

#### **EXECUTIVE DIRECTORATE**

### **EFSA PROGRESS REPORT**

The present report refers to the period from the  $1^{st}$  of June to the  $15^{th}$  of September 2016.

### **SCIENCE**

### Overview of the outputs produced in the reporting period

In the risk assessment area, EFSA adopted a total of 40 scientific opinions, 35 of which in the area of regulated products. These include in particular the guidance document on 'Establishment of the residue definition to be used for dietary risk assessment', a statement on the 'Diversity of *Xylella fastidiosa* subsp. *pauca* in Apulia' (PLH Panel), 'Urgent advice on lumpy skin disease' (AHAW Panel) and 'Update of the list of QPS-recommended biological agents intentionally added to food or feed' (CONTAM Panel). In addition, EFSA issued 3 scientific reports, 27 technical reports, 6 external reports, 4 event reports, 13 reasoned opinions on MRLs and 6 peer-review conclusions.

### Xylella

There is no proof that multiple types of Xylella fastidiosa are present in Apulia, southern Italy, according to recently available scientific evidence examined by EFSA. The opinion of EFSA's Panel on Plant Health is the last of three outputs addressing questions from the European Commission on Xylella fastidiosa in Apulia, where a disease outbreak is affecting olive trees and other plants. In this one the Panel addresses the finding of a study that raised the possibility that multiple genetic types of X. fastidiosa are present in the affected area. EFSA's plant health specialists have stated that there is currently no evidence to support this hypothesis.

#### **Lumpy skin disease**

Vaccination of cattle is the most effective option for controlling the spread of lumpy skin disease, EFSA concluded. This is the main findings of a scientific statement on the effectiveness of different options for controlling the spread of this economically damaging disease. The work was requested by the European Commission following the rapid spread of the disease in Greece and Bulgaria and other Balkan countries. Lumpy skin disease is a viral disease that affects cattle and is transmitted by blood-feeding insects, such as certain species of flies and mosquitoes, or ticks. EFSA experts say that when vaccination is thoroughly applied, partial culling of affected animals is as effective in eradicating the disease as whole-herd culling, which is currently required under EU legislation. In particular, vaccination is most effective if applied before the virus enters a region or a country. Experts have recommended that vaccination is applied uniformly across all areas.

### **Food colours**

EFSA has completed its re-evaluation of all food colours that were permitted for use in the European Union before 2009. In the last opinion of the series, EFSA's experts concluded that available data on titanium dioxide (E 171) do not indicate health concerns for consumers. But they recommended new studies be carried out to fill data gaps on possible effects on the reproductive system, which could enable them to set an Acceptable Daily Intake (ADI). Over the past seven years, EFSA's Panel on Additives and Nutrient Sources Added to Food (ANS) has re-assessed the safety of 41 food colours, taking into account all available scientific studies and data. Where possible and appropriate, the Panel has established or updated an ADI for each substance.



### Copper in animal feed

EFSA has proposed modifications to the maximum levels of copper in feed for some animal groups. It recommends a reduction in the maximum copper content in feed for piglets, cattle and dairy cows, and an increase in feed for goats. The proposed levels would reduce the amount of copper released into the environment, which could potentially play a role in reducing antimicrobial resistance. For most other animal groups the currently authorised upper levels are unchanged. The recommended levels are considered sufficient to satisfy the nutritional needs for copper of these animal groups.

### Microplastics and nanoplastics in food

EFSA has comprehensively reviewed existing literature on this topic and found there are insufficient data on the occurrence, toxicity and fate – what happens after digestion – of these materials for a full risk assessment. In the context of the review, EFSA could take stock of recent scientific developments in this area, identify data and knowledge gaps and recommend future research priorities to address them.

### **Dietary Reference Values: Choline**

EFSA has set dietary reference values for choline as part of its review of scientific advice on nutrient intakes. Choline plays an important role in the human body, in particular for the maintenance of normal liver function. Choline deficiency can have adverse effects, including fatty liver, and liver and muscle damage. Food sources of choline include eggs, meat, fish, whole grains, vegetables and fruit, as well as fats and oils.

The Panel on Dietetic Products, Nutrition and Allergies (NDA) has defined daily adequate intakes (AIs) for choline, for the different age categories and target populations..

### COMMUNICATIONS

### Overview of the outputs produced in the reporting period

In the reporting period, some 50 outputs were published during the reporting period with high-profile news and web content on *Xylella f.,* multi-stack GMOs, citrus black spot, copper, micro/nanoplastics and bisphenol A. Media coverage counted approx. 1200 articles, representing a 79% decrease compared to the previous report period. This can be explained by two factors: the decreasing attention towards sensitive dossiers which dominated the media landscape in previous months (e.g. Glyphosate) and the summer break. Despite the decline of media coverage, enquiries by journalists slightly increased (+15%), with focus on pesticides, contaminants and on the security incident at EFSA involving an explosive parcel. EFSA's twitter account includes 1,170 new followers (12 new followers a day). The EFSA Journal completed its move to the Wiley journal platform including all supporting publications.

### **EFSA Hackathon**

EFSA is holding a <u>Hackathon competition</u> to develop a mobile app that gives quick and user-friendly access to information on EFSA's work.

On 24 September, on the occasion of the competition's final round, EFSA held a one-day event on how information and communication technologies (ICT) drive innovation within the public sector. Innovation is a key value for EFSA, which aims to be at the forefront in thinking and practice both on scientific as well as management and administrative issues.



