

EFSA PROGRESS REPORT

The present report refers to the period from the 1st of June to the 15th of September 2015.

SCIENCE

Outputs produced in the reporting period

In the risk assessment area, EFSA adopted a total of 63 scientific opinions, 54 of which in the area of regulated products. Among them, to mention some, the opinion on African swine fever, Use of neonicotinoids in foliar treatment, Hot water treatment of *Xylella Fastidiosa*, and Dietary Reference Values for vitamin E, vitamin B12, Phosphorous and Magnesium. 15 public consultations were launched, among which: Guidance for stakeholders on health claims applications, Guidance on uncertainty in scientific assessment, and Dietary Reference Value for copper. EFSA Panels issued 2 statements on the Update of the list of QPS-recommended biological agents intentionally added to food or feed, and the FERA Guidance proposal on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments. EFSA issued 4 scientific reports, 17 technical reports, 31 reasoned opinions, 12 peer review conclusions, 4 external reports and 1 event report.

Renewal of the Scientific Committee and eight Scientific Panels

Over 170 scientists have started their three-year term as experts for the Scientific Committee and eight of EFSA's scientific Panels: Additives and Products or Substances used in Animal Feed (FEEDAP), Animal Health and Welfare (AHAW), Biological Hazards (BIOHAZ), Contaminants in the Food Chain (CONTAM), Dietetic Products, Nutrition and Allergies (NDA), Genetically Modified Organisms (GMO), Plant Health (PLH) and Plant Protection Products (PPR).

About half of all panel members are new to EFSA. Many of them come from universities and research institutes. These highly qualified scientists will help shape EFSA's work in the next three years and make important contributions to ensuring that food remains safe for Europe's 500 million consumers.

All Panels have elected their Chair:

- Scientific Committee: Prof Anthony Hardy
- AHAW Panel: Prof Simon More
- BIOHAZ Panel: Dr Antonia Ricci
- CONTAM Panel: Dr Helle Katrine Knutsen
- FEEDAP Panel: Prof Guido Rychen
- GMO Panel: Prof Hanspeter Naegeli
- NDA Panel: Prof Dominique Turck
- PLH Panel: Prof Michael Jeger
- PPR Panel: Prof Colin Ockleford

Draft guidance on uncertainty in risk assessment

Identifying and describing scientific uncertainties, and explaining their implications for assessment conclusions, are crucial parts of EFSA's responsibility to provide transparent scientific advice. Scientists routinely strive to address the wide range of factors that can create uncertainties in their scientific assessments. These include, among others, possible limitations in the quality and representativeness of data, difficulties in comparing non-standardised data across countries or categories, the choice of one predictive modelling technique over another, and the use of default factors (such as the weight of an average adult). How scientists report them and how public bodies like EFSA

communicate them to risk managers, stakeholders and the wider public can alter perceptions about the risks and benefits of assessments and related policy decisions or choices by individuals. EFSA's Scientific Committee has developed this guidance document to offer a tool-box of methodologies – both quantitative and qualitative – for analysing scientific uncertainties in all its scientific assessments.

EFSA called for feedback on its draft guidance. The consultation, which closed on the 10th of September, aimed at the international scientific community, European and national risk assessors, risk communicators and risk managers, as well as EFSA's stakeholders.

Use of neonicotinoids in foliar treatment

EFSA has published assessments on the risks to bees from clothianidin, imidacloprid and thiamethoxam for all uses other than seed treatments and granules. In cases where the assessment could be completed, high risks were either identified or could not be excluded. In other cases the risk assessment could not be finalised due to data gaps. The conclusions are in line with those reached by EFSA two years ago, when it assessed the risks to bees from the three substances when used as seed treatments or granules. The European Commission requested the assessments concerning all other uses after imposing tighter restrictions on the use of neonicotinoids in 2013. The use of the three substances in seed or soil treatments is currently prohibited on crops attractive to bees and on cereals other than winter cereals, except for uses in greenhouses. Their use in foliar treatments is prohibited on crops attractive to bees and on cereals, except in greenhouses or after flowering.

Xylella fastidiosa: hot water treatment

Hot water treatment (HWT) is used successfully to eliminate the phytoplasma disease *flavescence dorée* from dormant grapevine planting material (cuttings and grafts), meaning that the material can be safely traded to protected zones in the EU. EFSA was therefore asked by the European Commission to assess whether the treatment could also sanitise *Vitis* sp. plants against *X. fastidiosa*. The Panel on Plant Health concluded that the HWT procedure for *flavescence dorée* – whereby dormant plants and plant parts are submerged for 45 minutes in water heated to 50C – is also effective against *X. fastidiosa* on grapevines.

Zoonoses potential on scrapie

Recent scientific evidence reviewed by EFSA does not change the conclusion of a 2011 ECDC-EFSA joint scientific opinion: there is no scientific proof that Classical scrapie can be transmitted from animals to humans under real-life conditions.

A new study reviewed by EFSA shows that under laboratory conditions Classical scrapie could be transmitted from sheep to mice whose genes have been modified to resemble human genes. This transmission caused a disease similar to sporadic CJD, or "sCJD", which is a form of Creutzfeldt-Jakob Disease.

CJD is a transmissible spongiform encephalopathy (TSE) affecting humans. Various forms of CJD are recognised: sporadic CJD is the most common and its origin is uncertain; variant CJD was identified in the 1990s and is closely linked to exposure – probably through food – to the cattle disease bovine spongiform encephalopathy (BSE).

African swine fever

EFSA recommends a combination of different management measures to contain the spread of African swine fever among wild boar populations in Eastern Europe. The European Commission requested EFSA to assess the recent outbreak in Eastern Europe of African swine fever and to provide scientific advice on its spread and on its containment. The disease has entered into Estonia, Latvia, Lithuania and Poland, affecting wild boar populations since 2014. The disease was also found among domestic pigs in Latvia, Lithuania and Poland. African swine fever is a viral disease that is harmless to humans but deadly to domestic pigs and wild boar. Neither vaccines nor cures are currently available. Most outbreaks in domestic pig farms occurred in backyard

farms and were contained relatively quickly. The disease is still spreading locally among wild boar populations where containment is more difficult.

