



# EFSA Consolidated Annual Activity Report **2018**

[In pursuance of EFSA FR Art. 47, FFR No 1271/2013]<sup>1</sup>

Adopted in Parma on  
For EFSA's Management Board

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Chair of the Management Board

<sup>1</sup> REGULATION (EU) No 1271/2013 of 30 September 2013 on the framework financial regulation for the bodies referred to in Article 208 of Regulation (EU, Euratom) No 966/2012 of the European Parliament and of the Council

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# List of abbreviations

<b>AHAW Panel</b>	EFSA Panel on Animal Health and Welfare
<b>ALPHA</b>	EFSA Animal and Plant Health Unit
<b>AMR</b>	Antimicrobial resistance
<b>AMU</b>	EFSA Assessment and Methodological Support Unit
<b>ANS Panel</b>	EFSA Panel on Food Additives and Nutrient Sources Added to Food
<b>APDESK</b>	EFSA Applications Desk Unit
<b>AT</b>	Austria
<b>BAU</b>	Business as usual
<b>BE</b>	Belgium
<b>BG</b>	Bulgaria
<b>BIOCONTAM</b>	EFSA Biological Hazards and Contaminants Unit
<b>BIOHAZ Panel</b>	EFSA Panel on Biological Hazards
<b>BUS</b>	Business Services Department
<b>CBC</b>	EFSA Corporate Business Control Team
<b>CEF Panel</b>	EFSA Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
<b>CEN</b>	Communications Experts Network
<b>COM</b>	EFSA Communications Unit
<b>COMCO</b>	EFSA Communication, Engagement and Cooperation Department
<b>CONTAM Panel</b>	EFSA Panel on Contaminants in the Food Chain
<b>CORSER</b>	EFSA Corporate Services Unit
<b>CRM</b>	Customer Relation Management Project
<b>DATA</b>	EFSA Evidence Management Unit
<b>DE</b>	Germany
<b>DEV</b>	Development projects
<b>DG SANTE</b>	Directorate General for Health and Food Safety
<b>DK</b>	Denmark
<b>DOI</b>	Declaration of Interest
<b>doi</b>	digital object identifier
<b>DTS</b>	Digital Transformation Services
<b>EC</b>	European Commission
<b>ECDC</b>	European Centre for Disease Prevention and Control
<b>ECHA</b>	European Chemicals Agency
<b>EE</b>	Estonia

<b>EEA</b>	European Environment Agency
<b>EFSA</b>	European Food Safety Authority
<b>EKE</b>	Expert Knowledge Elicitation
<b>EL</b>	Greece
<b>EMA</b>	European Medicines Agency
<b>EMAS</b>	Eco-Management Audit Scheme certification
<b>ENCO</b>	EFSA Engagement and Cooperation Unit
<b>ENP</b>	European Neighbourhood Policy
<b>ES</b>	Spain
<b>EU</b>	European Union
<b>EUAN</b>	EU Agencies Network
<b>FEED</b>	EFSA Feed Unit
<b>FEEDAP Panel</b>	EFSA Panel on Additives and Products or Substances Used in Animal Feed
<b>FIN</b>	EFSA Finance Unit
<b>FIP</b>	EFSA Food Ingredients and Packaging Unit
<b>FR</b>	France
<b>FTE</b>	Full-Time staff Equivalent
<b>GMO</b>	Genetically Modified Organism / EFSA GMO Unit
<b>GMO Panel</b>	EFSA Panel on Genetically Modified Organisms
<b>GPS</b>	Global Performance Services Unit
<b>HR</b>	Croatia
<b>HUCAP</b>	EFSA Human Capital Unit
<b>IAS</b>	Internal Audit Service of the European Commission
<b>IPChEM</b>	Information Platform for Chemical Monitoring
<b>IPPC</b>	International Plant Protection Convention
<b>IS</b>	Iceland
<b>IT</b>	Italy
<b>JRC</b>	Joint Research Centre
<b>JRC-IPSC</b>	JRC Institute for the Protection and Security of the Citizen
<b>LA</b>	EFSA Legal and Regulatory Affairs Unit
<b>MB</b>	EFSA Management Board
<b>MD programme</b>	Managers' development programme
<b>MP</b>	Methodologies Programme
<b>MRL</b>	Maximum Residue Level
<b>MS</b>	Member States
<b>NDA Panel</b>	EFSA Panel on Dietetic Products, Nutrition and Allergies
<b>NL</b>	Netherlands

<b>NO</b>	Norway
<b>NUTRI</b>	EFSA Nutrition Unit
<b>OECD</b>	Organisation for Economic Co-operation and Development
<b>OHSAS</b>	Occupational Health and Safety Assessment Series
<b>Open ScAIE</b>	Open Scientific Advanced Information and Evidence Hub
<b>PII</b>	Process improvement initiatives
<b>PLH Panel</b>	EFSA Panel on Plant Health
<b>PPR Panel</b>	EFSA Panel on Plant Protection Products and Their Residues
<b>PRAS</b>	Pesticides Unit
<b>PROMETHEUS</b>	Promoting Methods for Evidence Use in Scientific Assessments project
<b>PT</b>	Portugal
<b>RA</b>	Risk assessment
<b>RAMPRO</b>	Risk Assessment Methodologies Programme
<b>RASA</b>	EFSA Risk Assessment and Scientific Assistance Department
<b>RAW</b>	Risk Assessment Workflow
<b>REGPRO</b>	regulated products area
<b>REPRO</b>	EFSA Scientific Evaluation of Regulated Products Department
<b>ROA</b>	Rapid Outbreak Assessment
<b>SC</b>	EFSA Scientific Committee
<b>SCER</b>	EFSA Scientific Committee and Emerging Risks Unit
<b>SDWH</b>	Scientific Data Warehouse project
<b>SE</b>	Sweden
<b>SEA</b>	Stakeholder Engagement Approach
<b>SI</b>	Slovenia
<b>SSD2</b>	Standard Sample Description project
<b>TDI</b>	Tolerable Daily Intake
<b>TERA</b>	Transparency and Engagement in Risk Assessment project
<b>UK</b>	United Kingdom

# Legend

Status	Symbol	Thresholds
Over-achieved	●	Actual/Target more than <b>105%</b>
Achieved	●	Actual/Target between <b>95%</b> and <b>105%</b>
Moderate deviation	●	Actual/Target between <b>75%</b> and <b>95%</b>
Relevant deviation	●	Actual/Target less than <b>75%</b>
N/A	●	Data not available for this period

# Foreword

This annual report for 2018 records another year of great work and progress at the European Food Safety Authority (EFSA) and we must acknowledge the huge number of people both in Parma and across Europe that make this work possible. I want to thank all those individuals and organisations who contributed to EFSA's mission, to protect public health in Europe, in 2018.

Every 6 years, an external contractor is tasked to assess EFSA activities in its scientific, communication and engagement work. The report of the third independent evaluation of EFSA recognised its many achievements

The Management Board was pleased that the evaluators welcomed EFSA's new mechanisms for engagement with stakeholders, as well as its initiatives on access to data and a strengthened independence policy. EFSA's cooperation with Member State authorities and other risk assessors at international level was also praised. Based on the results of the external evaluation, the Management Board adopted a series of recommendations, which included: enhancing capacity for fit-for purpose scientific advice; bolstering communication activities to strengthen EFSA's reputation; and securing the long-term efficiency and sustainability of EFSA's operations.

As well as providing an opportunity for assessing past performance, 2018 was an important year for the future of EFSA. The European Commission proposed reforms to the General Food Law, under which EFSA was created in 2002.

The proposals included a number of important changes, particularly in the areas of governance and of transparency and confidentiality that could transform the way EFSA works

A positive outcome to the ongoing discussions, together with the necessary financial means to implement the new tasks, would allow EFSA to make a big step forward in the transparency of its scientific processes and the sustainability of its science production model.

That model relies of course on the commitment and dedication of the members of our Scientific Committee and Scientific Panels. These bodies were renewed in 2018 following a call that attracted more than 1,000 applicants. We were delighted to welcome our new cohort of experts, who will serve until 2021, and will see how best we can encourage more talented scientists from under-represented Member States to apply in the future.

For the expert panels' renewal process EFSA implemented the updated rules on independence developed following the adoption of the new independence policy in 2017. Guaranteeing the independence of EFSA's scientific work and experts remains a top priority for the Management Board.

It was a great privilege for me to attend EFSA's third scientific conference in Parma, which attracted more than 1,100 delegates from around the world and was followed by another 800 via live video link. The theme of Science, Food, and Society neatly encapsulated the broad nature of EFSA's role and responsibilities in today's increasingly interlinked world.

With EFSA's Strategy 2020 approaching its final phases, the Parma scientific conference marked the start of EFSA's reflections for the future and this, provided input into the development, together with our stakeholders, of the next EFSA Strategy. The results of the external evaluation and the forthcoming outcome of the General Food Law review proposal will feed into the definition of the next EFSA Strategy (2021-2027).



The year ended on a high note for the Management Board as at our final meeting we had the great pleasure of reappointing Bernhard Url as the EFSA Executive Director (ED). Bernhard has led by example over the last 5 years and has defined and driven a vision for EFSA's evolution, remaining as committed to excellence and collaboration now as when he was first appointed.

We look forward to continuing our journey together.

*Jaana Husu-Kallio, Chair of the EFSA Management Board*

DRAFT

# Introduction

Last year EFSA closed around 700 questions via scientific outputs and technical reports. We prepare all of these outputs with the objective of satisfying the needs of risk managers whilst at the same time engaging our stakeholders as much as possible in the scientific assessment process. So behind the headline statistics lie dozens of workshops, webinars and public consultations. This involves a considerable investment of resources, but the return we get on our investment is invaluable: a common understanding of the risk assessment process, and fit-for-purpose, timely and independent scientific advice that helps risk managers to keep Europe's food safe.

The substantial body of work described in these pages is above all a collaborative effort. At the centre of this effort are the scientific experts who make up our 10 scientific panels and Scientific Committee. In 2018, we renewed all the panels from a pool of more than 1,000 applicants. We thank the 28 EU Member States and all the institutions and organisations that help us to maintain our complement of scientific experts.

Collaboration was the main theme of what was for me the highlight of 2018: the EFSA scientific conference, which attracted around 1,800 between on-site and on-line participants. The collaboration was not just among scientists but between all relevant sectors of society: national policy-makers, academia, consumers, industry and others. The breadth and depth of the discussions was truly inspirational and reinforced my conviction that by working together openly but critically we can achieve great things.

Hovering over everything we did last year was the prospect of a revision of the General Food Law, the legislation which led to the creation of EFSA in 2002. The proposals tabled by the European Commission are brave and exciting. If implemented, they will significantly increase the transparency and accountability of the work carried out by risk assessors and managers. In particular, the proposals regarding the sharing of the data used in the assessment of pesticides could play an important role in building trust between citizens and policy-makers.

Against this backdrop our scientists continued to deliver outstanding work. Among the many highlights in 2018 were the important outputs in the field of animal health: an update on lumpy skin disease (LSD) showed that the vaccination programme recommended by EFSA in 2016 had reduced outbreaks in south-eastern Europe by 95%; and a scientific opinion on African swine fever (ASF) assessed measures to combat the disease. EFSA also began funding a project aimed at improving the monitoring of wild boar populations in Europe.

In the area of plant health EFSA stepped up its activities in support of the new Plant Health Law and efforts by the European Commission to minimise the threat to Europe's crops and plants from plant pests. The tiered approach to pest risk assessment continued with 46 pest categorisations and the launch of a consultation on new guidance to support commodity risk assessments of high-risk plants. The pest categorisation of *Xylella fastidiosa* included detailed information about the European outbreaks and the plant species affected. A full risk assessment is to follow in 2019.

Updated assessments of three neonicotinoid pesticides confirmed the risk to wild bees and honeybees posed by these substances and EFSA also evaluated the scientific basis for emergency authorisations of neonicotinoid use granted by seven Member States in 2017. The newly agreed terms of reference for the European Bee Partnership, brokered by EFSA, were presented at the European Parliament, a major step forward in consolidating Europe-wide efforts to halt the decline in bee numbers.

Assessments of regulated products once again accounted for the bulk of our published outputs – more than 500 out of a total of around 700. Notable in this area was the accelerated activity around novel foods, with the reception of more than 50 applications following the implementation of the new regulation on novel foods.

The EFSA Panel on Dietetic Products, Nutrition and Allergies (NDA Panel) reached a major milestone in its work on dietary reference values (DRVs) with an update of its scientific opinion on upper levels for vitamin D in infants. A special issue of the *EFSA Journal* brought together all 32 opinions on DRVs and we also developed a special online tool that gives nutritionists and others quick and easy access to the full results from the catalogue of opinions.

EFSA continued to make advances in the development of methodologies that will improve the quality and robustness of EFSA's risk assessments. Following the guidance documents EFSA published in 2017 on weight of evidence and biological relevance, the Scientific Committee (SC) finalised its guidance on uncertainty analysis in scientific assessments. The guidance is already being implemented in general scientific areas and will be phased into the assessment of regulated products over the next few years.

EFSA's efforts under its current strategy 2020 to foster a results-based approach (i.e. focussing on expected results and monitoring progress via a new set of outcome and impact indicators) have already started yielding relevant insights, but those insights were accompanied by a number of challenges; such as the setting of appropriate indicators and targets, the availability of relevant process performance data, and the making sense of deviations due to factors outside the direct control of EFSA. I am confident that the lessons learnt from this experience will lead to a more streamlined yet robust performance management framework to accompany EFSA's new strategy 2027.

My observations here merely skim the surface of the activities described in this report. I invite you to delve further into the different chapters to judge for yourself how EFSA made good on its obligations in 2018.

*Bernhard Url, Executive Director*

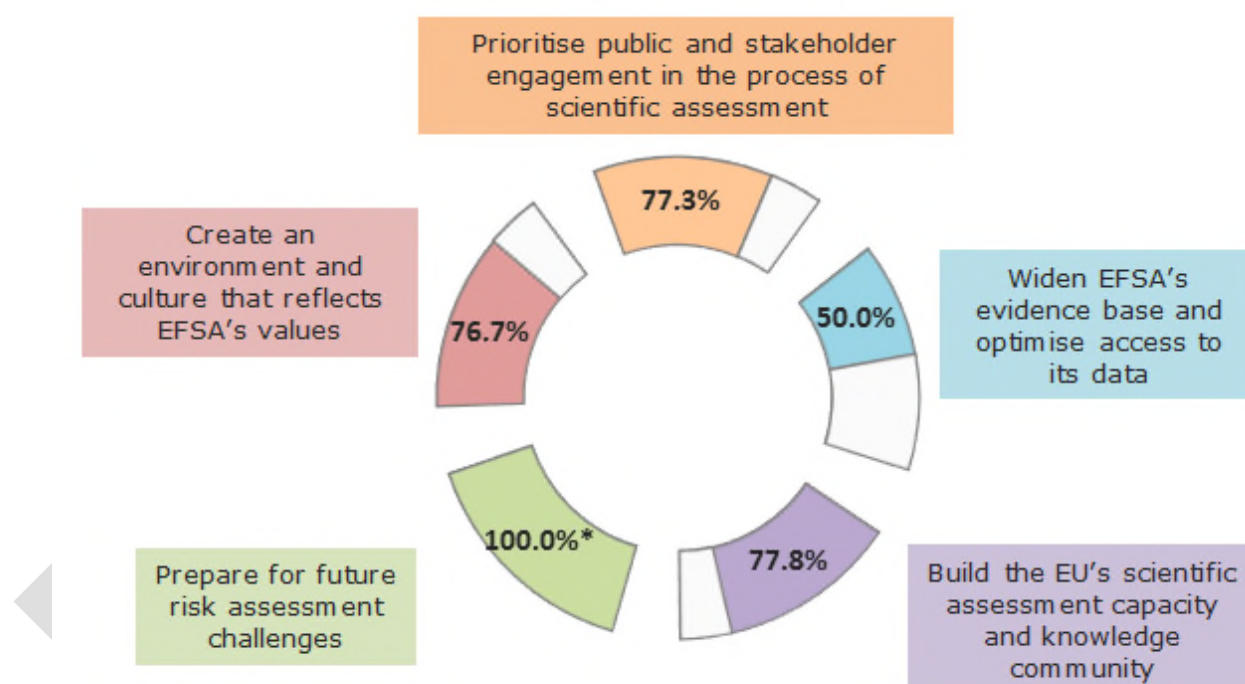
# Performance at a glance

In terms of compliance with the scientific-production deadlines, EFSA registered good results in all the strategic objectives (SOs), with the one exception of timeliness in the area of regulated products (83.6 % of the outputs were closed on time against a target of 90 %, but this delay was limited to few areas where significantly high workload is experienced).

The human resources (HR) and the budget employed in the production of scientific opinions were in line with the plans for 2018, and also with the introduction of a flexible resource-management approach to tackle the work peaks, leading to a shift of resources mid-year to the area of novel foods.

Finally, it is worth highlighting that EFSA fully respected its commitment to scientific independence, as all the declarations of interest (DOIs) of EFSA's scientific experts were submitted in compliance with the current rules.

**Figure 1:** % of indicators reaching (or surpassing) the target<sup>2</sup>



\* This performance is based only on 5 performance indicators

This operational performance is also reflected in the stakeholder satisfaction rate expressed in the latest EFSA survey: 71.1 % of the respondents were satisfied with the fitness for purposes of EFSA's scientific risk assessment.

Other significant achievements are the increased engagement of the public in the EFSA scientific work (testified by a higher than expected number of comments received

<sup>2</sup> Against measured indicators only.

through public consultations), as well as a marked improvement in the timeliness for the publication of EFSA's scientific outputs in the *EFSA Journal*.

EFSA also continued with its efforts in promoting scientific cooperation at European and international level, organising more cooperation activities than originally planned, which helped in increasing the number of research projects in which EFSA is participating.

Finally, EFSA continued with its efforts to make its production model more efficient, as the investments in IT are already paying off by enhancing and facilitating collaboration, evidenced for example by the considerably higher share of teleconference meetings.

One area that deserves attention is the low awareness of EFSA's customers and stakeholders on the Authority's efforts to increase data accessibility and re-usability, largely accounting for the lower score achieved in that strategic objective compared to the others (Figure 1). This has been impacted also by delays in key projects due to resource constraints and external factors, particularly the MATRIX project, which will allow the electronic submission of dossiers via structured data, and therefore their eventual accessibility. Actions to increase the awareness in these areas are already underway and the upcoming Customer/Stakeholder satisfaction survey to be launched in the first months of 2019, will give EFSA the opportunity to assess its progresses.

EFSA efforts to foster a results-based approach to e.g. focus on expected results and monitoring progresses through a new set of outcome and impact indicators has already started yielding relevant insights that were not available before the setup of the strategy 2020, when performance monitoring was activity-based. This effort has also been accompanied by a number of challenges, such as: setting appropriate indicators and targets, the availability of relevant process-performance data in line with the Authority new process architecture, and in making sense of larger-than-usual deviations due to factors out of EFSA's direct control. EFSA is also collecting lessons learnt from this experience, to ensure a more streamlined, yet comprehensive, performance monitoring framework in the development of the new Strategy. Detailed analyses of EFSA's performances can be found in the sections dedicated to each of the five strategic objectives that the Authority is pursuing.

# Section I — Work programme achievements

## 1. Prioritise public and stakeholder engagement in the process of scientific assessment

EFSA's scientific advice supports the decision-making process of the risk managers at the European Commission and in the Member States in the areas of general risk assessment for food and feed, plant health, animal health and welfare and nutrition. EFSA's mandate also covers the regulated products risk assessment which takes place before their authorisation in the EU market. These are substances in food and feed, food contact materials, pesticides, genetically modified organisms, food-related processes and processing aids and the evaluation of the scientific substantiation of nutrition and health claims made for these products and processes.

In the area of provision and communication of scientific advice for general risk assessment priorities and regulated products, the year 2018 was rich in achievements, the details of which are outlined in Annex IV. The opinions and reports reflect the efforts to improve risk managers satisfaction and prioritise stakeholders' engagement in the scientific assessment processes. EFSA's activities aim to improve stakeholders' involvement to ensure a common understanding of the risk assessment process, to guarantee access for EFSA and stakeholders to all available data and information, to promote transparency and ultimately to assist the risk managers with fit for purpose, timely and independent scientific advice.

In 2018 EFSA closed 118 questions through scientific outputs and 37 questions through technical reports for a total of 155 questions in the area of general risk assessment, while in the regulated products area 475 questions were closed through scientific outputs and 44 through technical reports, for a total of 519 questions. Detailed information on the scientific production per food sector area is provided in Annex IV. Highlights of EFSA's achievements in 2018 are presented in the sections that follow.

### 1.1. Highlights of 2018 achievements

#### 1.1.1. General risk assessment

##### Animal health and welfare

- Animal welfare

In June, EFSA published an updated guidance on the assessment criteria for applications for new or modified stunning methods regarding animal protection at the time of killing. According to the updated guidance, any modified protocols of existing stunning methods or new stunning methods shall ensure a level of animal welfare at least equivalent to that ensured by the existing ones.

- Lumpy skin disease (LSD)

In 2018, EFSA gave an update on the occurrence of LSD, the effectiveness of vaccination and analysed the risk factors for its spread in south-eastern Europe. The outbreaks of

LSD in the Balkan region fell consistently by 95 % <sup>(3)</sup>, confirming that vaccination of cattle, as recommended by EFSA in 2016, is the most effective way to contain the disease.

- African Swine fever (ASF)

The ongoing work on ASF culminated in a scientific opinion where the density of the wild boar population in Europe was investigated. Measures to reduce it and keep infected wild boar away from uninfected ones was assessed. In order to fill knowledge gaps, EFSA is additionally funding a project, [ENETWILD](#), aimed at improving data on the geographical distribution and abundance of wild boar across Europe. A scientific report was published in November and focussed on recommendations for ASF control.

### Plant health and plant diseases

The tiered approach for assessment of plant health risks for EU territory continued during the reported year. This was done via a two steps approach:

1. Pest categorisation and fast assessment for around 133 individual pests plus large taxonomic or crop groups.
2. Quantitative pest risk assessment, implemented at the risk managers' request and based on Step 1 results.

The EFSA Plant Health (PLH) Panel adopted 46 pest categorisations and worked on two quantitative pest risk assessments: *Xylella fastidiosa* and the fall army worm *Spodoptera frugiperda*. The work on the categorisation of the large groups for the non-EU viruses and viroids of the plant genera *Vitis*, *Malus*, *Pyrus*, *Cydonia*, *Fragaria*, *Rubus* and *Ribes* has started through a tasking grant signed with the National Research Council (Italy) [Consiglio Nazionale delle Ricerche (Cnr)].

- Risk assessment of high-risk plants

A technical report was published detailing the information needed in an application for risk assessment of high-risk plants. In addition to this, guidance on how to conduct the commodity risk assessment was endorsed for public consultation by the Plant Health Panel and a public consultation was launched in December.

- Horizon scanning for new plant health threats

The horizon scanning project for new plant health threats continued in 2018, with the delivery of monthly media monitoring newsletters for the Commission and Member States. The newsletters provide an update on the most recent findings on regulated and new plant pests threatening the EU. Work is ongoing to extend this project also to literature monitoring. In particular, the Joint Research Centre (JRC) is improving the automated search for scientific literature in the Medisys platform. Two 'tasking' grants with the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) have started to support this mandate in the areas of risk ranking/prioritisation and automated literature monitoring.

- *Xylella fastidiosa*

EFSA's Panel on plant health has updated its pest categorisation of *X. fastidiosa*. The update includes not only the latest information on the biology and distribution of *X. fastidiosa* inside and outside the EU together with the presence and distribution of insect vectors in Europe, but also detailed information about the European outbreaks and the plant species affected. The new full risk assessment of *X. fastidiosa* will be finalised in early 2019.

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<sup>(3)</sup> From 7 483 in 2016 to 385 in 2017.



## Zoonoses and antimicrobial resistance

The EU summary report on antimicrobial resistance in zoonotic and indicator bacteria from humans, animals and food for 2016 was published as expected at the beginning of 2018 by EFSA and the European Centre for Disease Prevention and Control (ECDC). The report highlights that antimicrobial resistance in zoonotic bacteria is still high in humans, animals and food and confirms that antimicrobial resistance is one of the biggest threats to public health, mainly due to the reduction of the effectiveness of treatment options.

The EU summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks for 2017 was published by EFSA and the European Centre for Disease Prevention and Control in December 2018. Comparing 2016 with 2017 data, it appears that only minor fluctuations in reported cases of three main zoonotic diseases in the EU were highlighted. The number of reported cases of salmonellosis and campylobacteriosis has remained stable over the past 5 years, although listeriosis continues to rise. *Salmonella* Enteritidis caused one in seven foodborne outbreaks. During 2013-2017, the number of infections due to *S. Enteritidis* in humans mirrored an analogous trend in laying hens.

The EU summary report on surveillance for the presence of transmissible spongiform encephalopathies (TSE) capturing data from 2017 was published in November 2018.

The report highlights:

- (i) no case of classical bovine spongiform encephalopathy (BSE) and six cases of atypical BSE reported;
- (ii) increase of scrapie cases in sheep and decrease in goats;
- (iii) no cases of chronic waste disease (CWD) in any of the tested cervids in the EU (however 11 cases of CWD were reported in Norway).

## Biological hazards

- Chronic wasting disease (CWD) - update on detection methods and occurrence

An opinion on Chronic Wasting Disease (part II) was adopted by the EFSA Biohaz Panel, concluding that diagnostic methods used in Norway were able to detect CWD in reindeer, moose and red deer in 2016 and 2017. EFSA experts could not rule out the possibility that the disease was present in Europe before the CWD 2006-2010 survey was conducted, despite no cases being detected.

- Updated quantitative risk assessment (QRA) of the bovine spongiform encephalopathy (BSE) risk posed by processed animal protein (PAP)

The opinion assessed the impact of quantitative real-time polymerase chain reaction method on the limit of detection of official controls when searching for constituents of ruminant origin in feed. The results of the applied models estimated that the total BSE infectivity was four times lower than that estimated in 2011 and that there would be an approximate 50% increase in the feed containing material of ruminant origin that would not be detected via official controls, if the threshold was set at 100 DNA copies.

- Food safety: a simplified approach to make food donation easier

EFSA supported the Commission in the development of a new food safety management approach that simplifies food donations for small retailers. The simplified system would mean that retailers are not required to have detailed knowledge of specific hazards. It includes steps for checking that donated food is safe, such as maintenance of the cold chain and ensured the exchange of information between donors and recipients.



## Contaminants in food

- Revised safe intake for  $\alpha$ -monochloropropane diol (3-MCPD) in vegetable oils and food

In the area of contaminants in food, EFSA's experts have updated their scientific approach to reassess the possible long-term adverse effects of 3-MCPD on the kidney and male fertility with updated dose-response analysis method. The safe level increased from 0.8 to 2  $\mu\text{g}/\text{kg}$  body weight (bw) per day and EFSA concluded that exposure to 3-MCPD in food is considered safe for most consumers but that there is potential health concern among high consumers in younger age groups.

- Opium alkaloids in poppy seeds assessment updated

An update on the opium alkaloids in poppy seeds risk assessment confirmed many previous findings such as the fact that the Acute Reference Dose (ARfD) of 10  $\mu\text{g}/\text{kg}$  of body weight may be exceeded by consumers of large amounts of seeds or food containing unprocessed poppy seeds, with uncertainties identified due to the limited information on the occurrence levels.

- Veterinary drug residues - non-compliance remains low

In the context of veterinary drug residues – non-compliance remains low. As published in June, the 2016 monitoring data for a range of veterinary medicines, unauthorised substances and contaminants found in animals and animal-derived food suggest an increase of the compliance rates. The EU monitoring of these substances is important to protect consumers and animals by ensuring a high degree of compliance with EU regulations.

- Dioxins in food and feed

EFSA set a new tolerable weekly intake (TWI) of 2  $\text{pg}/\text{kg}$  -bw per week. Exposure estimates exceeded the TWI across all age groups.

- Perfluorooctane sulfonic acid and perfluorooctanoic acid in food

Further to the European Commission request to reassess the risks that perfluoroalkylated substances (PFAS) pose to human health using data that has become available since its original assessment in 2008 a first scientific opinion was delivered. It concerns the main PFAS, known as perfluorooctane sulfonate (PFOS) and perfluorooctanoic acid (PFOA), two chemical contaminants to which humans are exposed through the food chain as a result of environmental pollution. The CONTAM Panel proposed to revise the tolerable intakes for these two chemical contaminants. The conclusions are provisional and will be reviewed, once the remaining PFAS are assessed in 2019.

## Rapid outbreak assessments

- *Listeria monocytogenes* outbreaks

An assessment done in March by EFSA and the ECDC concluded that frozen corn is the likely source of an outbreak of *Listeria monocytogenes* which has affected five EU Member States since 2015. The report recommended further investigations to identify the exact point of contamination in the food chain. An update done in July concluded that, besides frozen corn, it is possible that other frozen vegetables are the likely sources of the outbreak. Immediate withdrawal and recall of products followed to reduce the risk of human infections and to contain the outbreak. Consumers were advised to adequately heat frozen vegetables that are not ready-to-eat products.

In addition to the above, the likely source of an outbreak of *Listeria monocytogenes* that has affected Denmark, Germany and France since 2015 was found in the ready-to-eat cold-smoked and marinated salmon products. EFSA and the ECDC used whole genome

sequencing to identify the multi-country outbreak. Pregnant women, the elderly and the immunocompromised people are at higher risk of contracting listeriosis.

- Multi country *Salmonella Agona* outbreak possibly linked to ready-to-eat food

Five European countries have reported 147 people infected with the strains of *Salmonella Agona* between 2014 and 2016. EFSA and ECDC experts suggested that ready-to-eat products containing cucumbers and prepared in the United Kingdom, may be the source of the infection. The experts could, however, not identify the specific point in the production chain where contamination took place and warned that new cases might occur.

## Nutrition

- Tolerable Upper Intake Level of dietary sugars– Assessment protocol endorsed

Following an extensive public consultation and a stakeholder meeting counting approximately 60 participants, the NDA Panel endorsed a protocol in June which defines the approach it plans to use for collecting data, appraising the evidence, and analysing and integrating the evidence in order to draw conclusions that will form the basis for the opinion on dietary sugars.

- Update of the tolerable upper intake level for vitamin D for infants

A scientific opinion on the Tolerable Upper Intake Level for vitamin D that is unlikely to pose a risk of adverse health effects for infants (aged 0 to <1 year) was released in June. The opinion confirmed the value that was set in the EFSA opinion in 2012 only for infants up to 6 months (25 µg/day) and set the value of 35 µg/day for infants 6–12 months.

- The appropriate age of introduction of complementary feeding into an infant's diet

The NDA Panel is implementing its assessment protocol, i.e. for systematic literature review conducted, selection criteria for pertinent studies, the study population considered, the outcomes/endpoints addressed, and the criteria for appraising scientific evidence, in order to draw conclusions that will form the basis for the opinion on the appropriate age of introduction of complementary feeding into an infant's diet. The draft opinion is planned for release for public consultation and finalisation by July 2019.

- Dietary Reference Values (DRVs)

[Dietary Reference Values Finder](#) - EFSA has launched an interactive tool that gives quick and easy access to EFSA's dietary reference values (DRV) for nutrients. It is intended for end users of these values, such as nutrition and health professionals, risk managers, policy-makers, food manufacturers and scientists. The DRV Finder searches by population group or nutrient, allowing users to extract and combine the precise information they need from the 32 opinions on DRVs that EFSA NDA Panel has adopted in recent years.

## Food contact materials

- Phthalates

Following a European Commission mandate, the assessment of 5 phthalates authorised for use in food contact materials is being conducted by the working group established to study the phthalates. However, due to the complexity of the combined assessment of the different phthalates, both in terms of toxicology and exposure, the EFSA Panel on Food Contact Materials, Enzymes and Processing Aids ('CEP Panel') decided to submit the draft opinion to a 8-weeks public consultation in February 2019. The opinion is expected to be finalised by mid-2019.

### 1.1.2. Regulated products evaluation

#### Support to applicants

In the context of enhancing dialogue with applicants, several support initiatives were organised by EFSA. The pilot phase of the pre-submission administrative check of dossiers from small and medium-sized enterprises (SMEs) was concluded. A total of 5 teleconferences<sup>4</sup> were organised. The Pilot gave support to SMEs before the submission of their applications in two areas of regulated products: novel foods and feed additives. The purpose was to analyse the feasibility of implementing such a service in all regulated product areas, assessing the impact in terms of resources, as well as expected benefits and constraints to both EFSA and applicants.

In the scope of [EFSA's catalogue of support initiatives](#), the 5<sup>th</sup> Round table with Industry Associations was held in Brussels, hosting 29 industry associations. A webinar on guidance document on safety of feed additives for target animals was also held to explain new aspects and approaches to provide evidence of the safety of the additives, and to convey some helpful tips to prepare suitable submissions and perform solid risk assessments. The webinar was attended by 107 stakeholders simultaneously connected online.

In addition to the above, 68 support initiatives were organised to assist applicants with the submission process while 362 applications for regulated products were received and reviewed for completeness. Overall, 435 individual replies to requests for information were provided showing a 28% increase with respect to 2017 (341 requests) and an almost constant increase, even if lower, can be observed since 2015 with a small drop only in 2016, demonstrating a growing interest in EFSA's activities on regulated products and increased awareness of the applicants about the tools that are in place to facilitate contact with EFSA.

- Food enzymes

In order to increase productivity, a pilot project based on the lean methodology<sup>5</sup> was started. The goal was to identify any room for improvement in the current scientific production process to increase the number of scientific opinions produced per year. The first results, at the year end, showed that production capacity increased in line with the original objective of doubling the number of opinions on enzymes adopted by the CEP Panel compared to the historical baseline.

- Food additives

In response to a request from the EC for an assessment of four recent toxicological studies on titanium dioxide, EFSA provided a scientific opinion on the impact of these new findings on the re-evaluation of the food additive E 171. Calls for technical and toxicological data have been published during the year: one on sweeteners, another one on sodium aluminium silicate (E 554) and potassium aluminium silicate (E 555) and 15 calls for data for 18 foods additives permitted in foods for infants below 16 weeks of age.

- Genetically modified organisms (GMOs)

Following a mandate from the European Commission, EFSA prepared a Technical Note reflecting the current knowledge to generate and verify, in a standardised manner, DNA sequencing data including next generation sequencing data in the context of risk assessment (RA) of genetically modified (GM) plants.

<sup>4</sup> 3 for novel foods and 2 for feed additives.

<sup>5</sup> The [lean methodology](#) is a business methodology that promotes the flow of value to the customer through two guiding tenets: continuous improvement and respect for people.

This Technical Note puts together requirements and recommendations for when DNA sequencing is part of the molecular characterisation of GM plants, in particular for the characterisation of the inserted genetic material at each insertion site and flanking regions. As of October, the Technical Note replaces the Joint Research Centre guidelines related to the sequencing quality of genetic modifications.

#### ■ Pesticides

As a follow up of a previous assessment, the maximum residue levels (MRL) of glyphosate in food was reviewed, considering the new toxicological reference values proposed by EFSA in 2015 and covering all uses authorised by EU Member States and import tolerances.

Regarding the risk of neonicotinoids to bees, EFSA updated the assessment confirming the risk. Innovative approaches were applied to viewing the results per usage and scenario, and the way variability and uncertainties of the assessment were presented. In addition, EFSA examined the scientific basis for emergency authorisations of neonicotinoids granted in seven EU Member States until 2017.

As part of collaboration with the European Chemicals Agency (ECHA) and MSs through the pesticides steering network, both agencies have launched their first parallel public consultations. They addressed the pesticide risk assessment under EFSA remit, and a harmonised classification and labelling by rapporteur Member States, under the ECHA's remit. Additional improvements in the peer review process were undertaken by providing support to rapporteur Member States in all phases of the assessment process.

Moreover, EFSA published the scientific basis of recommendations prepared for the Codex Committee on Pesticides Residues (Codex) 2018 meeting. The recommendations helped the European Commission discussing international harmonisation and trade issues related to pesticides residues, and their risks to European consumers.

Finally, the publication of the EU report on pesticide residues in food contained a [graphical tool](#) to facilitate the view of the main findings by country and food product.

