia and New Zealand (FSANZ) visited EFSA.
- EFSA hosted the Global Summit on Regulatory Science 2015 (GSRs15), Workshop on the physico-chemical characterisation of nanomaterials and on Regulatory Bioinformatics.
- Bernhard Url met Stephen Ostroff, M.D., acting commissioner of Food and Drugs of the United States Food and Drug Administration (US FDA). The aim of the meeting was to prepare a high-level meeting scheduled for the middle of 2016 where US FDA and EFSA will discuss issues on research needs, prioritisation, work-sharing and international scientific cooperation.
- Visit of Junshi Chen, senior research professor at the China National Center for Food Safety Risk Assessment.
- EFSA signed a memorandum of cooperation with the Food Safety Commission of Japan.

## CORPORATE – RESOURCES AND SUPPORT

### Strategy based services

#### Corporate business control (PTT)

- Preparation of Single Programming Document 2016-2018 based on ceiling driven project and process activity planning of EFSA's Project and Resource Management (PaRMA) methodology.

#### Independence

- Conclusion of the pilot phase of the project aimed at centralising the screening of Annual Declarations of Interest.

### Expertise based services

#### Court cases

- On 16 September 2015, the General Court of the European Union ruled on Case T-231/14P, European Medicines Agency v. Mr D Drakeford, concerning the non-renewal of Mr Drakeford's employment contract. EFSA had intervened with ECDC and ECHA supporting EMA. The findings in this ruling have an impact on contract management in agencies.
- The Court judgment in Case C-615/13P, *ClientEarth & PAN Europe v EFSA*, was discussed at the meeting of the Heads of Agencies on 22-23 October 2015. The Inter-agency legal network (IALN) has been tasked to further analyze the ruling issued by the European Court of Justice and provide guidelines to the Heads of Agencies.
- On 24 September 2015, the General Court of the European Union ruled on cases T-124/13 and T-191/13, Italy and Spain v Commission, concerning the obligation for candidates participating to EPSO open competitions to choose between English, French, or German as second language. Following this judgment, EPSO has suspended publication of competitions, as well as publication of vacancies notices by agencies, until further notice.

#### European Ombudsman (EO)

- On 23 September, EFSA was notified the Decision of the European Ombudsman to close complaint 0048/2015/ANA filed by company Rubinum against EFSA. In its Decision, the Ombudsman confirms the legality and compliance with good administrative principles of EFSA's behavior vis-à-vis the complainant, thereby dismissing the claims that they had suffered inter alia discrimination and breach of the right to be heard.
- EO participated in the Inter-Agency Legal Network (IALN) meeting chaired by EFSA, to contribute in particular to the discussion on court case C-615/13P (see above).

#### Data protection

- Follow-up on the impact of the EU Court of Justice judgment C-362/15 of 06/10/2015, declaring the EC Decision 2000/520 (so-called 'Safe Harbor Decision') invalid with regard to IT systems for personal data processing. This includes cloud solutions, deployed or procured at EFSA, as well as answering specific a request of the EDPS in this

