European Food Safety Authority

Consolidated Annual Activity Report

2016

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

Adopted on 22 March 2017

For EFSA's Management Board

[NOT SIGNED]

Jaana Husu-Kallio

Chair of the Management Board

[1] 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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Foreword

It was another inspiring year for EFSA. The Authority finalised the new EFSA Strategy 2020, its beacon in the coming years. In an ever-changing and challenging global environment, the strategy will guide EFSA in carrying out its mission of protecting European consumers from health risks in the food chain.

EFSA's scientists and experts produced an impressive body of several hundred scientific outputs, providing scientific advice on a multitude of food and feed safety related issues. To list but a few, the Authority finalised the re-evaluation of food colours, published guidance on novel and traditional food applications, contributed to the international effort to fight antimicrobial resistance and made progress with its European partners in assessing cumulative risks from exposure to pesticides.

EFSA responded to a number of food-related outbreaks such as the highly pathogenic avian influenza virus H5N8 in wild birds and poultry, and lumpy skin disease in cattle. It also continued its important work on the outbreak of *Xylella fastidiosa* in olive groves in southern Italy.

At the same time, EFSA has not only been improving the scientific tools necessary for its work but opening them up to the wider risk assessment community. Last year saw the 'Knowledge Junction' come to life – an open repository for the exchange of evidence and supporting materials used in food and feed safety risk assessments.

Transparency and engagement continue to be embedded in EFSA's work. The Authority has opened up more of the data in its scientific data warehouse, improving not only transparency but also reproducibility and evidence re-use. EFSA also shared with Members of the European Parliament raw data it had used in its evaluation of the pesticide glyphosate.

Cooperation permeates EFSA so the Authority constantly looks at ways to work with its partners more efficiently. The fellowship programme EU-FORA launched in 2016 together with EFSA's Member State partners will help prepare the next generation of European risk assessors. Member States expressed their confidence in EFSA and its work through a Declaration of Commitment, reaffirming and moving forward their cooperation with EFSA in the coming years.

In line with its new strategy, EFSA reached out beyond Europe to strengthen international risk assessment capacities and harmonise methodological approaches. During visits to the U.S.A., Chile, Thailand, China and New Zealand, EFSA and its international partners addressed topical issues such as risk assessment of chemicals and pesticides, antimicrobial resistance and novel food.

Last year we also saw changes in the Management Board. We bade farewell to Sue Davies who steered the Board so expertly over recent years. I stepped into her shoes as Chair in October when we also welcomed five new members. As EFSA's Management Board we will continue to support EFSA in its endeavour to anticipate and to respond to the ever more complex challenges in the food safety field.
I would like to pay tribute to all those who dedicated their time and effort to advance EFSA's important scientific work in protecting public health in Europe: external experts, institutional partners, Member States, stakeholders and committed staff.

Jaana Husu-Kallio
Chair of the EFSA Management Board

Introduction

The year 2016 was significant for EFSA as we completed a strategic review of our work. The result is our new guiding document, the EFSA Strategy 2020, which translates the key priorities of our work into five strategic objectives, illustrating how EFSA will face new challenges and opportunities in the years to come. The strategy also introduces our new mission statement "Trusted science for safe food", which reflects the essence of our work: providing independent scientific advice to EU risk managers to ensure safe food for European citizens.

This Annual Report describes how we executed our work programme, making gains in efficiency and quality while addressing a growing workload. Our scientists and external experts produced close to 500 scientific outputs including important work on risk assessment methodologies such as the use of the benchmark dose. Last year's outputs include work on antimicrobial resistance, the presence of contaminants such as microplastics and nanoplastics in food, dietary reference values for vitamins as well as guidance documents on health claims applications and novel food – to name but a few. We responded to urgent requests on food-related outbreaks and provided high-quality scientific advice including on lumpy skin disease, avian influenza and *Xylella fastidiosa*.

EFSA's scientific data warehouse now provides access to more of the evidence that underpins our scientific assessments. Several data collections were published and are now available including datasets on pesticides, contaminants, chemical hazards, food composition, molecular typing and botanicals.

Being transparent and engaging with our stakeholders remains a top priority for us. We launched a new stakeholder engagement approach following close consultation with our stakeholders. It has already yielded first results – by the end of the year, over 80 organisations had expressed an interest in joining this new framework.