#### ■ Feed Additives

In November 2018 a meeting was organised with the EU association of specialty feed ingredients and their mixtures (FEFANA asbl), the European association for bio industries (EuropaBio) and the association of manufacturers and formulators of enzyme products (AMFEP) representatives and industry stakeholders. The purpose of the meeting was to address some questions stemming from the EFSA Feedap Panel on the *Guidance on the characterisation of microorganisms used as feed additives or as production organisms* and related to whole genome sequence in the RA of microorganisms, antimicrobial resistance and DNA analysis in fermentation products.

### 1.1.3. Stakeholders' engagement and communication

#### Stakeholder engagement

The review of the pilot-phase of the Stakeholder Engagement Approach (SEA) covering the period June 2016 – December 2017 was presented to the Management Board in March. Good progress was achieved in the implementation of the targeted and ad hoc mechanisms for stakeholder engagement, such as the annual roundtable with NGOs and discussion groups on data collection for bee-health and on emerging risks or the communicators' lab. SEA is a two-way process that allows EFSA to benefit from stakeholders' knowledge, data and expertise, and to contextualise its science and to anchor its outputs closed to the society. The Board agreed that SEA is delivering on its objectives and acknowledged that stakeholders are generally satisfied with the approach. The Management Board decision establishing SEA was amended to allow the election of

alternate members of Stakeholder Bureau. This change came as a follow up on recommendations arising from the mid-term report focussing on the stakeholder engagement activities implemented during the period from June 2016-November 2017. The interim report provided EFSA and its Management Board with an overview of how the registration system, categories of stakeholders, and engagement mechanisms delivered against expected results. The Management Board Members have regularly attended both the stakeholder bureau meetings (April and October) and the Stakeholder Forum meeting (November). The Chair of the Management Board welcomed participants at the Stakeholder Forum and contributed to discussions at the break-out sessions. The members of the stakeholder bureau have a prominent role in the shaping of the programme and the facilitating of break-out sessions on transparency, access to data, research priorities and risks communication.

- Food chemical occurrence data: nominations for stakeholder group

The 5<sup>th</sup> meeting of the [EFSA Stakeholder Discussion Group on Food Chemical Occurrence Data](#) took place with presentations on the new EFSA stakeholder engagement approach, open data, as well as hands-on training on data reporting of food additive usage data to EFSA. The discussion group meets at least once per year to enable EFSA to utilize stakeholders' specialist knowledge and data in the field of chemical usage and occurrence in food.

Several activities aimed at collaborating with stakeholders were implemented in the area of food additives. Authors of four publications on titanium dioxide were, for example, invited to the open plenary meeting of the EFSA Panel on Food Additives and Nutrient Sources added to food ('ANS panel') to present their findings and comment about their relevance on the safety assessment of the food additive E 171. In addition to this, a stakeholder workshop on data requirements for food additives used in foods for infants below 16 weeks of age was successfully organised.

- Ask EFSA service

Ask EFSA is the online service which provides individual responses to citizens that wish wanting to know more about EFSA's work. Questions are submitted through the dedicated web form which is accessible via EFSA's website. EFSA manages this service with the support of a network of over 30 'Ask EFSA' contact points in the organisation. In 2018, over 900 queries were handled and it took, in average five working days to provide responses to requestors.

A number of key initiatives were taken to improve the efficiency of the service:

- update of the Ask EFSA standard operating procedure to streamline the process and ensure quality and timely responses are provided to citizens' queries;
- compliance with new data protection rules;
- update of the content and design of the Ask EFSA Q&A section on the website;
- enhanced technical functionalities implemented in the risk assessment workflow (RAW) and the 'Ask EFSA' functional mailbox;

## Media and social media

EFSA's press office organised and supported 14 interviews with the Executive Director and 82 interviews with EFSA staff members on a variety of corporate and scientific issues. Interviews appeared in high profile media including Nature, Euronews, Der Spiegel, Politico, and a range of other national, regional and specialised publications. Approximately 700 media enquiries were processed in total in the reported year. Activities and contribution to the European Parliament's PEST Committee were coordinated by EFSA. They included a visit of the Committee to EFSA in Parma, two public hearings in Brussels, and responses to over 100 Committee questions about EFSA's work on pesticides.



Increasing the outreach and impact of EFSA's work was a core goal of the Authority's social media activities. A new application to facilitate greater sharing on social platforms was successfully introduced for EFSA staff. Social media was one of the main sources in attracting attendees to EFSA's Scientific Conference, while #EFSA2018 became a trending hashtag in Italy during the event.

### Content production and dissemination

Efficiency gains were implemented through: the rollout of Scholar One Manuscripts, an industry-standard editorial workflow platform; membership of the ORCID (author identifier) network; amendment of EFSA's reference style to reduce manual effort; and introduction of simplified output template system. The Journal moved to the Atypion platform which further improves the visibility and impact of EFSA's work. The *EFSA Journal* reached an important milestone when its inclusion in the Scopus database was confirmed and EFSA's authorship guidelines were listed in the National Academy of Sciences best practice list (TACS).

Key news stories from 2018 included items on pesticides – neonicotinoids and bees, glyphosate, EU pesticide residues report, endocrine disruptors – African swine fever, dioxins in food and feed, nanotechnology, 3-MCPD in vegetable oil, *Listeria*, DRVs for sodium, lumpy skin disease and the renewal in July 2018 of the EFSA Scientific Committee and all ten panels. A new dedicated social science function produced important first results including the EFSA guidance document on the communication of uncertainties in scientific assessments.

During the reported year EFSA continued to generate impactful and relevant multimedia and design products, including scientific posters, videos and flash interviews. An animation on African Swine Fever was viewed over 50,000 times, while a new data visualisation allowed audiences to explore the findings of the annual report on pesticide residues in foods in a simple but effective way.

Continuous improvement actions continued on the website and, as part of the Digital Collaboration project, pilot tests were launched on new platforms were launched with the long-term aim of improving collaboration and the exchange of knowledge amongst EFSA staff and external partners. The website was indexed in Google News, increasing content visibility alongside other improvements to the search function and email alerts. Better promotion of open meetings on the website homepage was implemented to improve transparency and a new mobile-friendly layout for the Topic pages was introduced, providing better access to information on different scientific topics.

## 1.2. Performance indicators

### 1.2.1. Intermediary impact indicators

**Table 1:** Intermediary impact indicators for SO1

KPI	Indicator	Baseline	Target 2018	Execution 2018		Status
<b>Intermediary impact:</b> Increased satisfaction of stakeholders regarding EFSA's scientific outputs (for EC/MS risk managers and stakeholders) and the scientific assessment process and communication tools and material						
Satisfaction via feedback surveys: positive and relative qualitative improvement (with regard to follow-up actions)	Risk managers (EC/MS)	81.6% <sup>6</sup>	N/A <sup>7</sup>	81.6%		●
	Stakeholders	74.7% <sup>8</sup>	N/A. <sup>9</sup>	74.7%		●
	Applicants	N/A <sup>10</sup>	N/A. Baseline set in 2018.	78.4%		●
User satisfaction rating of communication tools and materials	EFSA Journal	70%	80%	83%		●
	Other communication products	76.9% <sup>11</sup>	N/A.	76.9%		●
Impact of media coverage (EFSA's coverage in the media, including the favourability of articles)		18 <sup>12</sup>	22	16		●

### 1.2.2. Outcome indicators

**Table 2:** Outcome indicators for SO1

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Outcome:</b> Enhanced outreach of communication					
Social media effectiveness	Increase followers from social media platforms	40,742 (2016)	+10% <sup>13</sup> (60,745)	79,852	●
	Social interactions	14,881	+20% <sup>14</sup>	59,747	●

<sup>6</sup> Satisfaction rate comes from the customers/stakeholders survey launched in September 2017.

<sup>7</sup> Baseline set in 2018. Yearly survey.

<sup>8</sup> Satisfaction rate comes from the customers/stakeholders survey launched in September 2017.

<sup>9</sup> Status is N/A since results are coming from two different surveys, hence any comparison might be misleading. Yearly measurement. Baseline set in 2018 using the result from the Customers/Stakeholders Survey launched in September 2017.

<sup>10</sup> EFSA changed the approach in collecting feedback from applicants following comments received on a perceived survey fatigue and in order to tackle a low response rate. Due to synergies with the Customer/Stakeholder Feedback exercise (which was sent also to representatives of food industries), EFSA decided to take the satisfaction rate coming from this survey for measuring the indicator. Satisfaction rate comes from the Customers/Stakeholders Survey launched in September 2017.

<sup>11</sup> Satisfaction rate comes from the Customers/Stakeholders Survey launched in September 2017. Baseline set in 2018. Yearly measurement.

<sup>12</sup> 2017 result was 13.65.

<sup>13</sup> Increase calculated on the basis of 2017 execution (55,223).

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
		(2016)	(44,089)		
	Traffic to EFSA web content from social media	2.6% 63,464 (2016)	+20% <sup>15</sup> (80,004)	67,904	●
Traffic to EFSA's web content (web metrics): number of sessions		2,9 million	+0.5% <sup>16</sup> (3,200,534)	3,776,676	●
Number of subscribers to online subscription products (newsletter and alerts)		33,934 (2016)	+1% <sup>17</sup> (36,273)	34,068	●
Impact, visibility and discoverability of EFSA's scientific outputs <sup>18</sup>	access	Under definition	N/A	3,162,974	●
	downloads	Under definition	N/A	2,306,925	●
	citations	Under definition	N/A	18,347	●
<b>Outcome: Increased engagement of stakeholders in scientific activities</b>					
Stakeholders engagement during public consultations and other stakeholders' engagement activities	Number of contributions received — total and by stakeholder group	1,943	2,137 <sup>19</sup>	2219	●
	Survey feedback from SEA-registered members on the effectiveness of EFSA's stakeholder engagement activities	N/A	N/A	N/A <sup>20</sup>	●
<b>Outcome: Full availability of documentation relevant to EFSA's scientific outputs</b>					
Availability of documentation used in EFSA's scientific outputs	Proportion of regulated products food sector areas making dossiers data (non-confidential parts) fully available to the public <sup>21</sup>	0	N/A	N/A	●
	Proportion of EFSA's scientific outputs providing direct access (links) to datasets and metadata	TBD	25%	N/A	●

<sup>14</sup> Increase calculated on the basis of 2017 execution (36,741)

<sup>15</sup> Increase calculated on the basis of 2017 execution ((78,436).

<sup>16</sup> Increase calculated on the basis of 2017 execution (3,184,611).

<sup>17</sup> Increase calculated on the basis of 2017 execution (35,914).

<sup>18</sup> Linked to the WILEY Report for *EFSA Journal* issued every year in Q2.

<sup>19</sup> +10% with respect to the previous year.

<sup>20</sup> As per "Decision of the Management Board of the European Food Safety Authority of 9 October 2018 on the criteria for establishing a list stakeholders and the establishment of the Stakeholder Forum and Stakeholder Bureau" the effectiveness of EFSA's stakeholder engagement activities shall be carried out every 3 years. The next planned survey is to take place in 2019.

<sup>21</sup> The measurement of this indicator will be possible with the delivery of the MATRIX solution.



### 1.2.3. Output indicators

**Table 3:** Activity and outputs indicators for SO1 — General risk assessment

Activity — output indicators				
General risk assessment				
Indicator	Executed 2017	Target 2018	Executed 2018	Status
Number of questions delivered for scientific outputs and technical reports	174	91/154 (technically corrected) <sup>22</sup>	155	●
Number of questions delivered for 'other publications' <sup>23</sup> (external reports, event reports)	29 (28 external/ 1 event)	33 (30 external/ 3 event)/16 (technically corrected) <sup>24</sup>	16 (12 external/ 4 event)	●
Proportion of scientific/technical questions adopted within deadline	100%	100%	98.7%	●

**Table 4:** Activity and output indicators for SO1 — Regulated products

Activity — output indicators				
Regulated products evaluation				
Indicator	Executed 2017	Target 2018	Executed 2018	Status
Number of questions delivered for scientific outputs and technical reports	458	403/504 (technically corrected) <sup>25</sup>	519	●
Number of questions delivered for 'other publications' <sup>26</sup> (external reports, event reports)	8 (external reports)	5 (external reports)	5 (external reports)	●
Number of questions in backlog in PRAS (Art. 12 only) delivered	38	35	26 <sup>27</sup>	●

<sup>22</sup> The technically corrected plan is taking into account technical issues in the planning phase. The most impacting were: 48 questions in the plant health area were not taken into account during the planning phase, and 6 technical reports were erroneously planned under SO2 but delivered under SO1 – General risk assessment. The status of the indicator is calculated against this corrected plan.

<sup>23</sup> According to definitions of EFSA outputs <http://www.efsa.europa.eu/en/efsajournal/scdocdefinitions>

<sup>24</sup> The technically corrected plan is taking into account technical issues in the planning phase. In this case, 18 external scientific reports were erroneously included in plan. The status of the indicator is calculated against this corrected plan.

<sup>25</sup> The technically corrected plan is taking into account technical issues in the planning phase. The most impacting were: 95 questions for flavourings re-evaluations and 39 questions for the EFSA support to the preparation of an EU position in the 50<sup>th</sup> Session of The Codex Committee on Pesticides Residues (CCPR) were not included in the initial plan; 29 questions for the pesticides area were included in the initial plan but had to be excluded because of an updated workplan agreed with DG Health and Food Safety services in early 2018. The status of the indicator is calculated against this corrected plan.

<sup>26</sup> According to definitions of EFSA outputs <http://www.efsa.europa.eu/en/efsajournal/scdocdefinitions>.

<sup>27</sup> The target was not achieved within the year because of a delay of 8 working days in validating the statements related to 13 questions (visa given on 11/01/2019).

Activity – output indicators				
Proportion of scientific/technical questions adopted within deadline	86.3%	90%	83.04%	●
Number of service catalogue activities with applicants (meetings, webinars, info sessions etc.)	68	60	68	●
Percentage of positive feedback on regulated products opinions from applicants	N/A	N/A	53.6% <sup>28</sup>	●

**Table 5:** Activity and outputs indicators for SO1 – Communication and engagement

Activity – output indicators				
Communication and engagement				
Indicator	Executed 2017	Target 2018	Executed 2018	Status
Proportion of scientific outputs delivered within 28 working days of adoption (%)	75.58%	80%	87.77%	●
Number of media enquiries addressed within agreed deadlines	95%	95%	98%	●
Number of stakeholder enquiries addressed within agreed deadlines	95%	95%	99%	●
Number of public consultations on EFSA outputs	20	10	15	●
Percentage of positive feedback from engagement activities carried out with registered stakeholders	90%	85%	93%	●
Total number of registered stakeholders	107	115	112	●

A more detailed look at the achievements in the context of the strategic objective 1 shows an overall solid performance, which is reflected in the results measured through the outcome and impact indicators. The constant monitoring of the status of the ongoing projects under this strategic objective and their contribution to the expected results from the EFSA strategy implementation is presented in Annex III.

The feedback gathered through the Customer/ Stakeholder survey on EFSA's scientific outputs, scientific assessment process, and communication tools and materials was positive, with the overall satisfaction standing at 74.7%. In particular, risk managers registered a higher-than-the-average satisfaction rate of 81.6% that is reflected in the positive feedback received during the annual interviews conducted with DG Health and Food Safety on the quality of EFSA's scientific opinions.

### Scientific Production

Overall, in 2018 EFSA closed a number of scientific questions in line with the "technically corrected plan"<sup>29</sup> and with the results registered in 2017. Good compliance with the deadlines was ensured. In more detail, in the area of general risk assessment, 171 questions were closed against a 'technically corrected plan' of 170. This performance

<sup>28</sup> The 2018 execution will be also considered as a baseline for monitoring the indicators in the coming years; however, the response rate is quite low, so the measurement is to be considered provisional and will be updated if needed.

<sup>29</sup> Due to technical inaccuracies in the planning phase, such as the difficulty in translating the number of mandates in number of questions, there is a total deviation of about 140 questions. These technical corrections are all included in the "technically corrected plan" to allow proper comparison with 2017 and 2018 execution. However, this technical issue had no impact on the workload that EFSA faced in 2018, because the number of questions closed is not yet linked to productivity calculations. Details are provided in the output indicator tables per strategic objective.

is lower than the one registered in 2017, when 193 questions were closed through scientific outputs, technical reports, external reports or event reports (see table 3).

In the area of regulated products, 524 questions were closed through scientific outputs, technical reports and external reports, a result in line with the adjusted plan of 509, and more than what achieved in 2017 (see table 4).

Comparing 2017 and 2018, the differences in the volumes of the scientific production are in line with the decrease in human resources spent in the area of general risk assessment and the increase in full-time-staff equivalents (FTEs) dedicated to the evaluation of regulated products, as resources were successfully moved from one area to the other in order to tackle peaks of work in the regulated products area. A significant part of the increased resources was allocated to novel foods, for which the flow of applications has increased greatly after the implementation of the new Regulation (EU) 2015/2283 in 2018. EFSA received 53 novel food applications and 3 notifications for traditional foods from third countries, representing a ten-fold increase compared to the applications received in the previous year under the old regulation. It is observed that about 70% of applications were received after March and are expected to be closed in 2019 (in line with the legal deadline<sup>30</sup>).

In regulated products, the most significant over execution can be observed in the area of feed additives, as a result of the efficiency initiative put in place in 2017 that has improved the adoption rate. Efficiency gains were observed in the food enzymes area too. On the other hand, the number of questions closed for the MRL Art. 12 backlog<sup>31</sup> was below the target (see table 4) because of a delay in closing 13 questions in December 2018.

This increased number of questions closed was not followed by an improved compliance with the deadlines in the regulated products area. EFSA closed 83% of its regulated products evaluations respecting the legal deadline such a result is below the target (90%) and lower than the result achieved in 2017 (86.3%). It is worth noting that this indicator dropped between April and August from 88% to 82% during the period of the renewal of the EFSA scientific panels. It is also noteworthy that that, around 40% of the questions that were closed after the legal deadline had a delay of less than 3 weeks, and such a delay is linked to the periodicity of the EFSA Panel meetings<sup>32</sup>. An exception is represented by the case of Pesticides, which follows a different working model. In this area, the 90% target was not met because of the need to implement a new procedure for Art.12 confirmatory data assessment.

In the area of general risk assessment, an under-execution is observed for external scientific reports questions closed. This is mainly due to external reports in the animal health area, which were not finalised due to budget restrictions not taken into consideration during the target setting.

The area of general risk assessment was not affected by any relevant issue in terms of the timeliness of adoption, as 98.7% of the questions closed were on time (only 3 questions registered a delay, and the average delay was of 5 calendar days).

## Stakeholders Engagement

The number of EFSA's registered stakeholders increased (+5) compared to 2017, and EFSA's timeliness in replying to enquiries within the agreed deadlines was on time in 99% of the cases. These good performances were reflected in the positive feedback

<sup>30</sup> The deadline is 9 months from the receipt of a valid application (i.e. after the application has been checked for completeness).

<sup>31</sup> Starting from 2019 the term backlog will be replaced by "bulk evaluation" according to the agreement with the risk manager: "High volume of questions received in a bulk, for which an evaluation plan currently exists, or needs to be defined together with the Risk Manager".

<sup>32</sup> As there is more than one month between each Panel meeting.

given by the stakeholders on EFSA's engagement activities, (93% or +3% compared to the previous results, see table 5).

Regarding the relationship of EFSA with its applicants, the number of activities carried out, as described in the EFSA [service catalogue](#), remained stable (see table 4) compared to 2017. The low response rate to the survey sent to the applicants concerned at the end of each application process did not enable EFSA to gather statistically significant feedback and suggestions. However, the feedback coming from the Customer/Stakeholder feedback survey 2017 (sent to industry representatives rather than directly to the applicants) highlighted some actions that could be undertaken. Improvements to address some of those suggestions, such as increasing the transparency of EFSA's risk assessment procedure, are already in the EFSA's pipeline (i.e.: the implementing measures stemming from the transparency and engagement in risk assessment (TERA) TERA project and Matrix project).

The number of public consultations (see table 5) is another way of assessing EFSA's engagement with its stakeholders. Despite 5 public consultations fewer than the previous year being launched (15 vs 20), the number of comments received in 2018 was higher than in 2017 (2 219 vs 1 943). One reason for this result could be the high public interest of the topics addressed. An example is the dietary sugars, where the public consultation on the draft protocol for the scientific opinion received 374 comments.

### Communication of findings

In the area of the communication of findings, the full implementation of the enhanced publishing model for the *EFSA Journal* has increased EFSA's ability to publish its scientific outputs in a timely manner. In 2018, the publication of scientific outputs in the *EFSA Journal* took place within 28 working days in the 87.8% of the cases, a stark increase compared to 2017 (75.6%) and higher than the target of 80% set for 2018 (see table 5). Moreover, the satisfaction rating of the *EFSA Journal* users is positive, at 83% (see table 1).

Other measurements that are coming from the *EFSA Journal* statistics and that aim at showing the visibility of EFSA's scientific outputs were measured for the first time in 2018 and their results will be followed up in the future. These measurements will quantify how many of the EFSA's scientific outputs have been accessed, how many have been downloaded and, most important, how many have been cited by others (over 18,000 citations, as data show at the end of 2018, see table 2).

### Visibility

The impact of media coverage<sup>33</sup> registered a result lower than the target (see table 1); continued media coverage on sensitive issues such as glyphosate in 2018 resulted in a media impact score slightly lower than projected, although higher compared to 2017 and still in the "neutral range". Better-than-expected results were instead registered when assessing EFSA's online presence. In particular, followers on social media almost doubled since 2016 (see table 2). It therefore seems that the decision to launch a dedicated project on the topic and of providing training sessions for the EFSA staff that will be 'EFSA voices' on social media, is already paying off.

The number of sessions in the EFSA web content registered a significant increase (+18% compared to last year, and more than the target set for 2018, see table 2). On the other hand, the volume of traffic to the EFSA web content that is coming from social media is decreasing compared to 2017 (see table 2). This can be explained by the fact that some audio-visual contents is played directly in the social media platform rather than redirecting the users to the website. In addition, social media contents redirected the

<sup>33</sup> The index that measures the favourability of articles about EFSA in the media.

traffic to the EFSA Conference website rather than to the EFSA website, and this traffic was not reported in this indicator.

Regarding the other EFSA communication tools, the number of subscribers to newsletter and alerts is decreasing compared to 2017 (see Table 2). The reason might be found in the switch to social media (as already described above) as well as in the new data-protection law (GDPR) which led to the deletion of around 1,500 subscribers.

## 2. Widen EFSA's evidence base and optimise access to its data

Accurate and efficient data collection is essential for the integrity of the risk assessment process. The work done closely with the Member States, the European Commission and the international organisations to collect, analyse and summarise relevant scientific data is part of the sustained programme of scientific data collection activities falling under strategic objective 2. The scientific 'Open SCAIE', 'Data DOI', the Whole Genome Sequencing project and part of the Information Management Programme are examples of contributions to increase the transparency and reproducibility of EFSA's risk assessments. The constant monitoring of the status of the ongoing projects under this strategic objective and their contribution to the expected results from the EFSA strategy implementation are presented in Annex III.

### 2.1. Highlights of 2018 achievements

#### 2.1.1. Databases

- Comprehensive European Food Consumption Database

EFSA published a new release of its [Comprehensive European Food Consumption Database](#), which, for the first time, includes data collected under the umbrella of EFSA's EU Menu project. New food consumption data from Estonia, Spain, France, Croatia, Latvia and Portugal were included in the latest release. All data contained in the database are now classified according to FoodEx2 food classification and description system.

- Raw Primary Commodity (RPC) consumption database

In December, the RPC model that transforms 'food as consumed' in the EFSA comprehensive food consumption database into raw primary commodities was finalised. Using the model, EFSA obtained a new RPC consumption database, which contains 51 dietary surveys from 23 different countries. The added value is that it allows EFSA to strengthen its capacity to assess dietary exposure at different levels of the food chain, from raw primary commodities to foods as eaten.

- Xylella host plant database

EFSA has published an update of its database of plants that act as hosts for *Xylella fastidiosa* in its scientific data warehouse. The update includes 563 plant species identified through a literature search and from notifications to the EU's plant health interception service EUROPHYT. It covers both species of the pathogen – *X. fastidiosa* and *X. taiwanensis* and includes information on plant varieties that are resistant to, or tolerant of, *Xylella*.

- Chemical hazards database (OpenFoodTox)

The final External Scientific Report '*Further development and update of EFSA's Chemical Hazards Database*' together with the latest version of the database was published in EFSA's *Knowledge Junction*, the open repository for the exchange of evidence and supporting materials used in food and feed safety risk assessments, in July 2018.



- EFSA Compendium of botanicals

In the context of databases, the EFSA compendium of botanicals contains information on naturally occurring substances of possible concern for human health, as well as on reported toxicity/adverse effects via oral route. The database was further expanded in 2018, with data on 1,000 new plants being ready to be transferred to the EFSA data warehouse in addition to the 900 already existing ones. The assessment of novel and traditional foods was based on the above-mentioned database.

### 2.1.2. Scientific literature and data reports

- Scientific literature

Throughout the year continuous access to scientific literature was provided, including more than 60,000 articles and more than 3,000 documents provided by document suppliers. In order to widen the evidence base, this was combined with a more intense support in the development and appraisal of literature searches for scientific assessments.

- Publication of the food enzyme Intake Model (FEIM)

In 2018, EFSA has published the Food Enzyme Intake Model (FEIM), a tool for estimating chronic dietary exposure to food enzymes used in different food processes. It has been developed on the basis of actual food consumption data collected by Member States and stored in the EFSA [Comprehensive European Food Consumption Database](#). This user-friendly and open access tool allows applicants, risk assessors and risk managers to estimate dietary exposure to food enzymes used in individual food manufacturing processes, such as baking or brewing. It will be updated annually as more process-specific calculators are generated.

- Data reports

EFSA published a scientific report on the occurrence of residues of fipronil and other acaricides in chicken eggs and poultry muscle/fat, following the widespread detection of fipronil residues in eggs in 2017. The analysis showed that out of the 5000 samples of eggs and chickens, 742 samples, contained residues in quantities exceeding legal limits and almost all were related to fipronil. In addition to this, EFSA published on its *Knowledge Junction* a [statistical analysis of chlorate occurrence data in food](#).

- Feed additives consumer exposure (FACE) calculator

During the course of the year, the Feed Additive Consumer Exposure (FACE) calculator was finalised and published on the EFSA website. It is a tool for estimating chronic and acute dietary exposure to residues of feed additives and their metabolites present in food of animal origin. It allows users to estimate the exposure for different population groups (e.g., infants, toddlers, adults) in several European countries. This tool implements the exposure methodology recommended by the Guidance on the assessment of the safety of feed additives for the consumer and was used in assessments of several applications of certain feed additives, including opinions of the FEEDAP Panel.

### 2.1.3. Data standardisation

In the area of data standardization EFSA delivered hands-on training to Member States and 'candidate countries' on the use of its [FoodEx2 food classification and description standard](#) when coding foodstuffs. In addition, two [webinars on use of the FoodEx2 standard](#) were delivered to support wider use of the FoodEx2 standard at an international level. An hands-on training on how to report data on pesticide residues and on veterinary medicinal product residues was delivered to data providers in EU candidate countries using the standard sample description, version 2 (SSD2) reporting standard.

Scientific network meetings on chemical occurrence data, on veterinary medicinal product residue data, on Zoonoses monitoring data and on antimicrobial resistance data reporting covered topics with particular focus on annual data reporting and standardisation.

The funding for a pilot project concerning a feasibility study on a common open platform on chemical safety data was agreed within the frame of the EU 2019 budget. This was initiated by the European Parliament public health and food safety ENVI committee with the support of EFSA and ECHA with the goal of increasing chemical safety data harmonization and sharing from EU agencies.

#### 2.1.4. Information Management Programme (IMP)

The IMP coordinates all projects related to EFSA's information management: from information collection and creation, to information classification and registration, from data analysis and data reporting to information sharing and re-use. The programme focuses on changing the way EFSA collaborates both internally and externally: how EFSA shares information and communicates in its departments, units, teams, Knowledge information communities (KICs) as well as projects. IMP will modernise the Data Management and Data Analysis architecture adopting scalable and modern IT solutions in-the-cloud<sup>34</sup>. It will, finally, implement new ways of sharing information and collected evidence outside EFSA, by creating a machines-to-machine interface. IMP will furthermore increase the citability and re-usability of EFSA Evidence via assignment and publication of unique identifiers for evidence and data (DATA DOIs) in the *EFSA Journal*. In this context an automatic interface between EFSA and the European Open Data Portal will also be established.

- OpenSCAIE project

The OpenSCAIE project continued its work on delivering an EFSA's application programming interface (API) Portal, allowing the publication of datasets owned by the Agency using machine-to-machine interfaces. The starting point will be exposing data from RAW, data collection framework (DCF) catalogues, *Knowledge Junction* and the *EFSA Journal* via the API Portal that will be officially launched officially in 2019, followed by a communication campaign.

- DATA DOI project

Open government data is about the wide and free availability of public information created or collected by public entities. A technical report, prepared in collaboration with some Member States, was approved in December and published at the beginning of 2019. The report describes EFSA's proactive approach for publishing scientific data in an open, timely, comprehensive, comparable, interoperable, accessible and usable manner. The international Open Data charter and the findability, accessibility, interoperability and reusability (FAIR)<sup>35</sup> data principles were selected as the guiding principles for the development of this report. In 2019, the project, in collaboration with the Publications Office, will ensure the automatic publication of EFSA datasets into the European Open Data Portal using the data catalogue vocabulary interface, a standard developed by the European Commission.

<sup>34</sup> Cloud computing enables companies, public administrations and individuals, using networks such as the internet, to access their data and software on computers located somewhere else.

<sup>35</sup> FAIR refers to data that meet standards of findability, accessibility, interoperability and reusability. A March 2016 publication by a consortium of scientists and organizations called these the "FAIR Guiding Principles for scientific data management and stewardship", using FAIR as an acronym and making the concept easier to discuss.

- Information Access Management project (IAM)

The identity management (IDM) solution deployed in 2018 by the IAM Project was further refined. Security mitigating actions, including improved passwords management, were implemented in 2018. Streamlined Access Management processes have been analysed and will be implemented in 2019 by the projects that need to integrate with the IDM solution. The project analysed in particular the requirements for implementing master data management for Organisation, People and Identities managed in EFSA, these needs will be handed over to the Customer Relationship Management Project that will be launched in 2019.

- Whole Genome Sequencing Umbrella project

The '*Whole Genome Sequencing*' project explores the possibility to work 'in' EFSA with big data, such as DNA sequences, that are providing many information on organisms, including main food pathogens. It is running in close collaboration with KIC biotechnology, the ECDC and EU reference laboratories (EURLs). Relevant competency on bioinformatics and computation capacity and storage space is obtained particularly where sequences from the main three food-borne pathogens are already stored (i.e.: *Listeria monocytogenes*, *Salmonella* and *Escherichia coli* isolates). Different tools to analyse the sequences are tested and compared, and EFSA is already able to share and study data and compare results with the ones generated by others, i.e. for rapid outbreak assessments and antimicrobial resistance. A joint ECDC-EFSA working group is supporting the European Commission defining requirements and exploring the possible solutions that would allow expanding the current ECDC-EFSA joint molecular typing system to WGS data of these three pathogens (*Listeria monocytogenes*, *Salmonella* and *E. coli*). In addition, the storage capacity and IT-support to fulfill current GMO reporting needs have been provided.



## 2.2. Performance indicators

### 2.2.1. Intermediary impact indicators

**Table 6:** Intermediary impact indicators for SO2

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
Intermediary impact: Increased satisfaction of stakeholders regarding EFSA's evidence management services and fostered innovative reuse of data					
Satisfaction via feedback surveys: positive and relative qualitative improvement (with regard to follow-up actions)		57.8% <sup>36</sup>	N/A <sup>37</sup>	57.8%	●
Use and reuse of EFSA's accessible data and evidence	User statistics from the data warehouse <sup>38</sup>	421 <sup>39</sup> (2017)	463 <sup>40</sup>	713	●
	User statistics from the evidence hub (Open-ScAIE/Knowledge Junction)	1,105 <sup>41</sup>	1,216 <sup>42</sup>	NA <sup>43</sup>	●
	Data/evidence reused by stakeholders via citation/statistics	TBD in 2019	Increase TBD in 2019	N/A	●

### 2.2.2. Outcome indicators

**Table 7:** Outcome indicators for SO2

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
Outcome: Improved access to data					
Data accessibility index	Number of publicly accessible data collections published with no data aggregation from EFSA	5	7	6 <sup>44</sup>	●
	Number of data collection dashboards/aggregates published	15	17	16	●
Outcome: Wider data coverage					
Number of digital objects (evidence) uploaded to EFSA's open repository		500 (2017)	550 <sup>45</sup>	227	●

<sup>36</sup> Satisfaction rate comes from the customers/stakeholders survey launched in September 2017.

<sup>37</sup> Baseline set in 2018. Yearly survey.

<sup>38</sup> As mentioned in the Programming document 2019-2021 this indicator is measuring an outcome and therefore is moved under "wider data coverage" outcome indicator.

<sup>39</sup> The estimate provided in 2017 was 800. This has been now corrected to 421, which corresponds to the total number of registered and actual users at the end of 2017. The annual targets have been corrected accordingly.

<sup>40</sup> An increase of 10% compared to 2017.

<sup>41</sup> Number of uploaded and curated digital objects - consolidating 5-year period.

<sup>42</sup> 10% increase compared to previous year.

<sup>43</sup> As mentioned in the Programming Document 2019-2021 this indicator is measuring an outcome and therefore is moved under outcome indicator "wider data coverage".

<sup>44</sup> Mycotoxin data will be published in Zenodo in January, to properly check possible data quality issues before publication.

<sup>45</sup> 10% increase compared to previous year.

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Outcome:</b> Increased standardisation and interoperability of data					
	Share of regulated product areas covered by structured data	0	N/A <sup>46</sup>	N/A	●
	Increased maturity data interoperability - EIF/IMM index <sup>47</sup>	TBD in 2019	N/A	N/A	●
<b>Outcome:</b> Improved quality of data					
	Data quality index <sup>48</sup>	Accuracy 0.75; Completeness 0.76; Timeliness 0.46	N/A	Timeliness <sup>49</sup> 0.46	●

### 2.2.3. Output indicators

**Table 8:** Activity and output indicators for SO2

Activity – output indicators				
Indicator	Executed 2017	Target 2018	Executed 2018	Status
Number of questions delivered for scientific outputs and technical reports	10	8/2 (technically corrected) <sup>50</sup>	2	●
Number of questions delivered for 'other publications' (external reports, event reports)	21 (external report)	14 (external report)	13 (12 external report, 1 event report)	●
Proportion of scientific/technical questions adopted within deadline	100%	100%	100%	●
Number of operational data collections prepared and opened within deadline (total and open)	12	15	15	●
Number of enhancements to operational data collections	20	20	15	●
Number of new data collections implemented	2	2	2 <sup>51</sup>	●

<sup>46</sup> This measurement is linked to the progress of the MATRIX Project.

<sup>47</sup> The index was drafted based on the European Interoperability Framework recommendations developed by the [ISA2 Programme](#) (Interoperability solutions for public administrations, businesses and citizens) and the actual measurement of 2018 will be available by Q2-2019.

<sup>48</sup> Three data quality indicators relevant for EFSA scientific data collections: e.g. accuracy — data plausible, correctly coded; completeness — all information required/recommended is reported; timeliness — information is reported according to deadlines and update according to agreed timelines. The 2019 data quality indicator pertains to timeliness and is assessed for the following annual European data collections (contaminant occurrence, pesticide residues, veterinary medicinal product residues, and zoonoses and antimicrobial resistance). The indicator is measured as an average of i) the proportion of data records submitted by the annual (legal) reporting deadline, and ii) the proportion of data records confirmed in the scientific data warehouse by the deadline for acceptance agreed with data networks.

<sup>49</sup> The indicator has been reviewed during the year. Accuracy and completeness are not measured at this stage, while timeliness forms the baseline for 2019 plan.

<sup>50</sup> The technically corrected plan takes into account technical issues in the planning phase. 6 technical reports were erroneously planned under strategic objective 2 but delivered under SO1 – General risk assessment. The status of the indicator is calculated against this corrected plan.

<sup>51</sup> The new data collections implemented in 2018 are corn root worm (CRW) and Xylella. The "Number of enhancements to operational data collections" and the "Number of new data collections implemented" included are replaced as of 2019 by the new indicator "Number of new tools".