### SCIENTIFIC COOPERATION

### **Scientific Colloquium on Epigenetics**

About 100 scientists, risk managers and policy makers from 20 countries including five non-EU countries met in Valencia, Spain, on 14 and 15 June, to discuss and to look at the potential role of epigenetics in risk assessment. Epigenetics is a relatively new scientific field addressing changes thataffect how genes are read but not the underlying DNA sequence. Increasing evidence suggests that external factors such as individual lifestyle, diet and environmental stressors affect epigenetic processes. As a result, health and the susceptibility to disease may be altered with potentially beneficial or adverse effects. The overall objective of the discussions was to identify the potential role of epigenetics in food safety risk assessment.

### Chemical mixtures: debating the issues

Researchers, scientists, stakeholders and policymakers from around the world gathered to discuss issues surrounding the risk assessment of chemical mixtures in Europe. A number of innovative research projects were presented at the symposium, which was organised by EFSA and the Dutch National Institute for Public Health and the Environment (RIVM). Among others, delegates discussed work being carried out by EFSA and the RIVM aimed at integrating the assessment of mixtures into future decision-making on the safe use of pesticides and other regulated products.

### **Botanicals added to EFSA Data Warehouse**

EFSA has taken the first step in releasing a web-based version of its Compendium on Botanicals. The <u>searchable database</u>, which is still under development, will be expanded to include non-European botanical species. The complete version of the Compendium will be released early 2017. The Compendium is a database of botanicals that are reported to contain naturally-occurring substances of possible concern for human health when present in food. It is intended to help with the safety assessment of botanicals and botanical preparations that may be used in food, including supplements, by facilitating hazard identification.

### **EXTERNAL RELATIONS**

### Feed additives: Technical meeting with stakeholders

EFSA met with stakeholders to present and collect feedback on the statement "Analysis of the need for an update of the guidance documents" issued by the Panel on Additives and Products or Substances used in Animal Feed (FEEDAP). Over 110 participants, including applicants, representatives of industry associations, consultants, representatives of national competent authorities and academics met with EFSA experts from the FEEDAP Panel, EFSA staff and representatives of the European Commission. The event was organised in the framework of the "EFSA Info Sessions on Applications" aimed at increasing regular interaction and exchange of views with EFSA's stakeholders.

### EFSA stakeholders: registration open

Registration to become EFSA's stakeholders was open on 22 September. EFSA invites organisations interested in actively supporting and contributing to EFSA's work to register. Registered stakeholders will be able to engage with EFSA through a combination of standing and ad-hoc platforms, according to their interests and expertise. Registration is open to organisations addressing the requirements described in the EFSA's Stakeholder Engagement Approach.



### Visits

EFSA received the visit of MEP Mariya Gabriel to discuss EFSA's participation at the EU Bee Health Conference. EFSA's ED visited the food safety authorities in The Netherlands and Belgium, where a Framework Partnership Agreement was agreed with RIVM on the implementation of Cumulative Risk Assessment of Pesticides, and a joint project was proposed with Belgium on 'Physico-chemical characterization and exposure analysis of the fraction of engineered nanomaterials in food additives in the context of risk assessment'. EFSA and the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) also exchanged visits, on the occasion of the recent taking up of duties of both ANSES' new Director General and Deputy Director General in charge with activities in the area of pesticides. The two organisations discussed of work in the area of pesticides and more generally of scientific cooperation and EU Risk Assessment agenda.



	SCIENCE					
Scientific Committee and Emerging Risks	<ul> <li>SCER Unit         <ul> <li>Technical reports on: 'A mechanistic model to assess risks to honeybee colonies from exposure to pesticides under different scenarios of combined stressors and factors' and 'Annual report of the Emerging Risks Exchange Network 2015'.</li> <li>External report on 'Testing a procedure for the identification of emerging chemical risks in the food chain' and 'Baltic Countries 2016 Workshop on Crisis Preparedness'.</li> </ul> </li> </ul>					
Animal health and plant health	Panel on Animal health and welfare Opinion on 'Assessing the health status of managed honeybee colonies (HEALTHY-B): a toolbox to facilitate harmonised data collection'. Statement on 'Urgent advice on lumpy skin disease'.  Panel on Plant health Statement on 'Diversity of Xylella fastidiosa subsp. pauca in Apulia'.  ALPHA Unit Technical report on 'HERBICIDE protocol: protocol for data collection and evaluation of herbicides active substances, under Art.4.7 of Regulation (EC) No 1107/2009'. External report on 'Development of probabilistic models for quantitative pathway analysis of plant pest introduction for the EU territory'. Event reports on: 'Strengthening regional cooperation in South East Europe and Middle East for prevention and control of Lumpy Skin Disease', 'Workshop on the health status of a managed honeybee colony', 'Workshop on assessing risks of introduction of highly pathogenic avian influenza virus via wild birds' and 'Workshop on Xylella fastidiosa: knowledge gaps and research priorities for the EU'.					
Biological hazards and contaminants	<ul> <li>Panel on Biological hazards</li> <li>Opinions on: 'Evaluation of the safety and efficacy of ListexTM P100 for reduction of pathogens on different readyto-eat food products', 'Risks for public health related to the presence of <i>Bacillus cereus</i> and other <i>Bacillus</i> spp. including <i>Bacillus thuringiensis</i> in foodstuffs' and 'Growth of spoilage bacteria during storage and transport of meat'.</li> <li>Statement on the 'Update of the list of QPS-recommended biological agents intentionally added to food or feed as notified to EFSA 4: suitability of taxonomic units notified to EFSA until March 2016'.</li> <li>Panel on Contaminants in the food chain</li> <li>Opinion on Malachite green in food.</li> </ul>					