Communicating clearly, accurately, consistently and timely on EFSA's scientific risk assessments is crucial to our mandate. In spring 2016, our flagship scientific publication, the EFSA Journal, migrated to the international scientific publisher Wiley, thereby improving overall publishing quality and efficiency, while enhancing the clarity and outreach of our scientific work. We revised EFSA's authorship guidelines for scientific outputs to increase transparency and openness, and to improve our ability as an organisation to attract and retain expertise.

Expanding our activities in the social media realm, we launched thematic Twitter accounts on plants and on risk assessment methods. A new dedicated website, #EFSA4Bees, focuses on EFSA's work on bee health and features our first science blog. EFSA has become more present on Twitter with personal accounts for our senior managers – even I have become an avid tweeter.

I invite you to browse this Annual Report 2016 and see for yourself how we at EFSA have carried out our scientific risk assessment work in the interest of European consumers.

Bernhard Url

Executive Director, EFSA

List of acronyms

AMR	Antimicrobial resistance
DG SANTE	Directorate General for Health and Food Safety
DoI	Declaration of Interest
DRV	Dietary reference value
DW	Data warehouse
EAC	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EMA	European Medicines Agency
EU	European Union
FAO	Food and Agriculture Organization
FTE	Fulltime staff equivalent
FR	Financial Regulation
GM	Genetically modified
GMO	Genetically modified organism
IAC	Internal Audit Capability
IAS	Internal Audit Service of the European Commission
ICS	Internal Control Standards
IPCHeM	Information Platform for Chemical Monitoring data
LSD	Lumpy skin disease
MRL	Maximum residue level
QMS	Quality Management System
RASA	EFSA Risk Assessment and Scientific Assistance Department
REPRO	EFSA Scientific Evaluation of Regulated Products Department
SOP	Standard operation procedure
WHO	World Health Organization

Section I – Work programme achievements

1. Multi-annual work programme achievements

In March 2016, the Management Board adopted the EFSA Strategy 2020. The document takes into account the obligations of EFSA's Founding Regulation, the priorities of the European Commission and the external drivers that will impact on the Agency's direction in the coming years. Together with the detailed planning and programming documents, the document will guide EFSA in addressing the opportunities and challenges in the years until 2020.

The EFSA Strategy encompasses five strategic objectives that will enable EFSA to progress in the main areas of its work.

Table 1: Overview of strategic objectives

SO 1	Prioritise public and stakeholder engagement in the process of scientific assessment
SO 2	Widen EFSA's evidence base and optimise access to its data
SO 3	Build the EU's scientific assessment capacity and knowledge community
SO 4	Prepare for future risk assessment challenges
SO 5	Create an environment and culture that reflects EFSA's values

1.1. Strategic objective 1: prioritise public and stakeholder engagement in the process of scientific assessment

1.1.1. *Transparency and Engagement in Risk Assessment*

The TERA project (Transparency and Engagement in Risk Assessment) aims at increasing transparency and public engagement to transform EFSA into an open science organisation.

The transparency and engagement measures were identified during a wide-ranging consultation phase and are meant to be applied at the various steps of the EFSA risk assessment cycle. In 2016, EFSA assessed these measures for their impact through a study of risks and costs versus benefits. The simplest and most immediate measures were progressively rolled out in 2016, with EFSA delivering more than half of the new transparency and engagement requirements for the different phases of its risk assessment cycle.

Table 2: TERA project target under strategic objective 1

Target 2016	Status
Open EFSA roadmap: measures not requiring impact assessment implemented 50%	Achieved

1.1.2. *Interaction with applicants and the MATRIX project*

The MATRIX project was designed to improve interactions between EFSA and applicants. The project focuses on the streamlining and automation of EFSA's workflows, interactions and communications with applicants, Member States, the European Commission and other key actors during the lifecycle of an application for regulated products.

In 2016, a contract was signed for the design and implementation of the solution for the electronic management of applications. EFSA discussed and agreed the electronic dossier structure for the different regulatory areas, the specifications for the future administrative workflows and the identification of non-confidential parts of the dossiers.

Table 3: Interaction with applicants and the MATRIX project targets

Target 2016	Status
10% reduction of average time for processing an application	Achieved
Digital dossier management solution and pilot of the regulated product workflow	The pilot project to implement the regulated product workflow was delayed due to the complexity of drafting and publishing LOT 2 of the contract. The new target date is August 2017.

1.1.3. *EFSA Journal*

The EFSA Journal ensures effective dissemination of scientific outputs and provides access to EFSA's risk assessments in an open and transparent way.