Looking deeper into strategic objective 2, the feedback coming from the Customer/Stakeholder feedback survey on EFSA's evidence management services and the innovative reuse of data registered a satisfaction rate of 57.8%, with the low awareness of some respondent groups regarding EFSA's efforts in these areas as the main reason for this result.

### Improved access to data and wider data coverage

Regarding the accessibility and coverage of data domains, the number of registered users in the Scientific Data Warehouse registered a better-than-expected result (see table 6), with the updates of the *Xylella* host plant database and the EFSA 'Compendium of botanicals' database among the possible reasons for this increase. In the customer/stakeholder feedback survey<sup>52</sup>, only 51.8% of the respondents were aware of the EFSA's published evidence in the Scientific Data Warehouse, and attention will be paid to the results coming from the 2018 survey, (scheduled for early 2019), to analyse if stakeholders' awareness has improved.

This year EFSA started also measuring the use of *Knowledge Junction*.

The number of digital objects (evidence) uploaded to the *Knowledge Junction* was 227, a figure lower than the planned 550. Being an open repository, its use is connected to the availability of the Member States to share information. Training and promotion of *Knowledge Junction* activities undertaken at the Focal Points level in the last two quarters of 2018, together with the release of the data publication report in early 2019, will certainly increase the number of uploaded digital objects uploaded in the coming years and consequently improve the performance in this area.

Regarding the efforts in improving the accessibility of its data, EFSA published one additional data collection: the Feed Additive Consumer Exposure -FACE- template, thus increasing the number of data collection dashboards/aggregates published to 16, against a target of 17. The publication of the other dashboard on the Mycotoxin was postponed to 2019 in order to ensure a higher data quality. The delay on the Mycotoxin dashboard also affected the indicator on the number of publicly accessible data collections that were published with no data aggregation from EFSA (6, against a target of 7).

### Support to data collections

The number of operational data collections opened in 2018 reached the target of 15, while the number of enhancements on operational data collections was lower than planned, as an urgent large enhancement on the MRL pesticides database for pesticides was prioritised over four other small enhancements.

EFSA also closed a total of 15 questions through scientific outputs, technical reports, external scientific reports and event reports. Despite this being lower than 2017 (31 questions closed), but this is in line with the technically corrected plan for 2018. All the questions delivered were closed within the deadline.

## 3. Build the EU's scientific assessment capacity and knowledge community

In the area of scientific cooperation, capacity building and expertise management, cooperation with EU agencies and Commission activities, the achievements from the implementation of the EFSA work programme were many. EFSA aims to set up cooperation initiatives that make the best use of expertise for scientific assessment through a partnership between EFSA staff, scientific experts and Member State organisations. With the aim of ensuring that the scientific work and corporate initiatives

<sup>52</sup> Run in September 2017.

are supported with appropriate outreach tools to engage with the relevant audience. The constant monitoring of the status of the ongoing projects under this strategic objective and their contribution to the expected results from the EFSA strategy implementation is presented in Annex III.

### 3.1. Highlights of 2018 achievements

#### 3.1.1. European cooperation and networking

##### ■ Inter-Agency cooperation

In early 2018 EFSA initiated activities to step up scientific cooperation with EU sister Agencies<sup>53</sup> falling within the remit of the EP ENVI committee of the European Parliament (ENVI Agencies) and the European Commission Joint Research Centre (JRC), both at a strategic and operational level. The overall concept of inter-agency cooperation was presented to the EFSA Management Board in October and to the Advisory Forum in November. A dedicated Inter-Agency Scientific Collaboration group, comprising a Steering Group and an Inter-Agency Collaboration Team, was set up internally to ensure cooperation with the ENVI Agencies and the JRC. This approach, piloted with the ECHA, has led to a number of initiatives, including the exchange of strategic information, mutual consultation on work-programmes, collaboration on specific topics such as endocrine disruptors and harmonisation of chemical safety data, exchange of experts and the launch of a joint vacancy announcement, identification of research topics of common interest and a Horizon Europe shared vision. A strategic meeting involving the Executive Directors of the sister-Agencies is planned for February 2019 to further develop the benefits ('synergies') among Agencies and cooperation opportunities.

##### ■ EU Cooperation

During 2018, the Advisory Forum met four times to discuss important topics such as the review of the General Food Law, EFSA's 3<sup>rd</sup> external evaluation, scientific divergence, and the review of the EU-Risk Assessment Agenda (EU-RAA).

In 2018, three further joint cooperation projects were signed with Bulgaria, Austria and Slovenia, stemming from the ED visits. Romania will be the last country to be visited by the ED in 2019, during the Romanian presidency of the Council.

The decreasing trend of joint projects awarded under the EU Risk Assessment Agenda (EURAA) in 2018 when compared to 2017, is resulting from the concluded cycle of the ED visits and the prioritisation of new forms of cooperation projects with MS organisations not falling directly under the EURAA, i.e. *tasking grants* and the *EFSA Fellowship Programme* grants.

On the year of its 10th anniversary, the Focal Point network celebrated its main achievements and confirmed future collaboration initiatives through the implementation of new flexible, performance-based grant agreements for the period 2019-2022.

A series of visits of the ED of EFSA to Member States took place with the aim of strengthening scientific cooperation and partnering activities as anticipated in the EU-RAA. These included a visit to the Italian National Institute of Health [Istituto Superiore di Sanità] in May, the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) in June and visit to the Swiss Federal Food Safety and Veterinary Office (FSVO) and the Spanish Agency for Consumer Affairs, Food Safety and Nutrition (AECOSAN), both taking place in October. As a follow up of previous visits of the ED and partnering grant schemes, five new joint projects were agreed with the Member States during 2018, in particular with Bulgaria, Austria, and Slovenia.

<sup>53</sup> European Chemicals Agency, European Centre for Disease Prevention and Control, European Food Safety Authority, European Medicines Agency.

EFSA continued to involve the seven pre-accession countries as beneficiaries of the EU pre-accession instruments (IPA) Programme into its work, providing opportunities to strengthen the capacities for risk assessment and promoting networking and joint activities between EFSA, pre-accession countries and Member States. Significant progress has been achieved, especially in the harmonisation of data collection methodologies and reporting to EFSA (e.g. for veterinary medicinal product residues and pesticide data), as well as scientific cooperation on antimicrobial resistance and Lumpy Skin Disease. In September, the visit from a Turkish delegation, arranged by the United States Department of Agriculture Foreign Agriculture Service, was hosted on EFSA premises to exchange information on food safety issues with a focus on GMO.

In early 2018, national food safety authorities from all EU Member States, Iceland and Norway called for more public investment in food safety research and committed, through a joint statement with EFSA, to further support European research through partnership building and training. The statement also stressed the benefits of increased interaction between funders, EU Agencies and national partners on food safety research. The first Risk Assessment Research Assembly (RARA) took place in February with the aim of stimulating new partnerships and public funding on food safety research, bringing together over 200 people from 40 countries. The event, which attracted EU and national research funders, policy/decision makers, leading food safety researchers and risk assessors, provided an opportunity for the exchange of ideas and for the identification of partners and possible ways of funding.

- Biohaz scientific networks

The EFSA Network on Microbiological Risk Assessment discussed topics such as salmonella and antimicrobial resistance monitoring data, risk assessments and studies performed by Member States, existing tools for sharing and reusing models, microbiology of some food products, milk processing methods and the hepatitis E virus.

The EFSA Network on Bovine Spongiform Encephalopathy/Transmissible Spongiform Encephalopathy (BSE/TSE) covered topics related to Chronic Wasting Disease and its surveillance in Europe, the zoonotic potential of BSE, Camel prions disease, BSE and TSE surveillance data, BSE infectivity in edible tissues and the new EU Reference Laboratory on TSE.

- Communication Expert's Network (CEN)

The fourth meeting of the network took place on 15-16 March in Sofia. The main topics discussed were EFSA's work on social science, communicating uncertainty and future actions such as a new Eurobarometer survey. CEN members participated in ten 'hot topic' calls<sup>54</sup>, enhancing coordination of risk communication activities. Additionally, at the end of the year a video conference took place to discuss, among other things, topics for the 2019 workplan, including a hot topic call calendar, the future Eurobarometer, and joint EFSA Member States communication campaigns.

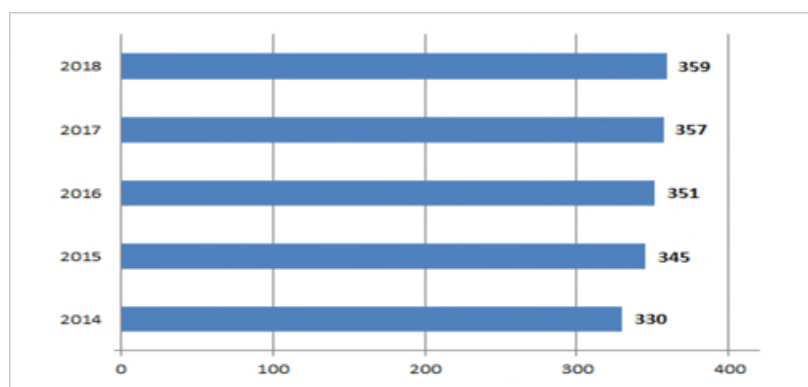
- Article 36 networking

Article 36 of EFSA's founding regulation<sup>55</sup> provides the legal basis for the cooperation with competent organisations designated by Member States, which may assist EFSA in its mission. By the end of 2018, the Article 36 list included 359 organisations from the 28 Member States, Iceland and Norway. The List of competent entities is kept updated on a continuous basis (see Figure 2) and in 2018 nine new organisations were included in the list and seven entries deleted.

<sup>54</sup> Tele-conference to discuss communication aspects on hot topics with the Member States.

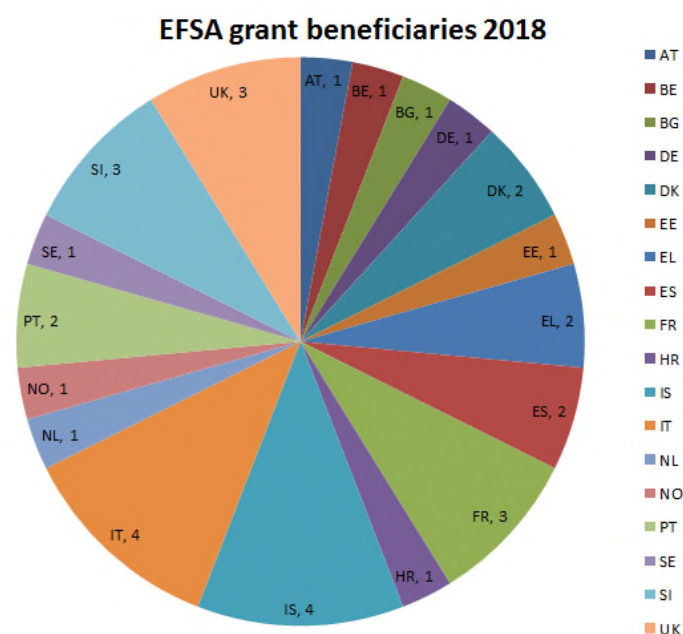
<sup>55</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1-24, as last amended.

**Figure 2:** Number of entries on the Article 36 list per year (2014-2018)



In 2018, 34 organisations out of 18 countries benefitted from the EFSA grants launched that year, focal point program excluded. It is worth noting that this number decreased compared to 2017 where 50 organisations out of 19 countries participated in a larger number of grants launched that year.

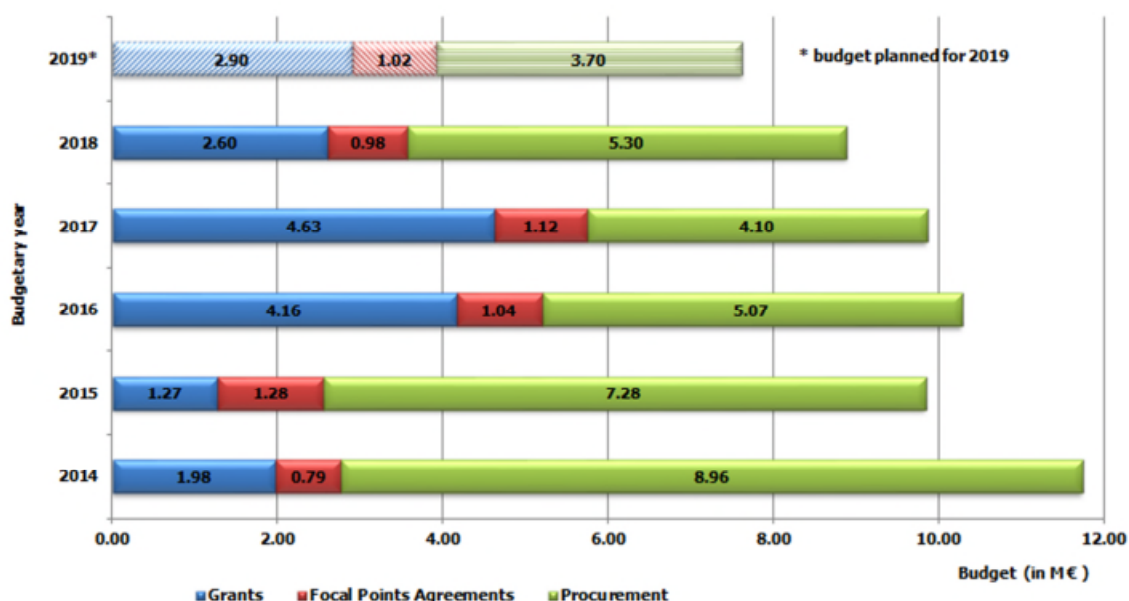
**Figure 3:** EFSA Grant's beneficiaries 2018



During the year the national Focal Points, in their role of supporting cooperation and networking, disseminated EFSA's open calls for proposals (grants) and calls for tenders (procurements) to competent organisations. A total of 39 grant agreements were awarded for a total amount of EUR 2.6 million) and 29 Focal Point agreements for a total value of almost EUR 1 million) were successfully awarded to Member States, Norway and Iceland. In addition, EFSA signed 84 scientific procurement contracts (amounting EUR 5.3 M). Trends in EFSA investment in Grants, Focal Point agreements and procurement are illustrated in Figure 2 together with investments planned for 2019.



**Figure 4:** EFSA's grant and procurement budget in the period 2014-2018 including plans for 2019



In 2018 the budget allocated through grant schemes was reduced by 10% compared to the 2017. Despite the overall budget decrease since 2016, EFSA has further encouraged networking and cooperation by introducing new cooperation tools such as 'thematic grants' in 2015-2017, and 'partnering grants' in 2017-2018, both requiring applicants to establish transnational consortia under a 50% EFSA's co-financing regime. Nine partnering grants projects were launched in 2018 and are currently under implementation for a total budget of almost EUR 0.8million while two more partnering projects were awarded at the year-end as a follow-up of the second call for proposals. The 11 partnering grants awarded in 2018 involved a total of 16 Member States and 49 partner organisations and cover areas such as vector-borne diseases, integrated risk-benefit analysis, antimicrobial resistance in sea food, food contact materials, insects as novel food and the improvement of data collection systems.

In December EFSA announced a review of the Art. 36 competent organizations connected with the new online tool supporting the process. The revision will occur in 2019.

#### ■ EFSA Scientific Colloquia

The 24th EFSA Scientific Colloquium was organised on 'OMICS in risk assessment: state-of-the-art and next steps'. The colloquium concluded that OMICS technologies are nearly mature and that, in some cases, are already being applied in EFSA's risk assessment and in other cases could be useful additions to risk assessment. EFSA will continue monitoring/collaborating at the international level in establishing standards for OMICS data and will scope internally the current status of the use or need of OMICS technologies in EFSA's risk assessments.

### 3.1.2. International cooperation

In April, EFSA hosted the 4th Food Safety Trilateral Exchange led by European Commission's DG Health and Food Safety with the Chinese general administration of quality supervision, inspection and quarantine (AQSIQ) and the United States Food and Drug Administration (FDA). The aim of the meeting was to strengthen cooperation between Europe, China and the United States, and to promote global governance on food safety.

In September, EFSA and the Indian food safety and standards authority signed a Memorandum of Cooperation. This was preceded by a visit, in January, of the Indian Ambassador to the EU, where areas of mutual interest in scientific cooperation were initially discussed. During the same month EFSA signed a memorandum of cooperation with the South Korean national institute for food and drug-safety evaluation.

EFSA continued its active participation in existing international liaison groups and on the occasion of its scientific conference, it hosted the meetings of the international liaison group for risk communication and the international liaison group on methods for risk assessment of chemicals in food.

In line with the international scientific cooperation strategy 2017-2020 EFSA had scientific discussions with the Saudi Arabian food and drug authority, focusing on issues related to data collection and the FoodEx2 standard for food description and classification.

Dialogue and scientific cooperation activities already established with authorities in Chile, the United States, Canada, Japan and China, continued during 2018.

### 3.1.3. Scientific capacity building

Following a successful start in 2017 EFSA launched a second innovation contest crowdsourcing challenge aimed at 'people scientists' and computer whizzes. The aim of the second challenge was to find ways to automate the data-extraction step in systematic literature reviews. As no satisfactory results came out of this second challenge a revised and slightly rephrased contest will be launched in 2019.

- EU-FORA a Fellowship Programme and other capacity building management

The first cycle of the EU-FORA Programme (2017-2018) finished in August. The fellows received their certificate of accomplishment in September and their final technical reports were published in a special issue of the *EFSA Journal* in August.

The second cycle (2018-2019) started in August with the new 15 participants from Germany, Greece, Spain, Italy, Cyprus, Portugal and Romania attending the induction training.

The 2018 edition of the Parma Summer School on 'Emerging risks for food safety and public perception' took place at EFSA premises in May welcoming 100 participants from 20 different countries. Across 2018 EFSA also hosted eight informative sessions for post-graduate students<sup>56</sup> and organised, together with *Istituto Superiore di Sanità* and Parma university, a workshop on 'Endocrine disruptors and alternative methods to animal testing – a scientific and regulatory perspective'.

Finally, EFSA participated in two technical workshops for scientists and competent authorities from European Neighbourhood Policy (ENP) countries organised in cooperation with the European Commission — TAIEX: a regional workshop on food RA in Tbilisi (Georgia) in November and a regional workshop on transboundary animal diseases in Kiev (Ukraine) in December.

### 3.1.4. Expertise management programme (EMP)

Through its Expertise Management Programme (EMP), EFSA is pursuing its efforts to develop a comprehensive competency-based approach to talent attraction, career management and talent retention for staff and experts. During the first quarter the successful conclusion of the Call for Expressions of Interest for Membership of the Scientific Panels and the Scientific Committee resulted in the appointment of 171 experts. The results, published in May, indicate an increase in gender balance of 7%, a

<sup>56</sup> From EU and outside EU countries.



slight decrease in the average age of experts (54 years) and a wider spread of nationalities. In the second quarter, the recruitment process was extended to the selection of scientific experts for working groups. This last step concluded the full centralization of the recruitment process for the talent pool of EFSA namely staff, panel experts and working group experts in the human capital resource unit. This full centralization benefits the organization in terms of efficiency and efficacy with a reduction of the effort and time to hire correlated (-20% for Panel experts) with an increase in the quality of the data linked to the talent pool allowing an enhanced informed planning of resources. The next outcome of the Programme in 2019 will be the finalisation of the productivity baseline heading to a flexible and pro-active management of a competency-based workforce planning. This will be complemented by the deployment of rights and obligations of EFSA staff in the IT system of the European Commission (Sysper). In parallel the programme is reviewing the process supporting the organization of scientific meetings within EFSA.

## 3.2. Performance indicators

### 3.2.1. Intermediary impact indicators

**Table 9:** Intermediary impact indicators for SO3

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Intermediary impact:</b> Increased efficiency at European and international level					
Identification of potential incidents of duplication and divergence and resolution of issues when identified within EU (development and rollout of a database for sharing MS RA activities)	Number of MS active in sharing risk assessment information	25	25 or more	25	●
	Potential duplication identified before an activity is started / potential divergence identified before the adoption of an opinion	Identified timely in 100% of cases	Identified timely in 100% of cases	100%	●
	Follow-up actions within 10 days of identification of potential duplication/divergence	100%	100%	100%	●
<b>Intermediary impact:</b> Increased satisfaction of MS, EU, and international partners with regard to the building and sharing of risk assessment capacity and a knowledge community at organisational and individual level, in general and via specific tools (e.g. grants)					
Satisfaction — general satisfaction with and usefulness of joint outputs — via feedback surveys: positive and	MS, EU, international, third country organisations	56.9% <sup>57</sup>	N/A	56.9%	●

<sup>57</sup> Satisfaction rate comes from the customer/stakeholder survey launched in September 2017.

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
relative qualitative improvement (with regard to follow-up actions)	Individual experts	72.0% <sup>58</sup>	N/A	72.0%	●
Outreach of supporting publications on grants and procurements	Number of page visits (access)	Under definition <sup>59</sup>	N/A	213,048	●
	Number of downloads (citations)			2.47 <sup>60</sup>	
	Number of citations (downloads)			201,251	

### 3.2.2. Outcomes indicators

**Table 10:** Outcomes indicators for SO3

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Outcome:</b> Building and sharing capacity within the risk assessment community at organisational level					
Risk assessment agenda take-up index <sup>61</sup>	Number of joint projects	13	7	5	●
	Number of priority areas covered	8	3	4	●
	Number of partners (Member States) in joint projects	15	7	9	●
	Number of partners (other than Member States) in joint projects	29	16	14	●
	Number of projects non funded primarily by EFSA	0	1	1	●
Number of joint activities (staff exchange, joint projects / workshops) with international partners under cooperation agreements <sup>62</sup>		5	50	55	●
Research agenda take-up index	Number of support letters written by EFSA of research proposals supporting the EURAA	0	3	N/A <sup>63</sup>	●

<sup>58</sup> Satisfaction rate comes from the customer/stakeholder survey launched in September 2017.

<sup>59</sup> Linked to the Wiley report on *EFSA Journal* issued every year in Q2.

<sup>60</sup> Average per article.

<sup>61</sup> Baseline reflects the execution of 2017. The target is not an increase of 2017 baseline, but it is set according to plans.

<sup>62</sup> Activities under international scientific cooperation agreements not related to risk assessment agenda and reported under SO3 annual indicator "Number of international cooperation activities (meetings, events, missions)".

<sup>63</sup> The indicator was considered not meaningful for measuring an outcome, therefore the measurement was not carried out in 2018 and the indicator has been revised to "Number of research recommendations taken up by MS/EU/International research programmes/funding schemes", and will be measured from 2019 onwards.

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
	Number of research projects (EU and international) in which EFSA is participating (actively or passively)	1	2	8	<div></div>
Participation of MS organisations to EFSA's work programme (science grants and procurement)	Application rate for EFSA's open calls <sup>64</sup>	2,15	>3	2.3	<div></div>
	Number of Article 36 organisations applying for EFSA grants	84	87 <sup>65</sup>	60	<div></div>
Outcome: Building and sharing capacity within the risk assessment community at individual level					
Increased common expertise pool coverage and availability index	Number of applicants (total and eligible) for panel renewals	Total 1,150 Eligible: 900 <sup>66</sup>	N/A	N/A	<div></div>
	Balance of applicants (total and eligible) for panel renewals, in terms of age, gender and geography	Defined in the 2017 call <sup>67</sup>	N/A	N/A	<div></div>
	Elapsed 'time to hire' for working group experts	TBD in 2019 <sup>68</sup>	N/A	N/A	<div></div>
Panel and WG quality evaluated via the expert impact factor <sup>69</sup>	Panel expert impact factor	N/A	N/A	N/A	<div></div>
	Working group expert impact factor				
Outcome: Strengthened capacity using innovative ways					
Number of innovative approaches (crowdsourcing, cognitive computing, artificial intelligence) included in EFSA's strategy implementation plan (original or revised) having been further developed in the different areas of EFSA's work (moved at least one stage from non-explored to feasibility, piloting, guidance endorsed training provided, application in risk assessment)		0	TBD in 2019 <sup>70</sup>	N/A	<div></div>

<sup>64</sup> Average number of applications to be calculated in Q1 of year N+1.

<sup>65</sup> As per Programming document: target to be increased by 3% each year.

<sup>66</sup> Total 1,150 applicants for 10 panels (2013-2015), Eligible: 900 applicants for 10 panels (2013-2015).

<sup>67</sup> Gender balance: men 55 %/women 45 %, Age distribution: < 40 years: 23 %, 40-55 years: 49 % > 55 years: 28 %, Geography (EU): mid-western Europe: 88 %, eastern Europe: 12 %.

<sup>68</sup> Information will be available in early 2019.

<sup>69</sup> The indicator will be deleted, since it is considered that the impact factor (author level metric based on the scientist most cited paper) for expert of panel and working group could be not systematically associated to the expert's role in EFSA.

<sup>70</sup> The indicator will be measured in 2019 in the context of the definition of EFSA's innovation process.

### 3.2.3. Output indicators

**Table 11:** Activity and output indicators for SO3

Activity – output indicators				
Indicator	Executed 2017	Target 2018	Executed 2018	Status
Number of questions delivered for scientific outputs and technical reports	3	2	5	●
Number of questions delivered for 'other publications' (external reports, event reports)	2	0	4 (event report)	●
Proportion of scientific/technical questions adopted within deadline	100%	100%	100%	●
Number of MS cooperation activities (network meetings, national FP events/workshops)	75	65	69	●
Number of cooperation agreements with international and third country organisations	15	16	16	●
Number of international cooperation activities (meetings, events, missions)	39	30	35	●

The feedback coming from the Customer/Stakeholder feedback survey on EFSA's efforts in building EU's scientific assessment capacity and knowledge community registered an overall satisfaction rate of 59.7%, with a high variability among the different respondent groups. Notably, the scientific experts registered a satisfaction rate of 72.0%, whilst representatives from the European Union, Member States, and international countries expressed a lower satisfaction rate, at 56.9%. Among the reasons that can explain this discrepancy, there is a lack of awareness of EFSA's efforts from some respondents groups.

#### Scientific cooperation

In line with the previous year, 25 Member States shared risk assessment plans with EFSA, thus ensuring a high level of alignment within the EU, allowing for a timely response and follow-up to potential duplications in 100% of the cases (see table 9).

Looking deeper into the area of scientific cooperation, EFSA executed the plan as expected, with a few indicators not reaching the expected targets. In general, 2018 targets in this area were lower than the ones set for 2017 to accommodate the reduction of financial resources allocated (the budget for grants and procurements decreased from almost € 10 million in 2017 to less than € 9 million in 2018).

EFSA carried out 69 cooperation activities with Member States, a figure higher than the plan (see table 11). As one of the results of these activities, 5 joint projects were awarded, one project shy of the target. Three of those projects were awarded to Bulgaria, Austria and Slovenia while the remaining ones to two consortia: one led by Greece and the other one by Portugal. This brought the number of partners participating in joint projects to 23, a figure in line with the target set. As an ultimate result, all these activities are covering 4 priority areas in 2018 (see table 10).

Article 36 of EFSA's Founding Regulation<sup>71</sup> provides the legal basis for the cooperation with competent organisations designated by Member States, which may assist EFSA with its mission. Within this framework, 60 organisations applied for EFSA grants in 2018, a figure that is lower than the target set and lower than the 2017 result (see table 10). However, this result is satisfactory, considering the amount of budget allocated for grants in 2018 (almost 50% lower than the one allocated in 2017 (EUR 2.60 million versus EUR 4.63 million). Moreover, in 2017 EFSA signed a series of multiannual framework partnership agreements which, because of their nature, increased the number of organisations that applied in 2017, and consequently might have affected the figure for 2018. In order to measure the impact of EFSA's cooperation activities to the EU risk assessment community, EFSA also started measuring the outreach of the external scientific reports produced through grants and procurements (in terms of number of accesses, number of downloads, and number of citations) through the *EFSA Journal*. This first measurement builds the baseline for the year to come.

For what concerns the cooperation outside the EU, EFSA signed, as planned, 16 cooperation agreements with international organisations and organised 35 international cooperation activities (5 more than planned). These activities led EFSA to carry out 55 joint activities (such as staff exchange, and joint projects/workshops) with international partners under cooperation agreements.

#### Capacity building and expertise management

In 2018, the first cycle of the EU-FORA Programme (2017-2018) successfully reached its end in August. The second cycle (2018-2019) of the programme started in the same month, with 15 participants attending the induction training.

In the area of expertise management, the call for expressions of interest for membership of the Scientific Panels and the Scientific Committee was successfully closed. A total of 171 experts were appointed. Data showed an increase in gender balance of 7%, a slight decrease in the expert average age (54 years old) and a wider spread of nationalities. The results of the indicators monitoring this activity (see table 14) will be used as baseline for the next call that will be launched only in 2020.

## 4. Prepare for future risk assessment challenges

Anticipating risk assessment priorities and related methodology and evidence needs ensures that EFSA is prepared for present and new challenges in a dynamic food safety system, whilst driving harmonisation of methodologies to improve food safety across Europe. In order to contribute to the EFSA's effort to be prepared for potential future challenges and crises in food risk assessment, EFSA produced many guidance documents and participated in numerous crisis simulation exercises. Continuous update and creation of standardised guidelines or methodologies to assess risks in a consistent and harmonised manner demonstrate this effort. Involvement of stakeholders in these processes has been an important step to ensure the relevance of EFSA's work while promoting transparency and trust. EFSA's constant monitoring of the status of the ongoing projects under this strategic objective and contribution to the expected results for the EFSA strategy implementation is presented in Annex III.

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<sup>71</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety. OJ L 31, 1.2.2002, p. 1-24, as last amended.

## 4.1. Highlights of 2018 achievements

### 4.1.1. Preparedness and response

To plan and practice how to respond to possible emergency situations, EFSA has developed a multi-annual crisis preparedness training programme. In 2018, a workshop with the ECDC and Austrian Agency for Health and Food Safety on preparedness for a multi-national food safety/public health incident in the investigation and assessment of a food borne multi-country outbreak was organised. Internal crisis preparedness training was carried out in November 2018, to practice applying the EFSA procedures for responding to urgent advice needs in the context of a fictitious multi-country foodborne outbreak. In the same context, EFSA also participated in numerous crisis simulation exercises organised by other parties: the Joint Initiative Food Emergency Exercise organised by the heads of food-safety agencies in October 2018; the EU hybrid exercise multilayer 18 (parallel and coordinated exercise) crisis-simulation exercise with NATO in November 2018; and the DG Health and Food Safety crisis-preparedness exercise in December 2018.

As a follow-up of the 2017 workshop on crisis communication and other work developed by the advisory forum communication experts network, the manual for crisis communicators: ENVI Agencies' Cooperation Guidelines', was produced.

EFSA has an important role in supporting the Rapid Alert System for Food and Feed network with its expertise and scientific advice. In the context of a Commission request for scientific technical assistance to risk evaluation of chemical contaminants, a technical report was approved in June. It includes the results of the work packages on hazard characterisation and exposure assessment to chemical contaminants. The final report will be released together with a tool for rapid risk evaluation in April 2019.

#### Animal health preparedness

In the area of animal health and welfare, the SIGMA project started in 2018 aiming at harmonising and automating data collection on animal disease and surveillance. Through this project, EFSA reinforces the proactive approach to continued analysis with respect to diseases like the African swine fever, lumpy skin disease and avian influenza. The results will be produced in the course of the next 3 years, to allow risk assessors at national and European level to give faster advice to risk managers in case of outbreaks.

- Avian influenza

Every 3 months, a scientific report is published providing an overview of the avian influenza situation in poultry and wild birds in Europe and around the world. Scientific advice is provided, aiming at increasing Member States preparedness. These outputs follow the 'One Health approach', as they are a joint publication of the ECDC, EFSA and the European Reference Laboratory on avian influenza.

- EU Bee Partnership

The EU Bee Partnership Discussion group - set-up in 2017 for improving the data collection, management and sharing of bee health information and knowledge in Europe - continued its activities and met twice in 2018. The discussion group, composed of members from NGOs, food industry, practitioners, farmers associations and academia, released a technical report, describing the terms of reference of the partnership. This was published in May and presented at the high level conference of the 2018 EU Parliament bee week. A mandate from the European Parliament has been received in July requesting a scientific opinion on the science behind the development of an integrated approach for the risk assessment of multiple stressors in managed honey bees.



- Emerging Risk networks of knowledge

The EFSA networks of knowledge include the Emerging Risks Exchange Network (EREN), the stakeholder discussion group on emerging risks, EFSA's scientific units, scientific panels and the Scientific Committee and its working groups. The network and the discussion group both met twice in 2018. The issues discussed included possible risks associated with the use of botanical preparations in food supplements and tea, the black colour food trend, the use of nanoemulsions, as well as animal and plant health issues.

- Climate change and food safety

In 2018 EFSA launched a new activity: the climate change and emerging risks for food safety project which has the overall objective of analysing climate change as a driver for emerging risks in EFSA's remit. The project aims at widening EFSA's horizon scanning capacity by involving a network of expertise across international organisations and EFSA science departments and to develop a multi-criteria decision analysis tool for prioritising and characterising identified issues.

- EU Insights – Consumer perceptions of emerging risks in the food chain

A survey with over 6,200 consumers in 25 EU Member States was performed to better understand the views of EU consumers on food related emerging risks, so as to inform future communication activities around emerging risks at EFSA and Member State national competent authorities. Amongst others the study found that consumers tended to be more concerned about established risks (e.g. chemicals used in food production, bacteria found in food) than about emerging risks (e.g. green smoothies, nanoparticles).

- Scientific Report on Emerging risks identification on food and feed

The scientific report on emerging risks in food and feed was published in July. It provides strategic direction, building on past experience and ongoing projects related to the emerging risks identification. A systematic approach for the identification of emerging issues based on experts' networks is the major strength of the procedure. Three recommendations were issued: (i) to further develop a food system based approach including social sciences for emerging risks identification; (ii) to improve data processing pipelines to prepare big data analytics; (iii) to increase transparency and improve communication.

- Emerging risks identification was considered of high priority by the advisory forum representatives and first priority on cross cutting issues of the EU risk assessment agenda. Several projects are being developed with EFSA partners to develop methodologies for identifying and characterizing emerging risks:
- EUROCIQUA, to characterise the risk of ciguatera food poisoning in Europe, through a description of the epidemiological characteristics of cases and outbreaks, evaluation of the toxicity of fish and ciguatoxin producing dinoflagellates, and development of analytical methodologies for identification and quantification. The annual meeting was held in Vigo, Spain in May 2018.
- AQUARIUS, to assess the feasibility of food chain analysis for identification of emerging risks and develop methodologies for the identification of key vulnerabilities and drivers of change within the aquaculture supply chain. In this context, ERIS, a text mining tool, was adopted and implemented to identify emerging hazards in aquaculture food production chains. Both projects were concluded in 2018.
- DEMETER (Methods and systems for identifying emerging food risks) was initiated in 2018 and aims to establish a collaborative platform to support emerging risks identification. The platform should allow EU Member State authorities and EFSA to share knowledge, data and methods for the identification of emerging food-related risks in a rapid and effective manner.



- REACH 2 aims to apply a tested procedure for the identification of potential emerging chemical risks in the food chain to the substances registered under REACH. The final report on this project including a list of priority substances will be finalized in early 2019.

### Plant health preparedness

- Conference on global change and the spread of plant pests

A major scientific conference on the role of global change in the emergence of plant diseases and pests in Europe has been co-organised in Paris in April 2018 by EFSA, the French Agency for Food, Environmental and Occupational Health and Safety (ANSES) and the European and Mediterranean Plant Protection Organization (EPPO). The conference brought together researchers, public decision-makers and stakeholders to discuss how best to assess and manage phytosanitary risks arising from global change.

- Support to MS for EU plant pests surveillance

In order to support the EU Member States plant health surveillance, work is also ongoing on production of pest survey datasheets and guidelines for plant pests included in the EU surveillance program. This work is conducted in cooperation with Member States via two tasking grants and two scientific cooperation projects.

### Biological hazards preparedness

- *Listeria* infections increase in vulnerable groups

The BIOHAZ Panel adopted an opinion on *Listeria monocytogenes* in ready-to-eat food, concluding that listeria cases have increased during 2008-2015 among people over 75 and women aged 25-44. Experts estimated that one third of the listeriosis cases are due to the growth of *Listeria monocytogenes* in food prepared and stored at home in the refrigerator, highlighting the importance of following good hygiene practices.