	<ul> <li>BIOCONTAM Unit</li> <li>Scientific report on 'Review of proposed MRLs, safety evaluation of products obtained from animals treated wit zilpaterol and evaluation of the effects of zilpaterol on animal health and welfare'.</li> <li>External reports on: 'Combined bioaccumulation/toxicity study on a broad mixture of mineral oil saturate hydrocarbons' and 'Procurement on the health risks related to the presence of furan and its methyl analogues if food'.</li> </ul>					
Additives and products or substances used in animal feed	<ul> <li>Panel on Additives and products or substances used in animal feed</li> <li>Opinions on feed additives applications: 2 sensory, 3 technological, 4 zootechnical.</li> <li>Opinion on 'Revision of the currently authorised maximum copper content in complete feed'.</li> <li>Endorsement of EFSA's draft output regarding the consultation on the amendment of Commission Regulation (EC) No 429/2008 as regards the preparation and presentation of applications and the assessment and the authorisation of feed additives.</li> </ul>					
Food ingredients and packaging	Panel on Food additives and nutrient sources added to food  Opinions on the re-evaluation of food additives (2) and the extension of use of food additives (1).  Panel on Food contact materials, enzymes, flavourings and processing aids  Opinions on: flavourings substances (3) and food contact materials (10, including BPA).					
Genetically modified organisms	Panel on Genetically modified organisms  ○ Opinions on applications for 'GM maize Bt11 x 59122 x MIR604 x 1507 x GA21' and 'GM soybean 305423 x 40-3-2'.  GMO Unit  ○ Technical reports (2) following assistance request from the European Commission on new scientific information (Bohn et al., 2016 and Hofmann et al., 2016) in relation to the risk assessment of genetically modified Bt crops.  ○ Meeting of the EFSA scientific network for risk assessment of GMOs.					
Dietetic products, nutrition and allergies	Panel on Dietetic products, nutrition and allergies  ○ Opinions on: Health Claims Art. 13.5 (4), Health Claims Art. 14 (1), Novel Foods (1) and Dietary Reference Values (vitamin D).  NUTRI Unit  ○ Technical reports on the outcome of a public consultation (vitamin D) and on comments received pursuant to Art. 16.6 (1).					



Pesticides and plant protection products and their residues	Panel on Plant protection products and their residues  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residues definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residues definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residues definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residues definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residues definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residues definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  PRAS Unit  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  Outdoor on the establishment of the residue definition to be used for dietary risk assessment.  Outdoor on the establishment of the residue definition to be used for dietary ris
Assessment and methodologic al support	AMU Unit  Technical report on 'Analysis of EFSA methodological needs for evidence use in scientific assessments', deliverable 2 of the PROMETHEUS project.  External report on 'Development and application of statistical methodology for analysis of the phenomenon of multidrug resistance in the EU: demonstration of analytical approaches using antimicrobial resistance isolate-based data'.
Evidence management	<ul> <li>DATA Unit</li> <li>Support to CONTAM (Scientific opinion on malachite green in food, Review of proposed MRLs, safety evaluation of products obtained from animals treated with zilpaterol and evaluation of the effects of zilpaterol on animal health and welfare) and FIP (ANS Scientific Opinion on the safety of annatto extracts (E 160b) as a food additive).</li> <li>Scientific report on 'Dietary exposure assessment to pyrrolizidine alkaloids in the European population'.</li> <li>Technical reports on 'Mapping from FoodEx2 to FoodEx1' and 'Summary of the 2015 Data Collection on Contaminant Occurrence Data'.</li> <li>External report on 'Spanish dietary survey on adults, elderly and pregnant women'.</li> </ul>
Application Desk	<ul> <li>APDESK Unit</li> <li>Receipt of 88 applications and 53 requests via web form.</li> <li>Support to the organisation of an Info session on feed additives applications.</li> <li>Set-up of the EFSA discussion group on E-submission of applications for regulated products.</li> </ul>
Quality Management	<ul> <li>Preparation for the ISO 9001:2015 certification based on recommendations from the pre-certification audit report.</li> <li>Organisation of ISO trainings for EFSA Units and senior management.</li> </ul>



	COMMUNICATION
Media and social media	<ul> <li>Approx. 1200 articles mentioning EFSA (-79% in coverage compared to the previous reporting period)</li> <li>Slight increase (+15%) in incoming enquiries by journalists, which amounted to a total of 150 over the three months period.</li> <li>Six interviews with EFSA staff, including three with EFSA's Executive Director, byBelgian newspapers Le Soir and De Standaard and also in pan-EU publication Politico. The first thematic Twitter account – @Plants_EFSA was launched (200 followers in the first three weeks).</li> <li>1,170 new followers on EFSA's twitter account (an average of 12 new users a day).</li> </ul>
Content production and dissemination	Content (news & multimedia)  Some 50 outputs were published during the reporting period with high-profile news and web content on Xylella f., multi-stack GMOs, citrus black spot, copper, micro/nanoplastics and bisphenol A.  Interviews, stories and blogs with EFSA experts and partners on bee stressor modelling, food colour re-evaluations, micro/nanoplastics in seafood and lumpy skin disease.  Promoted the addition of the Compendium of Botanicals to the EFSA Data Warehouse underling EFSA's efforts to optimise access to data.  Several activities on enhancing transparency and openness, including publication of multilingual glossary of scientific terms on the EFSA website and flash video interviews from open FEEDAP, NDA and PPR plenaries and reporting progress on AMR at working group meetings.  Production and dissemination of a promo video for trainee recruitment campaign.  Website development  Improvements on the website calendar and in the APDesk Section (guidance document).  Integration of the new Career mini-site into the web analytics tool.  EFSA Journal  Migration of the EFSA Journal to the Wiley journal platform completed.  First review of editorial workflow efficiency completed.  Digitization and loading of the complete archive of EFSA Supporting Publications to Wiley platform.  Revised guidelines on authorship implemented.  Special journal issue on Second EFSA Scientific Conference (EXPO 2015) published.