In spring 2016, the Journal moved to a professional publisher, Wiley, providing editorial, typesetting and hosting services via the Wiley Online Library. This milestone development is part of an overall improvement of publishing activities providing an integrated solution and introducing digital workflows to increase process efficiency and

enhance the interoperability of EFSA's data. Open access has been strengthened via the introduction of a Creative Commons license and enhanced data visualisation and linkage.

The initiative introduces a new and important quality assurance step in EFSA's publishing processes. It also provides access to the evidence base underpinning EFSA's outputs, for example by linking references to full text via CrossRef and similar mechanisms. The entire EFSA Journal back file up to 2003 is available, as is the complete set of EFSA's supporting publications. The move to Wiley also provides EFSA with tools like Altmetric to measure the impact of the Authority's work.

In addition, EFSA revised the authorship guidelines for its scientific outputs to increase transparency and openness, and to improve EFSA's ability to attract and retain expertise.

Table 4: EFSA Journal targets

Target 2016	Status
Indexing of EFSA Journal in key bibliographic databases enhanced	In May 2016, Google Scholar – one of the key bibliographic sources of scientific information online – has started indexing the EFSA Journal. In addition, EFSA now assigns authorship to its scientific outputs, thus greatly facilitating their inclusion in the bibliographic systems.
New editorial workflow embedded into scientific unit workflows	The integration of digital editorial workflows for all types of content included in EFSA's outputs has transformed the online functionality of EFSA's content and added new rigour and quality assurance to EFSA's referencing systems. The science units have adapted well to the online proofing system, resulting in 300 outputs already published in line with the new workflows.
Migration and conversion of EFSA outputs to the new publishing platform	The transfer of more than 6 000 scientific outputs (EFSA Journal and supporting publications) to the Wiley Online Library was completed in two phases by mid-2016. This included a significant clean-up of data and metadata.

1.1.4. *Development of online presence*

In 2016, EFSA started improving accessibility to data and information, e.g. via its Scientific Data Warehouse. EFSA also increased the clarity of its risk communications by re-designing its website content to meet target audience needs and integrate social media channels.

Table 5: Website content re-design targets

Target 2016	Status
Increase use, reach and satisfaction (baseline to be set)	At the end of 2016, a user survey was conducted, which will inform the setting of the KPI baseline.
Feasibility study on collaboration solutions	A series of interviews and workshops with external consultants were run to develop a business case, currently under finalisation. The digital collaboration project charter is under finalisation. The project will start with a series of pilots, aiming to confirm the service model and its cost/benefit structure.

1.2. Strategic objective 2: widen EFSA's evidence base and optimise access to its data

1.2.1. *EFSA information governance, information access management and DATA doi*

The information governance project (part of the Information Management Programme), aiming to set up organisation-wide information governance, was launched in 2016. The implementation of planned initiatives under the information access management project, meant to improve information interoperability, registered some delays. For instance, the new identity repository for user and user group authentication (including an extended security life cycle) is now planned for the second quarter of 2017. The delay was mainly due to changes in the architectural design of the final solution and software license negotiations at EU level.

EFSA published metadata of the comprehensive food consumption database, chemical occurrence database and botanical database as part of a pilot project to publish EFSA databases on the EU open data portal. Project implementation will continue with the chemical hazard database (OpenFoodTox), which was recently published in the scientific data warehouse on the EFSA website. A subset of contaminant occurrence data was published on IPCHeM, in line with the data warehouse access rules.

Table 6: Information governance projects targets

Target 2016	Status
Interoperability with major data collections in EFSA's remit EFSA adopts information architecture in line with ISA2[2] standards (EIRA) Interoperability infrastructure in place, including S.O.A. (service oriented applications) and enterprise service bus	The implementation of an interoperability infrastructure with information architecture, in line with ISA2 standards, was piloted during the year and the initiative is on track.
New identity repository in place for user and user group authentication, including extended security life cycle	Delayed due to license contract renewal issues and change in the architectural design; re-scheduled for second quarter 2017.
Chemical hazard database metadata published in the EU Open Data Portal (as a pilot)	Metadata of EFSA's comprehensive food consumption database, the chemical occurrence database and the botanicals database were published on the EU open data portal with links to their respective datasets on EFSA's website. Publication of EFSA's chemical hazards database (OpenFoodTox) metadata was delayed until January 2017 to give priority to the above-mentioned datasets.
Process for generation of DATA doi (digital object identifiers) discussed and drafted in collaboration with OP	Delayed due to re-prioritisation caused by internal resource constraints. Planned to start in February 2017.