<p><b>Expertise based services</b></p>	<p>regard.</p> <ul style="list-style-type: none"> <li>○ Participation of the DPO in the DPO/EDPS Network meeting.</li> </ul> <p><u>Event and campaign services</u></p> <ul style="list-style-type: none"> <li>○ Scientific Conference “Shaping the future of food safety, together”. The conference attracted 1100 delegates from 70 countries, plus 900 connections to the live streaming over the three days of the event.</li> <li>○ Global Summit on Regulatory Science Research (GSRSR15). The event, preceded by a meeting of the Global Coalition of Regulatory Science Research, was attended by 80 experts from 26 countries.</li> <li>○ Scientific session “Setting Dietary Reference Values for the European Union” in the framework of FENS 2015 (Berlin). The session was attended by nearly 150 nutritionists.</li> <li>○ Workshop on Xylella Fastidiosa. The event, jointly organized with the European Commission, attracted more than 120 scientists, experts and stakeholders.</li> </ul> <p><u>Talent Selection</u></p> <ul style="list-style-type: none"> <li>○ On 15<sup>th</sup> November, 432 posts were occupied and 8 job offers sent to the selected candidates bringing the total to 440 posts filled-in out of the planned 477 posts (including Seconded National Experts).</li> <li>○ EFSA expects to increase its occupancy rate by end of the year: offers in the pipeline are expected to allow for an occupancy rate of 94.9% as of 31.12.2015 and of 94.8% as 2015 yearly average (vs. target of 95% not including short term contract agents).</li> <li>○ Calls have been launched in the last quarter for wide scientific profiles to allow recruitment of contract agents at the beginning of next year.</li> <li>○ In preparing the 2016 recruitment plan, EFSA is planning to build reserve lists for most required positions as well as publishing open call for interest for junior positions.</li> <li>○ An analysis is currently undertaken to identify the main constraints and bottlenecks in the recruitment process (including a review of the timelines, the availability of panel members and the improvement of EFSA’s attractiveness). Actions have been taken as for the leaning of the assessment process of the declarations of interests for the on-boarding new staff. EFSA is also investing on the enhancement of its recruitment process, including a new IT solution to be implemented in May 2016 that will significantly streamline recruitment and selection process.</li> <li>○ EFSA is preparing to comply the reduction requested by the EU budgetary authority for 2016: no recruitment actions are taken on some Temporary Agents empty posts that are currently kept “frozen” in view of the suppression of posts.</li> </ul>
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<b>Expertise based services</b>	<table border="1"> <thead> <tr> <th>Staff Categories</th> <th>Target 2015</th> <th>Total Contracted and Offered</th> </tr> </thead> <tbody> <tr> <td>Temporary Agents and Officials</td> <td></td> <td></td> </tr> <tr> <td>Executives, Managers &amp; Officers (AD)</td> <td>234</td> <td>214</td> </tr> <tr> <td>Assistants functions (AST)</td> <td>103</td> <td>110</td> </tr> <tr> <td><b>Total</b></td> <td><b>337</b></td> <td><b>324</b></td> </tr> <tr> <td>Contract Agents</td> <td></td> <td></td> </tr> <tr> <td>Officers functions (CA FG IV)</td> <td>70</td> <td>62</td> </tr> <tr> <td>Assistants functions (CA FG I, II, III)</td> <td>50</td> <td>39</td> </tr> <tr> <td><b>Total</b></td> <td><b>120</b></td> <td><b>101</b></td> </tr> <tr> <td>Seconded National Experts</td> <td>20</td> <td>15</td> </tr> <tr> <td><b>Total all staff categories</b></td> <td><b>477</b></td> <td><b>440</b></td> </tr> </tbody> </table>			Staff Categories	Target 2015	Total Contracted and Offered	Temporary Agents and Officials			Executives, Managers & Officers (AD)	234	214	Assistants functions (AST)	103	110	<b>Total</b>	<b>337</b>	<b>324</b>	Contract Agents			Officers functions (CA FG IV)	70	62	Assistants functions (CA FG I, II, III)	50	39	<b>Total</b>	<b>120</b>	<b>101</b>	Seconded National Experts	20	15	<b>Total all staff categories</b>	<b>477</b>	<b>440</b>
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	<b>Transaction based services</b>	<p><u>Financial management</u> On 31 October 2015, €67.53 million or 84.87% of the €79.58 million budget was committed, and €54 million or 69.21% of the € 78.03 million payment appropriations were paid. Detailed information is available in mb151203-i2.</p> <p><u>Assurance, Business Engineering and Customer empowerment (PTT)</u></p> <ul style="list-style-type: none"> <li>○ Technology roadmap updated and integrated with the draft EFSA 2016-2020 strategic planning.</li> <li>○ IT execution achieved in 2015 high level targets and helped to improve EFSA wide project management quality for EFSA's strategic prioritized projects.</li> </ul>																																		

## 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  
**AMR** – Antimicrobial resistance  
**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

## Annex to the Progress Report

### Progress Indicators as of 31 October 2015

#### Executive Summary

This document includes:

- An overview of EFSA's results in the first 10 months of 2015 on key performance indicators.
- Detailed tables with figures and data referring to the period 1/1/15 – 31/10/15 on: outputs adopted by unit (figures 1 to 3), analysis of on-going questions by status and their monthly evolution (figures 4 and 5) and evolution of key indicators on Communication activities (figure 6).

In the first ten months of the year, **304 scientific outputs and 156 Supporting publications** have been finalized/adopted, representing respectively 77% and 106% of the yearly target. The updated forecast for the end of the year is to reach at least 92% of the scientific output.

The forecast of 92% for scientific outputs is a conservative estimate, based on the individual forecast provided by the units for work in progress.