Judgement of the Court of Justice of the EU in Case C-165/13P, *ClientEarth & PAN Europe v EFSA*

Case C-615/13P concerned a public access to document request (PAD), submitted under Regulation (EC) No 1049/2001, by ClientEarth and PAN Europe related to all draft versions of the Guidance on the submission of scientific peer-reviewed open literature for the approval of pesticide active substances prepared by EFSA in accordance with Article 8(5) of Regulation (EC) No 1107/2009. The court proceedings were initiated by the requestors against the EFSA's decision of 12 December 2011 to disclose the requested draft documents but refusing the transfer of personal data, i.e. the names of the scientific experts, involved in the drafting, linked to their comments in draft versions of the Guidance.

The Court annulled the judgement of the General Court in the (Case T-214/11) which had initially ruled in favour of EFSA. In doing so the Court annulled also the EFSA decision. The Court concluded that it is sufficient for the requestors to question in a general manner the impartiality of experts in carrying out their tasks as scientists for EFSA in order to prove the necessity to receive personal data of the experts. The Court accepts that there was a need for the appellants to receive the missing link between comment and name in order to check on their suspicion of Conflicts of Interest.

The Court highlighted in this regard that the transparency of the process followed by a public authority for the adoption of a measure likely to have an impact on economic operators contributes to that authority acquiring greater legitimacy in the eyes of the persons to whom that measure is addressed, increases confidence in that authority and ensures that the authority is more accountable to citizens in a democratic system.

EFSA will give full effect to the ruling and is currently implementing the respective follow-up measures.

Transparency and Engagement in Risk Assessment (TERA project)

On 15 July, EFSA organised an in-house workshop with all relevant internal stakeholders to identify the measures that would need to be further assessed through a fully-fledged impact assessment prior to deciding if implementing them. The workshop participants agreed on the prioritisation criteria to be applied and established a list of 7 measures to be subjected to an outsourced impact assessment, with 5 more measures to be possibly assessed depending on the procurement call outcome.

The methodological approach to carry out the impact assessment (cost/benefit, cost/effectiveness, etc.) is the first expected deliverable and its rationale will be included in the TERA comprehensive implementation plan. The final deliverable will include the measures' impact assessment and is expected to be ready by spring 2016.

Meanwhile EFSA is tackling the implementation of measures such as the: Requirements simplification to take active role in public consultations; Pre-notification of interested parties of forthcoming public consultation; Publish full biographies of experts; Transparency on the identification of key studies; Documentation of the criteria of selection of WG members; Consultation on missing data/information to be considered by EFSA; More feedback on the extent and on the reasons why certain data were or were not used; Ensure consistent decision making on the confidentiality of application dossiers; Detailed reasons to discard studies which document harmful effects; and Open Panel plenary meetings extended by half a day/year/panel.

COMMUNICATIONS

In the reporting period, media coverage counted approx. 4,000 articles, representing a +54% increase compared to last quarter. This increase is likely to be explained by high media interest in the on-going peer review of the active substance glyphosate. EFSA received 129 queries, representing a -32% decrease on last quarter. Queries stabilised to normal levels following larger than usual number of requests for last reporting period in relation to BPA opinion. On Twitter, there were 899 new followers (+2% compared to last quarter; average 9.8 new followers/day). EFSA published 18 news stories, 3 feature and event stories, and 10 news-in-briefs.

EFSA met the EU Commissioner Andriukaitis to discuss on Bisphenol A and *Xylella fastidiosa* outbreak in Italy and contributed to the DG SANTE high level Conference on "Challenges to food safety and nutrition in 2050". EFSA and the DG SANTE Secretariat of the Scientific Committee exchanged information on the work programmes of the Scientific Committee/Emerging risks and non-food Committees on-going activities.

MEP Tomáš Zdechovský, member of the CONT Committee, paid a visit to EFSA and received information on the Authority's work, challenges and relations with the European Parliament. The ENVI Committee visited EFSA on 23-24 Sept. Among others, the exchange touched upon the issues of EFSA's strategic perspectives, priorities and challenges.

As well, EFSA received visits from numerous delegations from the European Union and beyond. Among those: a Dutch Parliament representation (interested in GMOs and pesticides); a Taiwanese delegation (risk communication, capacity building, data collection, animal health and welfare and activities in the area of plant protection products); Ms J. Reed of the New Zealand Ministry for Primary Industries (health claims); Mr D. Dix of the US Environmental Protection Agency, Office of Chemical Safety and Pollution (endocrine active substances and cooperation agreement between US EPA and EFSA); and a delegation from the China Food and Drug Administration (EFSA's experiences in the area of risk assessment and risk communication).

The preparation of the Second Scientific Conference is progressing well. In September, the conference website (<http://www.efsaexpo2015.eu/>) received the international Euromediterraneo Award, a prestigious prize intended to reward institutional communication projects that enhance partnerships between the public and the private sector.

SCIENTIFIC COOPERATION

The Advisory Forum further discussed around the review of its operation and reached an agreement on 'Recommended Good Practice' on dealing with substantive divergence over scientific issues (Article 30(4) of the Founding Regulation).

Scientific cooperation activities with the Member States include the preparation of an international workshop on foodborne viruses under the lead of the UK, and the launch of two regional projects on 'Analysis of spatial distribution of African Swine Fever (ASF) virus in Baltic States and Poland' and 'Crisis preparedness training with the Baltic States'.

EFSA exchanged views with the International Food Chemical Safety Liaison Group on supplements/chemicals and update on regulatory action for apricot kernels by FSANZ and use of inserts as food from ANSES. In collaboration with WHO and FAO, EFSA held a Scientific workshop on 'Revisiting the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food'.

RELATIONS WITH STAKEHOLDERS

The Stakeholders Consultative Platform agreed to renew the mandates of the stakeholders' discussion groups on Emerging Risk and DATA, made proposals in relation to the future revision of the terms of reference for the Platform and provided feedback on EFSA's draft document on Good Administrative Practices in the area of applications. Members of the Platform also agreed to set up a pilot *focus group* to contribute to the soon-to-begin work of the GMO Panel Working Group on allergenicity (as part of the TERA project – see above). EFSA also launched a new stakeholder newsletter.