- Whole genome sequencing in food safety the state of play

In June 2018 EFSA has published two reports providing a picture of how whole genome sequencing can be used in food safety and how extensively such techniques are used in Europe. Whole genome sequencing is increasingly used in public health and food safety laboratories, but it is used in different ways and countries for different purposes.

- Comparative genomics of *Campylobacter* of poultry origin

*Campylobacter jejuni* isolates from poultry in 12 different EU countries were analysed by whole genome sequencing to examine the genomic diversity of fluoroquinolone resistant and susceptible clones. Different phylogenetic methods, ranging from single nucleotide polymorphisms analysis to gene-by-gene approaches (such as rMLST, cgMLST, wgMLST and core genome tree) provided aligned results. According to the report published in May, the analysis showed an association of *C. jejuni* populations in different Member States.

### 4.1.2. Guidance development

#### Cross-cutting guidance

In 2018 the on-boarding programme committee for the new panels developed a new approach for briefing new panel members on EFSA key rules and procedures, including the presentation of existing cross-cutting guidance documents to the new panel members.

The Guidance on uncertainty analysis in scientific assessments gives concise direction on how to identify which options are appropriate for uncertainty analysis in each assessment

and how to apply them. It is accompanied by a separate supporting opinion that explains the key concepts and principles and describes the methods in more detail.

In addition to the above, a symposium 'Lifting the fog on uncertainty – practical advances on assessing and communicating uncertainty in the European public arena' was organised in collaboration with the ECDC and the Cambridge University Winton Centre in Sweden at the annual meeting of the European Society for Risk Analysis.

The Guidance on communication of uncertainty in scientific assessments provides lines to take on how to communicate the various expressions of uncertainty described together with specific guidance for assessors on how to best report the different expressions of uncertainty.

The guidance on the human, animal and environmental risk assessment of the application of nanoscience and nanotechnologies in agro/food/feed was endorsed by the Scientific Committee in May for 1 year. It gives practical suggestions and provides applicants with the tools they need to prepare complete nanotechnology applications equipping risk assessors like EFSA with the appropriate tools to evaluate their safety.

- Mapping, development, implementation and dissemination of cross-cutting risk assessment guidance documents

In 2018, the Technical Report on EFSA cross-cutting guidance lifecycle was published. It describes how topics for cross-cutting guidance document are selected, the process for the development and implementation of cross-cutting guidance, including trainings, and gives suggestions on the way forward once the guidance documents will be adopted.

- Guidance on threshold of toxicological concern approach

EFSA launched a public consultation on its proposed guidance for the use of the threshold of toxicological concern (TTC) approach in food safety assessment in November 2018. Once finalised and adopted it will help EFSA's scientific panels and staff in the use of the TTC approach as a screening and prioritisation tool for the safety assessment of chemicals, when hazard data are incomplete and human exposure can be estimated as low.

## Feed additives

The FEEDAP Panel adopted Guidance on the characterisation of microorganisms used as feed additives or as production organisms.

A public consultation was launched on the draft guidance for assessing the safety of feed additives for the environment. They are both intended to assist the applicants in the preparation and presentation of an application for the authorisation of feed additives used in animal nutrition.

## Pesticides

In cooperation with the European Chemicals Agency the guidance on how to identify substances with endocrine disrupting properties in pesticides and biocides was published. It was drafted with the support of the Joint Research Centre, the European Commission's science and knowledge service, and has been adopted by the European Commission as mandatory guidance for the implementation of the new scientific criteria, applicable to pesticides since November 2018.

The EFSA Panel on plant protection products and their residues adopted an opinion addressing the risk of pesticides residues in foods intended for infants and young children. The opinion includes a number of recommendations to further protect young infants from potential risks posed by pesticide residues in food. EFSA recommends the review of the maximum residue levels of certain types of pesticide residues that can be present in foods intended for infants and young children.

EFSA has contributed to the international efforts for updating human risk assessment methodology using adverse outcome pathways (AOP) for linking mechanistic information with adverse outcomes directly relevant for human health. As a follow up of the PPR Panel activities, the EFSA proposal in the area of pesticides has been included in the OECD AOP Framework. In addition, EFSA organised a scientific workshop addressing the use of *in vitro* methods for addressing differences between humans and the standard animal models regarding the metabolisms of pesticides. All these developments directly contribute to improving our capacity for identifying and quantitating the risk of pesticides to professional users, residents and consumers.

## Plant health

The guidance on quantitative pest risk assessment was published in August 2018 and describes a two-phase approach for a fit-for-purpose method for the assessment of plant pest risk in the territory of the EU. Phase one consists of pest categorisation to determine whether the pest has the characteristics of a quarantine pest or those of a regulated non-quarantine pest for the area of the EU. Phase two consists of a pest risk assessment, which may be requested by the risk managers following the pest categorisation results. This guidance provides a template for the pest categorisation and describes in detail the use of modelling and expert knowledge elicitation to conduct a pest risk assessment.

### 4.1.3. Methodology and data preparedness

#### Cross cutting: Prometheus

The PROMoting METHods for Evidence Use in Scientific assessments project was finalised in 2018. Overall, it was concluded that in principle the approach is applicable to all types of EFSA assessment, as it inherently implies tailoring the degree of extensiveness and formality of the methods for the scientific assessment process, depending on the context.

#### Chemical risk assessment

Procurements on toxicokinetic models have been finalised in spring 2018. Further work is ongoing to publish the models as open source tools on EFSA's *Knowledge Junction* and in the literature with the help of collaborators in European Universities and Member States institutions. An additional call for tender was launched in July to support the creation of a common platform for toxicokinetic modelling integrating all open source models described above.

Following a public consultation and a technical hearing in Brussels, Belgium, the Scientific Committee adopted a Statement addressing the assessment of genotoxicity for chemical mixtures at its November plenary meeting. The Statement clarifies the peculiarities related to genotoxicity assessment of mixtures and addresses both component-based and whole mixture approaches.

### 4.1.4. Risk Assessment Methodologies Programme (RAMPRO)

The risk assessment methodologies programme (RAMPRO) supports the identification, prioritisation and management of scientific projects in three main areas: (i) chemical risk assessment for human and animal health; (ii) environmental risk assessment of chemicals; (iii) harmonisation of risk assessment methodologies including the use of evidence. The programme's objective is to identify synergies amongst the different projects developing new methodologies and achieve a harmonised use of EFSA's scientific solutions, methods and tools. RAMPRO stimulates scientific cooperation across EFSA as well as between EFSA and centres of excellence in and outside the EU.

In 2018, the programme showed good progress in its execution with 25 ongoing projects, 7 projects already delivered and closed and 10 new projects planned for 2019 (chartering phase).

## 4.2. Performance indicators

### 4.2.1. Intermediary impact indicators

**Table 12:** Intermediary impact indicators for SO4

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Intermediary impact:</b> Increased satisfaction of stakeholders with regard to EFSA's preparedness, methodologies and response					
Preparedness with data, methods and expertise to address a risk assessment question when received and mutually agreed <sup>72</sup>	% of questions for which data is readily available	79%	N/A	79%	●
	% of questions for which methods are readily available	88%	N/A	88%	●
	% of questions for which expertise is readily available	91%	N/A	91%	●
	% of questions (regular and urgent) delivered within the initially agreed timelines	94.3%	N/A	94.3%	●
<b>Intermediary impact:</b> Increased satisfaction of stakeholders with regard to EFSA's preparedness, methodologies and response					
Satisfaction via feedback surveys: positive and relative qualitative improvement (with regard to follow-up actions)	Risk managers (EU/MS)	66.6% <sup>73</sup>	N/A	66.6%	●
	Stakeholders (general)	66.3% <sup>74</sup>	N/A	66.3	●
	MS, EU, international, non-EU country organisations	69.9% <sup>75</sup>	N/A	69.9%	●
Use of EFSA's guidance (access, downloads, citations)	Number of page visits (visibility)	Under definition <sup>76</sup>	N/A <sup>77</sup>	285,603	●
	Number of downloads (usage)	Under definition <sup>78</sup>	N/A <sup>79</sup>	22.3 <sup>80</sup>	●
	Number of citations (impact)	Under definition <sup>81</sup>	N/A <sup>82</sup>	265,972	●
Use of EFSA's methodologies (access, download, citations)		TBD in 2019 <sup>83</sup>	N/A	N/A	●

<sup>72</sup> The sub-indicators were measured for the first time in 2018; the 2018 execution will be used as baseline for the coming years.

<sup>73</sup> Satisfaction rate comes from the customers/stakeholders survey launched in September 2017.

<sup>74</sup> Satisfaction rate comes from the customer/stakeholder survey launched in September 2017.

<sup>75</sup> Satisfaction rate comes from the customer/stakeholder survey launched in September 2017.

<sup>76</sup> Linked to the Wiley report on *EFSA Journal* issued every year in Q2.

<sup>77</sup> As defined in the Programming document 2018-2020, the target should represent a 3-5% increase every year.

<sup>78</sup> Linked to the Wiley report on *EFSA Journal* issued every year in Q2.

<sup>79</sup> As defined in the Programming document 2018-2020, the target should represent a 3-5% increase every year.

<sup>80</sup> Average per article.

<sup>81</sup> Linked to the Wiley report on *EFSA Journal* issued every year in Q2.

<sup>82</sup> As defined in the Programming document 2018-2020, the target should represent a 3-5% increase every year.

<sup>83</sup> To be developed in 2019 within the context of the further development of the *Knowledge Junction*, in the context of exploring the use of bibliometrics to measure the impact of EFSA outputs/publications.

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
Use of EFSA's tools (statistical models) <sup>84</sup>		304	334 <sup>85</sup>	687	●

#### 4.2.2. Outcome indicators

**Table 13:** Outcome indicators for SO4

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Outcome:</b> Fostered use of new approaches and enhanced ability to anticipate and respond to risks					
	Number of capabilities included in EFSA's strategy implementation plan (original or revised) having been further developed (moved at least one stage from non-explored to feasibility, piloting, guidance endorsed, training provided, application in risk assessment)	0 (2016)	5	5	●
<b>Outcome:</b> Accessibility of EFSA methods and tools					
	Number of methods and tools readily accessible for use by external users (available in online repositories and on platforms)	To be calculated in 2019 <sup>86</sup> .	N/A <sup>87</sup>	N/A	●
<b>Outcome:</b> Harmonisation of risk assessment methodologies					
	Increase in the use of cross-cutting guidance documents by EFSA Panels	Number of citations of cross-cutting guidance in <i>EFSA Journal</i> <sup>88</sup>	N/A <sup>89</sup>	N/A	●
	Use of 'compulsory' guidance documents by panels and working groups	TBD in 2019 <sup>90</sup>	N/A	N/A	●

<sup>84</sup> Number of registered users per model in the R4EU platform.

<sup>85</sup> As defined in the Programming document 2018-2020, the target should represent a 10% increase every year.

<sup>86</sup> Software uploads statistics from the knowledge junction.

<sup>87</sup> Each year 10% increase compared to previous year.

<sup>88</sup> Number of citations of cross-cutting guidance in *EFSA Journal* – Linked to the Wiley report.

<sup>89</sup> The first measurement will be carried out in 2019.

<sup>90</sup> Compliance check on use of compulsory guidance.

### 4.2.3. Output indicators

**Table 14:** Activity and output indicators for SO4

Activity – output indicators				
Indicator	Executed 2017	Target 2018	Executed 2018	Status
Number of questions delivered for scientific outputs and technical reports	49	30/40 (technically corrected) <sup>91</sup>	38	●
Number of questions delivered for 'other publications' (external reports, event reports)	27 (22 external reports/ 5 events)	47 (external reports)/ 28 (technically corrected) <sup>92</sup>	31 (29 external report/ 2 event)	●
Proportion of scientific/technical questions adopted within deadline	98%	100%	100%	●

The feedback on EFSA's efforts in being prepared to face future risk assessment challenges coming from the Customer/Stakeholder survey registered an overall satisfaction rate of 66.3%, with the results across the different respondent groups quite consistent (66.6% for risk managers and 69.9% for EU and international organisations).

Looking deeper in the sub-areas within the strategic objective 4, the area of harmonisation registered a higher satisfaction rate than the one of preparedness (69.5% vs 64.1%).

While these results measure the external stakeholders' perception on harmonisation, they cannot be compared with the internal indicators measuring the harmonised use of risk assessment methodologies in the EFSA's scientific work (see table 13) as they are still under elaboration. Work in this area was done in 2018 through 8 different projects that were aiming at producing cross-cutting guidance, methodologies, and tools.

For what concerns preparedness, the first measurements of the three indicators set up to assess EFSA's preparedness in the areas of data (79% of the cases), methodologies (88% of the cases), and expertise (91% of the cases) showed positive results. These figures are in line with the results of the Customer/Stakeholder feedback as EFSA's preparedness in the above-mentioned areas of data, methodologies, and expertise registered rates of 79.8%, 81.7%, and 83.5% respectively. Moreover, the indicator on the percentage of questions (regular and urgent) closed within the initially agreed timelines was very satisfactory, (94.3%). The result is coherent with the timeliness in general risk assessment as it takes into account only the requests with negotiated deadlines<sup>93</sup>. Finally, in the area of strategic objective 4, EFSA closed a number of questions in line with the technically corrected plan (see table 14).

All scientific and technical outputs have been adopted on time, thus allowing reaching the 100% target for timeliness.

<sup>91</sup> The technically corrected plan is taking into account technical issues in the planning phase. The most impacting factor was an updated plan agreed with DG Health and Food Safety services in Pesticides area early in 2018, which has shifted priorities between SO1 and SO4 outputs. The status of the indicator is calculated against this corrected plan.

<sup>92</sup> The technically corrected plan is taking into account technical issues in the planning phase. The number of questions delivered through external scientific reports in the initial plan was erroneously not taking into account the reduction of the budget for scientific grants and procurements for 2018 in the animal and plant health area. The status of the indicator is calculated against this corrected plan.

<sup>93</sup> Initially agreed versus updated deadline. Only applicable for negotiated deadlines, with the exclusion of regulated products applications and technical assistance.



## 5. Create an environment and culture that reflects EFSA's values

With the overall objective to develop an environment focused at improving organisational performance and capabilities, the following outcomes were achieved during 2018 (the status of the ongoing projects under this objective and their contribution to the expected results from the strategy implementation is presented in Annex III):

### 5.1. Highlights of 2018 achievements

#### 5.1.1. EFSA staying relevant in a changing world

EFSA published the [third external evaluation](#) of its activities, covering the period from 2011 to 2016, assessing the progress made in implementing previous recommendations and highlighting further areas for improvement. More detailed information can be found in Section III.

Midterm through its strategy cycle, EFSA carried out a gap analysis to take stock of achievements realised since 2016 as well as to identify initiatives and areas remaining to be tackled to fulfil the current strategy cycle commitments. The outcome of the exercise revealed some minor gaps particularly in the area of developing harmonised cross-cutting methodologies and guidance (under strategic objective 4). The initiatives proposed to partially tackle this gap were integrated in the Programming Documents covering the period 2019-2022.

EFSA started preparing for the changes the European Commission's review of the food law (178/2002) will entail, by conducting an assessment of its implications at the level of its processes and impacts on the strategy implementation plan. At the same time, EFSA recognised that notwithstanding the timing of the update of the regulation, it will have to focus on leaning its processes and accelerate its efficiency seeking efforts in order to implement the strategy 2020 objectives while getting prepared for addressing the expectations of the '178 review' proposal and new challenges and opportunities to be faced in the next strategic cycle post 2020. This will be the scope of the upcoming Architecture programme in 2019.

EFSA 3rd Scientific Conference took place Parma from 18<sup>th</sup> to 21<sup>st</sup> September. Over 90 esteemed speakers in 9 sessions tackled the topic at the heart of the event "*Where science meets society: Putting risk assessment in context*". 1100 participants from around the world attended and around 800 people followed the proceedings on line. The sessions explored how science, food and society might change the future.

In preparation of the future EFSA strategy, beyond 2020, an environment-scanning exercise was kicked-off. The first milestone was the collection of relevant inputs stemming from the 3<sup>rd</sup> scientific conference, which were further elaborated in a workshop to identify key challenges and opportunities against possible futures with the involvement of external stakeholders, such as the European Commission, sister Agencies, representatives from the Member States (Advisory Forum) and EFSA stakeholders forum. The conclusions of this exercise will be captured in an external environment analysis report foreseen to be submitted for the approval of the Management Board in June 2019 and that will report on the key challenges and opportunities and potential actions to address them.

#### 5.1.2. Setting up of an accountability framework with four pillars ensuring sound operational performance and overall compliance

##### Decision-making

As part of the setting up of an integrated accountability framework based on four pillars (governance and decision-making, results-based management, assurance management,



quality and continuous improvement), EFSA continued developing its governance and decision-making framework (DMF) established in 2017, by expanding to the areas of the governance of the scientific advice production process and quality of science and by taking advantage of the lessons learned from the pilot phase. In addition, EFSA started drafting an Accountability Policy, expected to be presented to the Management Board for approval in 2019, for formalising the setting-up of an integrated accountability framework. The policy will further clarify clear roles and responsibilities as well as authorities and delegations, and will delineate a hierarchy of norms to achieve better synergy and alignment around rules, regulations, policies and procedures with accountability for resources and results.

### Results-based management

EFSA's results-based management approach was enhanced with:

- The piloting of results-based budgeting (RBB) in cooperation with its partner DG Health and Safety, implemented in EFSA's Programming Documents 2018-2020 (final) and 2019-2021 (draft) in January and EFSA's Programming Documents 2019-2021 (final) and 2020-2022 (draft) in December, as adopted by the Management Board. It includes the special request to the budgetary authorities for additional resources to deliver timely against an increased workload particularly in the area of regulated products evaluation. Moreover, as a way to address its resources shortage, EFSA has implemented for the first time a more flexible allocation of internal resources, enabled by the availability of relevant data in its performance management system, moving budget and internal resources to cover priority areas in agreement with DG Health and Safety, such as in the area of Nutrition.
- The streamlining of planning and reporting activities and tools to EFSA's Strategy 2020 allowing for easier yet regular and insightful monitoring of performance at all levels. To this end, EFSA's Management Board adopted in its March meeting the *2017 Consolidated Annual Activity Report*, the first such report fully aligned with the new results-based management (RBM) approach and the 2017 programming document, while a leaner and improved approach to quarterly performance monitoring was implemented in agreement with the Management Board in its October meeting.
- The development of EFSA's intervention logic under the new Strategy to enable to integrated use of monitoring and analysis via performance indicators and evaluations. The new approach will be finalised and implemented in 2019 allowing for a sound and leaner performance analysis at the various levels (e.g. organisation, outcomes, programmes, projects).

### Quality and continuous improvement

To improve organisational performance and capabilities, robust management functions strengthening process performance and quality were further enhanced:

- EFSA's Management Team endorsed in its annual Management Review, the 2017 annual quality management report and the 2018 objectives, focussing on recommendations received following the first 2017 surveillance audit of its ISO 9001:2015 certification.
- In its journey towards continuous improvement, EFSA finalised its enhanced Process Architecture (EPA II) with the definition of the five remaining processes i.e. Governance and Decision Making, Operational Coordination, Developing EFSA, Methodologies management and Innovation management. Importantly, the full integration of EPA into the Plan-Do-Check-Act allows for managing resources and

activities at the level of processes and this is expected to streamline and strengthen EFSA's performance management and reporting at the appropriate level of granularity.

- Another key initiative in this area is the ongoing work on a revision of the EFSA Quality Policy, with the emphasis on strengthening the notion of scientific value and on integrating elements from the recent initiatives Prometheus, TERA and SEA in EFSA's processes.
- The quite positive results of the comprehensive 2017 customer feedback survey were shared and discussed with EFSA staff, DG Health and Safety, the Member States Advisory Forum and the EFSA Stakeholder platform for the joint identification of improvement areas; these will be reviewed in EFSA's Annual Quality Management Review at the beginning of 2019.

### Compliance, transparency and effective management through provision of integrated assurance mechanisms

To improve organisational governance, accountability and compliance for an efficient and effective delivery of its strategic objective, the following actions were performed:

- Efficient management of treasury, inventory and accounts was confirmed by the Court of Auditors (ECA), and EFSA received an unqualified opinion on its 2017 provisional accounts, stating their reliability and compliance with financial and accounting rules.
- EFSA followed up on the IAS recommendations on IT Governance and IT Project management and IAS concluded that all five related very important audit recommendations have been adequately and effectively implemented. EFSA also published all standard operating procedures related to the development of its scientific outputs to address the related audit recommendation.
- The 2016 Discharge was issued by the European Parliament and included largely positive and welcomed achievements such as the delivery of EFSA's Strategy 2020 according to plan, the excellent budget execution, the implementation of transparency and engagement measures as well as the adoption of the new independence policy and the launching of open data and evidence tools; as should be the case for the 2017 exercise. As a follow up to 2016 Budget Discharge issued in April, EFSA is addressing the comments related to external audit, internal audit and internal controls.
- Within the EFSA Accountability Framework, and as part of the Assurance Governance, the first Assurance Report (reference year 2017) covering activities supporting Management Assurance including an Internal Control Assessment based on monitoring criteria set in the programming document, was approved by the Management Board Audit Committee in March.
- EFSA implemented, in June, the new exception request workflow tool that monitors the compliance, implementation and effectiveness of EFSA's operations against all applicable regulations, policies and procedures.
- Accountability, compliance and a regulatory framework ensuring legality of the operations are confirmed with the continuous legal and regulatory business support services, including the Data Protection Officer function and its advisory role on data protection, the management of pre-litigations and PAD obligations. Overall EFSA handled, in 2018, 165 Public Access to Documents (PAD) applications, out of which 118 received between 1 January and 31 December 2018, 47 applications carried forward from 2017. Six cases are pending before the European Courts. In the

context of the implementation of EFSA's 2017 policy on independence, the centralised competing interest management function processed 4140 ADoIs submitted by members of EFSA's Scientific Committee, Scientific Panels, their working groups as well as of pesticides peer review meetings and of pesticides related networks and networking activities appointed by Member States competent authorities.

- During the first year under the New Independence Policy, EFSA published the Declarations of Interest (DoI) of its heads of unit, as well as the list of "Public Institutions" that EFSA used for the DoI screening process and increases the transparency applied to its governance in-line with its "Open EFSA" approach and EFSA Strategy 2020.
- New Implementing Rules to the Staff Regulations in the fields of middle management, advisers function, temporary occupation of management posts, working time and learning and development based on model rules of the European Commission were adopted by EFSA's Management Boards of 10th October and 12th December.
- EFSA participated to the EU-NATO Parallel and Coordinated Exercise with positive results aiming at fostering preparedness and management of crises related to food and feed safety.
- To address and reduce the risk of information security incidents, a new Information Security Policy and Manual are providing guidance for all users of EFSA IT systems and services.

### *5.1.3. Efficient talent management and development supporting a culture of performance and accountability*

- To foster expert attraction and to enable strategic workforce planning for experts and staff, specific efforts were deployed through the Expertise Management Programme (EMP) as described under the subsequent section in SO3.
- To promote EFSA's branding and the visibility of career opportunities, all EFSA's vacancies were efficiently disseminated via the European Personnel Selection Office (EPSO), LinkedIn and Focal Points, enabling the registration of over 45 000 followers on LinkedIn as of December 2018. A new traineeship call has also been launched and concluded with 2,288 eligible candidates. A joint recruitment procedure was launched with ECHA to establish a common reserve list for Toxicologists.
- In terms of talent development, EFSA aligned its learning and development strategy to EFSA 2020 objectives and continued investing in learning with 158 internal and 270 external training sessions organised at year-end vs.197/144 last year. Overall, 2,003 staff, experts and trainees were trained in 2018 (3,050 in 2017).
- Dedicated efforts were made to strengthen leadership and managerial competences with a tailor-made management development programme focusing this year on various initiatives such as training for Heads of Unit on the topic of "Head of Unit as a Coach", training for all managers on the topic of "Boosting Competencies – Getting Ready for the 2019 Performance Dialogues", and two "All Managers Forum" on the topic of disruption and transformation at EFSA and creative approaches to people development.
- The staff engagement survey (SES) run every two years, aims to measure organisational health and to provide valuable insights into how staff feel about specific aspects of their work, about the organisation and the managerial

community. The Management Feedback Survey (MFS) runs on alternating years and aims to see how managers can be a positive workforce and are a key driver of organisational performance and change. An action plan, outcome of a joint effort between EFSA staff and its Management to set out positive, practical and clear measures to address the 9 focus areas, highlighted for attention in the survey was published in 2018 and is being implemented and closely monitored. However, the total favourable rate decreased to 56% (vs 60% in 2016 and 66% in 2017). Top scoring pertains to collaboration and cooperation towards shared goals and on the understanding the department/unit/team's priorities, EFSA's strategy and strategic objectives. The two main areas for improvement remain decision making and organisational change and the proposed way forward will be embedded into a joint SES-MFS action plan in 2019.

#### *5.1.4. World-class environment enabling the achievement of EFSA's strategic capabilities*

- A World-class IT to enable the achievement of EFSA's strategic objectives was ascertained according to metrics on service delivery and end-user satisfaction (respectively 82 % and 93 %) which exceeded target. Service owners' satisfaction at 64 % was also above target. Project stakeholder satisfaction was the main focus during 2018 and through enhanced business partnering and improved service delivery activity a more than 50% increase in the rating, almost on target to world class benchmark is achieved.
- In the area of corporate services, further initiatives to streamline transactional processes were achieved with the development of a new travel model for EFSA experts to be concluded during 2019.

#### *5.1.5. EU Agencies Network (EUAN) in 2018*

As of March 2017, and for 1 year, EFSA has chaired the Network of EU Agencies, coordinating key activities and obtaining achievements as listed below.

- The EU Agencies Network (EUAN) meetings (Heads of Agencies and Heads of Resources) which took place in Brussels from 20-22 February marked the closing of a yearlong chairmanship for EFSA. The main achievements under EFSA's coordination were numerous, including increased shared services among EU Agencies in the area of IT and/or through joint procurement, a new virtual platform for exchanging HR practices and establishing an HR community of knowledge, the development of a maturity model within the EUAN Performance Management Framework to assess and monitor EU Agencies progress in the area. In addition, EU Agencies developed a common position to be presented to EU institutions in the context of the debate on the new Multiannual Financial Framework (MFF) and a working group drafted a paper examining the potential for new ways of funding for Agencies. The Sub-Network of EU Agencies in charge of providing Scientific Advice (EU-ANSA) adopted a paper addressing Agencies' engagement in the EU research cycle, identifying common interest research topics and potential ways for better advocating with EU research authorities. EFSA also created a EUAN Shared Support Office (SSO) in Brussels (inaugurated on 1 March), in charge of supporting future EUAN Chairs in the coordination efforts.
- After 1 March 2018, EFSA continued in its role of EUAN Troika Member, supporting the European Border and Coast Guard Agency (Frontex), which has headed up the network until 31 August, and the European Centre for Disease Prevention and Control (ECDC), which took over as new chair after that date. At the October EUAN meetings Heads of Agencies and Heads of Resources went through a rich agenda which included most notably MFF 2021-2027, the state-of-play of the Brexit

negotiations and expected impacts on EU Agencies. Key principles and the process for defining the EUAN Strategy post-2020 were also agreed.

### Highlights from EUAN-Sub-network/thematic work

EFSA led or actively participated to various activities carried out by the various EUAN sub-networks, among which the following can be highlighted:

- Within the Inter-Agency Legal Network (IALN), the analysis of the legal aspects of data sharing and on Brexit implications staff and other management issues.
- Within the Information and Communication Technologies Advisory Committee (ICTAC), the work on pooling knowledge and developing common solutions on the digital workplace, on emerging technologies (big data, artificial intelligence), on IT governance and cybersecurity, and on envisioning the next generation of corporate cloud services and a blueprint for a future EU 'data lake' model<sup>94</sup>.
- Within the Network of Procurement Officers (NAPO), the launching inter-agency calls and the coordination of ongoing procurement efforts.
- Within the Performance Development Network (PDN) the work on the EUAN performance management framework (KPIs' catalogue and impact indicators) and on the methodology to plan and monitor the shared services' usage and benefit

### 5.1.6. Information management programme (IMP)

In the wave of modernising information sharing, information co-creation and information reporting, the IMP worked on establishing information governance processes, on defining a corporate record management policy, in line with the European Commission Rules, and on analysing the introduction of business intelligence solutions to support the corporate reporting and decision making process. The programme started with the plan of the adoption of 'ARES', the European Commission solution for managing correspondence and records to then focus on the *New World of Work* project, that is changing the way staff and experts share and create information, communicate and collaborate.

#### ■ Information governance

In 2017, a corporate Information Governance Framework was established. The monitoring of the maturity level of information management at EFSA is now embedded in the newly established EFSA Decision Making Framework. Information Management (as a process) is one pillar of the newly established Assurance Council, against which reporting is done twice per year.

#### ■ Business Intelligence and Knowledge Exploitation (BIKE) project

The BIKE project aims at automating the EFSA corporate reporting and the internal decision making processes by means of business intelligence solutions. In 2018 the project has analysed all reporting needs and in 2019 will deliver new processes, new tools and new automatic reporting functionalities for the overall planning, monitoring and reporting needs.

#### ■ Records management project

The records management project (full implementation envisaged for 2019), with the objectives of satisfying EFSA legal obligations (i.e. on historical records archiving and records deletion for data protection and confidentiality) and underpinning EFSA's quality

<sup>94</sup> A *data lake* is a subject-specific repository for large quantities and varieties of data, both structured and unstructured. The data lake accepts input from various sources and can preserve both the original data fidelity and the lineage of data transformations. The lakes could help resolve the issue of accessibility and data integration for European businesses and citizens in different industries and application areas.



management system (i.e. applying appropriate filing and retention periods) in an efficient manner. The records management project produced a draft policy and supporting documentation, including a records list and retention schedules. EFSA's management team approved the key policy principles as well as a change in the scope of the project with the move of the technological solution from *Opentext* to the European Commission's 'Ares' in a shared service modality. The implementation and deployment of the records management policy will start in 2019 and will be completed in 2020.

- New World of Work (NWOW) project

The NWOW project (launched in 2017) aims to radically change the way EFSA staff and experts work and collaborate: a notable cultural transformation that should allow for greater productivity and knowledge exchange. Enhanced processes supported by digital systems, platforms, tools and more collaborative physical spaces to tackle future challenges are an important feature of EFSA's efficiency. To facilitate the cultural shift, EFSA started delivering tailored training to staff. New tools (Skype for Business), new devices and revamped meeting rooms were also delivered by the project as a means to foster collaboration and group productivity.

### 5.1.7. Institutional relations

- European Commission

A new EC proposal on transparency and sustainability of the risk assessment model in the food chain was adopted by the Commission in April. EFSA supported the EU Institutions with technical advice throughout the co-decision procedure in 2018 and an outcome is expected in 2019 (Q1).

EFSA and DG Health and Food Safety Senior Management met on a number of occasions to discuss important issues such as the General Food Law/178 review and the Multi-Annual Financial Framework.

The Joint Research Centre and EFSA renewed their commitment through a cooperation agreement to work together in a variety of scientific and technical areas related to food and feed safety, animal health and welfare, plant health and nutrition.

EFSA participated at Council Chief Veterinary Officers and Chief Plant Health Officers meetings upon invitation by the Bulgarian Presidency of the EU and the European Commission. EFSA's work on African swine fever and lumpy skin disease were the subject of exchanges with national risk managers.

- Interactions with Members of the European Parliament (MEPs)

Activities with the European Parliament (EP) in 2018 were well sustained. EFSA's Executive Director and the AGRI Committee held an exchange of views event (for the second time) in July, and a hearing in front of the ENVI Committee in October in view of the ED mandate renewal.

Upon invitation by MEPs, EFSA participated at a number of events supporting the implementation of EP ENVI and AGRI committees' work programmes e.g. on the interface between science and policy, on food packaging, on bee health and on antimicrobial resistance.

EFSA's Executive Director addressed the science, technology, options and assessment (STOA) panel in March during the EP's plenary session to present EFSA's activities, strategic ambitions and challenges. EFSA also participated at an EP pairing-scheme. The EP tasked EFSA to pursue the EU Bee Health partnership, an initiative organised by EFSA to improve data sharing among bee stakeholders. Moreover, the EP asked EFSA to deliver scientific opinions on the health and welfare of farmed rabbits in the EU, and on

the science behind the development of an integrated approach for the risk assessment of multiple stressors in managed honey bees (*Apis mellifera*).

In close cooperation with EFSA and the ECHA, an EP working group developed a proposal for a pilot project on a feasibility study to set up a common open platform on chemical safety data to increase and simplify access to the data collections held by the agencies, enriched with other public data and data fed by external sources; the pilot project is due to start in 2019.

Following the creation of a special EP Committee on the EU system of pesticides authorisation (PEST), EFSA established a task force overseeing two public hearings in Brussels, one visit of a MEPs' delegation to EFSA, responses to the PEST committee's questionnaires, the screening of more than a 1 100 amendments to the draft report and related media activities including one press conference at the EP in Brussels.

The Executive Director also attended a debate of the ENVI Committee on the Commission proposal to amend the General Food Law and provided EFSA's point of view.

#### ■ Visits of high-level French delegations

Following meetings with members of President Macron's government in January, EFSA welcomed a delegation of French ministers, members of the National Assembly [Assemblée Nationale] and diplomats to Parma in March where there was a constructive exchange of views on how best to strengthen food safety in Europe. EFSA also met with representatives from various French Ministries in Paris in May, and welcomed two delegations of the French Parliament in July to Parma - one from the French Parliamentary Office for Scientific and Technological Assessment (OPECST) in the context of their work on the trust level in European agencies responsible for the evaluation of regulated products, and one from the Assemblée Nationale for their fact-finding mission on industrial food.

#### ■ Visit of a Swiss delegation of cantonal enforcement authorities

In the context of EFSA's scientific collaboration with EU Member States and associated EU countries, EFSA welcomed a delegation of cantonal enforcement authorities (Cantonal Chemists) in March, during which EFSA presented its work, in particular in the areas of regulated products and risk communication.

## 5.2. Performance indicators

### 5.2.1. Intermediary impact indicators

**Table 15:** Intermediary impact indicators for SO5

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Intermediary impact:</b> Sound operational performance					
Proportion of KPIs of the programming documents	Intermediary impact	71%	80%	78%	●
	Outcome	97%	90%	65%	●
	Activity/output	86%	95%	89%	●
Clean discharge achieved	Discharge is granted	Yes	100%	Yes	●
	Accounts are closed	Yes	100%	Yes	●
	Observations are followed up within the prescribed deadlines	100%	100%	100%	●



KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Intermediary impact: Efficiency</b>					
Improved ratio of effort (FTE) spent in operational vs support activities		73.4:26.6	>75:25	73:27	●
Efficiency index in EFSA's activities	For mature processes: improved index (ratio of output & quality/satisfaction vs input)	TBD in 2019	N/A		●
	Process maturity index: percentage of mature vs total processes	TBD in 2019	N/A		●
	Projects: improved index (delivery on budget, on time, in scope or better)	85%	87%	87.2%	●

### 5.2.2. Outcome indicators

**Table 16:** Outcome indicators for SO5

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Outcome: People and culture</b>					
Staff engagement index via feedback survey (based on biannual survey - interagency framework) <sup>95</sup>	Total favourable	63 (2015)	66	66%	●
	Total engagement	76 (2015)	78	78%	●
	Organisational awareness/commitment	75% (2017)	75%	75%	●
Management and leadership index	Management feedback survey: Line management	69%	70%	64%	●
	Management feedback survey: leadership	46%	60%	52%	●
	Occupancy rate (%) Statutory staff year average	95%	>95.5%	97.5%	●
Competence management maturity level		TBD <sup>96</sup>	To be defined in 2018 <sup>97</sup>	86% <sup>98</sup>	●

<sup>95</sup> The target 2018 and the execution remain the same throughout the year reflecting the result of the 2017 Staff Engagement Survey. The next survey will take place in 2019.

<sup>96</sup> via: (i) feedback of participants in managers' development (MD) programme 2017 (ii) EFSA's compliance with European skills/competencies and occupations 2017.

<sup>97</sup> Increase in maturity level to be defined in 2018 based on feedback from first survey to be launched for managers who participate in the managers' development programme.