The main reasons for the deviation of 8% between forecast and target are: 1. complexity of the mandates higher than initially planned in the area of FEED, 2. public consultations not initially planned in the area of NUTRI and 3. late submission of mandates in the BIOCONTAM and PRAS areas.

By the end of October the supporting publications are already above the yearly targets.

Adoption timeliness for Activity 1 - provision of scientific opinions and advice & risk assessment approaches - is at 94% (target 100%).

Adoption timeliness for Activity 2 - evaluation of products, substances and claims subject to authorization - excluding questions already overdue at the beginning of the year, stands at 92% (target of 90%).

Communication activities are on track, with web visits and twitter followers constantly increasing. Also the number of subscribers is above the annual target and, thanks to the introduction of the new web platform, it will be possible to improve the subscribers monitoring system (e.g. analysis by segment of users).

Financial performance at global level as of 31 October is 1% above the monthly target for commitments and -7% below the monthly target for payments (global commitment is 85% of the total for the year). Commitments for Scientific Cooperation are below targets (-8%) and payments slightly above the target (+ 3%).

For further details on financial performance, please refer to document mb151203-i2 (Budget Execution & Transfers).



## Overview of Key performance indicators as of 31/10/2015

Description	Traffic light	Comment
1 Scientific Outputs Activity 1	☹️	51 outputs adopted/finalised, in line with monthly targets and representing 61% of the yearly target (see figure 1)
2 Scientific Outputs Activity 2	☹️	249 outputs adopted/finalised, in line with monthly targets and representing 82% of yearly target (see figure 2)
3 Scientific Outputs Activity 3 (including supporting publications)	😊	4 scientific outputs adopted/finalised, 33% above the yearly target, and 156 supporting publications, 6% above the yearly target (see figure 3)
4 Global Commitments & Payments rate	😊	Global commitments 1% above monthly target and global payments -7% below monthly target (for details, see document mb151203-i2-Budget Execution & Transfers) – Global commitment is 85% of the yearly target.
5 G & P Commitments & Payments rate	😊	Grants and procurements commitments slightly below monthly targets (-8%) and payments 3% above monthly targets (for details, see document mb151203-i2-Budget Execution & Transfers)
6 Adoption Timeliness Activity 1	☹️	Timeliness for scientific outputs under Activity 1 is 94%, below the SPD targets of 100%
7 Adoption Timeliness Activity 2 <sup>1</sup>	😊	Timeliness performance stands at 92% against the 90% of SPD targets
8 Scientific Outputs published within 15WD of adoption	☹️	The proportion of scientific outputs published within 15 Working days of adoption stands at 89% vs. a target of 100%.
9 % of press releases/web news items delivered within 20 WD of output adoption	☹️	The proportion of press releases/web news items accompanying scientific outputs is below the target (79% versus a target of 85%)
10 Traffic to EFSA WEB content	😊	Total nr. of visits to the EFSA web site is 2.5 million, above the monthly target 2 million (see figure 6)
11 Subscribers to online products	😊	Subscribers to online products at end October is 36.054 (29,036+7,018 alerts), above the annual target of 34.825 (see figure 6)
12 Impact score	-	First results are expected end of 2015
13 Twitter followers	😊	Number of twitter followers at end of October is 11.754, constantly increasing (see figure 6)
14 Number of SNEs	☹️	15 SNEs at end October, vs. a target of 20