Stakeholders	<ul> <li>NGO Roundtable meeting with representatives of 11 NGOs and advocacy groups. Topics discussed: environmental risk assessment, new breeding techniques and GMO risk assessment.</li> <li>Roundtable meeting with industry associations and representatives of the European Commission. Topics: access to submitted data, dialogue with applicants, and communication of EFSA's scientific opinions and press releases.</li> <li>Stakeholder Engagement Approach adopted in June. Implementation plan is being prepared. Registration launched in September.</li> </ul>
Institutional relations and scientific cooperation	European Commission  ○ Visit of Sabine Juelicher, Head of SANTE Directorate E, Food and feed safety, innovation, and Michael Scannell, Head of SANTE Directorate D, Food chain.  European Parliament  ○ Meeting with MEP Mariya Gabriel (BG, EPP).  ○ EFSA participated in the EU Bee Health Conference organised by the EP in June 2017 in Brussels.  Member States  ○ ED country visits: EFSA's ED visited the Netherlands on 6-7 June 2016 and Belgium on 28 June 2016. Topics: Framework Partnership Agreement (FPA) with RIVM on the implementation of Cumulative Risk Assessment of Pesticides was agreed; Joint project with Belgium 'Physico-chemical characterization and exposure analysis of the fraction of engineered nanomaterials in food additives in the context of risk assessment'.  ○ 28 <sup>th</sup> meeting of the Focal Point: new stakeholder engagement approach, 2017 G&P work programme, new Concept for Art.36 Networking and Management of the List.  EFSA's ED visited the French Agency for Food, Environmental and Occupational Health & Safety (ANSES) to meet the new Director General and to discuss cooperation with the Member States and Risk Assessment agenda.  ○ Visit of Francoise Weber, Deputy Director General of ANSES, and of an ANSES delegation to meet EFSA's Executive Director and discuss ANSES' cooperation with EFSA in the area of pesticides.  EU Agencies  ○ 7 <sup>th</sup> EU ANSA meeting in Brussels with the participation of Paul Rübig, MEP and Chairman of the Scientific Foresight (STOA) Unit of the EP Research Services on 1st July 2016.  ○ Interagency cooperation in different areas: ECHA and EFSA on Weight of Evidence framework, training session on guidance document on Uncertainty, joint communications activities in line with the HCIN's new approach, crisis workshop with ECHA's communications team.
International relations	<ul> <li>Visits of guest scientists from the Ministry of Health of Malaysia (FEED Unit, assessment of feed probiotics) and the New Zealand Ministry for Primary Industries (Nutrition unit, assessment of health claims).</li> <li>Participation in FSANZ' (Food Standards Australia New Zealand) 25<sup>th</sup> Anniversary Symposium in Canberra,</li> </ul>



	<ul> <li>Australia.</li> <li>International Food Safety Summit in Taipei (Bernhard Url, in combination with high-level meetings with the Council of Agriculture, the Bureau of Animal and Plant Health Inspection and Quarantine (BAPHIQ), and the Taiwan Food and Drug Administration).</li> <li>Training seminar under Pre-Accession Programme on basic concepts and methodologies of risk assessment Podgorica, Montenegro, organised by EFSA.</li> <li>EFSA participated at the conference: Improving Food Safety and Consumer Protection Following the EU Association Agenda: Experience of Georgia and Moldova (Tbilisi, Georgia, 28 July 2016).</li> </ul>				
Risk assessment capacity building activities	<ul> <li>EU Food Risk Assessment Fellowship Programme: call for tender to develop training modules launched in June.</li> <li>First PhD pilot kicked off with subject: research assistance for the development of in silico tools for human and ecological risk assessment of chemicals.</li> <li>One day Summer School (130 pp.) in EFSA, co-organised by University of Parma, EFSA, University of Barcelona, Istituto Superiore di Sanita' and Virginia Commonwealth University.</li> <li>BIOSAFE Summer School – 2 days student visit from Doctoral programme dealing with Biological Risk Assessment in food - co-organised by the Doctoral Schools of Università Cattolica del Sacro Cuore and Università degli Studi di Milano.</li> <li>Info session in EFSA on 15<sup>th</sup> of September for postgraduate students of Russia, Belarus and Ukraine, in cooperation with University of Parma.</li> </ul>				

### **CORPORATE - RESOURCES AND SUPPORT**

Strategy	based
services	

### Corporate business control (PTT)

- o Completed, first draft of the corporate performance dashboard providing strategic key performance indicators to guide EFSA strategy execution 2016-2020. Delivered a portfolio prioritization model based on fact-based project and process consumption data and strategic performance variables.
- Finalised the EFSA Process Architecture (EPA) containing the representation of the whole list of EFSA Macro Processes and along with a description of the macro processes, their scope, inputs and outputs and associated SOPs and WINs.

### <u>Independence</u>

o First compliance and veracity check of the procedure applied for the evaluation of ADoIs, SDoIs and ODoIs.