<sup>98</sup> EFSA's compliance with European skills/competences and occupations — 2017.

KPI	Indicator	Baseline	Target 2018	Executed 2018	Status
<b>Outcome: Compliance</b>					
Compliance index (to laws, regulations, decisions, standards, policies and procedures applicable to EFSA) <sup>99</sup>	Number of non-compliant events;	<25	<25	40	●
	Number of exception requests;	<90	<90	56	●
	Respective financial impact of non-compliance	<EUR 150,000	<EUR 150,000	EUR 228,878	●
	Percentage of compliance with internal control standards <sup>100</sup>	80% (2015)	90%	N/A	●
	Number of 'critical', 'significant' or 'very important' findings (ECA, IAS, audit adviser)	0; 4	0; <5	2	●
<b>Outcome: Enabling work environment</b>					
Innovative collaboration methods supported by world class IT tools	% of tele-meetings (experts & networks) over total meetings (tele-meetings + physical meetings)	20%	25%	24.3%	●
	Ratio of internal to external email traffic (staff, experts, networks)	Internal/ex ternal 95/5 <sup>101</sup>	Internal/ex ternal 47.5/52.5	Internal/e xternal 55/45 <sup>102</sup>	●
	Social collaboration platforms (staff, experts, networks)	TBD in 2019 <sup>103</sup>	N/A	N/A	●
<b>Outcome: Capabilities</b>					
Performance-based management maturity level		Between stages 2 and 3; TBC in 2018	Between stages 2 and 3	Between stages 3 and 4 <sup>104</sup>	●
World-class IT maturity level (PEMM <sup>105</sup> model)		1.7	1.9	1.9	●

<sup>99</sup> Overall, the Compliance Index presents a moderate deviation due to the fact that the two KPIs marked in red, even though have exceeded the ceilings set for 2018, do not require any managerial action.

<sup>100</sup> The indicator was deleted in 2018 since it is obsolete.

<sup>101</sup> Total mail received annually (average): 5.2 million/total mail sent annually (average): 2.1 million, of which EFSA internal traffic: 2.0 million=95%

<sup>102</sup> Total mail received annually (average): 11 million/total mail sent annually (average): 1.8 million, of which EFSA internal traffic: 1.0 million=55%

<sup>103</sup> The first measurement of this indicator is postponed to 2019, since the collaboration platform provider was changed in the course of 2018.

<sup>104</sup> To be confirmed in 2019 following the adoption of the maturity model by the EU Agencies Network.

<sup>105</sup> Process and Enterprise Maturity Model.

### 5.2.3. Outputs indicators

**Table 17:** Activity and output indicators for SO5

Activity – output indicators				
Indicator	Executed 2017	Target 2018	Executed 2018	Status
Proportion of experts with approved annual DOI (aDOI) before first meeting invitation	100%	100%	100%	●
Proportion of experts with approved specific DOIs (sDOI) before participation in an EFSA meeting	99.8%	100%	100%	●
Proportion of original budget committed/paid at year end – differentiated	94.1% 94.7%	100%	116.8% (C) 112.3% (P)	●
Proportion of original budget committed/paid at year end – non-differentiated	100.9% 91.9	100%/90%	98.3% (C) 88.9% (P)	●
Proportion of original science grants and procurement budget committed/paid at year end	103.6 104.9	100%	116.8% (C) 112.3% (P)	●
Carry-forward of payments to following year <sup>106</sup>	8.9	<10%	9.6%	●
Service delivery index	89%	80%	82%	●
Transformation performance index (development project execution index) <sup>107</sup>	64%	80%	75%	●

The feedback received from the customer/stakeholder feedback survey on EFSA's ability to create an environment and a culture that reflect EFSA's values registered an overall satisfaction rate of 61.8%, with a high variability among the different respondent groups. On one hand, respondents' groups that work closely with EFSA (such as EFSA's Management Board, partners, advisory forum and focal points) registered satisfaction rates higher than 70%, while stakeholders such as Art.36 organisations, international organisations, and national risk assessment bodies registered satisfaction rates lower than 55%. The satisfaction rates of the scientific experts were, instead, close to the general average.

#### Sound operational performance

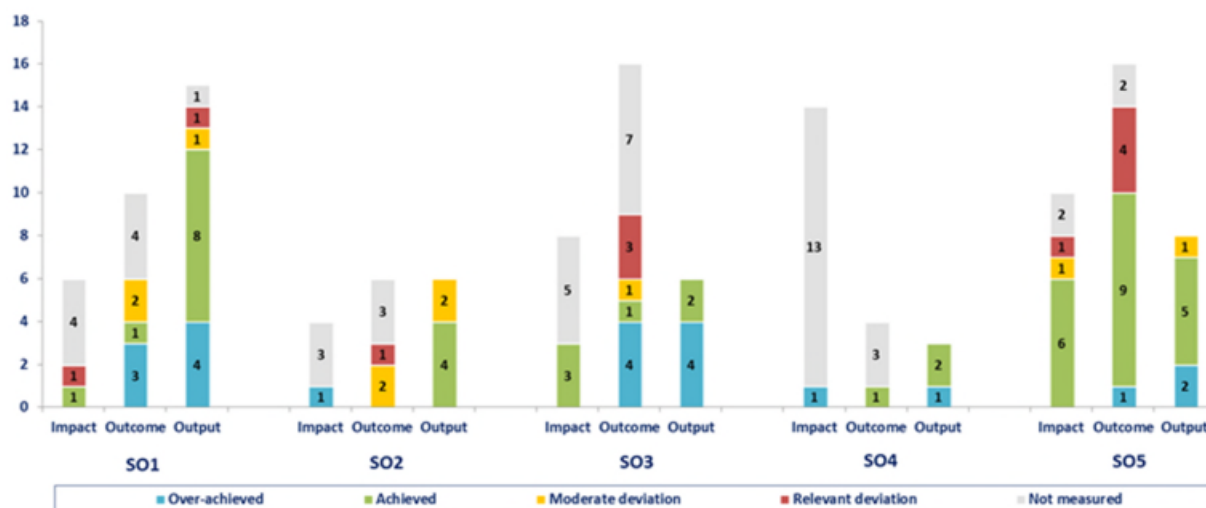
The sound operational performance is measured through 'the clean budget discharge' and the 'proportion of KPIs of the programming documents' (see table 15). As mentioned above, the discharge was granted in April, while the composite indexes that aggregate the overall performance of the different "tiers" (output-outcome-impact) of KPIs registered results at 89%-65%-78% compared to the targets of 95%-90%-80%. The performance of output and impact indicators were in line with the targets set for 2018 and they also registered an improvement compared to 2017, the overall performance of outcome indicators was below the target set and below the result achieved in 2017. More details on the points of attention are described under each strategic objective, where the various indicators are analysed in a comprehensive narrative, accounting for the 'relevance', the 'reasons', and the 'control' over these deviations. . It is worth noting that

<sup>106</sup> Non-differentiated credits.

<sup>107</sup> For the subset of key projects that were followed.

the vast majority of these deviations are either due to factors outside EFSA's control, are minor, or of technical relevance.

**Figure 5:** EFSA's KPIs: summary of 2018 performance by SO and by type of indicator



Moreover, these three indicators are summing up the KPIs with different levels of maturity (outcome and impact indicators have been set up for the first time in the current strategy), with ambitious targets that for the most part were set without previous experience, but aimed at driving the organisation forward. This has been useful in shedding light with regards to improving the quality of KPIs (e.g. focus on the few more relevant indicators and better coverage of process indicators, weighing the indicators according to significance), a direction that will be followed up in the next strategic cycle.

Lastly, some of the differences can be explained by the higher number of indicators that was measured in 2018 compared to the previous year (86 vs 63, see Figure 5 for a more detailed overview of 2018's indicators).

### Efficiency

While performing its activities, EFSA is constantly seeking for efficiency gains. In that perspective the "project improved index", which assesses the performance of projects compared to their plan (assessing dimensions such as resources, time, and scope), was on track at 87%, while the "transformation performance index", used to monitor the status of a subset of projects in the area of transformation, is at 75% and slightly below the target of 80% (78% registered in 2017), mainly due to the delays occurred in some projects.

### People and culture

The satisfaction rate in the strategic objective 5 of the EFSA staff who participated in the customer/stakeholder survey was 66.1%, a result that is in line also with the results coming from the bi-annual Staff Engagement Survey (SES) and from the MFS. More in detail, the 2017 Staff Engagement Survey conducted in November 2017 displayed excellent results with a 78% engagement index (vs 76% in 2015), an overall favourable rate of 66% (vs 63% in 2015) and a response rate of 80% (vs 64% in 2015).

Complementary to this data, the results of the Management Feedback surveys run in 2018 showed results below the targets set. However, the total favourable rate for

questions on the dimension of Leadership fared better than in 2016 (52% vs 46%). It is worth noting that, in 2018, the survey registered a very high response rate (83%).

Finally, the occupancy rate, the last element composing the “Management and Leadership index” registered an achievement of 97.5%, exceeding the target of more than 95.5% set for 2018. Regarding the allocation of the FTEs between operational and support activities, the ratio has been 73:27, slightly below the target of 75:25, but in line with 2017 results.

### Compliance

In the area of assurance, a significant increase of non-compliance events were registered (40 > KPI of 25). This seems to be due to an increased awareness from the staff, subsequent to the introduction of the new tool, targeted training sessions and dedicated tutorial. It is furthermore reported that the financial impact of non-compliance events was higher than the ceiling of € 150,000. The remaining indicators, on the number of exception requests and on the number of significant findings coming from audits, were instead on track (see table 16). A more detailed outlook is provided in Section III.

### Enabling working environment

Measurements regarding the development of an enabling working environment properly supported by world class IT tools that promote innovative collaboration methods are on track. More specifically, in the area of IT improvements, the investments in technological infrastructure, such as the introduction of social collaboration tools, are paying off, as the percentage of tele-meetings increased to 24.3% (20% registered in 2017). These investments affected also the traffic of internal emails sent, which decreased by 50% compared to last year (from 2 million in 2017 to 1 million in 2018), and in line with the target set.

### Financial performance

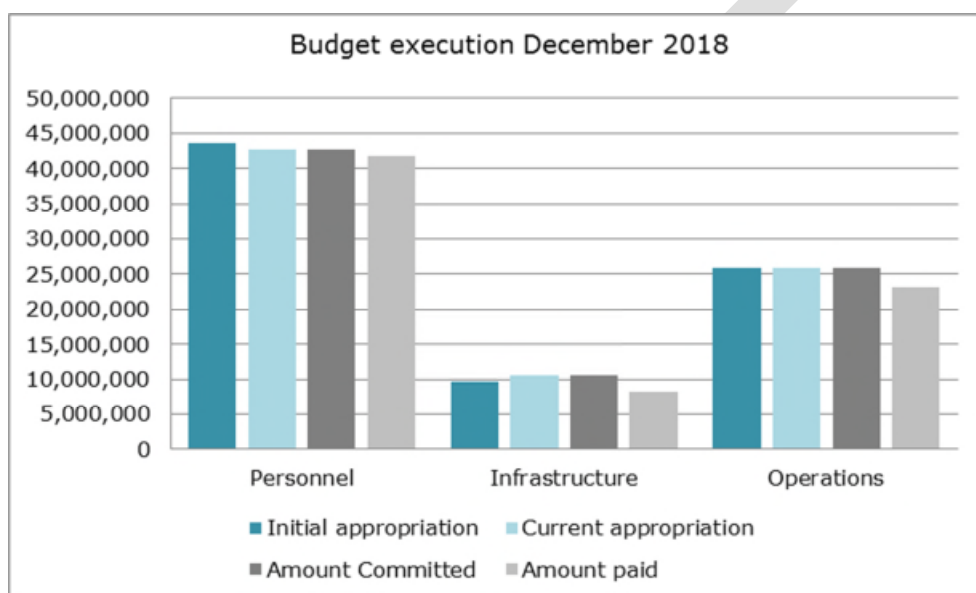
Focusing on the financial performance of EFSA in 2018, the indicators measuring the proportion of budget committed and paid are on track, with a minor deviation for what concerns the non-differentiated credits (commitments: 89.3% vs a target of 100%; payments: 88.9% vs a target of 90%). More details is provided in Section II.

# Section II – Management of resources

## 1. Budget and financial management

The year 2018 can be considered one of the most successful years in terms of budget implementation. More details are reported below.

### 1.1. Financial resources



**Table 18.** Budget appropriations

Title	Initial appropriation	Current appropriation	Δ	Amount Committed	%	Payment appropriation	Amount paid	%
Personnel	43,622,254	42,642,178	-980,076	42,642,178	100%	42,642,178	41,764,667	98%
Infrastructure	9,560,171	10,599,491	1,039,320	10,599,398	100%	10,599,491	8,252,673	78%
Operations	25,942,145	25,942,145	0	25,942,007	100%	26,829,037	23,091,791	86%
<b>Total:</b>	<b>79,124,570</b>	<b>79,183,814</b>	<b>59,244</b>	<b>79,183,582</b>	<b>100%</b>	<b>80,070,706</b>	<b>73,109,131</b>	<b>91%</b>

The initial budget of EFSA for 2018 was € 79.1 million in commitment and € 80.0 million in payment appropriations. Interest generated in the bank account (€ 59,244.25) became part of EFSA budget, allocated to building acquisition. This amendment increased the total budget to € 79.2 million in commitment and € 80.1 million in payment appropriations.

As of 31<sup>st</sup> December 2018, the indicators measuring the proportion of budget committed and paid were on track. Commitments total: 100.0% of available appropriations; payments total: 91.3% of available appropriations; differentiated commitments and payments: 116.8% and 112.3% vs a target of 100%; non-differentiated: commitments:



98.3% (vs a target of 100.0%), payments: 88.9% (vs a target of 90%), carry-forward of payments (non-differentiated credits): 9.6% (target < 10%). The main expenditure drivers in terms of commitment execution were staff cost (€ 42.6 million), scientific grants and procurements (€ 8.9 million), information technology (€ 8.5 million), building related cost (€ 6.23 million) and scientific meetings (€ 5.5 million).

Out of total of € 80.1 million of payment appropriations, €79.1 million was paid, mainly in staff cost (€41.8 million), followed by scientific cooperation (€9.5 million), information technology (€5.7 million) and scientific meetings (€ 5.2 million).

Out of 6.2 million carried forward from 2017, 96.7% has been paid (€6.0 million). An amount of € 0.2 million in C8<sup>108</sup> credits remained unused and was cancelled.

EFSA has since years implemented activities and received ad hoc grants from DG NEAR to support the Pre-accession programme in the field of food and feed safety). As of December 2017, a grant agreement of amount EUR 0.32 million entered the execution phase for a total duration of 18 months to be finalised in May 2019. The cost of 1 seconded national expert (SNE) is covered by the agreement. As of 31<sup>st</sup> December 2018, €0.24 million out of total grant agreement amount has been committed and € 0.20 million paid. The outstanding commitment amount to be implemented in 2019 is € 0.08 million.

All 76 debit notes issued in 2018 were effectively recovered to the amount of €80.3 million. This amount includes the EU budget contribution (€80 million). Two debit notes issued in previous years remained open at the end of the year to the amount of €0.024 million. One of these, to the amount of €0.02 million is in litigation before the courts.

Budget implementation by budget item can be found in Annex II of this document.

## 1.2. Budget transfers

Seven budget transfers took place during the year. Three of them were related to the scheduled transfers (May, September and November), three ad hoc transfers were done for urgent immediate needs (rent cost for EUAN Shared Services Office in January, legal and salary cost – both in November). The last transfer (in December) has been done to make use of the budgetary resources that resulted in excess in all Titles at the end of the year.

During the year, a budget surplus was identified mainly in salary related cost and to lower excess in other cost categories (e.g. Seconded National Experts, Trainees, EU School contribution). The budget surplus was partially reallocated within the same Title I (increase of training, consultancy and interim services budgets) and partially transferred to Title II to cover mainly increase of budget of New World of Work project (IT and building redesign related cost), refurbishment of premises as well as reallocated to building acquisition and used for anticipated building loan down payment

In Title III, a budget surplus identified mainly in scientific meetings and related centralised prepaid travels cost and mission was reallocated in scientific grants & procurement and consultancy related to operational development and control.

Details of transferred amounts can be found in Annex II.

## 2. Human resources management

On 31 December 2018, 447 of the available 459 posts were occupied (including officials, temporary agents, contract agents and seconded national experts). With specific reference to statutory staff (officials, temporary agents and contract agents), 433 posts

<sup>108</sup> A 'C8' credit is the automatic carryover of payment appropriations corresponding to commitments of non-differentiated appropriations.

out of the 444 available were occupied on 31 December (97.5%). The occupancy rate of 97.5% has also been reached in terms of statutory staff yearly average (vs the 2018 yearly target of >95.5%).

The effective management of the establishment plan/contract agent capacity as well as the timeliness of recruitment procedures led to an occupancy rate of 97.5 % (against the target of 95.5 %). Four temporary posts were suppressed in line with EC requirements hence reaching the target for the year (-4) and overall for the 5-year period (-36).

**Table 19:** Human resource overview

HUMAN RESOURCES	2017	2018 <sup>109</sup>	2018
	BUDGET REQUEST	BUDGET REQUEST	REPORTED PERIOD
Temporary agents and officials executives, managers and officers (AD)	227	218	211
Temporary agents and officials assistant functions (AST)	96	101	100
<b>Total</b>	<b>323</b>	<b>319</b>	<b>311</b>
Contract agents officer functions (CA FGIV)	90	92	95
Contract agents assistant functions (CA FG I, II, III)	35	33	27
<b>TOTAL</b>	<b>125</b>	<b>125</b>	<b>122</b>
<b>Seconded national experts</b>	<b>15</b>	<b>15</b>	<b>14</b>
<b>TOTAL STAFF ALL CATEGORIES</b>	<b>463</b>	<b>459</b>	<b>447</b>

### 3. Full time equivalents (FTEs) and budget indicators

The total amount of Human Resources is very much in line with the plan also in terms of distribution among the different strategic areas.

The slight increase of FTEs allocated under SO1 is mainly related to the Novel Food application processes, and also at budget level a slight shift of budget can be observed from the General Risk Assessment to the regulated products area.

The resources invested in strategic objective 2 and 4 are in line with the initial plan.

Under SO3 a lower than planned effort for the implementation of development activities (such as Talent Management, Strategic Competency Analysis, Fellowship Programme, ED Country Visits and Artificial Intelligence) can be observed as well as a lower consumption of financial resources.

Under SO5 the increase of the operational activities is mainly linked to the centralisation of activities previously managed at scientific process level, such as Competing interests Management, and to a higher than planned amount of training for EFSA's staff. The increase in the budget expenditure is related to anticipations of New World of Work related expenditures aiming at improving the organization efficiency and collaboration effectiveness and to the activities started for preparing the organisation to the possible impacts of the adoption of the EC proposal for modifying the EFSA founding regulation.

<sup>109</sup> The 2018 Establishment Plan figures refer to the ones approved by the EFSA's Management Board in December 2017 following the realignment requested by the European Commission. While confirming the total authorised posts, these figures are not fully aligned, in term of distribution by grade, to the ones of the 2018 budget published in the *Official Journal of the European Union*.

**Table 20:** Input indicators for SO1 (FTEs and Budget as full cost of all Titles)

INPUT INDICATORS			
Total SO1	Resources invested per year	Target 2018	Executed 2018
	FTEs	185	188
	Budget (M, €)	30.5	30.4
Scientific general risk assessment			
Input sub-indicator	FTEs	42	49
	Budget (M, €)	9.3	9.3
Scientific regulated products evaluation			
Input sub-indicator	FTEs	118	114
	Budget (M, €)	17.4	17.2
Communication and engagement			
Input sub-indicator	FTEs	24	25
	Budget (M, €)	3.8	3.8

**Table 21:** Input indicators for SO2 (FTEs and Budget as full cost of all Titles)

INPUT INDICATORS			
Total SO2	Resources invested per year	Target 2018	Executed 2018
	FTEs	19	18
	Budget (M, €)	3.3	3.9

**Table 22:** Input indicators for SO3 (FTEs and Budget as full cost of all Titles)

INPUT INDICATORS			
Total SO3	Resources invested per year	Target 2018	Executed 2018
	FTEs	38	33 <sup>110</sup>
	Budget (M, €)	10.0	8.8

**Table 23:** Input indicators for SO4 (FTEs and Budget as full cost of all Titles)

INPUT INDICATORS			
Total SO4	Resources invested per year	Target 2018	Executed 2018
	FTEs	32	31
	Budget (M, €)	8.4	8.0

<sup>(110)</sup> Decrease mainly linked to lower than planned effort for some development projects (Talent Management, Strategic Competency Analysis, Fellowship programme, ED Country Visits and Artificial Intelligence).

**Table 24:** Input indicators for SO5 (FTEs and Budget as full cost of all Titles)

INPUT INDICATOR			
Total SO5	Resources invested per year	Target 2018	Executed 2018
	FTEs	176	179 <sup>111</sup>
	Budget (M, €)	26.9	28.1

<sup>111</sup> Increase mainly related to centralisation of services before handled at scientific unit level (e.g. Competing Interests Management accounts for an increase of 2.6 FTEs) and an increased amount of training attendance for staff.

# Section III — Assurance

## 1. Assessment of audit results during the reporting year

### 1.1. Internal Audit Service (IAS)

The work of the European Commission Internal Audit Service IAS is based on the Strategic Internal Audit plan 2018-2020 that originates from an in-depth risk assessment. The purpose of the exercise is to review all processes to constitute risk-based plans and determine the priorities of the internal audit activity. In 2017 the IAS performed the risk assessment, whereby the IT Business Continuity process and, more in particular, the IT Disaster Recovery sub-process was identified as the only process where controls needed to be further improved. The related action plan for the Business Continuity Project was fully implemented by EFSA in 2018.

The IAS started an internal audit on the Human Resources Management and Ethics in EFSA in May 2018. The objective of the internal audit was to assess the adequacy of the design and the effectiveness and efficiency of the internal processes set up by EFSA to manage its human resources and to uphold the ethical values of the organisation and comply with the policy, rules and guidelines on HR management, ethics and fraud prevention and on the management of conflict of interest of staff. The draft internal audit report was received on 11 January 2019.

Two very important observations were identified on weaknesses in the recruitment and selection process and on weaknesses in the time management process.

### 1.2. European Court of Auditors (ECA)

The European Court of Auditors conducted its annual financial and regulatory audit of the Authority's 2017 accounts, and adopted its report on 9 October 2018. In the report, the ECA expressed the following audit opinions:

- Opinion on the reliability of the accounts

In the Court's opinion, the accounts of the Authority for the year ended 31 December 2017 present fairly, in all material respects, the financial position of the Authority at 31 December 2017, the results of its operations, its cash flows, and the changes in net assets for the year then ended, in accordance with its Financial Regulation and with accounting rules adopted by the Commission's accounting officer. These are based on internationally accepted standards for the public sector.

- Opinion on the legality and regularity of the transactions underlying the accounts

In the Court's opinion, revenue and payments underlying the accounts for the year ended 31 December 2017 are legal and regular in all material respects.

The European Court of Auditors audit report also included two observations, one on the independence of the accounting officer and one on the use of the cascading mechanism in framework contracts. The EFSA formal reply stated how the formal requirement on the independence of the accounting officer set by the EFSA Financial Regulation was ensured in EFSA and, as for reopening versus cascading mechanisms in framework contracts, the fact that there is no obligation to use the reopening model. Both models can be fit for purpose depending on the specific scenario.

## 2. Management assurance | 10 assurance pillars

Within the EFSA Accountability Framework, the governance for EFSA's assurance is organised and integrated into the following 10 assurance pillars to provide a holistic and integrated view on the activities and outcomes of assurance in EFSA.

- Audit management; follow-up of audit recommendations and action plans (2.1)
- Financial reporting; budget implementation, accounts and discharge (2.2)
- Risk management and anti-fraud strategy (2.3)
- Internal control (2.4)
- Legality and regularity compliance (2.5)
- Information management (2.6)
- Evaluation (2.7)
- Quality certification(2.8)
- Security and business continuity (2.9)
- Health and safety (2.10)

### 2.1. Audit management; follow-up of recommendations and action plans

At the end of 2018, after the full implementation of the action plans for six very important recommendations and respective follow-up audits performed during the year - mainly concerning the IAS audit recommendations on IT Governance and IT Project management - concluding that all very important audit recommendations had been adequately and effectively implemented, there were no critical and two very important audit recommendations included in EFSA's follow-up report on outstanding audit recommendations and action plans. They concern the following audit observations from the 2017 IAS audit report on "Evaluation of Regulated Products Assessment Phase in Pesticides Authorisation: one 'ready for review' audit recommendation on the improvement on the preparation of the Annual Report on Pesticides Residues and one 'open' audit recommendation that was delayed for six months on the review of the Internal Rules on Declaration of Conflict of Interest.

### 2.2. Financial reporting, budget implementation, accounts and discharge

On 18 April 2018, the European Parliament (EP) granted to EFSA the Discharge in respect of the implementation of the budget for the financial year 2016. This is the final approval of the budget implementation and the closure of the accounts for 2016. Regarding the observations made by the European Parliament in the Discharge 2016 with respect to some aspects of EFSA's financial and administrative management, EFSA has informed the European Parliament that the majority of the 2016 recommendations have been implemented, and the remaining are in the process of being completed.

### 2.3. Risk management and anti-fraud strategy

#### 2.3.1. Risk Management

Risk Management is a continuous, proactive and systematic process of identifying, assessing and managing risks that could affect the execution of EFSA's activities and the



achievement of its objectives. The intensity of mitigating actions and controls should be proportionate to the significance of the risk. EFSA finalised the mapping and description of its process landscape. Within the current process management methodology, the EFSA Process Architecture (EPA) is used for the planning of EFSA's activities at the process variant level. In 2018, EFSA's Risk Management was integrated into EFSA's annual activity planning. All risks were classified according to the COSO risk typology to facilitate the identification of the risks and to help ensure that all risks are covered and therefore providing a consistent basis for analysis across EFSA. A streamlined impact/likelihood approach was used to perform the risk assessment to select the appropriate risk response. The critical and cross-cutting risks that could potentially impact the achievement of EFSA's objectives and respective mitigating actions and controls that reduce the risks to acceptable levels were outlined in EFSA's Programming Document.

### 2.3.2. Anti-Fraud Strategy

EFSA developed its Anti-Fraud Strategy following an internal risk assessment carried out in accordance with the European Anti-Fraud Office methodology and guidance. There are four main objectives highlighted focusing on maintaining a high level of ethics and fraud awareness, ensure robustness of fraud detection, strengthening cooperation with OLAF as key actor in the fight against fraud and ensuring effective implementation of anti-fraud measures. EFSA fully implemented the action plan included in the Anti-Fraud Strategy. In 2018, a fitness-check was carried out with the aim to assess how to revise the EFSA's Anti-Fraud Strategy in 2019. During the reporting year, EFSA did not have to transmit or follow-up on any suspicions of fraud cases to OLAF.

## 2.4. Internal control

### 2.4.1. Internal Control Framework Assessment

The revised EFSA internal control framework, based on the equivalent Internal Control Management System laid down by the European Commission, was adopted by EFSA's Management Board in December 2017 and is applicable as from 1 January 2018. The Internal Control Framework consists of five internal control components and 17 principles based on the COSO Internal Control Integrated Framework. During the course of 2018 the internal control monitoring criteria of EFSA were updated and internal control indicators were set and included in the EFSA programming documents to ensure an appropriate assessment of the presence and functioning of all internal control principles. The assessment performed for the reported year concluded that, overall, all internal control components were present and functioning. Measures will be taken to further improve (i) the control environment component on enhanced monitoring for outside activities and management of conflict of interest for EFSA staff; (ii) the control activities component with the implementation of a Human Resources and Information Management Control Strategy.

### 2.4.2. Conflict of interest compliance and veracity checks

In June 2017, EFSA adopted a new Policy on independence followed by an implementing decision on the management of competing interests (see Annex VII, *Annual Report on the implementation of EFSA's policy on independence* for more details). The policy and decision are applicable to all members of EFSA's Scientific Committee, scientific panels, working groups, participants in peer review meetings, Networks members, members of EFSA's Governance bodies, Hearing experts, Observers, participants to procurement and grant awarding procedures as well as staff of EU institutions, bodies or other agencies taking an active role in EFSA's meetings. Pursuant to its Decision of the Executive Director on Competing Interest Management, twice a year EFSA performs a check of the compliance and veracity of a sample of DoIs submitted by experts who participated in

meetings of the Scientific Committee, Scientific Panels, Working Groups (WGs), peer review or outsourcing procedures held.

In the reference period, EFSA screened a total of 6.415 Declarations of Interest submitted by its scientific experts. EFSA processed also 23 ADoIs submitted by current members of its Management Board. Under the new rules, DoIs have to be submitted also by all tenderers and participants to grants awarding procedures regarding the outsourcing of scientific tasks or projects. In the reference year, this resulted in thirteen calls being launched for which DoIs were requested, which led to the screening of 20 "Institutional DoI" as well as of 50 "individual DoIs". None of the conflicts of interest identified were in the context of these screening processes. Finally, EFSA also processed 380 ADoIs of its staff members, as well as 45 DoIs of candidates being pre-selected for engagement as contract agents, temporary agents, seconded national experts, or national experts in professional training. As far as the screening of DoIs of staff members are concerned, no conflicts of interest were identified, while for candidates, ordinary mitigating measures were adopted in a number of cases to ensure that no perception of conflicts of interest could be caused by certain past interests held by candidates selected for EFSA statutory staff, Seconded National Experts and National Experts in Professional Training vacant positions.

The compliance checks of 2018 demonstrated that, for 26 out of 30 experts checked, EFSA's DoI Rules had been followed correctly. Three minor findings and one non-conformity were identified. For this case, a non-conformity report was filed by the relevant Unit. Further, EFSA will review the scientific output in question to clarify the extent of the contribution of the expert. To avoid the occurrence of the same non-conformity in the future, further efforts will be made to raise staff awareness on the requirements set out in EFSA's policy on independence (see Annex VII), and to enhance the DoI tool to automatize the notifications of identified conflicts of interest.

The veracity checks of 2018 revealed that the ADoIs of 21 experts out of 30 were complete, while for six experts the ADoIs revealed omissions, that upon declaration were evaluated as not leading to a conflict of interest.

In addition to the customary checks performed on DoI screening processes concerning EFSA's scientific experts, the second compliance and veracity check exercise of 2018 was run for the first time also on DoI screening processes performed by EFSA in the context of its scientific grant and procurement schemes. Three out of four Institutional DoIs and 8 out of 12 Individual DoIs checked in the context of procurement and grant procedures, were found to be fully compliant. Minor findings not leading to conflicts of interest were identified. In terms of veracity, it was found that seven out of the eight Individual DoIs checked, were complete, while one omission not leading to a conflict of interest was identified with respect to the DoI of a grant beneficiary.

## 2.5. Legality and regularity compliance

In accordance with the Internal Control Principle 12, EFSA has implemented a process for the management and control of exceptions, including the analysis of the root cause, the assessment of the risks and the identification of corrective and/or preventive actions. To ensure traceability, the deviations from all applicable rules and regulations are documented in an exception request, which is recorded in an exception register. In 2018, EFSA implemented a new Exception Request Workflow tool to manage the process. At year-end there were 96 recorded deviations, 56 deviations concerned exception requests approved ex-ante, whereas 40 deviations concerned non-conformities noted ex-post. The financial value of the deviations amounted to EUR 228.877. The exceptions mainly relate to expert reimbursements and missions. The fact that the number and amount of recorded deviations exceeded the monitoring criteria set for 2018 is mainly explained by the increased staff awareness, subsequent to the introduction of the new tool, targeted training sessions and a dedicated tutorial.

## 2.6. Information management

### 2.6.1. Information security

EFSA is actively committed to safeguarding the confidentiality, integrity and availability of all information that it manages, to ensure that regulatory, operational and contractual requirements are fulfilled. In 2018, EFSA adopted the updated Information Security Policy and new Information Security Manual. EFSA performed a gap analysis for ISO 27001:2013 Information Security certification and conducted a feasibility study on the implementation of additional technical protections recommended by CERT-EU. Cloud security measures were implemented, super-user accounts were further restricted and mandatory trainings on information security continued to be provided to all staff.

### 2.6.2. Data protection

Following the General Data Protection Regulation (EU) 2016/679 (GDPR) which became applicable in the EU Member States on 25 May 2018, the 'GDPR for EU institutions, bodies, offices and agencies', Regulation (EU) 2018/1725 came into force on 11 December 2018. The new GDPR legal framework puts increased emphasis on accountability of controllers and business owners for compliance on the personal data management within their remits following a risk-based approach.

Throughout 2018, various awareness-raising initiatives on the new GDPR rules and principles took place in the form of dedicated information sessions to EFSA units and teams where the processing of personal data is specifically relevant. Specific alignment work required in view of the new GDPR rules on data protection management and tools has initiated. Support was provided in negotiating and adjusting contracts and service terms & conditions for several tools and applications, including cloud computing solutions. Specific sections in Terms of Reference of procurement calls were drafted, on a case-by-case basis complemented with specific data processing agreements with service providers. Tailored data protection notices were drafted for systems and tools implemented at EFSA.

At the end of 2017, the European Data Protection Supervisor (EDPS) performed an inspection at EFSA focusing on anti-harassment informal procedures, video-surveillance and data subjects' rights. EFSA provided the EDPS in October 2018 with a report on the follow-up of the nine recommendations included in the inspection report, demonstrating that seven recommendations were implemented. Furthermore, EFSA is responding an EDPS request for information in the context of an ongoing remote inspection of the europa.eu-domain websites.

## 2.7. Evaluation

### 2.7.1. External Evaluation of EFSA

The 3rd external evaluation covered the EFSA's working practices and the impact of its activities in terms of effectiveness, efficiency, coherence, complementarity and EU added value for the period 2011-2017. As a result of the external evaluation, EFSA will implement the recommendations below as from 2019:

- enhance the capacity for fit-for purpose and responsive scientific advice, improving the planning and responsiveness of the Agency;
- enhance communication activities to strengthen EFSA's reputation by increasing proactivity of communication and communicating more collaboratively;
- secure long-term efficiency and sustainability of operations enhancing efficiency of the advice production system and finding additional ways to utilize expertise;

- continue the transformation to an Open Science Organisation, making evidence transparent and re-usable, making the advice-development process accessible, enhancing the dialogue with stakeholders and safeguarding and explain the organisation's independence;
- invest in preparedness to cope with complex futures scanning emerging risks, co-developing adequate assessment methodologies, co-developing European capacity for future risk governance and co-influencing EU research funding priorities;
- collaborate, cooperate and co-design to meet integrated "One health" protection targets upgrading collaboration to a strategic level, utilizing the opportunities of big data and sharing limitless to tackle complexity and resources constraints.

### 2.7.2. Internal Evaluations

Evaluations refer to a wide range of activities assessing EFSA's performance in reaching its policy, operational and financial objectives. They include activities that focus on the reporting on specific aspects of the performance of the organisation, its programmes and projects. At programme level no development programmes closed and no programme evaluations were done.

The activities of the Portfolio Coordination Office were regularly executed over the year granting ex-ante evaluation based on evaluation criteria before investing resources.

The ex-post evaluation of the STEP 2018 project has been outsourced because of its significant impact on the organization and considerable investments. Quantitative and qualitative data collected during the fieldwork, desk research and survey were analysed and the efficiency, effectiveness, coherence, added value and relevance were confirmed by the Contractor. The nine recommendations were translated into four actionable items to be implemented in 2019 focussing on the further centralisation of procurement and the development of strategic sourcing capabilities, the fine-tuning of monitoring and reporting indicators, the recasting of coordinators and planners roles and the application of lessons learned. At the end of 2018 an evaluation was initiated to assess the fit-for purpose of the EU summary reports on zoonoses and antimicrobial resistance and their added value to the operational work of EFSA and of relevant stakeholders.

## 2.8. Quality certification

EFSA was awarded in 2016 the ISO 9001:2015 Quality certification attesting EFSA's ability to consistently produce services that meet EFSA's customers' requirements and foster a culture of continuous improvement. In 2018, EFSA reviewed the ISO internal quality audit programme by providing references to the individual clauses of the standard that are addressed, streamlined the design of new procedures and working instructions, and reviewed the administrative guidance for applicants.