<sup>1</sup> Excluding questions already overdue at beginning of 2015

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15 Occupancy Rate



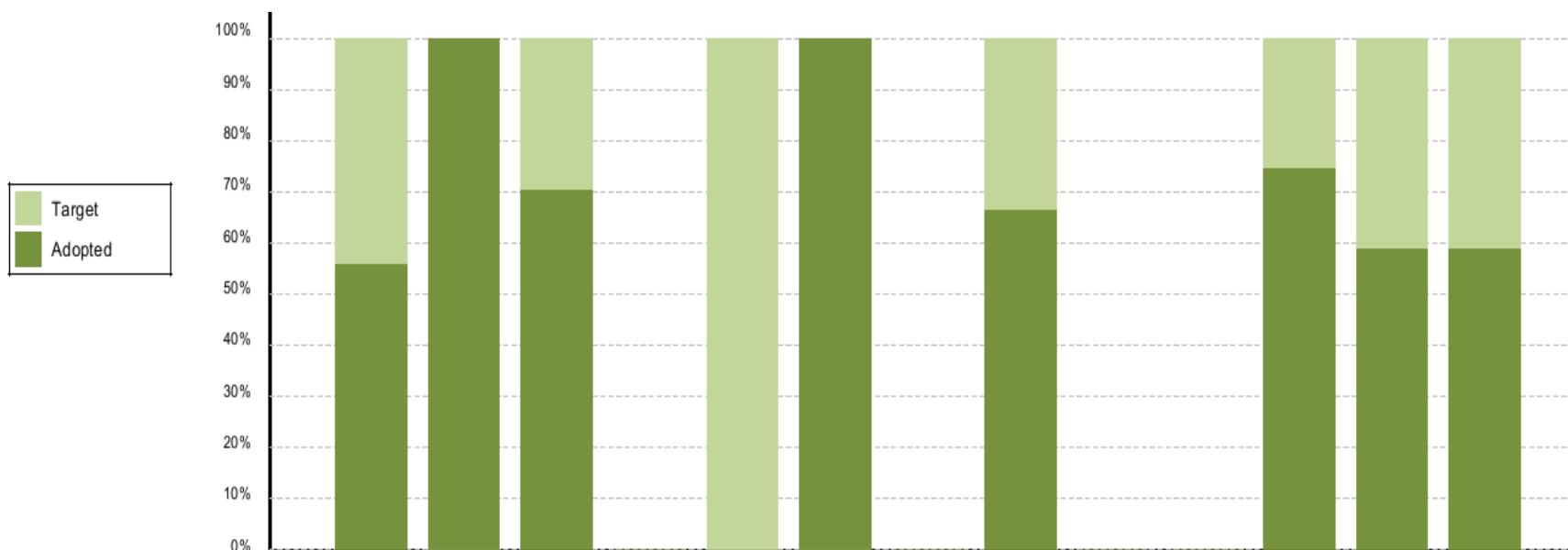
Staff occupancy rate - excluding short term contract agents - is 94%, below the 95% yearly target.

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## Progress indicators: detailed tables

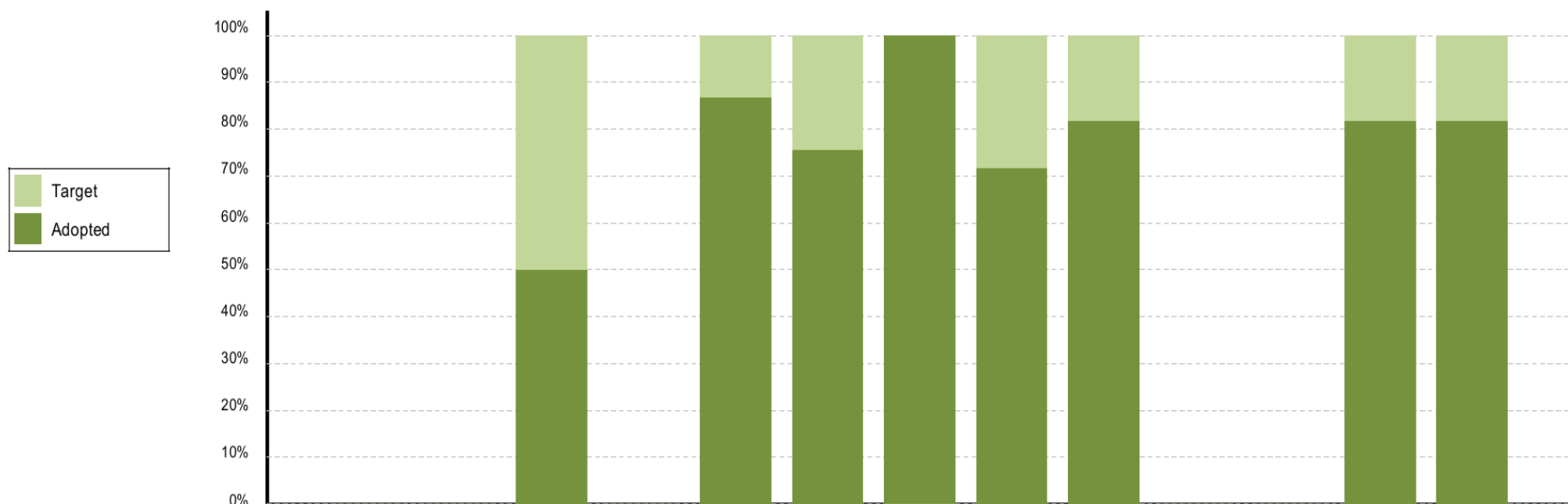
### SCIENTIFIC ACTIVITIES

**Fig.1. Provision of scientific opinions and advice & risk assessment approaches (Activity 1)  
01.01.2015 –31.10.2015 vs. Annual Target**