Strategy based services	<ul> <li>Talent management</li> <li>Successful go-live of 1<sup>st</sup> phase in May 2016 with a streamlined recruitment and onboarding tool: 3 job opportunities published, 2900 applications received, 20 e-offers sent to candidates. 2<sup>nd</sup> phase on the way with improved solutions for selecting WGs members, learning and development system, strategic workforce planning, new DoI assessment and validation engine.</li> </ul>
Expertise based services	Data protection  The DPO addressed data protection aspects in relation to Talent Management project, document management, whistleblowing guidelines, acceptable use policy of corporate communication tools & devices, staff directory on the EFSA website, use of SlideShare as dissemination tool.  Court cases  On 14 June 2016, EFSA was notified by the Court of Justice of the European Union the Order of its Vice-President ruling on the appeal and on the request for interim measures in case C-134/16 P R (R) brought by Chemtura Netherlands. The case had been brought by Chemtura Netherlands plc against the order issued in February this year by the General Court of the European Union in case T-725/15 R. In the order of the Court of Justice, the Court ruled in EFSA's favor by upholding the legality of the order under appeal and by condemning Chemtura Netherlands to pay for the costs of the appeal.  On 8 July 2016, EFSA lodged its rejoinder in the main case T-725/15, brought by Chemtura Netherlands plc against EFSA. In this case, the applicant challenges EFSA's decision partially rejecting the confidentiality claims of the applicant and publishing EFSA's conclusions on its website.  On 22 June 2016, EFSA lodged responses to questions posed by the General Court at the hearing held on 12 May 2016 in case T-177/13 brought by TestBiotech and Others against the European Commission. In this case, the applicant challenges the legality of the Commission's decision reviewing the authorisation process of the GM soy MON 87701 × MON 89788.  In case T-493/14, Mayer v EFSA, the written phase of the procedure was closed and the oral hearing was held on 6 July 2016 in Luxembourg. EFSA could expect a final judgment by the end of the year, early 2017 at the latest.  Ombudsman  On 30 August 2016, EFSA was notified a complaint for alleged maladministration in case 0747/2016/ANA brought by PAN Europe before the Ombudsman. The case concerns the process leading to the joint conference co-organised in 2014 by WHO and EFSA on the Threshold of Tox

Scientific Colloquium on Epigenetics (Valencia, 14-15/06/2016).



### Expertise based services

- o Annual conference of the International Pest Risk Research Working Group (Parma, 23-26/08/2016).
- o EFSA's information session in the context of Dioxins 2016 (Florence, 02/09/2016).
- o EFSA's information session in the context of Eurotox 2016 (Seville, 04/09/2016).

### Site management and outreaching services

o Brussels liaison office: a negotiated procedure was launched and awarded. The new office will be located in Square de Meeus and is operative from 1 September 2016.

#### **Talent Selection**

On 15 Sept., 443 posts were occupied and 7 job offers accepted by the selected candidates bringing the total to 450 posts filled-in out of the planned 470 posts (including Seconded National Experts). With regards to the Establishment Plan (Officials and Temporary Agents) the recruitment execution rate is at 97.6%, while that for Contract Agents is at 92.8%, leading to a total occupancy rate of Statutory Staff of 96.3%. This gives an overall recruitment execution rate, including Seconded National Experts (which is 80%) of 95.7%.

Staff Categories	Target 2016	Total Contracted and Offered
Temporary Agents and Officials (Establishment Plan)		
Executives, Managers & Officers (AD)	230	213
Assistants functions (AST)	100	109
Total	330	322
Contract Agents		
Officers functions (CA FG IV)	75	83
Assistants functions (CA FG I, II, III)	50	33
Total	125	116
Seconded National Experts	15	12
Total all staff categories	470	450

### Technology Services (PTT)

o Completed first successful intra-Agency procurement for shared services based on cloud technologies (more than 23 agencies subscribed more than €60 Mio of volume).



Exper	tise
based	services

o EFSA Hackathon innovation prize looked for developers and designers with innovative ideas for creating a mobile app that facilitates general public access information on EFSA's work. The winning application design will be awarded a prize of 20.000 €, the second 6.000 € and the third one 3.000 €. A roundtable discussion on "ICT-enabled innovation within public administration" will be organized on the occasion of the award ceremony.

### Transaction based services

#### IT Services (PTT)

o Achieved a high of 78% services delivered within service level agreement against the 2016 target of 60%.

### <u>Financial management</u>

On 31 August 2016,



### 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

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

**PMEM** – Post Market Environmental Monitoring

PRAS - EFSA Unit on Pesticides

**PPR** – EFSA Panel on Plant protection products and their residues

**QPS** – Qualified Presumption of Safety

RASA – EFSA 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 2016

### **Executive Summary**

#### This document includes:

- An overview of EFSA's results in the first eight months of 2016 on key performance indicators
- Detailed tables with figures and data referring to the period 1/1/16 31/08/16 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, 196 scientific outputs (228 same period previous year), 62 technical reports (68 same period previous year) and 39 Supporting publications (49 same period previous year) have been finalized / adopted, representing respectively 61%, 76% and 87% of the yearly target (respectively 58%, 81% and 78% in the same period of the previous year).

The updated forecast at the end of the year is to reach at least 100% of the scientific output target (A1, A2 & A3 together), and more than 100% of the technical reports and supporting publications targets.

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

Adoption timeliness for Activity 2 - evaluation of products, substances and claims subject to authorization - stands at 78%, and it will be challenging to reach the year-end target of 90%, in view of high workload, particularly in the pesticides area.

Financial performance at global level is 0.03% above the monthly plan for commitments and 3% below the monthly target for payments (global commitment is 75% and global payment at 57% of the total for the year). Commitments for Scientific Cooperation are below August plan and stand at  $\leq$ 5.62 million (58% of the yearly target). Scientific cooperation payments are above the August plan and stand at  $\leq$ 5.57 million (59% of the yearly target). The year-end forecast is to reach the targets for scientific cooperation commitments and payments.

For further details on financial performance, please refer to document mb1601005-i5 (Budget Execution & Transfers).