The 2018 surveillance audit by the certification body confirmed EFSA's ISO 9001:2015 Quality certification. The ISO 9001:2015 certification report concluded that EFSA's Quality management is robust and fit for purpose with zero findings and some further room for improvement. The few improvements suggested from the audits were followed-up, such as with the initiation of the work for a further simplification and integration of management systems, as well as in further strengthening a process-based approach.

## 2.9. Security and business continuity

EFSA's approach on security is established in the context of risk assurance to operate in a safe and secure environment, providing appropriate levels of protection for staff, assets and information commensurate with identified risks and ensuring a proper resiliency of the Agency.

EFSA's Business Continuity is to maintain the continuity of its activity, systems, facilities and processes and where these are disrupted by an event to enable it to return to normal operations as soon as possible, taking fully into account the impact of any delay on the EFSA's quality of service, reputation and budget. EFSA's business continuity plan is based on a business impact analysis and used by trained staff to ensure that EFSA is able to continue working to the extent possible in the event of a major disruption. In 2018, EFSA closed the business continuity project with the full implementation of the IT Disaster Recovery solutions. At the end of the year, EFSA obtained the ISO 22301:2012 Business Continuity certification.

## 2.10. Health and safety

EFSA is committed to establish and continuously promote a sound management system that aims at ensuring a healthy and safe work and a sustainable business environment. In 2018, EFSA's ISO 14001:2015 Environmental management certification has been updated to the last version of the management standard and the EMAS registration has been maintained. The BS-OHSAS 18001:2007 certification attesting the compliance of its Health and Safety Management System with the international standard and with the regulation in the field of health and safety at work, has also been confirmed in 2018.

# Declaration of assurance

I, the undersigned, Executive Director of the European Food Safety Authority,

In my capacity as authorising officer,

Declare that the information contained in this report gives a true and fair view.

State that I have reasonable assurance that the resources assigned to the activities described in this report have been used for their intended purpose and in accordance with the principles of sound financial management, and that the control procedures put in place give the necessary guarantees concerning the legality and regularity of the underlying transactions.

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the activities and outcome of the 10 Assurance Pillars reported in EFSA's Assurance report, the work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for the years prior to the year of this declaration.

Confirm that I am not aware of anything not reported here which could harm the interests of the EFSA.

Parma, 15 February 2019

Bernhard Url

# Statement of the Head of Business Services

I the undersigned, Head of Business Services Department of the European Food Safety Authority declare that, in accordance with EFSA's Internal Control Framework, I have reported my advice and recommendations on the overall state of internal control in EFSA to the Executive Director.

I hereby certify that the information provided in the present report and in its annexes is, to the best of my knowledge, accurate and complete.

Parma, 15 February 2019

Selomey Yamadjako



# Management Board assessment

DRAFT

# Annex I. Resource allocation per strategic objective

## 1. Financial resources per strategic objective

**Table 25:** Budget allocations per strategic objective (% of the total EFSA budget)

EFSA'S STRATEGIC OBJECTIVE	EXECUTED 2017	BUDGET 2018		EXECUTED 2018	
	M€	%	M€	%	M€
SO1 Prioritise public and stakeholder engagement in the process of scientific assessment	29.12	38%	30.45	38%	30.37
SO2 Widen EFSA's evidence base and optimise access to its data	4.95	4%	3.38	5%	3.96
SO3 Build the EU's risk assessment capacity and knowledge community	8.75	13%	10.02	11%	8.78
SO4 Prepare for future risk assessment challenges	8.58	11%	8.37	10%	7.99
SO5 Create an environment and culture that reflects EFSA's values	27.81	34%	26.90	35%	28.08
Of which operations	9.85	12%	9.70	13%	10.20
Of which support	17.96	22%	17.20	22%	17.88
<b>Total EFSA</b>	<b>79.21</b>	<b>100%</b>	<b>79.12</b>	<b>100%</b>	<b>79.18</b>

## 2. Human resources per strategic objective

**Table 26:** FTE allocations per strategic objective

EFSA'S STRATEGIC OBJECTIVE	EXECUTED 2017	PLAN 2018		ACTUAL 2018	
	FTE <sup>112</sup>	FTE	%	FTES <sup>54</sup>	%
SO1 Prioritise public and stakeholder engagement in the process of scientific assessment	194	185	41%	188	42%

<sup>112</sup> Actual available FTEs not including interim resources.

EFSA'S STRATEGIC OBJECTIVE	EXECUTED 2017	PLAN 2018		ACTUAL 2018	
	FTE <sup>112</sup>	FTE	%	FTES <sup>54</sup>	%
SO2 Widen EFSA's evidence base and optimise access to its data	23	19	4%	18	4%
SO3 Build the EU's risk assessment capacity and knowledge community	32	38	9%	33	7%
SO4 Prepare for future risk assessment challenges	35	32	7%	31	7%
SO5 Create an environment and culture that reflects EFSA's values	172	176	39%	179	40%
Of which operations	51	56	12%	60 <sup>113</sup>	13%
Of which support	121	120	27%	119	27%
<b>Total EFSA</b>	<b>456</b>	<b>450</b>	<b>100%</b>	<b>449</b>	<b>100%</b>

<sup>113</sup> Increase mainly related to centralisation of services before handled at scientific unit level (e.g. Competing Interests Management accounts for an increase of 2.6 FTEs) and an increased amount of training attendance for staff

# Annex II. Financial resources

**Table 27:** Expenditures<sup>114</sup>

TITLE	COMMITMENT APPROPRIATIONS	PAYMENT APPROPRIATIONS	EXECUTED COMMITMENT	EXECUTED PAYMENT
Title I - Staff expenditure	42,642,178	42,642,178	42,642,178	41,764,667
Title II - Infrastructure and operating expenditure	10,599,491	10,599,491	10,599,398	8,252,673
Title III - Operational expenditure	25,942,145	26,829,037	25,942,007	23,091,791
<b>TOTAL EXPENDITURE</b>	<b>79,183,814</b>	<b>80,070,706</b>	<b>79,183,582</b>	<b>73,109,131</b>

<sup>114</sup> C1 credits.

**Table 28:** budget execution per budget line<sup>115</sup>

Budget Item	Description	Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Initial Payment Appropriation	Current Payment Appropriation	Executed Payment	% Paid
1100	Basic salary	23,467,000.00	23,070,994.76	23,070,994.76	100.0%	23,467,000.00	23,070,994.76	23,070,994.76	100.0%
1101	Family allowance	3,147,000.00	3,027,245.52	3,027,245.52	100.0%	3,147,000.00	3,027,245.52	3,027,245.52	100.0%
1102	Transfer and expatriation allowance	2,563,000.00	2,492,845.98	2,492,845.98	100.0%	2,563,000.00	2,492,845.98	2,492,845.98	100.0%
1103	Secretarial allowance	13,000.00	12,316.98	12,316.98	100.0%	13,000.00	12,316.98	12,316.98	100.0%
1113	Stagiaires	907,127.00	816,769.39	816,769.39	100.0%	907,127.00	816,769.39	816,769.39	100.0%
1115	Contract staff	6,846,000.00	6,652,706.61	6,652,706.61	100.0%	6,846,000.00	6,652,706.61	6,652,706.61	100.0%
1130	Insurance against sickness	825,000.00	822,529.38	822,529.38	100.0%	825,000.00	822,529.38	822,529.38	100.0%
1131	Insurance against accidents and occupational disease	94,000.00	92,500.97	92,500.97	100.0%	94,000.00	92,500.97	92,500.97	100.0%
1132	Unemployment insurance for temporary staff	306,000.00	306,141.93	306,141.93	100.0%	306,000.00	306,141.93	306,141.93	100.0%
1133	Establishment or maintenance of pension rights for TA	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%
1140	Birth and death allowance	5,000.00	793.24	793.24	100.0%	5,000.00	793.24	793.24	100.0%
1141	Annual leave travelling expenses	290,000.00	264,970.44	264,970.44	100.0%	290,000.00	264,970.44	264,970.44	100.0%
1147	Call on duties	75,000.00	43,866.69	43,866.69	100.0%	75,000.00	43,866.69	43,866.69	100.0%
1149	Other allowances and repayments	15,000.00	21,676.17	21,676.17	0.0%	15,000.00	21,676.17	21,676.17	0.0%
1171	Translation centre Luxembourg (administrative matters)	80,000.00	40,000.00	40,000.00	100.0%	80,000.00	40,000.00	29,850.00	74.6%

<sup>115</sup> C1 credits only.

Budget Item	Description	Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Initial Payment Appropriation	Current Payment Appropriation	Executed Payment	% Paid
1172	Payment for administrative assistance from the Community institutions	252,001.00	244,372.84	244,372.84	100.0%	252,001.00	244,372.84	243,372.84	99.6%
1175	Interim services	750,000.00	892,187.36	892,187.36	100.0%	750,000.00	892,187.36	745,940.31	83.6%
1176	Consultancy	81,000.00	282,440.72	282,440.72	100.0%	81,000.00	282,440.72	78,344.30	27.7%
1177	Other services	280,545.00	195,320.80	195,320.80	100.0%	280,545.00	195,320.80	86,916.00	44.5%
1180	Miscellaneous expenditure on recruitment	100,000.00	130,359.00	130,359.00	100.0%	100,000.00	130,359.00	111,012.96	85.2%
1181	Travel expenses (including for members of the family)	15,000.00	4,577.63	4,577.63	100.0%	15,000.00	4,577.63	4,577.63	100.0%
1182	Installation, resettlement and transfer allowances	200,000.00	98,357.11	98,357.11	100.0%	200,000.00	98,357.11	98,357.11	100.0%
1183	Removal expenses	120,000.00	11,568.28	11,568.28	100.0%	120,000.00	11,568.28	11,568.28	100.0%
1184	Temporary daily subsistence allowance	60,000.00	49,528.92	49,528.92	100.0%	60,000.00	49,528.92	49,528.92	100.0%
1190	WEIGHTINGS	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%
<b>Chapter 11</b>	<b>Staff in active employment</b>	<b>40,491,673.00</b>	<b>39,574,070.72</b>	<b>39,574,070.72</b>	<b>100.0%</b>	<b>40,491,673.00</b>	<b>39,574,070.72</b>	<b>39,084,826.41</b>	<b>98.8%</b>
1300	Mission and travel expenses	180,000.00	215,000.00	215,000.00	100.0%	180,000.00	215,000.00	193,601.32	90.0%
1301	Shuttles for missions and duty	80,000.00	64,000.00	64,000.00	100.0%	80,000.00	64,000.00	56,264.39	87.9%
<b>Chapter 13</b>	<b>Missions and duty travel</b>	<b>260,000.00</b>	<b>279,000.00</b>	<b>279,000.00</b>	<b>100.0%</b>	<b>260,000.00</b>	<b>279,000.00</b>	<b>249,865.71</b>	<b>89.6%</b>
1400	Restaurants, meals and canteens	50,000.00	43,488.53	43,488.53	100.0%	50,000.00	43,488.53	40,687.25	93.6%
1410	Medical service	265,000.00	251,221.41	251,221.41	100.0%	265,000.00	251,221.41	193,907.41	77.2%



Budget Item	Description	Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Initial Payment Appropriation	Current Payment Appropriation	Executed Payment	% Paid
1420	Further training, language courses and retraining for staff	397,189.00	598,390.10	598,390.10	100.0%	397,189.00	598,390.10	307,048.63	51.3%
<b>Chapter 14</b>	<b>Sociomedical infrastructure</b>	<b>712,189.00</b>	<b>893,100.04</b>	<b>893,100.04</b>	<b>100.0%</b>	<b>712,189.00</b>	<b>893,100.04</b>	<b>541,643.29</b>	<b>60.6%</b>
1520	Visiting experts, National Experts on Detachment	825,392.00	647,136.31	647,136.31	100.0%	825,392.00	647,136.31	647,136.31	100.0%
1521	Authority officials temporarily assigned	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%
<b>Chapter 15</b>	<b>Exchange of officials and experts</b>	<b>825,392.00</b>	<b>647,136.31</b>	<b>647,136.31</b>	<b>100.0%</b>	<b>825,392.00</b>	<b>647,136.31</b>	<b>647,136.31</b>	<b>100.0%</b>
1600	Special assistance grants	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%
1610	Social contacts between staff	65,000.00	35,660.39	35,660.39	100.0%	65,000.00	35,660.39	30,451.14	85.4%
1620	Other interventions	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%
1630	Early childhood centres and other crèches	1,250,000.00	1,206,859.32	1,206,859.32	100.0%	1,250,000.00	1,206,859.32	1,206,859.32	100.0%
1640	Complementary aid for the handicapped	10,000.00	1,023.96	1,023.96	100.0%	10,000.00	1,023.96	1,023.96	100.0%
<b>Chapter 16</b>	<b>Social welfare</b>	<b>1,325,000.00</b>	<b>1,243,543.67</b>	<b>1,243,543.67</b>	<b>100.0%</b>	<b>1,325,000.00</b>	<b>1,243,543.67</b>	<b>1,238,334.42</b>	<b>99.6%</b>
1700	Reception and entertainment expenses	8,000.00	5,327.02	5,327.02	100.0%	8,000.00	5,327.02	2,861.02	53.7%
<b>Chapter 17</b>	<b>Reception and entertainment expenses</b>	<b>8,000.00</b>	<b>5,327.02</b>	<b>5,327.02</b>	<b>100.0%</b>	<b>8,000.00</b>	<b>5,327.02</b>	<b>2,861.02</b>	<b>53.7%</b>
<b>Title 1</b>	<b>STAFF</b>	<b>43,622,254.00</b>	<b>42,642,177.76</b>	<b>42,642,177.76</b>	<b>100.0%</b>	<b>43,622,254.00</b>	<b>42,642,177.76</b>	<b>41,764,667.16</b>	<b>97.9%</b>
2000	Rent	45,000.00	90,000.00	90,000.00	100.0%	45,000.00	90,000.00	64,914.00	72.1%
2001	Acquisition	1,780,000.00	2,364,335.01	2,364,335.01	100.0%	1,780,000.00	2,364,335.01	2,364,335.01	100.0%
2010	Insurance	38,000.00	32,656.30	32,656.30	100.0%	38,000.00	32,656.30	32,656.30	100.0%

Budget Item	Description	Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Initial Payment Appropriation	Current Payment Appropriation	Executed Payment	% Paid
2020	Water, gas, electricity and heating	525,000.00	513,523.42	513,523.42	100.0%	525,000.00	513,523.42	462,163.10	90.0%
2030	Maintenance	342,000.00	341,382.11	341,382.11	100.0%	342,000.00	341,382.11	254,935.34	74.7%
2031	Cleaning	300,000.00	289,899.62	289,899.62	100.0%	300,000.00	289,899.62	228,151.62	78.7%
2040	Refurbishment of premises/ Fitting out	304,000.00	583,018.15	582,924.45	100.0%	304,000.00	583,018.15	112,677.26	19.3%
2050	Security and surveillance of buildings	791,800.00	765,074.95	765,074.95	100.0%	791,800.00	765,074.95	568,445.38	74.3%
2080	preliminary to construction, acquisition or rental of immovable property	243,500.00	377,188.50	377,188.50	100.0%	243,500.00	377,188.50	151,889.50	40.3%
2090	Other expenditure on buildings	885,500.00	873,148.87	873,148.87	100.0%	885,500.00	873,148.87	752,464.73	86.2%
<b>Chapter 20</b>	<b>Investments in immovable property, rental of buildings and associated cost</b>	<b>5,254,800.00</b>	<b>6,230,226.93</b>	<b>6,230,133.23</b>	<b>100.0%</b>	<b>5,254,800.00</b>	<b>6,230,226.93</b>	<b>4,992,632.24</b>	<b>80.1%</b>
2100	Purchase/ Maintenance of equipment	720,000.00	985,114.48	985,114.48	100.0%	720,000.00	985,114.48	536,586.35	54.5%
2101	Purchase / maintenance of software	1,109,752.00	1,074,313.83	1,074,313.83	100.0%	1,109,752.00	1,074,313.83	1,029,429.80	95.8%
2103	Software development	858,316.00	830,327.74	830,327.74	100.0%	858,316.00	830,327.74	668,447.96	80.5%
2104	User Support	720,544.00	699,122.76	699,122.76	100.0%	720,544.00	699,122.76	600,170.15	85.8%
<b>Chapter 21</b>	<b>Expenditure on data processing</b>	<b>3,408,612.00</b>	<b>3,588,878.81</b>	<b>3,588,878.81</b>	<b>100.0%</b>	<b>3,408,612.00</b>	<b>3,588,878.81</b>	<b>2,834,634.26</b>	<b>79.0%</b>
2200	Technical equipment and installations	81,599.00	71,572.96	71,572.96	100.0%	81,599.00	71,572.96	47,517.96	66.4%
2201	Hire or leasing of technical equipment and installations	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%

Budget Item	Description	Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Initial Payment Appropriation	Current Payment Appropriation	Executed Payment	% Paid
2202	Maintenance and repair of technical equipment and installations	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%
2210	Purchase of furniture	86,060.00	105,009.34	105,009.34	100.0%	86,060.00	105,009.34	17,498.10	16.7%
<b>Chapter 22</b>	<b>Movable property and associated costs</b>	<b>167,659.00</b>	<b>176,582.30</b>	<b>176,582.30</b>	<b>100.0%</b>	<b>167,659.00</b>	<b>176,582.30</b>	<b>65,016.06</b>	<b>36.8%</b>
2300	Stationery and office supplies	56,000.00	56,997.16	56,997.16	100.0%	56,000.00	56,997.16	50,923.94	89.3%
2320	Bank charges	1,000.00	150.00	150.00	100.0%	1,000.00	150.00	70.00	46.7%
2330	Legal expenses	185,000.00	41,730.00	41,730.00	100.0%	185,000.00	41,730.00	22,605.00	54.2%
2340	Damages	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%
2350	Miscellaneous insurance	11,000.00	5,523.16	5,523.16	100.0%	11,000.00	5,523.16	4,418.53	80.0%
2353	Removals and associated handling	0.00	0.00	0.00	0.0%	0.00	0.00	0.00	0.0%
2390	Publications	10,000.00	3,530.56	3,530.56	100.0%	10,000.00	3,530.56	2,708.25	76.7%
<b>Chapter 23</b>	<b>Current administrative expenditure</b>	<b>263,000.00</b>	<b>107,930.88</b>	<b>107,930.88</b>	<b>100.0%</b>	<b>263,000.00</b>	<b>107,930.88</b>	<b>80,725.72</b>	<b>74.8%</b>
2400	Postal charges	35,500.00	22,000.00	22,000.00	100.0%	35,500.00	22,000.00	14,648.89	66.6%
2410	Telecommunications subscriptions and charges	201,000.00	253,217.46	253,217.46	100.0%	201,000.00	253,217.46	69,620.17	27.5%
2411	Purchase and installation of equipment	129,600.00	147,435.63	147,435.63	100.0%	129,600.00	147,435.63	136,855.89	92.8%
<b>Chapter 24</b>	<b>Postal charges and communications</b>	<b>366,100.00</b>	<b>422,653.09</b>	<b>422,653.09</b>	<b>100.0%</b>	<b>366,100.00</b>	<b>422,653.09</b>	<b>221,124.95</b>	<b>52.3%</b>
2500	Management Board meetings	100,000.00	73,219.34	73,219.34	100.0%	100,000.00	73,219.34	58,539.67	80.0%

Budget Item	Description	Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Initial Payment Appropriation	Current Payment Appropriation	Executed Payment	% Paid
<b>Chapter 25</b>	<b>Governance expenditure</b>	<b>100,000.00</b>	<b>73,219.34</b>	<b>73,219.34</b>	<b>100.0%</b>	<b>100,000.00</b>	<b>73,219.34</b>	<b>58,539.67</b>	<b>80.0%</b>
<b>Title 2</b>	<b>BUILDING, EQUIPMENT AND MISCELLANEOUS OPERATING EXPENDITURE LINKED TO THE AUTHORITY</b>	<b>9,560,171.00</b>	<b>10,599,491.35</b>	<b>10,599,397.65</b>	<b>100.0%</b>	<b>9,560,171.00</b>	<b>10,599,491.35</b>	<b>8,252,672.90</b>	<b>77.9%</b>
3020-APDESK	APDESK: Experts meetings	45,832.00	9,982.83	9,982.83	100.0%	45,832.00	9,982.83	9,982.83	100.0%
3020-FEED	FEED: Experts meetings	638,341.00	570,816.73	570,816.73	100.0%	638,341.00	570,816.73	542,326.73	95.0%
3020-FIP	FIP: Experts meetings	1,034,652.00	1,167,353.42	1,167,353.42	100.0%	1,034,652.00	1,167,353.42	1,111,203.43	95.2%
3020-GMO	GMO: Experts meetings	432,560.00	387,913.73	387,913.73	100.0%	432,560.00	387,913.73	387,913.73	100.0%
3020-NUTRI	NUTRI: Experts meetings	388,154.00	467,248.00	467,248.00	100.0%	388,154.00	467,248.00	451,329.18	96.6%
3020-PRAS	PRAS: Experts meetings	597,495.00	432,582.54	432,582.54	100.0%	597,495.00	432,582.54	410,938.36	95.0%
3020	REPRO Experts meetings	3,137,034.00	3,035,897.25	3,035,897.25	100.0%	3,137,034.00	3,035,897.25	2,913,694.26	96.0%
<b>Chapter 30</b>	<b>Scientific Evaluation of regulated products</b>	<b>3,137,034.00</b>	<b>3,035,897.25</b>	<b>3,035,897.25</b>	<b>100.0%</b>	<b>3,137,034.00</b>	<b>3,035,897.25</b>	<b>2,913,694.26</b>	<b>96.0%</b>
3120-AMU	AMU: Experts meetings	40,831.00	21,070.16	21,070.16	100.0%	40,831.00	21,070.16	21,065.63	100.0%
3120-BIOCONTAM	BIOCONTAM: Experts meetings	1,087,580.00	912,640.00	912,640.00	100.0%	1,087,580.00	912,640.00	874,031.53	95.8%
3120-ALPHA	ALPHA: Experts meetings	953,983.00	1,037,143.00	1,037,143.00	100.0%	953,983.00	1,037,143.00	949,567.87	91.6%
3120-DATA	DATA: Experts meetings	61,077.00	60,085.03	60,085.03	100.0%	61,077.00	60,085.03	60,085.03	100.0%
3120-SCER	SCER: Experts meetings	467,390.00	381,734.50	381,734.50	100.0%	467,390.00	381,734.50	355,513.51	93.1%

Budget Item	Description	Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Initial Payment Appropriation	Current Payment Appropriation	Executed Payment	% Paid
3120	RASA Experts meetings	2,691,611.00	2,412,672.69	2,412,672.69	100.0%	2,691,611.00	2,412,672.69	2,260,263.57	93.7%
3130	Crisis support	6,850.00	0.00	0.00	0.0%	6,850.00	0.00	0.00	0.0%
<b>Chapter 31</b>	<b>Risk assessment and scientific assistance</b>	<b>2,698,461.00</b>	<b>2,412,672.69</b>	<b>2,412,672.69</b>	<b>100.0%</b>	<b>2,698,461.00</b>	<b>2,412,672.69</b>	<b>2,260,263.57</b>	<b>93.7%</b>
3210-COMMS	COMMS Grants & Procurement	2,105,000.00	2,106,489.16	2,106,489.16	100.0%	1,810,126.00	2,031,359.67	1,908,359.08	93.9%
3210-RASA	RASA Grants & Procurement	4,905,000.00	4,971,639.03	4,971,501.04	100.0%	4,602,153.00	5,606,479.99	5,594,546.98	99.8%
3210-REPRO	REPRO Grants & Procurement	614,000.00	1,827,820.99	1,827,820.99	100.0%	2,038,213.00	2,087,450.29	1,986,032.06	95.1%
3210	EFSA Grants & procurement	7,624,000.00	8,905,949.18	8,905,811.19	100.0%	8,450,492.00	9,725,289.95	9,488,938.12	97.6%
3220	Scientific Cooperation meetings	98,000.00	45,666.79	45,666.79	100.0%	98,000.00	45,666.79	44,058.09	96.5%
<b>Chapter 32</b>	<b>EFSA Scientific Cooperation</b>	<b>7,722,000.00</b>	<b>8,951,615.97</b>	<b>8,951,477.98</b>	<b>100.0%</b>	<b>8,548,492.00</b>	<b>9,770,956.74</b>	<b>9,532,996.21</b>	<b>97.6%</b>
3410	Risk communications activities & materials	958,000.00	1,027,954.45	1,027,954.45	100.0%	958,000.00	1,027,954.45	851,112.00	82.8%
3420	External relations	280,000.00	144,508.85	144,508.85	100.0%	280,000.00	144,508.85	116,045.21	80.3%
<b>Chapter 34</b>	<b>Communications</b>	<b>1,238,000.00</b>	<b>1,172,463.30</b>	<b>1,172,463.30</b>	<b>100.0%</b>	<b>1,238,000.00</b>	<b>1,172,463.30</b>	<b>967,157.21</b>	<b>82.5%</b>
3500	Operational IT Systems	5,029,650.00	4,479,841.70	4,479,841.70	100.0%	5,029,650.00	4,479,841.70	2,563,817.18	57.2%
3501	Multiannual operational IT projects	0.00	0.00	0.00	0.0%	60,400.00	67,551.23	67,551.23	0.0%
3511	Translation, Interpretation Linguistic proofreading and editing	220,000.00	130,000.00	130,000.00	100.0%	220,000.00	130,000.00	110,936.40	85.3%
3512	Library	580,000.00	569,035.44	569,035.44	100.0%	580,000.00	569,035.44	477,886.98	84.0%
3513	Mission of staff	915,000.00	692,000.00	692,000.00	100.0%	915,000.00	692,000.00	664,564.60	96.0%

Budget Item	Description	Initial Commitment Appropriation	Current Commitment Appropriation	Executed Commitment	% Committed	Initial Payment Appropriation	Current Payment Appropriation	Executed Payment	% Paid
	related to operational duties								
3514	Shuttles	2,543,000.00	2,017,000.00	2,017,000.00	100.0%	2,543,000.00	2,017,000.00	1,967,347.96	97.5%
3520	Conferences & Outreach	1,128,000.00	1,216,514.11	1,216,514.11	100.0%	1,128,000.00	1,216,514.11	1,046,800.18	86.0%
3530	Operational Development & Control	691,000.00	1,157,495.64	1,157,495.64	100.0%	691,000.00	1,157,495.64	478,825.00	41.4%
3540	Quality management	40,000.00	107,608.90	107,608.90	100.0%	40,000.00	107,608.90	39,950.00	37.1%
<b>Chapter 35</b>	<b>Horizontal operations</b>	<b>11,146,650.00</b>	<b>10,369,495.79</b>	<b>10,369,495.79</b>	<b>100.0%</b>	<b>11,207,050.00</b>	<b>10,437,047.02</b>	<b>7,417,679.53</b>	<b>71.1%</b>
<b>Title 3</b>	<b>OPERATING EXPENDITURE LINKED TO AUTHORITY</b>	<b>25,942,145.00</b>	<b>25,942,145.00</b>	<b>25,942,007.01</b>	<b>100.0%</b>	<b>26,829,037.00</b>	<b>26,829,037.00</b>	<b>23,091,790.78</b>	<b>86.1%</b>
<b>GRAND TOTAL</b>	<b>EFSA</b>	<b>79,124,570.00</b>	<b>79,183,814.11</b>	<b>79,183,582.42</b>	<b>100.0%</b>	<b>80,011,462.00</b>	<b>80,070,706.11</b>	<b>73,109,130.84</b>	<b>91.3%</b>

**Table 29:** Carry forward

Title	Carry forward 2017	Amount paid	% used	Carry forward 2018
Personnel	576,992	541,290	93.8%	877,511
Infrastructure	1,321,353	1,259,092	95.3%	2,412,921
Operations	4,278,240	4,170,038	97.5%	3,504,884
<b>Total</b>	<b>6,176,585</b>	<b>5,970,420</b>	<b>96.7%</b>	<b>6,795,316</b>



**Table 30:** Budget Transfers 2018

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>1</b>	<b>STAFF</b>			
11	STAFF IN ACTIVE EMPLOYMENT			
<b>110</b>	<b>Staff in active employment</b>			
1100	Basic salary	23,467,000.00	-396,005.24	23,070,994.76
1101	Family allowance	3,147,000.00	-119,754.48	3,027,245.52
1102	Transfer and expatriation allowance	2,563,000.00	-70,154.02	2,492,845.98
1103	Secretarial allowance	13,000.00	-683.02	12,316.98
	<b>tot. of 110</b>	<b>29,190,000.00</b>	<b>-586,596.76</b>	<b>28,603,403.24</b>
<b>111</b>	<b>Other staff</b>			
1113	Stagiaires	907,127.00	-90,357.61	816,769.39
1115	Contract staff	6,846,000.00	-193,293.39	6,652,706.61
	<b>tot. of 111</b>	<b>7,753,127.00</b>	<b>-283,651.00</b>	<b>7,469,476.00</b>
<b>113</b>	<b>Employer's social security contributions</b>			
1130	Insurance against sickness	825,000.00	-2,470.62	822,529.38
1131	Insurance against accidents and occupational disease	94,000.00	-1,499.03	92,500.97
1132	Unemployment insurance for temporary staff	306,000.00	141.93	306,141.93
1133	Establishment or maintenance of pension rights for temporary staff	0.00	0.00	0.00
	<b>tot. of 113</b>	<b>1,225,000.00</b>	<b>-3,827.72</b>	<b>1,221,172.28</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>114</b>	<b>Miscellaneous allowances and grants</b>			
1140	Birth and death allowance	5,000.00	-4,206.76	793.24
1141	Annual leave travelling expenses	290,000.00	-25,029.56	264,970.44
1147	Call on duties	75,000.00	-31,133.31	43,866.69
1149	Other allowances and repayments	15,000.00	6,676.17	21,676.17
	<b>tot. of 114</b>	<b>385,000.00</b>	<b>-53,693.46</b>	<b>331,306.54</b>
<b>117</b>	<b>Supplementary services</b>			
1171	Translation and interpretation	80,000.00	-40,000.00	40,000.00
1172	Payment for administrative assistance from the Community institutions	252,001.00	-7,628.16	244,372.84
1175	Interim services	750,000.00	142,187.36	892,187.36
1176	Consultancy	81,000.00	201,440.72	282,440.72
1177	Other services	280,545.00	-85,224.20	195,320.80
	<b>tot. of 117</b>	<b>1,443,546.00</b>	<b>210,775.72</b>	<b>1,654,321.72</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>118</b>	<b>Recruitment costs and expenses on entering and leaving the service</b>			
1180	Miscellaneous expenditure on recruitment	100,000.00	30,359.00	130,359.00
1181	Travel expenses (including for members of the family)	15,000.00	-10,422.37	4,577.63
1182	Installation, resettlement and transfer allowances	200,000.00	-101,642.89	98,357.11
1183	Removal expenses	120,000.00	-108,431.72	11,568.28
1184	Temporary daily subsistence allowance	60,000.00	-10,471.08	49,528.92
	<b>tot. of 118</b>	<b>495,000.00</b>	<b>-200,609.06</b>	<b>294,390.94</b>
<b>119</b>	<b>Salary weightings</b>			
1190	Salary weightings	0.00	0.00	0.00
	<b>tot. of 119</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
	<b>tot. of 11</b>	<b>40,491,673.00</b>	<b>-917,602.28</b>	<b>39,574,070.72</b>
13	MISSIONS AND DUTY TRAVEL			
<b>130</b>	<b>Mission and travel expenses</b>			
1300	Mission and travel expenses	180,000.00	35,000.00	215,000.00
1301	Shuttles for missions and duty	80,000.00	-16,000.00	64,000.00
	<b>tot. of 130</b>	<b>260,000.00</b>	<b>19,000.00</b>	<b>279,000.00</b>
	<b>tot. of 13</b>	<b>260,000.00</b>	<b>19,000.00</b>	<b>279,000.00</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
14	SOCIOMEDICAL INFRASTRUCTURE			
<b>140</b>	<b>Restaurants, meals and canteens</b>			
1400	Restaurants, meals and canteens	50,000.00	-6,511.47	43,488.53
	<b>tot. of 140</b>	<b>50,000.00</b>	<b>-6,511.47</b>	<b>43,488.53</b>
<b>141</b>	<b>Medical service</b>			
1410	Medical service	265,000.00	-13,778.59	251,221.41
	<b>tot. of 141</b>	<b>265,000.00</b>	<b>-13,778.59</b>	<b>251,221.41</b>
<b>142</b>	<b>Further training, language courses and retraining for staff</b>			
1420	Further training, language courses and retraining for staff	397,189.00	201,201.10	598,390.10
	<b>tot. of 142</b>	<b>397,189.00</b>	<b>201,201.10</b>	<b>598,390.10</b>
	<b>tot. of 14</b>	<b>712,189.00</b>	<b>180,911.04</b>	<b>893,100.04</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
15	EXCHANGE OF OFFICIALS AND EXPERTS			
<b>152</b>	<b>Exchange of officials and experts</b>			
1520	Visiting experts, National Experts on Detachement	825,392.00	-178,255.69	647,136.31
1521	Authority officials temporarily assigned to national civil services, to international organisations or to public or private institutions	0.00	0.00	0.00
	<b>tot. of 152</b>	<b>825,392.00</b>	<b>-178,255.69</b>	<b>647,136.31</b>
	<b>tot. of 15</b>	<b>825,392.00</b>	<b>-178,255.69</b>	<b>647,136.31</b>
16	SOCIAL WELFARE			
<b>160</b>	<b>Special assistance grants</b>			
1600	Special assistance grants	0.00	0.00	0.00
	<b>tot. of 160</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>161</b>	<b>Social contacts between staff</b>			
1610	Social contacts between staff	65,000.00	-29,339.61	35,660.39
	<b>tot. of 161</b>	<b>65,000.00</b>	<b>-29,339.61</b>	<b>35,660.39</b>
<b>162</b>	<b>Other interventions</b>			
1620	Other interventions	0.00	0.00	0.00
	<b>tot. of 162</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>163</b>	<b>Early childhood centres and other creches</b>			
1630	Early childhood centres, other creches and EU school contribution	1,250,000.00	-43,140.68	1,206,859.32
	<b>tot. of 163</b>	<b>1,250,000.00</b>	<b>-43,140.68</b>	<b>1,206,859.32</b>
<b>164</b>	<b>Complementary aid for the handicapped</b>			
1640	Complementary aid for the handicapped	10,000.00	-8,976.04	1,023.96
	<b>tot. of 164</b>	<b>10,000.00</b>	<b>-8,976.04</b>	<b>1,023.96</b>
	<b>tot. of 16</b>	<b>1,325,000.00</b>	<b>-81,456.33</b>	<b>1,243,543.67</b>
17	RECEPTION AND ENTERTAINMENT EXPENSES			
<b>170</b>	<b>Reception and entertainment expenses</b>			
1700	Reception and entertainment expenses	8,000.00	-2,672.98	5,327.02
	<b>tot. of 170</b>	<b>8,000.00</b>	<b>-2,672.98</b>	<b>5,327.02</b>
	<b>tot. of 17</b>	<b>8,000.00</b>	<b>-2,672.98</b>	<b>5,327.02</b>
	<b>tot. of 1</b>	<b>43,622,254.00</b>	<b>-980,076.24</b>	<b>42,642,177.76</b>



Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>2</b>	<b>BUILDINGS, EQUIPMENT AND MISCELLANEOUS OPERATING EXPENDITURE LINKED TO THE AUTHORITY</b>			
20	INVESTMENTS IN IMMOVABLE PROPERTY, RENTAL OF BUILDING AND ASSOCIATED COSTS			
<b>200</b>	<b>Building</b>			
2000	Rent	45,000.00	45,000.00	90,000.00
2001	Acquisition <sup>116</sup>	1,780,000.00	525,090.76	2,364,335.01
	<b>tot. of 200</b>	<b>1,825,000.00</b>	<b>570,090.76</b>	<b>2,454,335.01</b>
<b>201</b>	<b>Insurance</b>			
2010	Insurance	38,000.00	-5,343.70	32,656.30
	<b>tot. of 201</b>	<b>38,000.00</b>	<b>-5,343.70</b>	<b>32,656.30</b>
<b>202</b>	<b>Water, gas, electricity and heating</b>			
2020	Water, gas, electricity and heating	525,000.00	-11,476.58	513,523.42
	<b>tot. of 202</b>	<b>525,000.00</b>	<b>-11,476.58</b>	<b>513,523.42</b>

<sup>116</sup> March 2018 budget amendment for additional € 59.244,25.