SCIENCE

Scientific Committee and Emerging Risks	<p><u>SCER Unit</u></p> <ul style="list-style-type: none"> Publication of the report on EFSA's activities on emerging risks in 2014 and of the annual report of the Emerging Risks Exchange Network 2014. External reports on: 'Specialised training courses on certain aspects of food safety risk assessment for EFSA Panel/Scientific Committee members, open to EFSA scientific staff'; 'Data collection on combined toxicity of multiple chemicals for animal health and ecological risk assessment'; and 'Update of the EFSA's chemical hazards database'.
Animal health and plant health	<p><u>Panel on Animal health and welfare (AHAW)</u></p> <ul style="list-style-type: none"> Opinions on: 'Enzootic bovine leucosis'; 'Update on oral vaccination of foxes and raccoon dogs against rabies'; 'African swine fever'. <p><u>Panel on Plant health (PLH)</u></p> <ul style="list-style-type: none"> Opinion on 'Hot water treatment of <i>Vitis</i> sp. for <i>Xylella fastidiosa</i>'. <p><u>ALPHA Unit</u></p> <ul style="list-style-type: none"> Report of EFSA on 'Drivers for occasional spillover event of Ebola virus'. Event report on 'Information session with stakeholders on the AHAW Panel guidance on the assessment criteria for studies evaluating the effectiveness of stunning interventions regarding animal protection at the time of killing'. Workshop and a gap analysis on the use of animal-based measures to assess animal welfare in the EU.
Biological hazards and contaminants	<p><u>Panel on Biological hazards</u></p> <ul style="list-style-type: none"> Opinions on 'Alternative method for the hygienic treatment of bovine colostrum through a series of filtration steps'; 'Review of a scientific publication concerning the zoonotic potential of ovine scrapie prions'. Statement on the 'Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA'. <p><u>Panel on Contaminants in the food chain (CONTAM)</u></p> <ul style="list-style-type: none"> Opinions on: 'Risks for public health related to the presence of chlorate in food'; 'Nitrofurans and their metabolites in food'; 'Risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin'. <p><u>BIOCONTAM Unit</u></p> <ul style="list-style-type: none"> Report of EFSA on 'Scientific and technical assistance on the evaluation of the temperature to be applied to pre-packed fishery products at retail level'. Technical reports on: 'EFSA's assistance for the 2015 Codex Committee on Residues of Veterinary Drugs in Food'

	<p>(CCRVDF) in relation to rBST'; 'Fatal human case of <i>Bacillus anthracis</i> infection and bovine meat contamination in Bulgaria'.</p> <ul style="list-style-type: none"> External report on 'Occurrence of Pyrrolizidine Alkaloids in food'.
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: sensory (1), technological (5), nutritional (4) and zootechnical (9).
Food ingredients and packaging	<p><u>Panel on Food Additives and Nutrient Sources added to Food (ANS)</u></p> <ul style="list-style-type: none"> Opinions on: re-evaluation of food additives (6); new application for food additives (1); nutrient sources (1, i.e. Isoflavones). <p><u>Panel on Food contact materials, enzymes, flavourings and processing aids (CEF)</u></p> <ul style="list-style-type: none"> Opinions on: flavourings (5); food contact materials (6, of which three substances and three recycling processes); processing aids (1). <p><u>FIP Unit</u></p> <ul style="list-style-type: none"> Public consultation on the 'Draft opinion on recent developments in the risk assessment of chemicals in food and their potential impact on the safety assessment of substances used in food contact materials'.
Genetically modified organisms	<p><u>Panel on Genetically modified organisms</u></p> <ul style="list-style-type: none"> Opinions on: maize NK603 x T25; soybean FG72; and soybean MON 87705 x MON 89788. <p><u>GMO Unit</u></p> <ul style="list-style-type: none"> Technical reports on: soybeans MON 87705 x MON 89788; soybean FG72; soybean MON 87708 x MON 89788; maize MON 87427; and maize NK603 x T25. In addition, Technical reports (2) following request from the European Commission on two complaints under the Aarhus convention against Commission Decision to authorise i) oilseed rape MON 88302 and ii) soybeans 305423, MON 87705 and MON 87769; and a Technical report on arguments provided by Monsanto with regards to EFSA's opinion on Monsanto's Insect Resistance Management (IRM) strategy on GM maize MON 810 Workshop on allergenicity assessment of GM plants.
Dietetic products, nutrition and allergies	<p><u>Panel on Dietetic products, nutrition and allergies (NDA)</u></p> <ul style="list-style-type: none"> Opinions on: DRV (vitamin E, vitamin B12, Phosphorous and Magnesium); Health Claims Art. 14 (5); Novel food (2'-0-Fucosyllactose, Lacto-N-neotetraose, and bread treated with UV light). Opinions endorsed for public consultation: DRVs for copper; Guidance on applications for foods for special medical

	<p>purposes; and Guidance for Health Claims.</p> <p><u>NUTRI Unit</u></p> <ul style="list-style-type: none"> Technical report following the request for scientific assistance on comments received pursuant to Article 16(6) of Regulation (EC) N°1924/2006. In addition, technical reports on the outcomes of public consultations on DRVs for vitamin E, vitamin B12, Phosphorous and Magnesium.
Pesticides and plant protection products and their residues	<p><u>Panel on Plant protection products and their residues (PPR)</u></p> <ul style="list-style-type: none"> Opinion on the 'Effect assessment for pesticides on sediment organisms in edge-of-field surface waters'. Scientific statement on the 'FERA Guidance proposal on how aged sorption studies for pesticides should be conducted, analysed and used in regulatory assessments'. <p><u>PRAS Unit</u></p> <ul style="list-style-type: none"> 12 Peer-review conclusions. Guidance of EFSA on 'Reporting data on pesticide residues in food and feed according to Regulation (EC) No 396/2005' (2014 data collection). 31 Reasoned opinions covering 32 questions. Scientific report (1) covering 35 questions, one external report and 3 technical reports.
Assessment and methodological support	<p><u>AMU Unit</u></p> <ul style="list-style-type: none"> PROMETHEUS project: Scientific report on 'Principles and process for dealing with data and evidence in scientific assessment'. The report was endorsed by the Scientific Committee. Methodological support to BIOHAZ (Development of a risk ranking toolbox), AHAW ('Canine Leishmaniosis', 'Systematic reviews of the efficacy and safety of sometribove zinc suspension', 'Welfare aspects of perches for poultry' and 'Welfare assessment of dairy cows in small scale farming systems') and NDA (Dietary Reference Values for calcium). Assistance to ALPHA for the 'Urgent reaction from EFSA to comment the scientific and technical information provided by an Italian NGO on <i>Xylella fastidiosa</i>'. Technical Report on 'Tools for critically appraising different study designs, systematic review and literature searches'.
Evidence management	<p><u>DATA Unit</u></p> <ul style="list-style-type: none"> Technical report on 'Specific requirements for chemical contaminant and food additive occurrence data submission'. Support to: BIOCONTAM ('Risks for public health related to the presence of chlorate in food'; 'Nitrofurans and their metabolites in food'; 'Risks for human health related to the presence of tetrahydrocannabinol (THC) in milk and other food of animal origin'); NUTRI (DRVs for calcium, vitamin E, cobalamin, phosphorus and magnesium); and FIP (Re-evaluation of sorbic acid (E 200), potassium sorbate (E 202), calcium sorbate (E 203) and polyethylene