## Overview of Key performance indicators as of 31/08/2016

	Description	Traffic light	Comment
1	Scientific Outputs/Technical Reports Activity 1	8	21 outputs adopted and 5 technical reports finalised for A1 in the first 8 months of the year.  Current forecast to be reached at the end of 2016 is 96% for scientific output (47 vs 49) and 77% for technical report (17 vs 22).  Main reason: deadlines of some mandates have been postponed to 2017 and some mandates have not been received as initially planned.
2	Scientific Outputs/Technical Reports Activity 2	☺	170 outputs adopted and 43 technical reports finalised for A2 in the first 8 months of the year.  Current forecast to be reached at the end of 2016 is 101% (267 vs 265) for scientific outputs and exceeds 100% for technical reports (82 vs 47).
3	Scientific Outputs/Technical Reports Activity 3	☺	5 outputs adopted and 14 technical reports finalised for A3 in the first 8 months of the year.  Current year end forecast is to exceed the yearly target for scientific outputs (10 vs 5) and for technical reports (23 vs 13).
4	Supporting publications	☺	39 supporting publications finalised in the first 8 months of the year.  Current forecast for the end of the year is to exceed the target for supporting publications (59 vs 45).
5	Global Commitments & Payments rate		Global commitments 0.03% above and payments 3% below monthly target (for details, see document mb1601005-i2-Budget Execution & Transfers) – Global commitment rate is at 75% of the yearly target and global payment is 57% of the yearly target.  Current forecast for the end of the year is to reach the 100% target for commitments and 90% for payments execution.
6	G&P Commitments & Payments rate		Grants and procurements commitments below (-10%) and payments above (+8%) monthly plans (for details, see document mb1601005-i2-Budget Execution & Transfers) Current forecast for the end of the year is to reach 100% for G&P commitments and payments.
7	Adoption Timeliness Activity 1	©	Timeliness for scientific outputs under A1 is 100% aligned with target of 100%.
8	Adoption Timeliness Activity 2	8	Timeliness for scientific outputs under A2 is 78% below target of 90%.  Main reasons are: high workload in the pesticides area, prioritisation of tasks and complexity of the opinions.



9	% of press releases/web news items delivered within 20 WD of output adoption (new Wiley process)	8	Timeliness for scientific outputs published with communication activities is 64% below target of 95%.  Main reason: a new process started in 2016 for the publication of outputs with the external contractor Wiley which considers 28 WD instead of the 20WD of the current KPI. From June first data was available and the low result has to be considered as a trial period in order to understand where the process needs to be improved.
10	Traffic to EFSA WEB content	☺	Total nr. of visits to the EFSA website is 1.860.000 above the monthly target and representing 69% of the yearly target. Current forecast to be reached at the end of 2016 is more than 100%.
11	Subscribers to online products	<b>=</b>	Subscribers to online products at end of August is 33.744, slightly below the monthly target and representing 94% of the yearly target (36.000).  Current forecast to be reached at the end of 2016 is 97%.  Main reason is: With the setup of the specific platforms for Journal and careers, many subscribers to subscriptions products have been deleted from the current database and are invited to the new services.
12	Impact score	©	Impact score of articles dedicated to EFSA is 15.5, aligned with target range 5-20.  Current forecast to be reached at the end of 2016 is 100%.
13	Increase followers from social media platforms	☺	Nr. of followers from social media platforms (Twitter, LinkedIn, Youtube) at end of August is 34.971above yearly target.  Current forecast to be reached at the end of 2016 is to exceed the yearly target (36.000 followers instead of 27.730 followers initially planned).
14	Number of SNEs	<b>(3)</b>	14 SNEs were present at the end of August representing 93% of the target (15SNEs)  Current forecast to be reached at the end of 2016 is 73% of the yearly target (11vs 15).  Main reason is: New SNE application tool suspended from July till October 2016 slowing down the recruitment of new SNEs in order to replace the ones leaving this year.
15	Occupancy Rate	☺	Average Statutory staff occupancy rate is 94.8% slightly below the 95% yearly target.  Current forecast to be reached at the end of 2016 is to exceed the yearly target (95.2% vs 95%).



### Progress indicators: detailed tables

### **SCIENTIFIC ACTIVITIES**

Fig.1. Provision of scientific opinions and advice & risk assessment approaches (Activity 1) 01.01.2016 -31.08.2016 vs. Annual Target

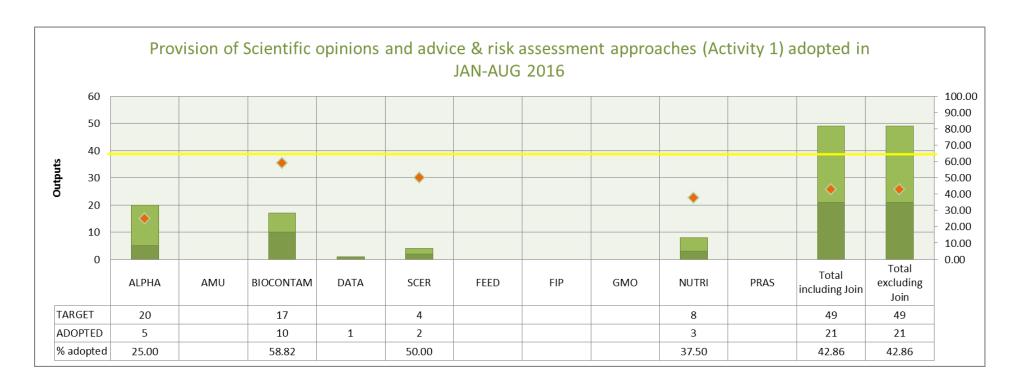




Fig. 2. Evaluation of products, substances and claims subject to authorisation (Activity 2), 01.01.2016 – 31.08.2016 vs. Annual Target