1.2.2. *Data warehouse*

The scientific data warehouse has been further developed as a central data hub providing access to European data across several domains, such as zoonoses, pesticide residues, contaminants, chemical hazards, botanicals and food consumption.

In 2016, the scientific data warehouse project achieved the majority of planned deliverables, in particular, the publication of data on contaminants, chemical hazards, and food consumption; ad-hoc data collections, such as the Compendium of botanicals,

[2] ISA: Standards for automation; EIRA: European Interoperability Reference Architecture.

molecular typing data, and veterinary drug residue reports, are now operational to receive data in the data warehouse.

Table 7: Data warehouse project targets

Target 2016	Status
Scientific data warehouse finalised and integrated in the EFSA website (chemical hazard DW including pesticides and contaminants; food composition DW operational; ad-hoc data collections DW operational; molecular typing DW operational)	Partially achieved. Publication of pesticides and food composition dashboards delayed to the first quarter of 2017.
Molecular typing data collection operational and joint analysis with ECDC in place	Achieved
Veterinary drug residues DW operational	Achieved
Chemical monitoring data published on IPCHeM platform	Achieved

1.2.3. *Open advanced scientific information (Open ScAIE)*

The Open ScAIE project (part of the Information Management Programme) aims at providing access to the scientific information needed for evidence-based risk assessment, such as peer and non-peer reviewed documents, mathematical models and data not in the scientific data warehouse. Such access will improve the efficiency of the risk assessment process for the community of experts.

In the context of this project, the 'Knowledge Junction', a repository and community for evidence and tools, has been developed and is now in place and publicly available. Scientific models used by EFSA over the past 15 years were brought together into this new open platform. The models can be shared and cited, and interested parties can present their own models.

A selection of these tools is also available as web applications on the new EFSA statistical models platform. Modelling plays a crucial role in scientific risk assessment, and EFSA set up this new community platform to make all the models used by EFSA available to those interested in food and feed risk assessment. The aim is to improve transparency, reproducibility and evidence re-use. By depositing their own supporting evidence and tools, interested parties will contribute to food safety in Europe.

Table 8: Open ScAIE target

Target 2016	Status
Repository for peer and non-peer reviewed documents developed	Achieved

1.3. Strategic objective 3: build the EU's scientific assessment capacity and knowledge community

1.3.1. *Expertise programme*

The talent management project reflects EFSA's strategic approach to its workforce requirements with a particular focus on attracting, developing and rewarding staff and experts.

During the first semester of 2016, the talent management project implemented an integrated set of policies, processes and best-of-breed sourcing technology solutions (TALEO/FUSION) for the selection of EFSA scientific staff and experts. The second semester of 2016 was dedicated to the activation of the Expertise Management Programme to complement the talent management project. The Programme objective covers the planning, sourcing, selection and competencies management for scientific staff and experts. The scope is to define and manage the pool and tools to attract scientific staff and experts in alignment with the classification of European Skills, Competencies, qualifications and Occupations (ESCO). The outcome of the programme will be used for the renewal of ten panels in 2017-2018.

In 2016, the project progressed in several areas. The software solutions for supporting the sourcing and selection of staff, the management of competencies, and the monitoring of EFSA's workforce were set up and put in place. Marking an important milestone, EFSA signed a contract for the implementation of the project in a number of areas, including competency management, sourcing and selection, learning and development and strategic workforce planning.

Table 9: Talent management targets

Target 2016	Status
Time to hire reduced by 10%	Achieved (4.7 months on average per procedure)
Cost to hire reduced by 10%	Achieved (0.35 FTEs on average per procedure)
Expert engagement ratio of 70%	The expert survey was not implemented due to a lack of internal resources.

1.4. Strategic objective 4: prepare for future risk assessment challenges

1.4.1. *PROMETHEUS and methods*

EFSA implemented and extended the PROMETHEUS project (PROmoting METhods for Evidence Use in Scientific assessments) to further promote quality and excellence in its scientific processes, and contribute to realising the strategic objectives related to evidence and methods for scientific assessments (see EFSA Strategy). Through this initiative, the Agency defined a set of principles for evidence use, outlined and tested in a series of case-studies a four-step approach (plan/carry out/verify/report) to implement those principles (EFSA, 2015 – 1st deliverable), and carried out an analysis of its 'methodological needs for evidence use' (EFSA, 2016 – 2nd deliverable).