	sorbitans (E432-436)).
Application Desk	<u>APDESK Unit</u> <ul style="list-style-type: none"> ○ Receipt of 109 applications and 100 requests via web form. ○ Contribution to meetings with stakeholders.
Quality Management	<ul style="list-style-type: none"> ○ The External Review Working Group (ERWG) gave a first positive feedback to the new Quality Assurance System for Science. An in depth review of the system is being performed by the ERWG. ○ EFSA aligned the Internal Control Standards (ICS) with the ISO 9001 Quality Management Standard. Work is being carried out to develop an EFSA Management System based on the two standards. ○ Work has started on producing the EFSA Quality Manual.

COMMUNICATION

Media and social media	<ul style="list-style-type: none"> ○ Coverage in 3999 articles, representing a +54% increase compared to last quarter. Increase likely to be explained by high media interest in the on-going peer review of the active substance glyphosate including the debate around the IARC classification. ○ Number of queries to press office: 129, representing a -32% decrease on last quarter. Queries stabilised to normal levels following larger than usual number of requests for last reporting period in relation to BPA opinion. ○ Highlights from the quarter included an interview with Science Magazine on EFSA's upcoming opinion on edible insects for food and feed, an interview with French media Science & Vie on EFSA's opinion on animal cloning and an interview with the Executive Director for influential Chinese newspaper Southern Weekly on EFSA's remit in general and future challenges for the Authority. ○ During his recent visit to Lithuania, Bernhard was interviewed by Lithuania's prestigious daily newspaper Postimees. British and French national dailies The Guardian and Le Monde interviewed EFSA's José Tarazona on the Authority's recent conclusions on the risks to bees from three neonicotinoids. EFSA's Media Relations team assisted the delegation of Commissioner Andriukaitis for its visit to the Apulia region in Italy in relation to the outbreak of the plant pest <i>Xylella fastidiosa</i>. ○ On Twitter, there were 899 new followers (+2% compared to last quarter; average 9.8 new followers/day).
Publications	<u>Content overview</u> <ul style="list-style-type: none"> ○ 18 news stories, 3 feature and event stories, 10 news-in-briefs were published; 19 of which were science related and 12 were on corporate issues. Highlights included news stories on: the first report of PROMETHEUS project (Promoting methods for evidence use in scientific assessments), acrylamide, new guidance on GM risk assessment,

	<p>launch of MUST-B (multiple stressors in bees) project, announcement of inaugural plenaries of newly-reconstituted Panels, EFSA assessment of IARC report on carcinogenicity of glyphosate, foliar uses of neonicotinoids confirmed as risk to bees, new data call for risks from fipronil to bees, and use of hot water treatment for <i>xylella</i> in grapevines.</p> <p><u>Website</u></p> <ul style="list-style-type: none"> ○ EFSA's Second Scientific Conference website (http://www.efsaexpo2015.eu/) received the international Euromediterraneo Award, a prestigious prize intended to reward institutional communication projects that enhance partnerships between the public and the private sector. ○ Website successfully migrated to a new web platform (Drupal), hosted on the cloud (Acquia/Amazon). This enabled increasing the speed of page-load for end-users by approximately 250%, while internal resources for web publishing tasks should be reduced of 50%, once the stabilisation activities are completed. <p><u>EFSA Journal</u></p> <ul style="list-style-type: none"> ○ The implementation of new templates meeting recognised publishing standards and reflecting EFSA corporate identity continued. The pre-publishing quality assurance checks continued and have virtually eliminated the republication of EFSA's scientific outputs for editorial reasons. A plagiarism checking software programme was introduced and awareness of plagiarism was raised at the induction meetings of the new Panels.
Advisory Forum and scientific cooperation	<p><u>Advisory Forum</u></p> <ul style="list-style-type: none"> ○ At the 11-12 June meeting, among others the Advisory Forum (AF) further discussed around the review of the operation of the AF and reached an agreement on 'Recommended Good Practice' on dealing with substantive divergence over scientific issues (Article 30(4) of the Founding regulation). ○ The 1st round of the EU Risk Assessment Agenda Delphi study was finished and EFSA's Scientific Committee was consulted on the questionnaires of the 2nd round. <p><u>Scientific cooperation with the Member States</u></p> <ul style="list-style-type: none"> ○ First teleconference of the Organising Committee of the international workshop on foodborne viruses under the lead of the UK: definition of the main themes of the workshop (3 July). ○ Two regionals projects have been agreed with the Baltic States and Poland: 'Analysis of spatial distribution of African Swine Fever (ASF) virus in Baltic States (Estonia, Latvia and Lithuania) and Poland' and 'Crisis preparedness training'. ○ Visit of ANSES (3 June): Exchange on strategic and multi-annual plans of both organisations and on experiences of reciprocal cooperation. Possible future joint projects have been discussed in the areas of bee health and surveillance of wildlife. <p><u>Networks</u></p> <ul style="list-style-type: none"> ○ Following the strategic planning envisaged on the Scientific Cooperation Roadmap, some training courses organised by EFSA were opened to the participation of network representatives, in addition to Panel and WG members.