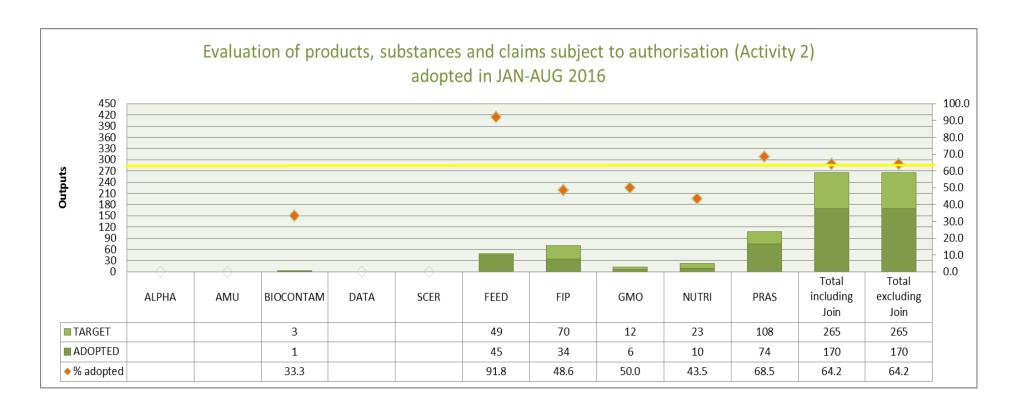




Fig. 3. Data Collection, Scientific Cooperation and Networking (Activity 3) 01.01.2016 – 31.08.2016 vs. Annual Target

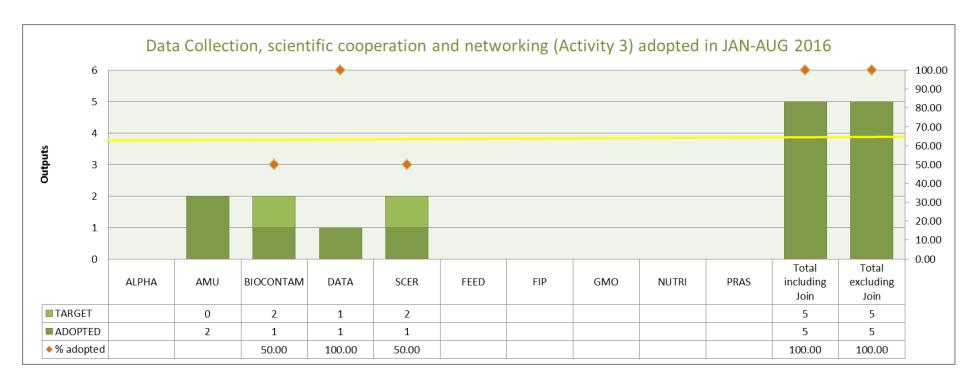
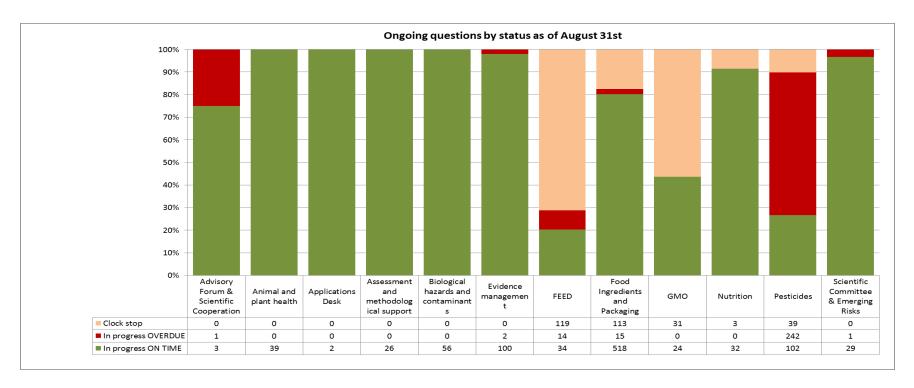




Fig. 4. Ongoing questions by status



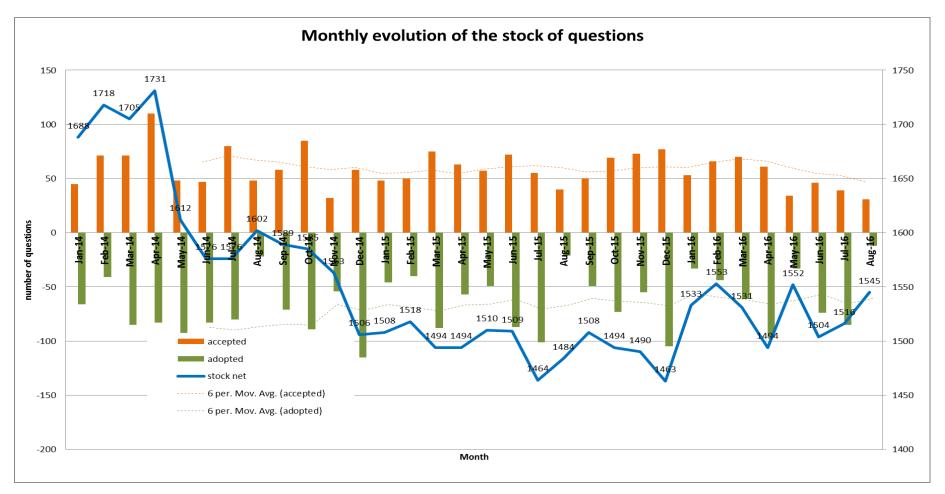
At end of August, 271 questions (linked to the adoption of EFSA Scientific Outputs) were overdue, +20% compared to May 2016 (224 questions) and -4% compared to December 2015 (280 questions).

Questions in clock stop status stand at 302 as of August with an increase (+2%) compared to May 2016 (295 questions) and a decrease (-28%) compared to December 2015 (415 questions).

<sup>&</sup>lt;sup>1</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.