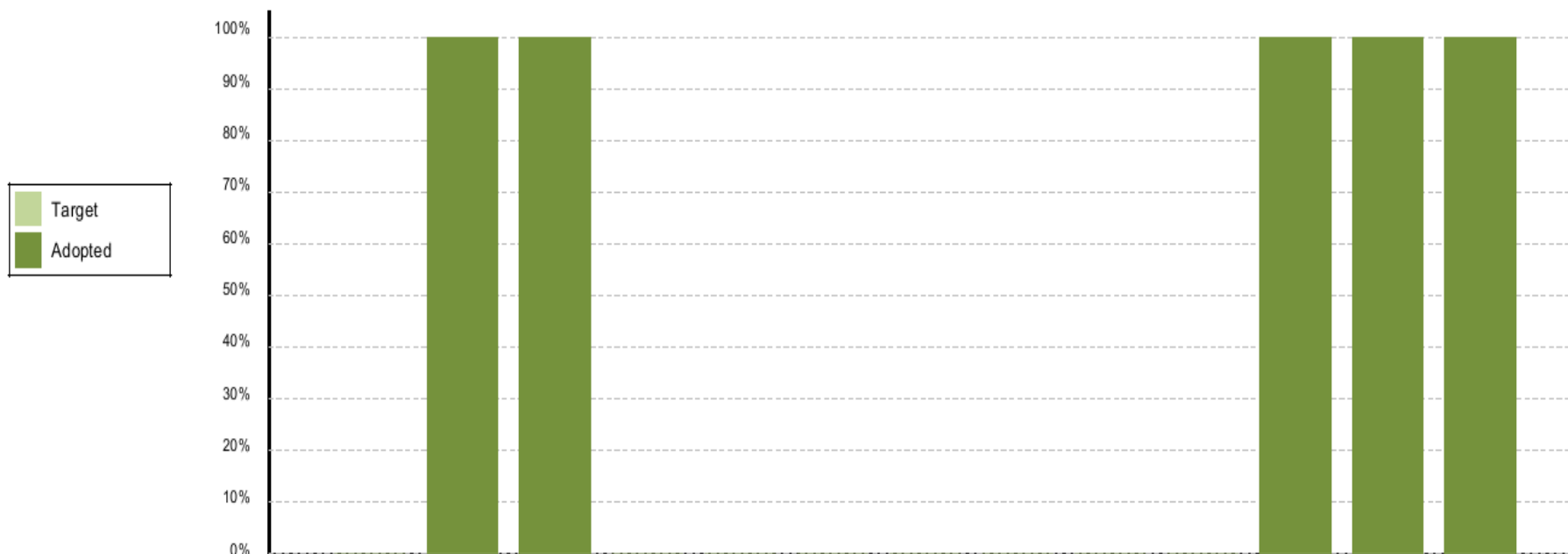
	RASA				REPRO					SCISTRAT		Total INCLUDING Join	Total EXCLUDING Join
	ALPHA	AMU	BIOCONTAM	DATA	FEED	FIP	GMO	NUTRI	PRAS	AFSCO	SCER		
<b>TARGET</b>	32	1	24	0	8	2	0	15	0	0	4	86	86
<b>ADOPTED</b>	18	1	17	0	0	2	0	10	0	0	3	51	51

**Fig. 2. Evaluation of products, substances and claims subject to authorisation (Activity 2), 01.01.2015 – 31.10.2015 vs. Annual Target**