	<ul style="list-style-type: none"> ○ Meetings with Network coordinators were held to discuss practical issues of further harmonisation the coordination of Scientific Networks. <p><u>EFSA Expert Database (EDB)</u></p> <ul style="list-style-type: none"> ○ In line with the new ED Decision on the selection of experts the gradual phase-out of EDB was initiated with, first step being the closing of ad-hoc applications to the EDBas of 1st July. <p><u>Pre-accession Programme and European Neighbourhood Policy Programme</u></p> <ul style="list-style-type: none"> ○ EFSA expert mission to the Ministry of Agriculture of Azerbaijan. Participation of 20 experts from the national food safety authorities. ○ Pre-accession Programme: Technical annex and the budget for the new grant for the Pre-Accession Programme was approved by DG NEAR (IPA). Contract signature between DG NEAR and EFSA is expected by October, after MB approval.
Stakeholders	<ul style="list-style-type: none"> ○ At the 15 June meeting, the Stakeholders Consultative Platform agreed to renew the mandates of the stakeholders' discussion groups on Emerging Risk and DATA, proposed revised terms of reference for the Platform and provided feedback on EFSA's draft document on Good Administrative Practices in the application area. Members also agreed to set up a pilot <i>focus group</i> to contribute to the soon-to-begin work of the GMO Panel Working Group on allergenicity (part of the TERA project). ○ EFSA launched a new stakeholder newsletter to keep its partners informed about upcoming work and to facilitate their contribution to the Authority's work. ○ Meeting with the industry associations. EFSA discussed how to increase transparency and dialogue during its risk assessment processes with industry associations representing applicants and those with an interest in other areas of EFSA's work. (23 June). ○ Stakeholder meeting on the 'Revision of the International Estimate of Short-Term Intake (IESTI equations) used to estimate the acute exposure to pesticide residues via food' (7 Sept., WHO Geneva, Switzerland): Open meeting organised for collecting the views of EFSA stakeholders in preparation of the Scientific Workshop the following day (see international cooperation below).
Institutional and international relations	<p><u>European Commission</u></p> <ul style="list-style-type: none"> ○ Meeting with EU Commissioner Andriukaitis to discuss Bisphenol A and the Xylella fastidiosa outbreak in Italy, the latter in view of a visit that the Commissioner paid to the affected Italian region in July and that EFSA was part of, to provide technical support (23 June) ○ Participation in DG SANTE high level Conference on "Challenges to food safety and nutrition in 2050" (17 July) ○ Participation in a Conference on endocrine active substances (1 June) ○ Visit of the Secretariat of the Scientific Committees of DG SANTE: exchange of information on work programme of

Institutional and international relations

the Scientific Committee/Emerging risks and non-food Committees on-going activities (18 June)

European Parliament

- Visit of MEP Tomáš Zdechovský, member of the CONT Committee. Discussion mainly centered around the Agency's work, challenges and relations with the EP (21 July).
- Presentation at the ENVI Committee of EFSA's work on Campylobacter together with ECDC and the EC (15 Sept).
- Participation at a 'lunch debate' with MEPs on GMOs (15 Sept).
- Visit of the ENVI Committee. Among others, the exchange touched upon the issues of EFSA's strategic perspectives, priorities and challenges, and the working processes of the Authority and its Scientific Committee and Panels (23-24 Sept).

Member States

- Visit of a Dutch Parliament delegation. Among others, the discussion included exchanges in the areas of GMO and pesticides (21 July).
- To support liaison with Italian authorities, EFSA's ED addressed the local Parliament of Emilia Romagna region (14 July).
- Participation at a Conference on Food Fraud organised by the Italian Nucleo Anti-Sofisticazioni at the EXPO (9 July).

EU Agencies

- EU Network of EU Agencies for Scientific Advice (EU ANSA): publication of the report on 'Overview of the Scientific Processes of the EU-ANSA'.
- ECDC: Visit of Mike Catchpole, ECDC Chief Scientist (5 June). Among the subjects discussed: EFSA/ECDC collaboration on foodborne disease, zoonoses and antimicrobial resistance, SOP on rapid risk assessments, and joint database initiative for molecular surveillance.
- ECHA: Teleconference about the latest developments on EFSA's Open Data project (18 June).
- ECHA participated in EFSA's nanotechnology network meeting (7-8 July).
- EMA: EFSA participated in the consultation of the strategy document 'EU Medicines Agencies Network Strategy to 2020 - Working together to improve health' (30 June). EMA's network strategy includes areas of relevance for EFSA, such as animal health and human health, antimicrobial resistance, and promotion of one health approach.

International relations

- International Food Chemical Safety Liaison Group (IFCSLG): exchange of views on supplements/chemicals and update on regulatory action for apricot kernels by FSANZ and use of inserts as food from ANSES.
- Animal Health Policy Branch of the Department of Agriculture Australia provided foresight training to AFSCO and SCER Units.
- EFSA participation in the EU-India seminar on food control in India.
- WHO and FAO: Scientific workshop on 'Revisiting the International Estimate of Short-Term Intake (IESTI

Institutional and international relations	<p>equations) used to estimate the acute exposure to pesticide residues via food' (8-9 Sept., WHO Geneva, Switzerland). International Scientific Workshop, co-sponsored by WHO and FAO, for revising the methodology for estimating the acute oral exposure to pesticides in the consumers risk assessment.</p> <ul style="list-style-type: none"> ○ Visit of Ms J. Reed, New Zealand Ministry for Primary Industries. Exchange on health claims. ○ Visit of a delegation from Taiwan: discussion on risk communication, capacity building, data collection, animal health and welfare and activities in the area of plant protection products. ○ Visit of Mr D. Dix, US Environmental Protection Agency, Office of Chemical Safety and Pollution: endocrine disruptor screening programme and development of cooperation agreement between US EPA and EFSA. ○ Visit of a delegation from the China Food and Drug Administration: discussion around EFSA's experiences in the area of risk assessment and risk communication.
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CORPORATE – RESOURCES AND SUPPORT