In the context of achieving and maintaining an ISO 9001:2015 certification, the project has played, and plays, a key role in the following respects: Firstly, the methodological framework defined in PROMETHEUS may serve as a basis for developing a definition for 'quality' in EFSA's scientific processes and for subsequently defining a quality management system. Secondly, the analysis undertaken as part of deliverable two provides a picture of the methodological needs for evidence use in EFSA, as perceived by panel members and scientific staff. These methodological needs can be considered for implementing measures to further improve the process for evidence use in EFSA's scientific assessments.

Two main deliverables were achieved:

Deliverable 1

"Principle and process for dealing with data and evidence" (EFSA, 2015)

Deliverable 2

"Analysis of EFSA methodological needs for evidence use in scientific assessments"

All 2016 milestones were achieved, while the timeline to include case studies for all EFSA panels with a view to further evaluate the utility and feasibility of the new approach was extended to 30 April 2018.

Table 10: Prometheus project target

Target 2016	Status
Gap analysis completed for both regulated and non-regulated risk assessments (as-is)	Publication of the technical report on the 'Analysis of EFSA methodological needs for evidence use in scientific assessments'. Pilot studies in all EFSA working areas on-going.

1.5. Strategic objective 5: create an environment and culture that reflects EFSA's values

1.5.1. *EFSA Strategy 2020*

In 2016, EFSA adopted its Strategy 2020, including a multi-annual implementation plan. EFSA developed a performance framework that: i) links the strategic objectives to its portfolio of projects and processes as well as to its resources; and ii) includes a set of KPIs to monitor progress and performance at input, output, outcome and impact levels. The performance framework was included in the production of EFSA's programming document 2017-2019 and draft programming document 2018-2020.

1.5.2. *Revision of the EFSA independence policy*

In 2016, the revision of EFSA's independence policy evolved into a project closely related to both the TERA project and the Expertise Management Programme. A Management Board working group was established to support the revision of the Authority's independence policy.

The results in terms of EFSA's key performance indicators related to compliance with the independence policy and rules in the reporting period are detailed in Section 2 (Tables 25 & 26).

Table 11: TERA project target under strategic objective 5

Target 2016	Status
Independence policy revised and adopted by the Management Board	In agreement with the Management Board, the adoption of the revised independence policy was rescheduled to mid-2017.

The policy revision aims at providing a more fit-for-purpose approach to ensure the independence of actors involved in EFSA's decision-making processes while addressing institutional partners' demands for more clarity and accountability. The final outcome is

expected to contribute to increasing the trust of EFSA's stakeholders in the organisation's processes and resulting science.

1.5.3. *STEP 2018*

EFSA went through an important change following the adoption of a new organisational model. The STEP 2018 project was designed to improve efficiency in (transactional and enabling) support processes through the centralisation of the strategy, portfolio, budget, procurement and contract management processes. The development of the EFSA process architecture (EPA), covering 28 macro-processes, and a process mapping and documentation methodology increased EFSA's maturity in process management. This strengthened EFSA's planning and analytical capability with regard to resource management and optimisation, with a focus on efficiency (see also section II, 2.1: Resource optimisation and efficiency gains).

Table 12: STEP 2018

Target 2016	Status
New strategic planning and controlling function operational	Achieved
75% of staff dedicated to operational activities	74% While the performance was improved compared to last year, the KPI was not fully reached due to deviations from the planned effort in other support and operational activities (this is a composite indicator covering all EFSA processes). The project, however, achieved more than the expected savings (17.5 FTEs out of the 14 planned over the years 2015 and 2016), thereby contributing to the reduction of the effort dedicated to support activities.

2. Activities

2.1. Activity 1: provision of scientific advice and risk assessment approaches

2.1.1. *Overview of the activity*

EFSA contributes to the safety of the EU food chain and to a high level of human health protection in relation to food. The Authority's scientific advice and risk assessment methodologies support the decision-making process of risk managers at the European Commission and in Member States in the areas of food and feed safety, animal health and welfare, and plant health. EFSA is committed to carry out its risk assessments based on the available scientific evidence and in an independent, objective and transparent manner.