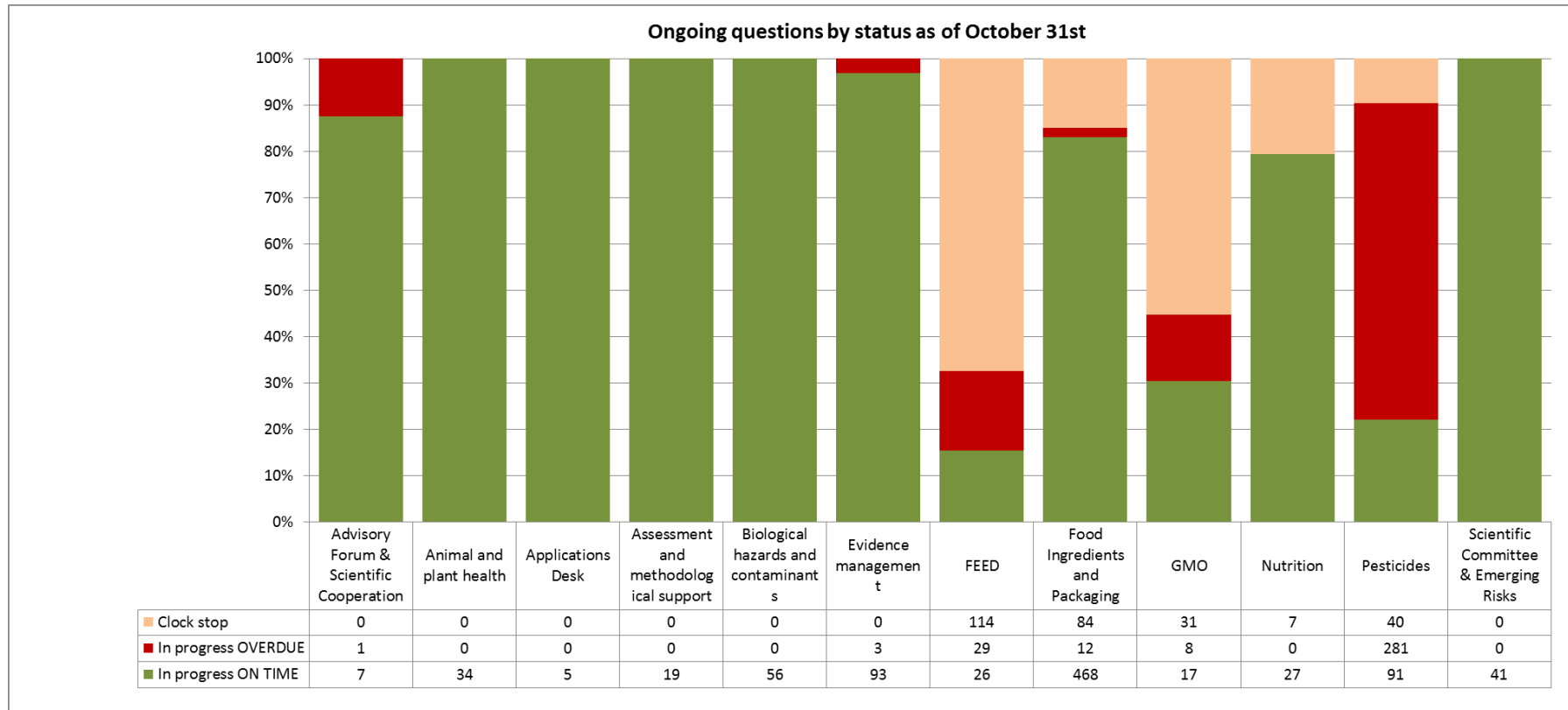
	RASA				REPRO					SCISTRAT		Total INCLUDING Join	Total EXCLUDING Join
	ALPHA	AMU	BIOCONTAM	DATA	FEED	FIP	GMO	NUTRI	PRAS	AFSCO	SCER		
<b>TARGET</b>	0	0	4	0	61	74	12	32	121	0	0	304	304
<b>ADOPTED</b>	0	0	2	0	53	56	16	23	99	0	0	249	249

**Fig. 3. Data Collection, Scientific Cooperation and Networking (Activity 3) and Supporting Publications 01.01.2015 – 31.10.2015 vs. Annual Target**



	RASA				REPRO					SCISTRAT		Total INCLUDING Join	Total EXCLUDING Join
	ALPHA	AMU	BIOCONTAM	DATA	FEED	FIP	GMO	NUTRI	PRAS	AFSCO	SCER		
<b>TARGET</b>	0	0	2	0	0	0	0	0	0	0	1	3	3
<b>ADOPTED</b>	0	1	2	0	0	0	0	0	0	0	1	4	4