Strategy based services	<p><u>Corporate business control (PTT)</u></p> <ul style="list-style-type: none"> ○ Implemented a comprehensive programme management approach, which together with the project and resource management governance provides a corporate business control system of ex-ante, ex-post and continuous evaluation of programme and project investment returns. <p><u>Independence</u></p> <ul style="list-style-type: none"> ○ As of the 1st of July, to respond to the input received from the European Parliament and interested parties, EFSA undertook a pilot project aimed at verifying the feasibility of centralising the screening process of the Annual Declarations of Interest (ADoI) of its experts and staff members within its Legal and Regulatory Affairs Unit. The pilot phase will last until the end of the year, when EFSA will take a decision on the appropriate degree of centralisation to be implemented.
Expertise based services	<p><u>Data protection</u></p> <ul style="list-style-type: none"> ○ Reply to a questionnaire of the EDPS as part of the general monitoring exercise 2015. ○ Continuation of the DPO notification process, focusing on data processing in the area of HR management: Engagement of Temporary Agents, Education allowances for dependent children, unpaid leave and leave on personal grounds. <p><u>Talent Selection</u></p> <p>On 15th September, 433 posts were occupied and 4 job offers sent to the selected candidates bringing the total to 437</p>

Expertise based services

posts filled-in out of the planned 477 posts (including Seconded National Experts). With regards to statutory staff, the overall recruitment execution rate is at 94.4% (corresponding to 92.3% including the 10 short term contracts).

Staff Categories	Target 2015	Total Contracted and Offered
Temporary Agents and Officials		
Executives, Managers & Officers (AD)	234	214
Assistants functions (AST)	103	113
Total	337	327
Contract Agents		
Officers functions (CA FG IV)	70	55
Assistants functions (CA FG I, II, III)	50	40
Total	120	95
Seconded National Experts	20	15
Total all staff categories	477	437

Court cases

- Case C-615/13P, ClientEarth & PAN Europe v EFSA. On 16 July, the Court of Justice delivered its judgment setting aside the appealed judgment of the General Court T-214/11 and annulling the EFSA decision of 12 December 2011 disclosing all drafts of the Guidance on the submission of scientific peer-reviewed open literature for the approval of pesticides' active substances but excluding the personal data of experts involved in the drafting. The Court concluded EFSA should disclose the names of the experts linked to their comments in draft versions of the Guidance. EFSA was supported in this case by the European Commission and the European Data Protection Supervisor.
- Case T-493/14 Mayer v EFSA. EFSA lodged its reply before the General Court to an additional submission of the applicant. The case concerns the non-extension of the secondment of a national expert.
- Case T-334/12, Plantavis GmbH and NEM, v European Commission and EFSA. The General Court issued a ruling dismissing the case, deeming the action inadmissible, and condemning the applicant to pay both the Commission and EFSA's costs

European Ombudsman (EO)

- Case 0684/2012/JF: EO adopted the decision closing the inquiry and welcoming EFSA acceptance of the friendly solution. The case refers to the payment of dependent child allowances to a former staff member.

	<ul style="list-style-type: none"> ○ Case 176/2015/JF. EFSA submitted its opinion on the complaint concerning alleged maladministration regarding the manner in which the Authority replied to a Parliamentary enquiry and follow up questions received from an NGO. ○ Case 346/2013/ANA. EFSA addressed the Ombudsman's remarks in her decision taken on 28 January 2015. The complaint concerned the way in which the Authority prevented conflicts of interest among the experts of the Working Group of its Scientific Committee dealing with "Genetically Modified insects", and in its communication EFSA outlined its position vis-à-vis the Ombudsman's decision.
Transaction based services (Routine activities, high volume tasks and highly sensitive to scale)	<p><u>Outreach and support services</u></p> <p>Organisation of four public hearings welcoming 278 participants. Average satisfaction rate: 92%.</p> <p><u>Financial management</u></p> <p>On 31st August 2015, €51.77 million or 65.05% of the €79.58 million budget was committed, and €42.54 million or 54.52% of the € 78.03 million payment appropriations were paid, reflecting a better execution of budget compared to year 2014 in the same quarter. Detailed information is available in mb151001-i4.</p>

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

Annex to the Progress Report

Progress Indicators as of 31 August 2015

Executive Summary

This document includes:

- An overview of EFSA's results in the first eight months of 2015 on key performance indicators;
- Detailed tables with figures and data referring to the period 1/1/15 – 31/8/15 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 eight months of the year, **228 scientific outputs and 116 Supporting publications** have been finalized / adopted, representing respectively 58% and 79% of the yearly target. The updated forecast for the end of the year is to reach at least 90% of the scientific output and more than 100% of the supporting publication yearly targets.

Adoption timeliness for Activity 1 (provision of scientific opinions and advice & risk assessment approaches) was slightly below the target, 98% versus 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 80%, below the 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 August is -3% below the monthly target for commitments and -5% below the monthly target for payments; while the global commitment until year end is 65%. Commitments for Scientific Cooperation are well above targets (+ 25%) and payments slightly above the target (+ 5%).

For further details on financial performance, please refer to document mb151001-i4 (EFSA's 2015 budget execution & transfers).

Overview of Key performance indicators as of 31/8/2015

	Description	Traffic light	Comment
1	Scientific Outputs Activity 1	😊	40 outputs adopted/finalised, in line with monthly targets and representing 46% of the yearly target (see figure 1)
2	Scientific Outputs Activity 2	😊	185 outputs adopted/finalised, in line with monthly targets and representing 61% of yearly target (see figure 2)
3	Scientific Outputs Activity 3 (including supporting publications)	😊	3 scientific outputs adopted/finalised, 100% of the yearly target, and 116 supporting publications, 79% of yearly target (see figure 3)
4	Global Commitments & Payments rate	😊	Global commitments - 3% below monthly target and global payments -5% below monthly target (for details, see document mb151001-i9-Budget Execution & Transfers) – Global commitment is 65% of the yearly target.
5	G & P Commitments & Payments rate	😊	Grants and procurements commitments and payments above monthly targets (for details, see document mb151001-i9-Budget Execution & Transfers)
6	Adoption Timeliness Activity 1	😊	Timeliness for scientific outputs under Activity 1 is 98%, slightly below the SPD targets of 100%
7	Adoption Timeliness Activity 2 ¹	😊	Timeliness performance - excluding overdue at the beginning of the year - stands at 80% 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 2.01 million, above monthly target (see figure 6)
11	Subscribers to online products	😊	Subscribers to online products at end August is 36.011, above the annual target of 32,000 (see figure 6)
12	Impact score	-	First results are expected in September 2015
13	Twitter followers	😊	Number of twitter followers at end of August is 11.135, constantly increasing (see figure 6)
14	Number of SNEs	😞	13 SNEs at end August, vs. a target of 20
15	Occupancy Rate	😊	Staff occupancy rate - excluding short term contract agents - is 94, 6%, below the 95% target.