Advances in risk assessment

EFSA completed the update of its guidance on the use of the benchmark dose approach in risk assessment. It also finalised the draft guidance on the expression of uncertainty in risk assessment. The guidance is now being tested by the different panels and will be finalised in 2017. Work was carried out to develop guidance on biodiversity and ecosystem services, and to define protection goals for EFSA's environmental risk assessment. Progress was made in developing a guidance document on the weight of evidence approach in scientific assessment, and on how to define biological relevance.

In addition, EFSA started developing guidance documents on the risk assessment of chemical mixtures, and on the human and animal risk assessment of the application of nanoscience and nanotechnologies in the food chain. Upon request of the European Commission, EFSA is developing guidance for the risk assessment of substances present in food intended for infants below 16 weeks of age.

EFSA also launched a public consultation on the draft terms of reference for a working group of the Scientific Committee on 'Harmonisation of risk assessment methodologies for human health and ecological risk assessment of combined exposure to multiple chemicals'.

EFSA reviewed its cross-cutting guidance documents for scientific assessment in order to identify gaps requiring either the development of new or the revision of existing guidance. It identified several topics to be included in its work programme, such as individual susceptibility and uncertainty factors, interpretation of epidemiological studies, and history of use.

The multi-annual project to assess bee stressors and attributes of healthy honey bee colonies continues to progress with regular updates provided on a dedicated blog and microsite. EFSA also published a technical report on 'A mechanistic model to assess risks to honeybee colonies from exposure to pesticides under different scenarios of combined stressors and factors'.

EFSA further developed and applied statistical and methodological tools for scientific risk assessment, and developed a quantitative risk assessment methodology using the new draft uncertainty guidance. In 2016, EFSA tested the new methodology for four scientific opinions on quarantine pests in support of the new plant health legislation.

Outbreak assessments

Lumpy skin disease

In response to an urgent request for advice on lumpy skin disease (LSD), EFSA carried out an assessment of the effect of combinations of different eradication and vaccination options on the spread of the LSD virus, using a mathematical model to simulate the spread of LSD between farms. EFSA also conducted a survival analysis by using field

data from Greece to estimate the effectiveness of vaccinations. As follow-up, a project to collect outbreak and vaccination data started in the last quarter of 2016, involving all affected countries in the Balkan area.

Avian influenza

In response to an urgent request of the European Commission, EFSA published a statement on outbreaks of the highly pathogenic avian influenza virus H5N8 in wild birds and poultry. Outbreak data were collected in close collaboration with the EU reference laboratories on avian influenza and affected Member States. The outcome of an expert knowledge elicitation indicated that strict enforcement of biosecurity measures was the most effective way to prevent the introduction of the virus in poultry farms. EFSA recommended passive surveillance to detect the virus in wild birds and poultry. EFSA and ECDC cooperated to confirm the low risk to humans.

Food-borne outbreaks

EFSA and ECDC also worked jointly on multi-country outbreak assessments caused by shiga toxin-producing *Escherichia coli* (STEC) in foods, *Salmonella* Enteritidis in eggs, and food-borne botulism associated with the consumption of dried salted fish.

Xylella fastidiosa

In 2016, the Authority addressed several requests from the European Commission regarding the outbreak of *Xylella fastidiosa* in Apulia, Italy, where the disease affects olive trees and other plants. EFSA assessed some treatments already being tested on olive trees in the region, and confirmed that there is no evidence suggesting that multiple types of *X. fastidiosa* are present in Apulia. According to the available scientific evidence, only one multi-locus sequence type belonging to a subspecies of *X. fastidiosa* has been identified so far.

Scientific opinions and advice

EFSA continued its work on food hygiene in small retail enterprises, the presence of *Bacillus cereus* and other *Bacillus* spp. in foodstuffs, spoilage microorganisms in meat, food-borne zoonoses like *Listeria*, transmissible spongiform encephalopathies (TSE), and antimicrobial resistance (AMR). In collaboration with other EU agencies, EFSA also worked on several multi-sectoral opinions.

EFSA and EMA jointly reviewed measures taken in the EU to reduce the need for and use of antimicrobials in food-producing animals, and analysed the resulting impact on AMR. EFSA's contribution to this work covered the use of feed additives to improve the immune capacity of animals, a review of husbandry and management measures that prevent on-farm pathogen entry and spread, as well as measures improving animals' resilience and resistance towards diseases.