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>203</b>	<b>Cleaning and maintenance</b>			
2030	Maintenance	342,000.00	-617.89	341,382.11
2031	Cleaning	300,000.00	-10,100.38	289,899.62
	<b>tot. of 203</b>	<b>642,000.00</b>	<b>-10,718.27</b>	<b>631,281.73</b>
<b>204</b>	<b>Refurbishment of premises/Fitting out</b>			
2040	Refurbishment of premises/Fitting out	304,000.00	279,018.29	583,018.15
	<b>tot. of 204</b>	<b>304,000.00</b>	<b>279,018.29</b>	<b>583,018.15</b>
<b>205</b>	<b>Security and surveillance of buidings</b>			
2050	Security and surveillance of buidings	791,800.00	-26,725.05	765,074.95
	<b>tot. of 205</b>	<b>791,800.00</b>	<b>-26,725.05</b>	<b>765,074.95</b>
<b>208</b>	<b>Preliminary expenditure relating to construction, acquisition or rental of immovable property</b>			
2080	Preliminary to construction, acquisition or rental of immovable property	243,500.00	133,688.50	377,188.50
	<b>tot. of 208</b>	<b>243,500.00</b>	<b>133,688.50</b>	<b>377,188.50</b>
<b>209</b>	<b>Other expenditure on buildings</b>			
2090	Other expenditure on buildings	885,500.00	-12,351.13	873,148.87
	<b>tot. of 209</b>	<b>885,500.00</b>	<b>-12,351.13</b>	<b>873,148.87</b>
	<b>tot. of 20</b>	<b>5,254,800.00</b>	<b>916,182.82</b>	<b>6,230,226.93</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
21	EXPENDITURE ON DATA PROCESSING			
<b>210</b>	<b>Purchase and maintenance of IT for administration and non operational</b>			
2100	Purchase/ maintenance of IT equipment	720,000.00	265,114.48	985,114.48
2101	Purchase / maintenance of software	1,109,752.00	-35,438.17	1,074,313.83
2103	Software development	858,316.00	-27,988.26	830,327.74
2104	User Support	720,544.00	-21,421.24	699,122.76
	<b>tot. of 210</b>	<b>3,408,612.00</b>	<b>180,266.81</b>	<b>3,588,878.81</b>
	<b>tot. of 21</b>	<b>3,408,612.00</b>	<b>180,266.81</b>	<b>3,588,878.81</b>
22	MOVABLE PROPERTY AND ASSOCIATED COSTS			
<b>220</b>	<b>Technical equipment and installations</b>			
2200	Technical equipment and installations	81,599.00	-10,026.04	71,572.96
2201	Hire or leasing of technical equipment and installations	0.00	0.00	0.00
2202	Maintenance and repair of technical equipment and installations	0.00	0.00	0.00
	<b>tot. of 220</b>	<b>81,599.00</b>	<b>-10,026.04</b>	<b>71,572.96</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>221</b>	<b>Furniture</b>			
2210	Purchase of furniture	86,060.00	18,949.34	105,009.34
2211	Hire of furniture	0.00	0.00	0.00
2212	Maintenance and repair of furniture	0.00	0.00	0.00
	<b>tot. of 221</b>	<b>86,060.00</b>	<b>18,949.34</b>	<b>105,009.34</b>
	<b>tot. of 22</b>	<b>167,659.00</b>	<b>8,923.30</b>	<b>176,582.30</b>
23	CURRENT ADMINISTRATIVE EXPENDITURE			
<b>230</b>	<b>Stationery and office supplies</b>			
2300	Stationery and office supplies	56,000.00	997.16	56,997.16
	<b>tot. of 230</b>	<b>56,000.00</b>	<b>997.16</b>	<b>56,997.16</b>
<b>232</b>	<b>Financial charges</b>			
2320	Bank charges	1,000.00	-850.00	150.00
2321	Other financial charges	0.00	0.00	0.00
	<b>tot. of 232</b>	<b>1,000.00</b>	<b>-850.00</b>	<b>150.00</b>
<b>233</b>	<b>Legal expenses</b>			
2330	Legal expenses	185,000.00	-143,270.00	41,730.00
	<b>tot. of 233</b>	<b>185,000.00</b>	<b>-143,270.00</b>	<b>41,730.00</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>234</b>	<b>Damages</b>			
2340	Damages	0.00	0.00	0.00
	<b>tot. of 234</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>235</b>	<b>Other operating expenditure</b>			
2350	Miscellaneous insurance	11,000.00	-5,476.84	5,523.16
2353	Removals and associated handling	0.00	0.00	0.00
	<b>tot. of 235</b>	<b>11,000.00</b>	<b>-5,476.84</b>	<b>5,523.16</b>
<b>239</b>	<b>Publications</b>			
2390	Publications	10,000.00	-6,469.44	3,530.56
	<b>tot. of 239</b>	<b>10,000.00</b>	<b>-6,469.44</b>	<b>3,530.56</b>
	<b>tot. of 23</b>	<b>263,000.00</b>	<b>-155,069.12</b>	<b>107,930.88</b>
24	POSTAL CHARGES AND TELECOMMUNICATIONS			
<b>240</b>	<b>Postal charges</b>			
2400	Postal charges	35,500.00	-13,500.00	22,000.00
	<b>tot. of 240</b>	<b>35,500.00</b>	<b>-13,500.00</b>	<b>22,000.00</b>

Title Chapter Article Item	Budget Headings Transfers from year start	Commitment and payment appropriation 2018		
		Initial	Transfers	Current
<b>241</b>	<b>Telecommunications</b>			
2410	Telecommunications subscriptions and charges	201,000.00	52,217.46	253,217.46
2411	Purchase and installation of equipment	129,600.00	17,835.63	147,435.63
	<b>tot. of 241</b>	<b>330,600.00</b>	<b>70,053.09</b>	<b>400,653.09</b>
	<b>tot. of 24</b>	<b>366,100.00</b>	<b>56,553.09</b>	<b>422,653.09</b>
25	GOVERNANCE EXPENDITURE			
<b>250</b>	<b>Governance expenditure</b>			
2500	Management Board meetings	100,000.00	-26,780.66	73,219.34
	<b>tot. of 250</b>	<b>100,000.00</b>	<b>-26,780.66</b>	<b>73,219.34</b>
	<b>tot. of 25</b>	<b>100,000.00</b>	<b>-26,780.66</b>	<b>73,219.34</b>
	<b>tot. of 2</b>	<b>9,560,171.00</b>	<b>980,076.24</b>	<b>10,599,491.35</b>

Title Chapter Article Item	Budget Headings Transfers from year start	B 2018 Commitment appropriation			B 2018 Payment appropriation		
		Initial	Transfers	Current	Initial	Transfers	Current
<b>3</b>	<b>OPERATING EXPENDITURE LINKED TO THE AUTHORITY</b>						
30	SCIENTIFIC EVALUATION of REGULATED PRODUCTS						
<b>302</b>	<b>REPRO Experts meetings</b>						
3020	REPRO Experts meetings	3,137,034.00	-101,136.75	3,035,897.25	3,137,034.00	-101,136.75	3,035,897.25
	<b>tot. of 302</b>	<b>3,137,034.00</b>	<b>-101,136.75</b>	<b>3,035,897.25</b>	<b>3,137,034.00</b>	<b>-101,136.75</b>	<b>3,035,897.25</b>
	<b>tot. of 30</b>	<b>3,137,034.00</b>	<b>-101,136.75</b>	<b>3,035,897.25</b>	<b>3,137,034.00</b>	<b>-101,136.75</b>	<b>3,035,897.25</b>
31	RISK ASSESSMENT & SCIENTIFIC ASSISTANCE						
<b>312</b>	<b>RASA Experts meetings</b>						
3120	RASA Experts meetings	2,691,611.00	-278,938.31	2,412,672.69	2,691,611.00	-278,938.31	2,412,672.69
	<b>tot. of 312</b>	<b>2,691,611.00</b>	<b>-278,938.31</b>	<b>2,412,672.69</b>	<b>2,691,611.00</b>	<b>-278,938.31</b>	<b>2,412,672.69</b>
<b>313</b>	<b>Crisis support</b>						
3130	Crisis support	6,850.00	-6,850.00	0.00	6,850.00	-6,850.00	0.00
	<b>tot. of 313</b>	<b>6,850.00</b>	<b>-6,850.00</b>	<b>0.00</b>	<b>6,850.00</b>	<b>-6,850.00</b>	<b>0.00</b>
	<b>tot. of 31</b>	<b>2,698,461.00</b>	<b>-285,788.31</b>	<b>2,412,672.69</b>	<b>2,698,461.00</b>	<b>-285,788.31</b>	<b>2,412,672.69</b>



Title Chapter Article Item	Budget Headings Transfers from year start	B 2018 Commitment appropriation			B 2018 Payment appropriation		
		Initial	Transfers	Current	Initial	Transfers	Current
32	EFSA SCIENTIFIC COOPERATION						
<b>321</b>	<b>EFSA Grants &amp; Procurement</b>						
3210	EFSA Grants & Procurement	7,624,000.00	1,281,949.18	8,905,949.18	8,450,492.00	1,274,797.95	9,725,289.95
	<b>tot. of 321</b>	<b>7,624,000.00</b>	<b>1,281,949.18</b>	<b>8,905,949.18</b>	<b>8,450,492.00</b>	<b>1,274,797.95</b>	<b>9,725,289.95</b>
<b>322</b>	<b>Scientific cooperation meetings</b>						
3220	Scientific cooperation meetings	98,000.00	-52,333.21	45,666.79	98,000.00	-52,333.21	45,666.79
	<b>tot. of 343</b>	<b>98,000.00</b>	<b>-52,333.21</b>	<b>45,666.79</b>	<b>98,000.00</b>	<b>-52,333.21</b>	<b>45,666.79</b>
<b>323</b>	<b>Pre-accession and ENP Programmes*</b>						
3230	Pre-accession programme	0.00	0.00	0.00	0.00	0.00	0.00
3231	ENP (European Neighbourhood programme)	0.00	0.00	0.00	0.00	0.00	0.00
	<b>tot. of 323</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
<b>324</b>	<b>Collaboration with other organisations*</b>						
3240	Collaboration with FAO	0.00	0.00	0.00	0.00	0.00	0.00
	<b>tot. of 3324</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>	<b>0.00</b>
	<b>tot. of 32</b>	<b>7,722,000.00</b>	<b>1,229,615.97</b>	<b>8,951,615.97</b>	<b>8,548,492.00</b>	<b>1,222,464.74</b>	<b>9,770,956.74</b>

Title Chapter Article Item	Budget Headings Transfers from year start	B 2018 Commitment appropriation			B 2018 Payment appropriation		
		Initial	Transfers	Current	Initial	Transfers	Current
34	COMMUNICATIONS						
<b>341</b>	<b>Risk Communication</b>						
3410	Risk Communication, Web management, communication activities materials	958,000.00	69,954.45	1,027,954.45	958,000.00	69,954.45	1,027,954.45
	<b>tot. of 341</b>	<b>958,000.00</b>	<b>69,954.45</b>	<b>1,027,954.45</b>	<b>958,000.00</b>	<b>69,954.45</b>	<b>1,027,954.45</b>
<b>342</b>	<b>External relations</b>						
3420	External relations	280,000.00	-135,491.15	144,508.85	280,000.00	-135,491.15	144,508.85
	<b>tot. of 342</b>	<b>280,000.00</b>	<b>-135,491.15</b>	<b>144,508.85</b>	<b>280,000.00</b>	<b>-135,491.15</b>	<b>144,508.85</b>
	<b>tot. of 34</b>	<b>1,238,000.00</b>	<b>-65,536.70</b>	<b>1,172,463.30</b>	<b>1,238,000.00</b>	<b>-65,536.70</b>	<b>1,172,463.30</b>
35	HORIZONTAL OPERATIONS						
<b>350</b>	<b>Operational IT Systems</b>						
3500	Operational IT Systems	5,029,650.00	-549,808.30	4,479,841.70	5,029,650.00	-549,808.30	4,479,841.70
3501	Multiannual IT Projects	0.00	0.00	0.00	60,400.00	7,151.23	67,551.23
	<b>tot. of 350</b>	<b>5,029,650.00</b>	<b>-549,808.30</b>	<b>4,479,841.70</b>	<b>5,090,050.00</b>	<b>-542,657.07</b>	<b>4,547,392.93</b>

Title Chapter Article Item	Budget Headings Transfers from year start	B 2018 Commitment appropriation			B 2018 Payment appropriation		
		Initial	Transfers	Current	Initial	Transfers	Current
<b>351</b>	<b>Operational support</b>						
3511	Translation, Interpretation, Linguistic Proofreading and Editing	220,000.00	-90,000.00	130,000.00	220,000.00	-90,000.00	130,000.00
3512	Library	580,000.00	-10,964.56	569,035.44	580,000.00	-10,964.56	569,035.44
3513	Mission of staff related to operational duties	915,000.00	-223,000.00	692,000.00	915,000.00	-223,000.00	692,000.00
3514	Shuttles and prepaid travel for experts and shuttles for staff related to operational duties	2,543,000.00	-526,000.00	2,017,000.00	2,543,000.00	-526,000.00	2,017,000.00
	<b>tot. of 351</b>	<b>4,258,000.00</b>	<b>-849,964.56</b>	<b>3,408,035.44</b>	<b>4,258,000.00</b>	<b>-849,964.56</b>	<b>3,408,035.44</b>
<b>352</b>	<b>Conferences &amp; Outreach</b>						
3520	Conferences and Outreach	1,128,000.00	88,514.11	1,216,514.11	1,128,000.00	88,514.11	1,216,514.11
	<b>tot. of 352</b>	<b>1,128,000.00</b>	<b>88,514.11</b>	<b>1,216,514.11</b>	<b>1,128,000.00</b>	<b>88,514.11</b>	<b>1,216,514.11</b>
<b>353</b>	<b>Operational development &amp; Control</b>						
3530	Operational Development & Control	691,000.00	466,495.64	1,157,495.64	691,000.00	466,495.64	1,157,495.64
	<b>tot. of 353</b>	<b>691,000.00</b>	<b>466,495.64</b>	<b>1,157,495.64</b>	<b>691,000.00</b>	<b>466,495.64</b>	<b>1,157,495.64</b>
<b>354</b>	<b>Quality Management</b>						
3540	Quality Management	40,000.00	67,608.90	107,608.90	40,000.00	67,608.90	107,608.90
	<b>tot. of 354</b>	<b>40,000.00</b>	<b>67,608.90</b>	<b>107,608.90</b>	<b>40,000.00</b>	<b>67,608.90</b>	<b>107,608.90</b>
	<b>tot. of 35</b>	<b>11,146,650.00</b>	<b>-777,154.21</b>	<b>10,369,495.79</b>	<b>11,207,050.00</b>	<b>-770,002.98</b>	<b>10,437,047.02</b>
	<b>tot. of 3</b>	<b>25,942,145.00</b>	<b>0.00</b>	<b>25,942,145.00</b>	<b>26,829,037.00</b>	<b>0.00</b>	<b>26,829,037.00</b>

# Annex III. Status of projects

**Table 31:** Projects and Process improvement initiatives under SO1 – Status report

Intermediary Impact	Expected result – Outcome	Project	Overall Status
Increased satisfaction of stakeholders regarding EFSA's scientific outputs (for EC/MS risk managers and stakeholders) and the scientific assessment process and communication tools and materials	Increased engagement of stakeholders in scientific activities	Transparency and Engagement in Risk Assessment (TERA) project	● Closed
		Stakeholder Engagement Approach (SEA)	●
	Full availability of documentation relevant to EFSA scientific outputs	Matrix	●
	Enhanced outreach of communication	Reputation Management	●
		Evidence-Based Approach to Risk Communications	●
		Social Media 2020 strategy	●

**Table 32:** Projects and Process improvement initiatives under SO2 – Status report

Intermediary impact	Expected result - outcome	Project	Overall Status
Increased satisfaction of stakeholders regarding EFSA's evidence management services and fostered innovative re-use of data	Improved access to data	Information Management Programme	●
		Developing a system for assigning digital object identifiers (dois) project	●
		Open ScaIE project	●
	Wider data coverage	Standard Charter of the DATA Unit within the framework of the "Set up of Sample Based Veterinary Drug Residues Data Collection and Compilation of First Annual Summary Report based on Sample Level Data"	●
	Increased standardisation and interoperability of data	Introduction of a framework for Information Access Management	●
		Support to national dietary surveys in compliance with the EU Menu methodology	●
		Provision of end user scientific support to EFSA on FoodEx2: entrustment of tasks to article 36 competent organisations	●
		Framework Partnership Agreement on Data Quality	● Closed
		Service catalogue for the DATA Unit (Data collection service)	● Closed

**Table 33:** Projects and Process improvement initiatives under SO3 – Status report

Intermediary impact	Expected result - Outcome	Project	Overall Status
Increased satisfaction of MS, EU and international partners with regard to the building and sharing of risk assessment capacity and a knowledge community at organisational and individual level		3rd Scientific Conference (2018)	●
Increased efficiency at European and international level	Building and sharing within the risk assessment community at individual level	Expertise Management Programme	●
		Scientific Risk Assessment capacity building - Training & Teaching activities	●
		Training in Systematic reviews or in specific steps of Systematic reviews for EFSA Risk Assessment.	●
		Training on Expert Knowledge Elicitation	●
		Knowledge & Innovation Communities (KICs)	●
	Building and sharing capacity within the risk assessment community at organisational level	International Scientific Cooperation - Implementation of the ISC Work Plan 2017-2020	●
		2017 Interagency -including EUANSA and EU bodies / Institutions-Scientific Cooperation'-IASC	●
		2017-19 Pre-accession project - Preparatory measures for the participation of IPA beneficiaries in EFSA 2017-2019	●
		EU-FORA: Fellowship Programme	●
		Innovative approach for Article 36 networking and management of the List	●
	Strengthened capacity using innovative ways	Joining forces at EU level on the implementation of Artificial Intelligence	●
		Hackathon	●
		The use of machine learning techniques (MLT) for literature reviews and systematic reviews	● Closed
		CROWDSOURCING: Engaging communities effectively in scientific assessment	●

**Table 34:** Projects and Process improvement initiatives under SO4 – Status report

Intermediary impact	Expected result - outcome	Project	Overall Status
Increased effectiveness of preparedness and response		PLH preparedness to the risks of new plant pests	●
		Implementation of the Guidance on the establishment of residue definition for dietary risk assessment	●
		Guidance on non-target terrestrial organisms	●
		PLH procurement on Xylella vectors	●
		Adjusting for threats to validity in individual studies	● Not started
		Benchmark Dose Model (BMD) <sup>117</sup>	●
		Development of Risk Assessment Guidance for pesticides in the area of aquatic organisms	●
		Scientific Opinion on the updated proposal for an Aged Soil Adsorption Guidance	● Closed
		Pesticides in food for infants and young children	● Closed
		Revision of the EFSA Guidance on Risk assessment for Birds and Mammals	●
	Fostered use of new approaches and enhanced ability to anticipate and respond to risks	RAM-Pro: Risk Assessment Methodology Programme	●
		Wildlife surveillance	●
		EFSA's activities on emerging risks (REACH2; Aquarius; Demeter; Ciguatera)	●
		BIOHAZ Food-borne parasites	●
		Generation of occurrence data on zearalenone and its modified forms in food and feed	● Not started

<sup>117</sup> The project on *Updating of the guidance of the Scientific Committee on the use of the benchmark dose approach in risk assessment* is closed while the development of the model is ongoing.



Intermediary impact	Expected result - outcome	Project	Overall Status
		Implementation of Cumulative Risk Assessment of Pesticides <sup>118</sup>	●
		Data collection on endocrine activity for EATS via several projects	●
		Development of conversion model for recoding food commodities used in pesticide residues	●
		In vitro comparative metabolism	●
	Fostered use of new approaches and enhanced ability to anticipate and respond to risks	Use and reporting of historical control data (HCD) for the carcinogenesis studies	● Not started
		Proposal by the EFSA Panel on Genetically Modified Organisms (GMO) for a self-task activity to develop supplementary guidelines for the allergenicity assessment of GM plants to incorporate new developments	●
		Integrating new approaches in chemical risk assessment	●
		Adjuvanticity / immunogenicity assessment of proteins	●
		EFSA Guidance documents and preparatory activities for RA methodological updates	● Closed
		EFSA Guidance Document for predicting environmental concentrations of active substances of plant protection products in soil	●
		EFSA Guidance on completing risk assessment for active substances that have isomers	●
		Guidance Document for the Implementation of the Hazard-based Criteria to identify Endocrine Disruptors	● Closed
		Integrated testing strategy for evaluation of developmental neurotoxicity with special emphasis to pesticides	●
		QSAR dermal absorption: Applicability of in silico tools for the prediction of dermal absorption for pesticides	● Closed
		Repair action of the FOCUS surface water scenarios	●
		PROC_NT Lepidoptera model	●

<sup>118</sup> Implementation of Cumulative Risk Assessment of Pesticides Part1 and Part2.

Intermediary impact	Expected result - outcome	Project	Overall Status
		MUST-B : EU efforts towards the development of a holistic approach for the risk assessment on MULTIPLE STressors in Bees	●
		QPS self-task 2017-2019	●
		Arthropod vectors	●
		Data collection and analyses processes on animal disease outbreaks and surveillance	●
		WGS Umbrella	●
		Specialised training courses on certain aspects of food safety RA	● Closed
		Guidance on submissions for evaluation of nutrients or of other ingredients proposed for use in the manufacture of foods	● Closed
		Guidance documents for the substantiation of health claims	● Closed
		Feed Additives: Update of Guidance documents produced by the FEEDAP Panel	●
		Workshop for the evaluation of phototoxicity and photomutagenicity	● Not started
		Scientific opinion on the state of the science of pesticide risk assessment for bats	●
	Accessibility of EFSA methods and tools	Risk Assessment Tools for the Safety of Global Food and Feed Supply Chains (FPA BfR)	●
Increased satisfaction of stakeholders with regard to EFSA's preparedness, methodologies and response	Harmonisation of risk assessment methodologies	Scientific opinions of the Scientific Committee on overarching elements of environmental risk assessment (ERA)	●
		PRO-METH-EU-S: Promoting Methods for Evidence Use in Science	● Closed
		Guidance on how to characterise, document and explain uncertainties in risk assessment	●
		Guidance on the human, animal and environmental risk assessment of the application of nanoscience and nanotechnologies in agro/food/feed	●

Intermediary impact	Expected result - outcome	Project	Overall Status
		Strategic approach to International Cooperation (ILMERAC)	<span style="color: blue;">●</span> Closed
		MixTox: Developing harmonised methods for the risk assessment of combined exposure to multiple chemicals	<span style="color: orange;">●</span>
		Scientific Committee Guidance Document Review framework	<span style="color: green;">●</span>
		Update of the 2012 SC scientific opinion on the TTC	<span style="color: green;">●</span>

**Table 35:** Projects and Process improvement initiatives under SO5 – Status report

Intermediate impact	Expected result - Outcome	Project	Overall Status
Sound operational performance  Efficiency	People and culture	Data Management and Data Virtualisation (DAMA)	<span style="color: green;">●</span>
		Talent Management Project	<span style="color: green;">●</span>
		EFSA Academy	<span style="color: grey;">●</span> Not started
		Strategic Competencies Analysis - SCA Project	<span style="color: green;">●</span>
	Enabling work environment	New World Of Work (NWOW)	<span style="color: green;">●</span>
		Travel Management Model (TMM)	<span style="color: green;">●</span>
		Digital collaboration	<span style="color: green;">●</span>
	Compliance	Records and Correspondence Management Project	<span style="color: green;">●</span>
		Business Continuity Implementation	<span style="color: blue;">●</span> Closed
		Secure Email	<span style="color: grey;">●</span> Not started
		Independence Policy Review	<span style="color: green;">●</span>
	Capabilities	BIKE project	<span style="color: green;">●</span>
		Customer relationship management (CRM)	<span style="color: grey;">●</span> Not started
		Strategic environment analysis	<span style="color: green;">●</span>

# Annex IV. Questions closed 2018

**Table 36:** Questions closed 2018

Questions per strategic objective and type of EFSA output	REPRO						RASA					TOTAL
	APDESK	FEED	FIP	GMO	NUTRI	PRAS	ALPHA	AMU	BIOCONTAM	DATA	SCER	
SO1 – Prioritise public and stakeholder engagement in the process of scientific assessment												
SO1 – EFSA scientific outputs – general risk assessment			1	7	2		90		17	1		118
Of which:												
– Opinion of the Scientific Committee / Scientific Panel			1 <sup>119</sup>	2	1		66 <sup>120</sup>		10 <sup>121</sup>			82
– Guidance of the Scientific Committee / Scientific Panel									1			1
– Statement of the Scientific Committee / Scientific Panel									1			1
– Scientific report of EFSA							11		5	1		28
– Guidance of EFSA												
– Statement of EFSA				5	1							6
SO1 – Technical reports – general risk assessment				1	3		31		7	7	1	37
SO1 – Other publications (external scientific reports/event reports) – General risk assessment							4	0	12			16
– Other publications - External Scientific Report							1		11			12
– Other publications - Event Report							3		1			4
SO1 – Sub total – general risk assessment			1	8 <sup>122</sup>	5		112		36	8	1	171

<sup>119</sup> 1 question from ANS Panel.

<sup>120</sup> Of which: 3 questions from AHAW Panel and 63 questions from PLH Panel.

<sup>121</sup> Of which: 2 questions from BIOHAZ Panel, 8 questions from CONTAM Panel.

<sup>122</sup> In addition, GMO Unit closed 15 questions for Non Scientific Outputs - Other outputs.

Questions per strategic objective and type of EFSA output	REPRO						RASA					TOTAL
	APDESK	FEED	FIP	GMO	NUTRI	PRAS	ALPHA	AMU	BIOCONTAM	DATA	SCER	
<b>SO1 – EFSA scientific outputs</b> – evaluation of regulated products		79	194	14	12	175			1			475
Of which:												
– Conclusion on pesticides peer review						38						38
– Opinion of the Scientific Committee / Scientific Panel		78	194 <sup>123</sup>	14	11				1 <sup>124</sup>			298
– Guidance of the Scientific Committee / Scientific Panel												
– Statement of the Scientific Committee / Scientific Panel		1			1							2
– Reasoned opinion						92						92
– Scientific report of EFSA						42						42
– Guidance of EFSA						1						1
– Statement of EFSA						2						2
<b>SO1 – Technical reports</b> – evaluation of regulated products	1			13	4	26						44
<b>SO1 – Other publications (external scientific reports/event reports)</b> – evaluation of regulated products			2	2		1						5
– Other publications - External Scientific Report			2	2		1						5
– Other publications - Event Report												
<b>SO1 – Sub total</b> – evaluation of regulated products	1	79	196	29	16	202			1			524
<b>SO1 – Total</b>	1	79	197	37	21	202	112		37	8	1	695
<b>SO2 – Widen EFSA’s evidence base and optimise access to its data</b>												
<b>SO2 – EFSA scientific outputs</b>										1		1
<b>SO2 – Technical reports</b>										1		1

<sup>123</sup> Of which: 27 questions from ANS Panel, 47 questions from CEF Panel (until end of June 2018); 22 questions from CEP Panel, 98 questions from FAF Panel (as of July 2018, following the change of Panels name and scope in accordance with [Commission Regulation \(EU\) 2017/228](#) of 9 February 2017 amending Regulation (EC) No 178/2002 of the European Parliament and of the Council as regards the names and the areas of competence of the scientific panels of the European Food Safety Authority)

<sup>124</sup> 1 question from BIOHAZ Panel

Questions per strategic objective and type of EFSA output	REPRO						RASA					TOTAL
	APDESK	FEED	FIP	GMO	NUTRI	PRAS	ALPHA	AMU	BIOCONTAM	DATA	SCER	
<b>S02 – Other publications (external scientific reports/event reports)</b>										12	1	13
– Other publications - External Scientific Report										11	1	12
– Other publications - Event Report										1		1
<b>S02 – Total</b>										<b>14</b>	<b>1</b>	<b>1</b>
<b>S03 – Build the EU's scientific assessment capacity and knowledge community</b>												
<b>S03 – EFSA scientific outputs</b>												
<b>S03 – Technical reports</b>				1			1		2		1	5
<b>S03 – Other publications (external scientific reports/event reports)</b>							2				2	4
– Other publications - External Scientific Report												
– Other publications - Event Report							2				2	4
<b>S03 – Total</b>				1			<b>3</b>		<b>2</b>		<b>3</b>	<b>9</b>
<b>S04 – Prepare for future risk assessment challenges</b>												
<b>S04 – EFSA scientific outputs</b>		3	1		1	4	2		3		4	18
Of which:												
– Opinion of the Scientific Committee / Scientific Panel						3	1		1			5
– Scientific report of EFSA							1				1	2
– Statement of the Scientific Committee / Scientific Panel (general risk assessment)									2		1	3
– Guidance of the Scientific Committee / Scientific Panel (regulated products)		3	1		1						1	6
– Guidance of EFSA (regulated products)						1					1	2

Questions per strategic objective and type of EFSA output	REPRO						RASA					TOTAL
	APDESK	FEED	FIP	GMO	NUTRI	PRAS	ALPHA	AMU	BIOCONTAM	DATA	SCER	
<b>SO4 – Technical reports</b>		2	1		1	1	4	1	1		9	20
<b>SO4 – Other publications (external scientific reports/event reports)</b>						7	7	6	4		7	31
– Other publications - External Scientific Report						6	6	6	4		7	29
– Other publications - Event Report						1	1					2
<b>SO4 – Total</b>		5	2		2	12	13	7	8		20	<b>69</b>
<b>Total questions</b>	<b>1</b>	<b>84</b>	<b>199</b>	<b>38</b>	<b>23</b>	<b>214</b>	<b>128</b>	<b>7</b>	<b>47</b>	<b>22</b>	<b>25</b>	<b>788</b>



**Table 37:** Questions closed per Food sector area – SO1 general risk assessment

<b>SO1 - General risk assessment</b>			
<b>EFSA UNIT</b>	<b>Total per Unit</b>	<b>Food sector area</b>	<b>Questions closed</b>
<b>Animal and plant health</b>	<b>112</b>	Animal Diseases	17
		Animal welfare	2
		Plant Health	93
<b>Biological hazards and contaminants</b>	<b>36</b>	AMR	1
		BIOCONTAM - Other areas	7
		Contaminants in Feed	4
		Contaminants in Food	6
		Contaminants in food and feed	3
		Data collection and analysis	4
		Food Hygiene	1
		Foodborne outbreaks	1
		Foodborne zoonosis	7
		TSE	2
<b>Evidence management</b>	<b>8</b>	Contaminants in Food	1
		Contaminants in food and feed	1
		EFSA Guidance documents	6
<b>Food Ingredients and Packaging</b>	<b>1</b>	Food additives	1
<b>GMO</b>	<b>8</b>	GMO generic	8
<b>Nutrition</b>	<b>5</b>	Dietary reference values	4
		NUTRI - Other areas	1
<b>Scientific Committee &amp; Emerging Risks</b>	<b>1</b>	SCER - other areas	1
<b>Total questions closed in general risk assessment</b>			<b>171</b>

**Table 38:** Questions closed per Food sector area – SO1 regulated products

<b>SO1 - Regulated products</b>			
<b>EFSA UNIT</b>	<b>Total per Unit</b>	<b>Food sector area</b>	<b>Questions closed</b>
<b>Applications Desk</b>	<b>1</b>	Novel Foods application	1
<b>Biological hazards and contaminants</b>	<b>1</b>	Animal By-Products	1
<b>FEED</b>	<b>79</b>	Feed additives - applications	79
<b>Food Ingredients and Packaging</b>	<b>196</b>	Enzymes	26
		Flavourings	127
		Food additives	23
		Food contact materials	13
		Food Hygiene	1
		Nutrient sources	4
		Other substances Reg. 1925/2006	2
<b>GMO</b>	<b>34</b>	GMO generic	9
		GMOs applications for renewal under Reg. 1829/2003	1
		GMOs applications for renewal under Reg. 1829/2003 / Commission Implementing Regulation (EU) No 503/2013	9
		GMOs applications under Reg. 1829/2003	5
		GMOs applications under Reg. 1829/2003 / Commission Implementing Regulation (EU) No 503/2013	10
<b>Nutrition</b>	<b>16</b>	Health claims Art. 13/5	3
		Health claims Art. 14	1
		Health claims other	1
		Notification on traditional foods from third countries	3
		Novel Foods application	7
		Nutrient sources	1

SO1 - Regulated products			
EFSA UNIT	Total per Unit	Food sector area	Questions closed
Pesticides	202	Pesticides - Other areas	11
		Pesticides MRL Application (Reg. 396/2005 - Art. 10)	65
		Pesticides MRL Monitoring (Reg. 396/2005 - Art. 31)	4
		Pesticides MRL Request (Reg. 396/2005 - Art. 43) <sup>125</sup>	42
		Pesticides MRL Review (Reg.396/2005 - Art. 12)	26
		Pesticides peer review - amendment approval conditions	1
		Pesticides peer review - basic substances	4
		Pesticides peer review - confirmatory data	10
		Pesticides peer review - new active substances	12
		Pesticides peer review - renewal of approval	18
		Pesticides peer review - review of approval	9
Total questions closed in regulated products			529

In some areas of the regulated products evaluation the delays registered with respect to the initial deadline lead to the accumulation of backlog. These questions are part of the ongoing work programme and efforts are made to reduce their number during the actual year. To be noted that questions received in bulks and pending evaluation, are not part of this backlog. For these cases, called "bulk evaluations", a work plan is agreed or pends agreement with the risk managers. Details on the actual backlog and its reduction per food sector area during 2018 are presented in table 43, while current status of bulk evaluations is included in table 44.

<sup>(125)</sup> 39 Questions which were merged in the scientific report in support to the preparation of an EU position in the 50<sup>th</sup> Session of The Codex Committee on Pesticides Residues (CCPR) are included here.