¹ Excluding questions already overdue at beginning of 2015

Progress indicators: detailed tables

SCIENTIFIC ACTIVITIES

**Fig.1. Provision of scientific opinions and advice & risk assessment approaches (Activity 1)
01.01.2015 –31.08.2015 versus Annual Target**



Fig. 2. Evaluation of products, substances and claims subject to authorisation (Activity 2), 01.01.2015 – 31.08.2015 vs Annual Target



**Fig. 3. Data Collection, Scientific Cooperation and Networking (Activity 3) and Supporting Publications
01.01.2015 – 31.08.2015 vs Annual Target**

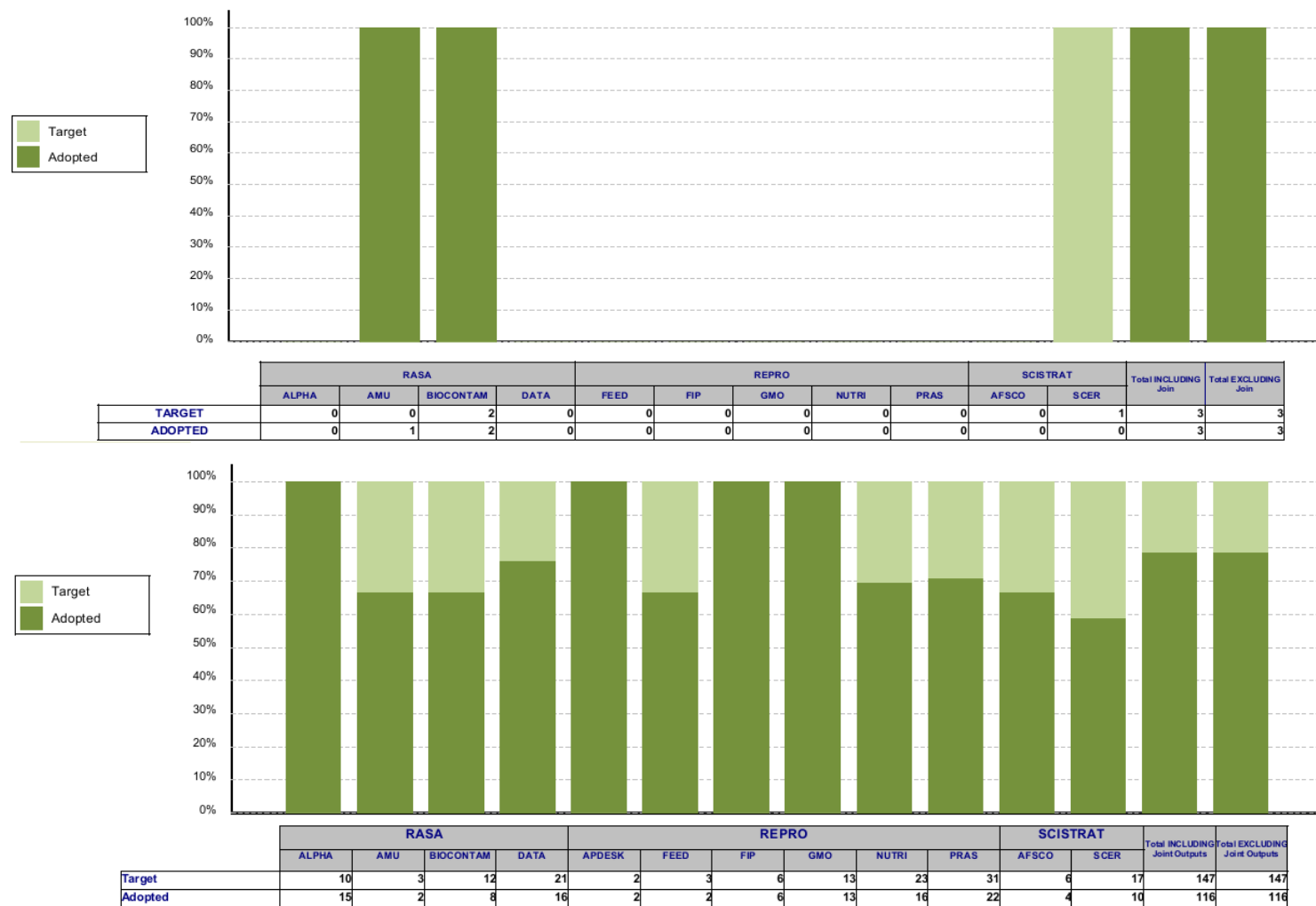
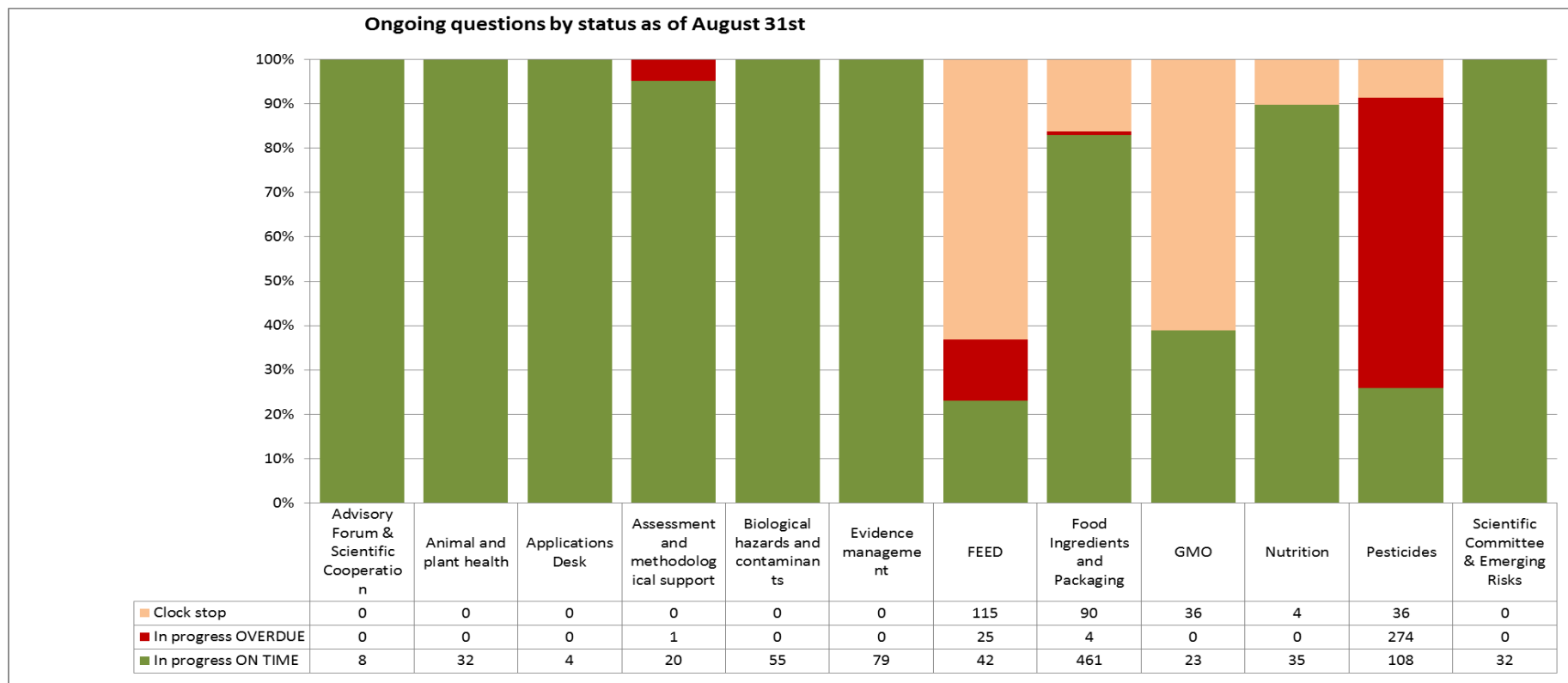