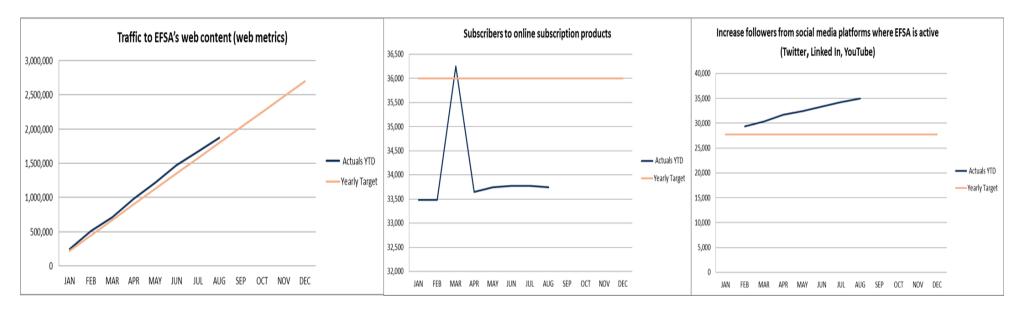
Fig. 5. Monthly evolution of the stock of questions



The stock of questions in the Register of Question system (RAW) at end of August 2016 is 1545, +5% compared to August 2015 (1484), and mainly related to Enzymes applications (40 questions received in the period).



Fig. 6. Evolution of selected Communication KPI





### Appendix to the EFSA Progress Report

### **EFSA** interaction with the European Ombudsman

### **Background**

At the 69<sup>th</sup> meeting held on 15 June 2016, the Management Board asked to receive information on the interaction of EFSA with the European Ombudsman (EO). This appendix to the EFSA Progress Report (mb161005-i1) aims to provide an overview on the on-going and past activities carried out by EFSA in pursuing the highest standards of good administrative practice while addressing the recommendations of the EO.

### Dialogue with the European Ombudsman

EFSA entertains regular contacts with the EO. In 2015, EFSA's Executive Director paid a bilateral visit to Ms Emily O'Reilly and exchanged views on a number of subjects high in EFSA's agenda, among which: EFSA's independence and management of conflicts of interests, the Open EFSA initiative and transparency measures applied by the Authority, application of the Article 16 of the Staff Regulations ("revolving doors") and relations with stakeholders. The meeting gave the opportunity to reflect around the challenges related to the long-term sustainability of EFSA's Panel system, as well as to the increasing demand for public scrutiny and greater stakeholders' engagement.

EFSA also cooperates with the EO at operational level in the context of the development of policy documents. The EO provided comments on the discussion paper "Transformation to an Open EFSA", and contributed in the past to the discussion held at the EFSA Stakeholder Consultative Platform on the review of EFSA's rules with a presentation on the management of conflicts of interests. The views of the EO were also sought by EFSA in the context of an impact assessment of the judgement of the Court (C-615/13 P) regarding data protection which EFSA leads under the real of the Interagency Network. In the report "Putting it Right? – How the EU institutions responded to the Ombudsman in 2014", the EO highlighted that EFSA replied to the only critical remark that the EO had on EFSA in a fully satisfactory manner, rating EFSA's overall compliance with her proposals at 100%.<sup>2</sup>

#### On-going case

Case n.	Complainant	Issue	Status
176/2015/JF	Non governmental organisation	Alleged failure to reply properly to questions related to the procedure for the authorisation of GM maize MON 810.	EFSA responded to the complaint with its opinion on the case. Pending feedback from the EO.
747/2016/ANA	Non governmental organisation	Alleged infringement of law, scientific procedural aspects and independence.	The complaint was notified to EFSA on 29 August. EFSA to submit an opinion by the end of October.

<sup>&</sup>lt;sup>2</sup> Putting it Right? – How the EU institutions responded to the Ombudsman in 2014: http://www.ombudsman.europa.eu/en/cases/followup.faces/en/61644/html.bookmark# ftn9



### Cases closed in the past two years

Case n.	Complianant	Issue	Conclusion
822/2016/DR	Private	EFSA failed to reply complainant's letters.	EO concluded that EFSA had to find a rapid solution to the issue (01/07/2016).
0048/2015/ANA	Private	Breach of the complainant right to be heard in the context of the scientific evaluation of its application dossier.	EO concluded that there was no maladministration by EFSA (24/09/2015).
0952/2014/OV	Non- governmental organisation	Public consultation on the reassessment of glyphosate.	EO concluded that there was no maladministration by EFSA (18/11/2015).
1493/2014/PMC	Private	Decision of the Staff Committee of EFSA.	Decision of the EO: the complainant has not brought forward valid grounds capable of challenging the position of the Staff Committee (4/11/2014).
346/2013/ANA	Non- governmental organisation	CoI of members of the working group on the guidance on environmental risk assessment of GM insects.	Decision of the EO: (1) EFSA failed to ensure that experts working in academia declare all relevant information to EFSA; (2) While acknowledging the "great efforts that EFSA put into improving its conflicts of interest rules", the EO asked EFSA to change its rules on DoIs and CoIs to ensure that they reflect the "evolving nature of academia" (28/01/2015).
OI/4/2013/CK	EU institution	Disclosure of the names of Selection Board members.	EO issued the Good Practice Guidelines for all EU Agencies encouraging them to proactively disclose the name of the members of the Selection Boards (19/05/2014). EFSA followed the recommendation.



0684/2012/JF	Private	Staff Regulations: person to be treated as dependant.	EO closed the inquiry welcoming EFSA acceptance of a friendly solution (25/03/2015).
2522/2011/VIK	Non- governmental organisation	CoI of members of the working group on Threshold of Toxicological Concern	EO concluded that there was maladministration by EFSA: EFSA failed to conduct an in depth, detailed investigation on the complaint (27/03/2014).
0397/2014/PMC	Private	Staff Regulations	EO decided the inadmissibility of claims due to submission of new complaints (16/06/2014).
140/2013/EIS	Private	Recruitment procedure	EO concluded that there wasn't maladministration by EFSA (09/04/2014)

EFSA will continue to maintain the current interaction with the EO with the aim to pursue the enhancement of the Authority's activity through the implementation of best administrative practices. EFSA would also aim to establish a close communication exchange within the context of the on-going discussion on the revision of its independence rules.