**Table 39:** SO1 regulated products - Backlog reduction

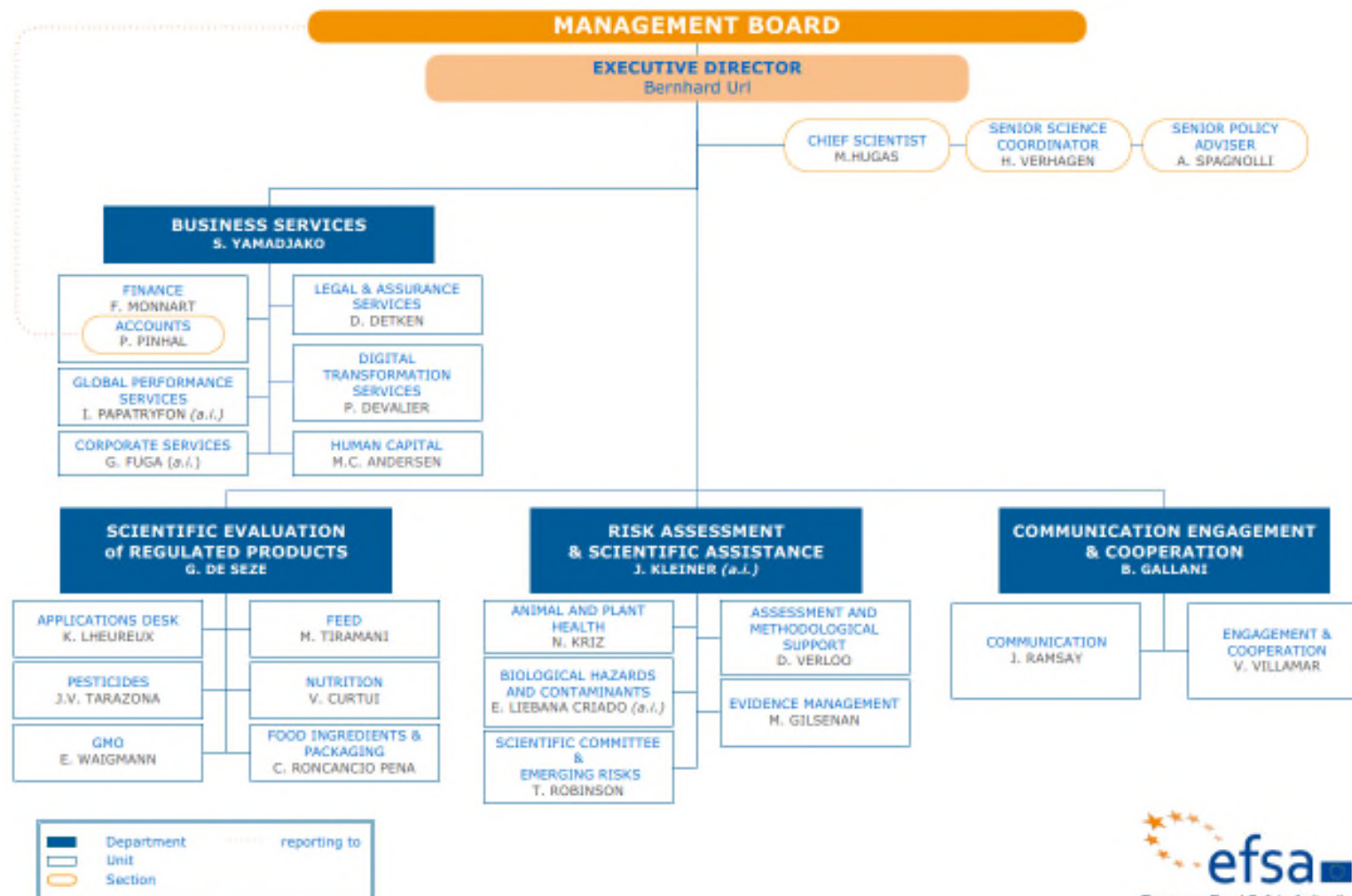
Regulated area	Start 2018	End 2018
FEED	<b>105</b>	<b>55</b>
– Feed additives – applications	105	55
FIP	<b>12</b>	<b>8</b>
– Food additives	10	6
– FIP - miscellaneous	2	2
GMO	<b>9</b>	<b>5</b>
PRAS	<b>54</b>	<b>24</b>
– Pesticides MRL Application (Reg. 396/2005 - Art. 10)	43	18
– Pesticides – miscellaneous	11	6
<b>TOTAL</b>	<b>180</b>	<b>92</b>

**Table 40:** SO1 regulated products – Bulk evaluations

Status	Regulated area	Start 2018	End 2018
Deadlines agreed with RM	FIP	<b>471</b>	<b>436</b>
	– Enzymes	295	268
	– Food additives – re-evaluation	176	165
	PRAS	<b>186</b>	<b>170</b>
	– Pesticides MRL Review (Reg. 396/2005 - Art. 12) - ex backlog -	186	160
Pending RM decision	NUTRI	<b>1548</b>	<b>1548</b>
	– Health Claims (Art.13.2) - botanicals	1548	1548

# Annex V. Human resources

**Figure 6** Organisational chart (31/12/18)



**Table 41 :** Establishment plan 2018

Function group and grade	2018			
	Authorised <sup>126</sup> under the EU Budget		Filled as of 31/12/2018	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16				
AD 15		1		
AD 14				1
AD 13		1		
AD 12		6		6
AD 11		8		6
AD 10		16		13
AD 9		34		26
AD 8	1	57	1	60
AD 7	4	49	4	48
AD 6		31		38
AD 5		10		8
<b>AD TOTAL</b>	<b>5</b>	<b>213</b>	<b>5</b>	<b>206</b>
AST 11				
AST 10				
AST 9				
AST 8		1		
AST 7		2		3
AST 6		5		4
AST 5		18		16
AST 4		35		36
AST 3		21		22
AST 2		17		17
AST 1		2		2

<sup>126</sup> The 2018 Establishment Plan figures refer to the ones approved by the EFSA's Management Board in December 2017 following the realignment requested by the European Commission. While confirming the total authorised posts, these figures are not fully aligned, in term of distribution by grade, to the ones of the EU Budget 2018 published in the Official Journal of the EU.

**Table 42:** Results of the benchmarking exercise in accordance with provision of Art. 29 (3) Framework Financial Regulation and Methodology for Agencies Job Screening <sup>(a)</sup>

Job type (sub)category	Year 2017	Year 2018
<b>Administrative support and Coordination</b>	<b>20.8%</b>	<b>19.1%</b>
Administrative support	18.8%	17.6%
Coordination	2.0%	1.5%
<b>Operational</b>	<b>72.6%</b>	<b>75.3%</b>
Top Level Operational Coordination	2.6%	2.6%
Programme Management and Implementation	56.6%	59.4%
Evaluation & Impact Assessment	0.0%	0.9%
General operational	13.3%	12.4%
<b>Neutral</b>	<b>6.6%</b>	<b>5.6%</b>
Finance/Control	6.1%	5.1%
Linguistics	0.6%	0.5%
<b>TOTAL</b>	<b>100%</b>	<b>100%</b>

# Annex VI. Negotiated procedures and time to grant

**Table 43:** 2018 negotiated procedure

2018 Exceptional Negotiated Procedures under FR 966/2012 as amended Article 134 (1) a to f art 53 RAP (pre-02/08/18) and under FR 2018/1046 (post 02/08/18)				
No.	Procedure type	Contractor name	Subject of contract	Contract amount
1	Art. 134.1(a)	MOSAICO SRL	VIDEO/AUDIO/MAINTENANCE/SERVICES AND SMALL ACQUISITIONS FOR MEETING ROOMS	1,400,000
2	Art. 134.1(b)	CLARIVATE ANALYTICS LLC	WEB OF SCIENCE	98,963.71
3	Art. 134.1(b)	POLITICO	ANNUAL SUBSCRIPTION 2018	25,000
4	Art. 134.1(b)	BARTLETT MEDIA LTD	SUBSCRIPTION TO EU FOOD POLICY	8,300
5	Art. 134.1(b)	DTU	PREPARATORY WORK FOR FLAVOURINGS EVALUATION'	40,000
6	Art. 134.1(b)	APPLIED MATHS NV	BIONUMERICS	20,000
7	Art. 134.1(b)	AMERICAN CHEMICAL SOCIETY	ACCESS TO SCIFINDER DATABASE	158,000
8	Annex 1 - 11.1 ( b )	DIGITAL SCIENCE & RESEARCH SOLUTION	ACCESS TO THE ALTMETRIC PLATFORM AND SERVICES	28,200
9	Annex 1 - 11.1 (b)(ii) and (c)	FASTWEB	FIXED TELEPHONY AND TELECOMMUNICATION SERVICES	36,000
10	Annex 1 - 11.1 (c)	LOGITEC	ORGANISATIONAL AND LOGISTICAL SERVICES	500,000
11	Art. 134.1(e)	OPEN ANALYTICS	ASSISTANCE TO THE AMU UNIT FOR THE PROVISION OF SERVICES TO EFSA ON R CODING, PROGRAMMING, AD-HOC R CONSULTATION AND THE PROVISION OF A SCALABLE HIGH PERFORMANCE COMPUTING ENVIRONMENT UPON REQUEST	290,000



**Table 44:** Time to grant

Procedure Title	Procedure reference	Deadline for applications	Signature of award decision	Grant Agreement signature date	Committed amount	Art 189 3c (E-D)	Art 189 (F-E)
Partnering projects: Grants to stimulate joint projects among 2 or more Member States to exchange knowledge and expertise, in support of the EU risk assessment agenda priorities. Such projects shall maximise return of existing risk assessment capacity in Member States, in order to strengthen Europe's capacity in food safety risk assessment	GP/EFSA/ENCO/2018/03 - GA01	31/10/2018	05/12/2018	17/12/2018	98063.5	35	12
	GP/EFSA/ENCO/2018/03 - GA02			12/12/2018	99812.24	35	7
Image analysis for early detection of quarantine plant pests	GP/EFSA/ALPHA/2018/02	11/10/2018	27/11/2018	06/12/2018	200000	47	9
LOT 1: Framework Partnership Agreement in various lots: Flavouring re-evaluation/ enzymes applications/ recycled plastic materials/ BPA/ Implementation of evidence based RA in scientific opinions falling within the FIP remit	GP/EFSA/FIP/2018/01 – LOT 1	03/09/2018	29/10/2018	07/11/2018	na	56	9
LOT 3: Framework Partnership Agreement in various lots: Flavouring re-evaluation/ enzymes applications/ recycled plastic materials/ BPA/ Implementation of evidence based RA in scientific opinions falling within the FIP remit	GP/EFSA/FIP/2018/01 – LOT 3			09/11/2018	na	56	11
Fellowship Programme - grant call for fellow hosting sites Grant	GP/EFSA/AFSCO/2017/08_GA04	31/01/2018	22/05/2018	22/06/2018	34,480.16 €	111	31
	GP/EFSA/AFSCO/2017/08_GA03			10/07/2018	37,846.38 €		49
	GP/EFSA/AFSCO/2017/08_GA01			27/06/2018	34,197.02 €		36
	GP/EFSA/AFSCO/2017/08_GA02			26/07/2018	34,165.56 €		65
	GP/EFSA/AFSCO/2017/08_GA05			26/07/2018	34,165.56 €		65
	GP/EFSA/AFSCO/2017/08_GA06			27/06/2018	31,460.00 €		36

Procedure Title	Procedure reference	Deadline for applications	Signature of award decision	Grant Agreement signature date	Committed amount	Art 189 3c (E-D)	Art 189 (F-E)
	GP/EFSA/AFSCO/2017/08_GA07			27/06/2018	31,460.00 €		36
	GP/EFSA/AFSCO/2017/08_GA08			22/06/2018	28,125.24 €		31
	GP/EFSA/AFSCO/2017/08_GA09			22/06/2018	42,848.52 €		31
	GP/EFSA/AFSCO/2017/08_GA10			22/06/2018	42,848.52 €		31
	GP/EFSA/AFSCO/2017/08_GA11			22/06/2018	31,176.86 €		31
	GP/EFSA/AFSCO/2017/08_GA12			03/07/2018	37,437.40 €		42
	GP/EFSA/AFSCO/2017/08_GA13			27/06/2018	40,111.50 €		36
	GP/EFSA/AFSCO/2017/08_GA15			25/06/2018	28,125.24 €		34
	GP/EFSA/AFSCO/2017/08_GA16			06/08/2018	31,176.86 €		76
AVERAGE						57	34

#### Financing not linked to costs under art. 125(3) points (a) – (f)

No.	Beneficiary name	Subject of contract	Contract amount
None			

#### FPA exceeding 4 years duration (art. 130(4)(c) FR)

No.	Beneficiary name	Subject of contract	Contract amount
None			

#### Flat-rate indirect costs higher than max. 7 % of total eligible direct costs (art. 181(6) FR)

Given the nature of the EFSA grants, 10 % flat-rate indirect costs corresponds better to the reality of the cost composition (Management Board decision of 10.02.2011)

# Annex VII. Annual Report on the implementation of EFSA's policy on independence

Reporting period: 1 January – 31 December 2018

## 1. Background

Regulation (EC) No 178/2002<sup>127</sup> laying down the general principles and requirements of food law, establishing the European Food Safety Authority, prescribes that EFSA shall be a point of reference for risk assessment in the food chain through its scientific outputs and its independence. Independence and high standards of professional conduct are crucial to EFSA's work, for it is essential that interested parties and the public at large trust the process leading to the adoption of its scientific outputs.

Against this background, as acknowledged in the EFSA Strategy 2020, EFSA's motto of delivering "Trusted science for safe food" requires adherence to robust ethics and integrity standards<sup>128</sup>. An impartial scientific process populated with objectively developed datasets and managed by scientists devoid of conflicts of interest is of fundamental importance to achieve EFSA's objective of being truly accountable to EU citizens and its institutional partners.

Adequate management of Conflicts of Interest (CoI) is of key importance for EFSA. In June 2017, EFSA adopted a new policy on independence followed by an implementing decision on the management of competing interests applicable to all members of EFSA's Scientific Committee, Scientific Panels, Working Groups, participants in peer-review meetings, network members, members of EFSA's governance bodies, hearing experts, observers, participants to procurement and grant awarding procedures as well as staff of EU institutions, bodies or other agencies taking an active role in EFSA's meetings<sup>129</sup>.

In its Policy on Independence document, EFSA committed to making publicly available an annual report on independence-related activities, thereby increasing the transparency of

<sup>127</sup> Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 031, 01/02/2002, 2-24 as last amended.

<sup>128</sup> EFSA, EFSA Strategy 2020. Trusted science for safe food. Protecting consumers' health with independent scientific advice on the food chain, available online at [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/strategy2020.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/strategy2020.pdf).

<sup>129</sup> EFSA, Decision of the Executive Director of EFSA on Competing Interest Management, EFSA/LA/DEC/19568050/2018, available online at <http://www.efsa.europa.eu/en/corporate/pub/independencepolicy17>.

related processes.<sup>130</sup> This annual report is the first on independence- related matters and aims at providing a clear picture of the investments made by the Authority to meet the expectations of EU citizens and its institutional partners.

2018 was an important year for EFSA in terms of independence. The policy commitment of enacting two-year cooling off periods requested by the European Parliament was enforced for the first time during the 2018 scientific panel selection process; a brand-new internal regulatory framework was put in place, ranging from implementing rules to Standard Operating Procedures (SOP); the technological solution supporting Declarations of Interests (DoIs) screening and processing was revised, and work started on a new regulatory framework applicable to EFSA staff.

## 2. Regulatory developments

Independence is one of EFSA's core values, together with openness, scientific excellence, innovation and cooperation. For this reason, in line with the idea of a lean evolution, the Authority adopts a continuous improvement approach characterised by the "Plan-Do-Check-Act" cycle<sup>131</sup>.

In the reference period, EFSA developed and put in place the internal regulatory framework necessary for the implementation of its 2017 policy on independence. This included the "Decision of the Executive Director on Competing Interest Management" of 20 October 2017<sup>132</sup>, which was first applied in the context of the 2018 panel renewal procedure, and which was subsequently amended on 29 June 2018, with the amended version entering into force on 1 July 2018. The new Decision on Competing Interest Management introduces the following novelties:

- Two-year "cooling-off" periods from any EFSA scientific activity for experts employed by industry or NGOs.
- Two-year "cooling-off" periods for a wide range of other professional interests, if they overlap with the type of work the expert will carry out for EFSA
- Requirements for experts to declare the financial impact of their interests on their total earnings.
- Sliding scale of restrictions depending on an expert's financial declaration, up to a two year "cooling-off" period from any EFSA scientific activity.
- Publication of a register of activities of Management Board members after they finish their term of office.
- Publication of the list of EFSA's partner organisations, such as national and international authorities, universities or research institutes.
- Publication of the declarations of interest of EFSA's Heads of units.

<sup>130</sup> EFSA's policy on independence. How the European Food Safety Authority assures the impartiality of professionals contributing to its operations, mb170621-a2, available online at <http://www.efsa.europa.eu/en/corporate/pub/policyonindependence>.

<sup>131</sup> So called "Deming cycle", as further reviewed by Imai and Ishikawa, contemplates a continuous improvement process based on four phases: Planning, where issues are identified, hypothesis developed and strategic decisions taken; Doing, where the solutions are tested and implemented on a small scale, and the results measures; Checking, where the results are evaluated and a decision is taken whether the hypothesis and related solution is concerned; and Acting, where the successful solution is implemented: Deming, W.E., 1950. *Elementary Principles of the Statistical Control of Quality*, JUSE; Ishikawa, K., 1985. *What is Total Quality Control? The Japanese Way*. Translated by David, J. Lu. Englewood Cliffs, NJ: Prentice-Hall, Inc, pages 56-61

<sup>132</sup> Decision of the Executive Director on Competing Interest Management, EFSA/LA/DEC/1857/1869/2017 of 20 October 2017, available online at [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/competing\\_interest\\_management\\_17.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf).

- Requirements for pesticide experts from national authorities in the Member States to be subject to the same transparency measures and DoI screening rules as experts on EFSA's scientific panels.
- Strengthened enforcement measures for breaches of the independence rules, up to a ban on working with EFSA for 10 years.

A new version of the SOP on Competing interest Management<sup>133</sup> came into effect on 13 July 2018, aligning the applicable procedures and workflows to the new decision, and detailing the operational steps to be followed.

Finally, in 2018, EFSA started developing a regulatory framework implementing articles 11 and 11a of the EU Staff Regulations on the prevention of conflicts of interest of EFSA employees and candidates to EFSA vacant positions.<sup>134</sup> In view of the fact that this forthcoming Decision is implementing the EU Staff Regulations, it must undergo the *ex-ante* agreement by the European Commission set out in Article 110 of the EU Staff Regulations. EFSA aims at proposing the new rules for adoption by its Management Board in Q4 2019.

### 3. *Ex-ante* controls - Figures on DoI processing operations

In the reference period, EFSA screened a total of 6 415 Declarations of Interest submitted by its scientific experts, 4 140 of which as Annual Declarations of Interests (ADoIs), and 2 275 as Specific Declarations of Interests (SDoIs).

With the entry into force of the new Decision on Competing Interest Management on 1 July 2018, SDoIs are not needed anymore due to the fact that based on the new screening criteria as well as enforcement of cooling off periods, no interest conflicting with specific items on the agenda is expected to pass the ADoI screening.<sup>135</sup> This is due to the fact that the identification of a conflict of interest now leads directly to the exclusion of the concerned expert from membership of the relevant scientific group. The only exception to this will be publications and intellectual property rights, for which specific conflicts will continue to be prevented by oral declarations of interests (ODOIs).

In the course of 2018, EFSA also processed 23 ADoIs submitted by current members of its Management Board and made publicly available four ADoIs as part of the registry of activities of former Management Board members.<sup>136</sup>

Under the new rules, DoIs have to be submitted also by all tenderers and participants to grant awarding procedures regarding the outsourcing of scientific tasks or projects. In the reference year, this resulted in thirteen calls being launched for which DoIs were requested, which led to the screening of 20 "institutional DoI" as well as of 50 "individual DoIs". None of the conflicts of interest identified were in the context of these screening processes.

Finally, the Authority also processed 380 ADoIs of its staff members, as well as 45 DoIs of candidates being pre-selected for engagement as contract agents, temporary agents, seconded national experts, or national experts in professional training. As far as the screening of DoIs of staff members is concerned, no conflicts of interest were identified,

<sup>133</sup> SOP on management of competing interests, 13 July 2018, SOP\_039\_A, available online at [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/SOP-039\\_A.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/SOP-039_A.pdf).

<sup>134</sup> Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community, OJ P 045 14.6.1962, p. 1385.

<sup>135</sup> Except for intellectual property rights or publications of relative impact for the mandate of the scientific group.

<sup>136</sup> The disclosure of activities of former Board members for two years after termination of their mandate is a voluntary transparency measure proactively adopted by the Management Board in EFSA's policy on independence.

while for candidates, ordinary mitigating measures were adopted in a number of cases to ensure that no perception of conflicts of interest could be caused by certain past interests held by candidates selected for EFSA statutory staff, seconded national experts and national experts in professional training vacant positions.

These ordinary mitigating measures consist in the exclusion for the concerned individual from taking part in processes and projects regarding their previous employer in the private sector, such as those regarding the evaluation of application dossiers submitted to EFSA's attention by applicants, participation in the evaluation of tenders by previous employers, or the review of the candidate's own work.<sup>137</sup>

### 3.1. Competing Interests prevented by sector

In the reference period, in the context of *ex ante controls* performed on the DoIs submitted by its experts, EFSA identified and prevented 36 conflicts of interest at ADoI level, and none at SDoI level. This systematically resulted in the exclusion of the expert either from membership or from participation in the discussion at the relevant meeting of the scientific group.

The breakdown by sector of the conflicts prevented is provided in Table 1.

**Table 1:** Competing interests prevented by sector

Sector	Number of conflicts of interest prevented
Animal Health and Welfare	7
Biological Hazards	1
Contaminants	2
Feed	2
Food Additives and Flavourings	1
Food Contact Materials, Enzymes and Processing Aids	3
Genetically Modified Organisms	2
Nutrition	4
Plant Health	4
Plant Protection Products and their Residues	4
Pesticides	4
Scientific Committee	2
<b>Total</b>	<b>36</b>

<sup>137</sup> For a definition of this concept, see SOP 039 on management of competing interests, available on EFSA's website at [https://www.efsa.europa.eu/sites/default/files/corporate\\_publications/files/SOP-039\\_A.pdf](https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/SOP-039_A.pdf).

## 4. *Ex post* controls: compliance and veracity checks

### 4.1. Background and aggregated results

Pursuant to its Decision of the Executive Director on Competing Interest Management, twice a year EFSA performs a check of the compliance and veracity of a sample of DoIs submitted by experts who participated in meetings of the Scientific Committee, scientific panels, working groups (WGs), peer review or for outsourcing procedures.

For each reporting period, 15 DoIs screening processes are randomly selected, and relevant ADoIs, SDoIs and ODoIs are checked for compliance with the regulatory framework in force at the time the act was adopted and for the veracity of the information contained. Experts participating as Chairs or members in scientific meetings are included in the list for random selection. Experts participating as hearing experts or observers, as well as experts participating in meetings of the Management Board, (scientific) networks, Advisory Forum or Focal Points, those participating in scientific preparatory or follow-up meeting and in scientific conferences and/or workshops on EFSA's behalf are excluded as they do not hold responsibilities in adopting EFSA's scientific outputs.

Overall, in 2018 these checks identified 17 findings, one of which was a relevant non-compliance, which will trigger a review of the relevant scientific output by EFSA's Legal and Assurance Services.

### 4.2. Findings of compliance and veracity check of 2018

The compliance checks of 2018 demonstrated that, for 26 out of 30 experts checked, EFSA's DoI Rules had been followed correctly. Three minor findings and one non-compliance were identified:

- The SDoI of an expert was missing. A non-conformity report was filed for the non-compliance by the relevant Unit. No further action was adopted since SDoIs have been phased out as of 1 July 2018 and no potential for a conflict of interest was identified.
- The minutes of a meeting were found not to contain reference to the screening of the ODoIs, although it had been performed. A non-conformity report was filed for the past non-compliance by the relevant Unit, and the meeting minutes were republished with a reference to ODoIs. No further action was deemed necessary.
- In another SDoI, the same item was listed twice on the agenda, while another item was missing altogether, thereby potentially impacting on the experts' ability to submit meaningful SDoIs and ODoIs. Since each item on the agenda was correctly linked to the correct mandate publicly available on EFSA's risk assessment workflow (RAW), in view of the fact that at the beginning of the scientific meeting at stake the expert did not declare any ODoI, no further action was deemed necessary.
- Since the validation decision is not automatically notified in full to the operational unit, a conflict of interest of a specific nature identified at ADoI level had not been addressed at SDoI and ODoI level, which resulted in the failure to exclude the expert from the meeting in question. For this case, a non-conformity report was filed by the relevant Unit. Furthermore, EFSA's assurance service will review the scientific output in question to clarify the extent of the expert's contribution. To avoid the occurrence of the same non-conformity in the future, further efforts will be made to raise staff awareness on the requirements set out in EFSA's policy on independence, and to enhance the DoI tool to automatise the notifications of identified conflicts of interest.



The 2018 veracity checks revealed that the ADoIs of 21 experts out of 30 were complete, while for six experts the ADoIs revealed the following omissions, that upon declaration were evaluated as not leading to a conflict of interest:

- a collaborative research and plant health capacity building undertaking of an academic institution in a third country as well as membership in an international learned society.
- Membership in an expert committee evaluating the same substance discussed at EFSA. Upon clarification by the expert, EFSA concluded that the interest was already reflected in the DoI of the expert under another interest category.
- A research funding.
- The evaluation of research projects for two public institutions. In light of the clarifications provided by the expert, EFSA concluded that the missing activities were outside EFSA's remit, and therefore there was no need to declare them.
- Membership in the board of a learned society.
- Membership in a peer-review committee evaluating certain research applications for a public institution. Upon clarification by the expert, EFSA concluded that the missing activity was older than five years prior to the submission of the DoI, and therefore there was no need to declare it.
- Eight research activities falling within EFSA's remit by the same expert.
- Membership in a scientific committee and two learned societies. Upon clarification by the expert, EFSA concluded that the involvement in these scientific organisations either terminated more than five years prior to DoI submission or that the activity was limited to simple membership and that therefore there was no need to declare them in the ADoI.
- Membership in a research organisation.

In addition to the customary checks performed on DoI screening processes concerning EFSA's scientific experts, the second compliance and veracity check exercise of 2018 was run for the first time also on DoI screening processes performed by EFSA in the context of its scientific grant and procurement schemes.

In terms of the outcome of the compliance checks, three out of four institutional DoIs and 8 out of 12 individual DoIs checked in the context of procurement and grant procedures, were found to be fully compliant. Minor findings not leading to conflicts of interest were identified as follows:

- a team member of a grant beneficiary failed to declare past employment terminated in the five years preceding the day of submission of the DoI, the impact of his employment on annual earnings as well as whether he was empowered to take risk management decisions. Following up the outcome of the check, the team member submitted an updated individual DoI which was re-evaluated, and no conflict of interest was identified.
- the indication of whether for the declared research projects the funding received from the private sector exceeds 25% was found to be missing in the individual DoIs of three team members. Following up the outcome of the check, the team members updated their individual DoIs, which were re-evaluated and no conflict of interests was identified.
- For all DoIs checked, the DoI assessment by the Evaluation Committee prior to the screening by the Authorising Officer was found to be missing. This did not impact on the DoI screening outcome, which was secured by the authorising officer. EFSA staff supporting outsourcing operations will be subject to targeted training on this specific aspect as preventive measure.



In terms of veracity, it was found that 7 out of the 8 individual DoIs checked were complete, while the following omission, not leading to a conflict of interest, was identified with respect to the DoI of a grant beneficiary:

- Omission of 6 research activities falling within EFSA's remit. The grant beneficiary submitted an updated ADoI including the missing activities. The updated ADoI was re-evaluated accordingly and no conflict of interest was identified.

## **5. *Ex post* controls: audit of the Internal Audit Service on Human resources management and ethics**

In May 2018, the European Commission's Internal Audit Service performed an internal audit on 'human resources management and ethics' at EFSA. This audit topic was included in the Strategic Internal Audit Plan for 2018–2020 following a risk assessment exercise where the IAS identified a number of processes in relation to risks.

The scope of the audit performed in May 2018 included an assessment of the way conflicts of interests of EFSA staff are prevented or managed by the Authority. The audit fieldwork was performed in 2018 and the final IAS internal audit report is expected in early 2019.

## **6. Assurance Working Group on Independence/Committee on Conflicts of Interest**

Pursuant to Article 22 of the Decision on Competing Interest Management, EFSA's Legal and Assurance Services are advised by the Assurance Working Group on Independence. Prior to the entry into force of the Decision on Competing Interest Management in July 2018, a similar role was performed by the Committee on Conflicts of Interest. The AWGI reports to EFSA's Assurance Council, which in turn informs the Audit Committee of EFSA's Management Board.

Five AWGI/CCI meetings took place in 2018 focusing mainly on the implementation of the new CIM rules and resulting in the issuing of nine opinions.

## **7. Activities undertaken by former EFSA staff members**

### **7.1. Background**

In accordance with Article 16 of EU Staff Regulations<sup>138</sup>, an official, temporary agent or contract agent intending to engage in an occupational activity, whether gainful or not, shall inform EFSA within two years of leaving the service. If the activity is related to the work carried out by the official, temporary agent or contract agent during the last three years of service and could lead to a conflict with the legitimate interests of the institution, the authority empowered to conclude contracts may, having regard to the interests of the service, either forbid him/her from undertaking it or give its approval subject to any conditions it thinks fit. The authority empowered to conclude contracts shall, after consulting the Joint Committee, notify its decision within 30 working days of being so informed. If no such notification has been made by the end of that period, this shall be deemed to constitute implicit acceptance.

<sup>138</sup> Regulation (EU, Euratom) No 1023/2013 of the European Parliament and of the Council of 22 October 2013 amending the Staff Regulations of Officials of the European Union and the Conditions of Employment of Other Servants of the European Union.

In the case of former senior officials as defined in implementing measures of the EU Staff Regulations, the authority empowered to conclude contract shall, in principle, prohibit them, during the 12 months after leaving the service, from engaging in lobbying or advocacy *vis-à-vis* staff of their former institution for their business, clients or employers on matters for which they were responsible during the last three years in the service. Each institution shall publish annually information on its implementation, including a list of the cases assessed, in compliance with Regulation (EC) No 2018/1725 of the European Parliament and of the Council<sup>139</sup>.

## 7.2. Overview

In the reference period, no former senior officials or agents left EFSA nor informed the Authority of their intention to engage in outside activities. Furthermore, 7 staff members left EFSA in 2018, 6 of whom opted for the public sector, and 1 of whom for the private sector (see Table 2).

**Table 2** – Overview of dossiers submitted under Article 16 of the Staff Regulations.

Reference year	Total number of cases	Of which to the private sector	Of which overlapping with EFSA's tasks	Restrictions applied
2018	6	1*	0	0

\*Research organisation.

For completeness, it should be noted also that a former EFSA staff member who left EFSA in 2017 started 2 activities with the public sector in 2018. Moreover, 2 former staff members, who had also left EFSA in 2017, in 2018 started activities with industry in areas overlapping with the EFSA remit. In both instances these activities were approved by EFSA with restrictions. These consisted in the prohibition to act as contact point *vis-à-vis* EFSA; to engage in lobbying and advocacy *vis-à-vis* EFSA staff or experts; or to exploit their relationships with former colleagues to obtain professional advantages or information.

## 8. Awareness raising and training

EFSA attaches great importance to the need of establishing a corporate culture aware of the importance of ethics and integrity matters, and the fact that the Authority comes across as a workplace intolerant of situations conducive to conflicts of interest.

Against this background, in 2018, several physical and e-training sessions were delivered to EFSA staff, members of the Management Board and experts, in order to raise awareness about the changes brought about by the new Decision on Competing Interest Management (see Table 3).

<sup>139</sup> Regulation (EU) No 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC.

**Table 3** –Training activities

Training activities	
Online e-training tool for experts	1
Sessions for DoI assessors	2
Session for EFSA procurement team in the Finance unit	1
Ethics and integrity session for all staff	1

## 9. IT developments

In 2018, EFSA modernised the component of its IT solution permitting the automated processing of DoIs of staff members, members of its Management Board and experts, thereby ensuring the sustainability of the DoI tool operated by EFSA and improving its availability and efficacy. The tool currently operated by the Authority relies on a proprietary interface combined with a commercial off-the-shelf software.

In the reference year, EFSA also started exploring the so called “complete solution” that is planned to replace the legacy part of the current IT solution in line with the criteria set out in the EFSA IT strategy. This substantiated in the trigger of a “proof of concept” regarding one of the solutions identified as suitable to address EFSA’s needs.

2018 also saw the delivery of a report from the University of Parma’s Department of Engineering that analysed the possibility of using artificial intelligence to screen DoIs processed by EFSA. The report explored approaches based on deep learning and a novel hybrid method using a combination of if/else-like statements, rules and machine learning. The improvements achieved in the evolution of the different systems designed highlight the necessity of adding external knowledge and context awareness to the information content included in the DoIs. Moreover, a drastic increment in the amount of data available would impact positively on the reliability and overall performance of the proposed system. The report concludes that at this stage, however, the automatic classification of DoIs using machine learning remains a challenging issue.

## 10. Transparency

Building on already highly transparent standards, in 2018 EFSA moved further ahead in making independence-related processes more accessible to citizens and interested parties.

As part of the implementation plan of EFSA’s Policy on Independence adopted by its Management Board in June 2017, in Q4 2018 EFSA made publicly available on its website the list of “public institutions”.<sup>140</sup> This list is instrumental to the screening of the DoIs submitted by the concerned individuals in accordance with EFSA’s Policy on independence and its Decision on Competing Interest Management. In general terms, the inclusion of an entity in this list certifies that the institutional activities performed by its employees in the public interest do not create a risk of conflict with EFSA’s interest.

The list is regularly updated by EFSA with new entries based on the DoIs it receives, and the inclusion of an entity presupposes compliance with the criteria set out in Article 2(1)

<sup>140</sup> The list is publicly available on EFSA’s website at this address:  
<https://www.efsa.europa.eu/en/howwework/independentscience>.

point m of the Decision on Competing Interest Management. In 2018, 514 organisations have been classified by EFSA.

Another measure adopted by EFSA to implement its recent Policy on Independence consisted in the publication, in Q4 2018, of the Declarations of Interests of the members of its operational management team, comprising EFSA's Heads of departments as well as Heads of Unit.<sup>141</sup>

In the reference period, EFSA also finalised a report addressing feasibility issues related to the publication of individual decisions taken by the Authority's Legal and Assurance Services in the context of the screening of DoIs submitted by EFSA's experts.

In accordance with EFSA's policy on independence, the findings of the study are expected to be presented to the Management Board in Q1 2019, resulting in a decision on whether these decisions should be made publicly available.

## 11. Engagement

In 2018, EFSA kept participating to the interagency task force managed by the European Commission's DG Health and Safety, comprising also representatives of the European Chemicals Agency, European Medicines Agency, Community Plant Variety Office and European Centre for Disease Prevention and Control. This forum is instrumental in optimising the use of resources deployed by these actors to prevent competing interests; as well as benchmarking and identifying best practices.

Moreover, EFSA engaged with an ad hoc working group of its Advisory Forum tasked with the development of a document to be undersigned by EFSA and the Advisory Forum to acknowledge relevant applicable principles on independence.<sup>142</sup>

In the reporting period, EFSA also provided constant support to internal and external stakeholders for the interpretation of the applicable regulatory framework and its operational implementation, by providing the requested support in 551 instances. In 2018, EFSA also engaged 31 times with members of the European Parliament, citizens, media professionals and external parties inquiring about EFSA's independence policy and competing interest management practices by providing the requested clarifications or support.

## 12. Conclusions

In the reference year, EFSA has devoted its investments in this sector to the implementation of its policy on independence. To deliver the activities described in the previous paragraphs, EFSA invested a total of 3.15 full-time equivalents and EUR 367 500.

A comparable level of investment is expected to continue in 2019 with ongoing work on competing interest management for staff members, cooperation with Member States' authorities, investigation of a complete IT solution as well as transparency.

Furthermore, margins for improvement identified in terms of implementation and compliance in the context of the *ex-ante* and *ex-post* controls are to be addressed in a manner adequate to the risk they represent.

Out of 6 910 DoIs screened by EFSA in the context of the *ex-ante* controls, 36 cases of conflicts of interest were identified and prevented. The *ex post* controls resulted in 17

<sup>141</sup> The DoIs of the Heads of units and of the Heads of departments are publicly available at this address: <https://www.efsa.europa.eu/en/people/operationalmanagement>.

<sup>142</sup> This initiative aims to address point 3.3 of the Policy on Independence and Article 12(2) of the Decision on Competing Interest Management.

findings, only one of which consisted in a non-compliance requiring the adoption of remedial measures. (see table 4)

The qualitative analysis of the detailed findings of these operations supports the efficacy of the regulatory system currently in place and improvements in the awareness-raising and IT sectors. Since the full impact deriving from the implementation of the 2017 policy on independence is expected to unfold as of 2019, further improvements in the overall level of compliance will be identifiable over the next two years.

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**Table 4:** Overview of 2018 facts and figures on independence

<i>Ex Ante Control</i>									<i>Ex Post Control</i>		Awareness-raising	Resources	
No of DoIs screened	No of meeting agenda items scrutinised	No of conflicts of interest prevented	No of waivers granted	No of Hearing experts	DoIs screened for tenderers and participants in grant-awarding procedures	No of Staff ADoIs screened	No of staff members leaving EFSA	No of organisations classified	No of compliance and veracity check	Breach of trust procedures	No of training activities	M€	FTEs
4 140 ADoIs 2 275 SDoIs	15 116	36: ADoIs 0: SDoIs	16	308	20: Institutional DoIs 50: Individual DoIs 0: conflict of interest prevented	380: statutory staff 0: conflict of interest prevented 45: candidate staff 0: conflict of interest prevented	Total: 6 Private sector: 1* Restrictions: 0	514	16 non-compliances not leading to a conflict of interest  1 non-compliance leading to the adoption of mitigating measures	0	1: online e-training tool for experts 2: sessions for DoI assessors 1: session for EFSA procurement team in the Finance unit 1: Ethics and Integrity session to all staff	0.4	3.15

\* Research organisation