Fig. 4. Ongoing questions² by status

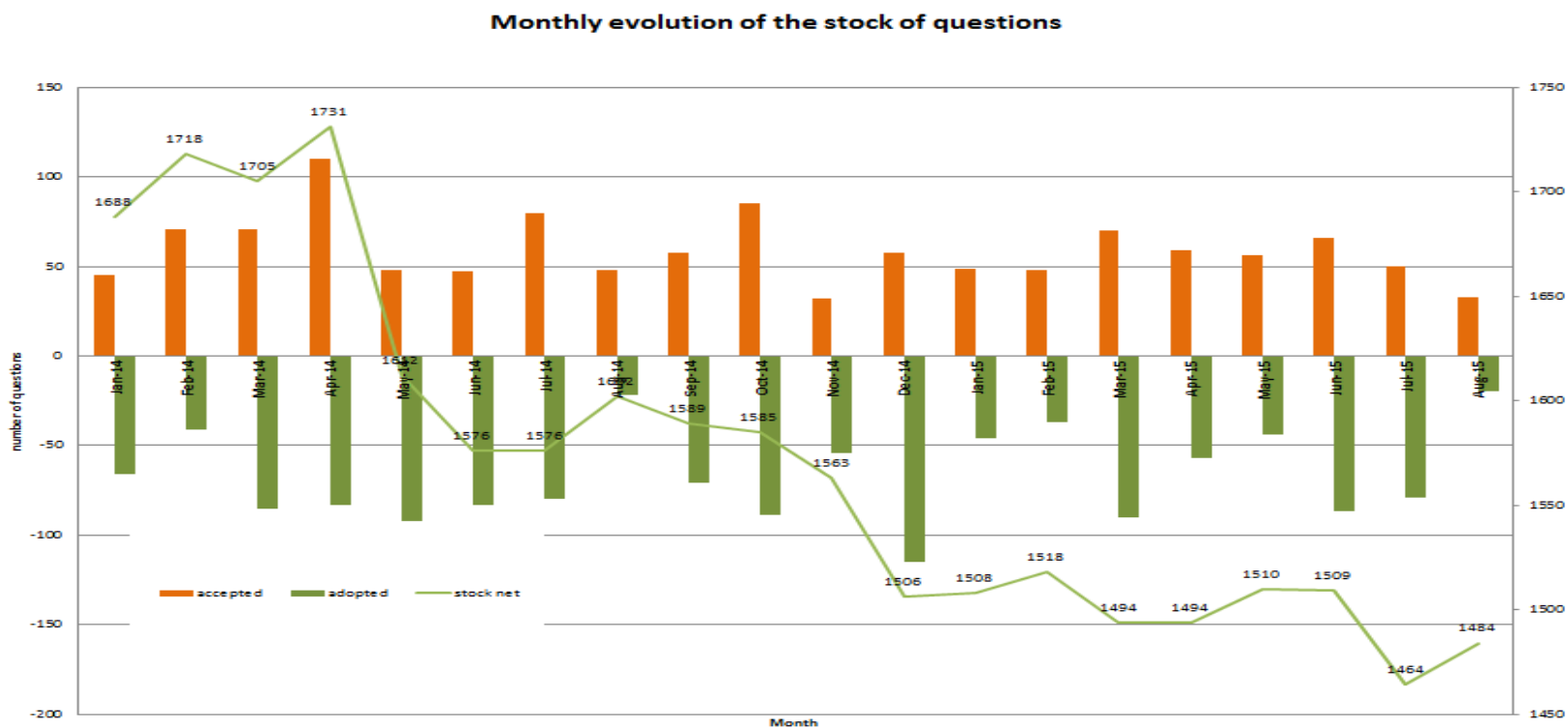


At end of August, 304 questions (linked to the adoption of EFSA Scientific Outputs) were overdue, -8% compared to May 2015. The decrease is mainly concentrated in the Pesticides Unit and related to Scientific Reports of EFSA.

Questions in clock stop status (281 as of August) show an overall reduction (-4%) compared to last quarter (292 at end of May).

²On-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 August 2015 is 1484, a decreased amount (-7%) compared to August 2014.

Fig. 6. Evolution of selected Communication KPI