**Fig. 4. Ongoing questions<sup>2</sup> by status**

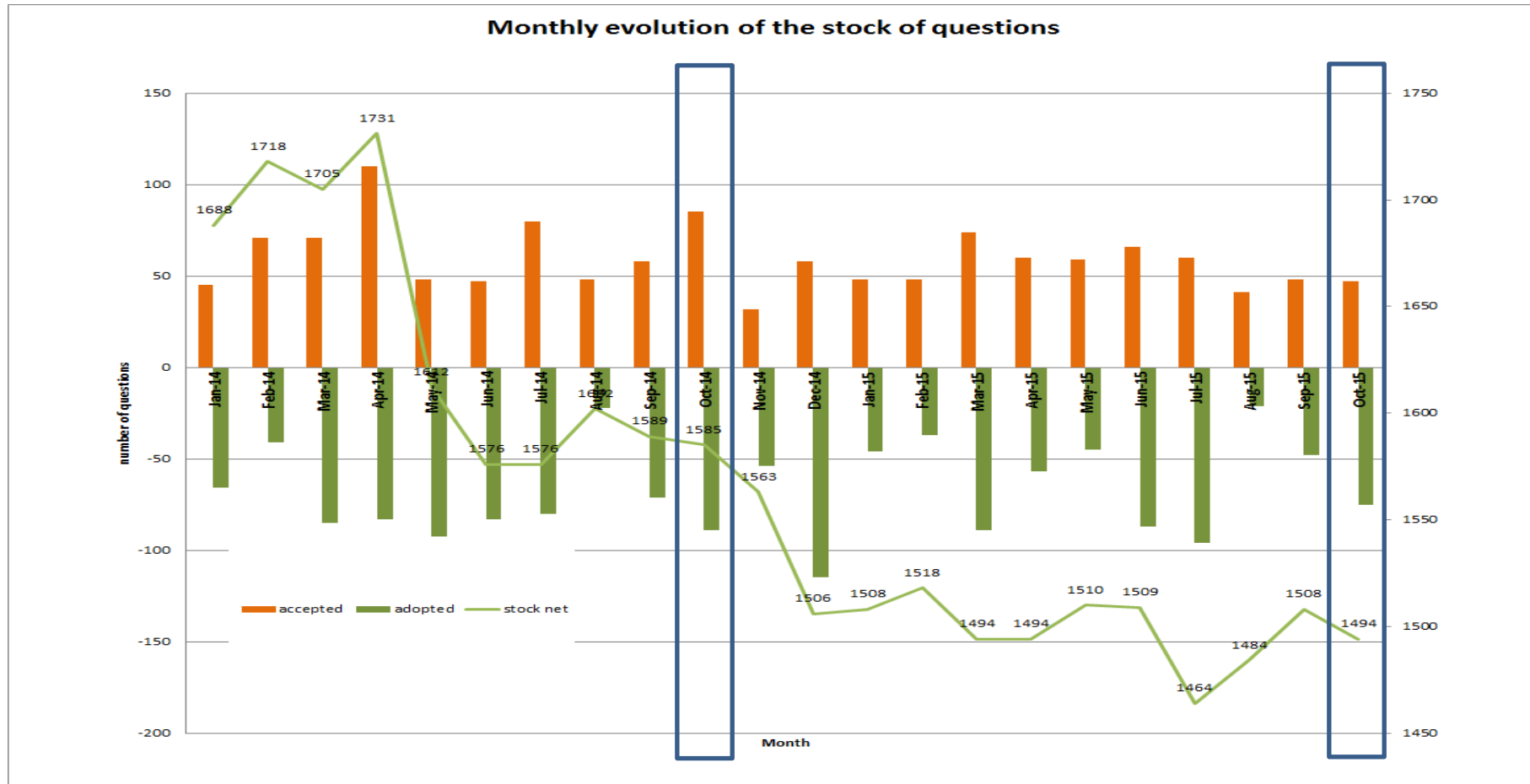


At end of October, 331 questions (linked to the adoption of EFSA Scientific Outputs) were overdue, +8% compared to August 2015 (304 questions) and +3 % compared to October 2014.

Questions in clock stop status (276 as of October) show an overall reduction (-2%) compared to last quarter (281 at end of August) and the same compared to October 2014 (nr. 281).

<sup>2</sup>On-going questions excluding the over 1500 questions under consideration referring to health claims pursuant to article 13 of Regulation 1924/2006 on nutrition and health claims made on food.

**Fig. 5. Monthly evolution of the stock of questions**



The stock of questions in the Register of Question system (RAW) at end of October 2015 is 1494, a decreased amount (-6%) compared to October 2014.

**Fig. 6. Evolution of selected Communication KPI**