EFSA, EMA and ECDC started updating the Joint Interagency Antimicrobial Consumption and Resistance Analysis (JIACRA) with surveillance data from 2013, 2014 and 2015. The work will be completed in 2017. The three agencies jointly proposed a list of indicators that will enable risk managers to monitor the reduction of AMR and the use of antimicrobials in humans, food-producing animals and food. The indicators, requested by the European Commission, will also help risk managers assess the impact of mitigation measures and the effectiveness of their action plans.

EFSA continued working on generic scientific opinions on the risks related to the presence of pharmacologically active substances, natural toxins, and environmental and process contaminants. More specifically, EFSA assessed the acute health risks related to the presence of cyanogenic glycosides in raw apricot kernels and products derived from raw apricot kernels. EFSA also completed work on erucic acid, a naturally occurring contaminant present in vegetable oil, and on the presence of microplastics and nanoplastics in food, with a particular focus on seafood.

EFSA delivered scientific reports on the review of proposed maximum residue levels (MRLs), as well as on the safety evaluation of products obtained from animals treated with zilpaterol and the evaluation of the substance's effects on animal health and welfare.

EFSA worked on outputs in relation to animal welfare at time of slaughter and reviewed scientific updates on main stunning methods. In the context of categorisation and prioritisation of animal diseases, EFSA worked on the assessment of 21 selected animal diseases, transmissible in terrestrial and aquatic animals, with the aim of listing and categorizing them in accordance with Animal Health Law.

EFSA reviewed new evidence regarding the categorisation of *Vitis* spp. (grapevine), *Citrus* spp., *Quercus ilex* (holm oak) and *Phoenix roebelenii* (ornamental dwarf palm) as host plants of *X. fastidiosa*. In this context, EFSA continued to update and maintain a bibliographic database of *X. fastidiosa* host plants reported worldwide. EFSA produced risk assessments on the following plant pests: *Ditylenchus destructor*, *Ceratocystis platani*, *Cryphonectria parasitica* and Grapevine flavescence dorée, and reviewed literature on citrus black spot.

EFSA finalised five scientific opinions on dietary reference values (DRVs) for vitamin D, vitamin B6, thiamine, potassium and choline. EFSA continued the preparatory work on DRVs for vitamin K, riboflavin, chloride and sodium. EFSA also initiated the PROMETHUS approach (see above) in setting DRVs for sodium.

2.1.2. *Key performance indicators and resources*

Table 13: Key performance indicators for Activity 1

Objective	Indicators	Achieved 2015	Target 2016	Achieved 2016
Ensure effective delivery of work programme	Number of scientific outputs adopted	62	49	42[(a)]
	Number of technical reports finalised[(b)]	-	22	9[(c)]
Improve the timeliness of scientific advice	Proportion of scientific outputs/questions(d) adopted within deadline[(e)]	92%	100%	100%
Ensure full compliance with EFSA's Policy on Independence	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	100%	100%	99.9%
Ensure effective use of financial resources	Proportion of original budget for Activity 1 committed/paid at year end[(f)]	99.7% 89.8%	100% 90%	101.4% 91.0%

(a) The minor discrepancy in achievement results from the extension of deadlines for some opinions (from 2016 to 2017).
(b) Technical reports were previously reported under Activity 3. From 2016 onwards, technical reports are reported under the different activities (1, 2 and 3).
(c) The achieved result is mainly due to the reallocation of technical reports from Activity 1 to Activity 3.
(d) The number of questions and the number of outputs under Activity 1 are usually the same and therefor reported together.
(e) Timeliness of adoption is calculated excluding initial backlog.
(f) Including staff and infrastructure cost.

Table 14: Resources allocated to Activity 1

	Executed 2015		Plan 2016		Executed 2016	
	M€	FTE[(a)]	M€	FTE[(a)]	M€	FTE[(a)]
A1 Provision of scientific advice and risk assessment approaches	12.12	66	13.33	75	13.52	77
% Total EFSA	**15**	**14**	**17**	**17**	**17**	**17**

(a) Actual available FTE.

2.2. Activity 2: evaluation of regulated products

2.2.1. *Overview of the activity*

Regulated products include substances used in food and feed, food contact materials and pesticides, genetically modified organisms, food-related processes and processing aids. EFSA's mandate for regulated products refers to the scientific safety assessment of such products before they can be authorised for the European market. This includes the evaluation of the scientific substantiation of nutrition and health claims made for these products and processes. Organisations or companies set to profit from regulated substances or products must provide evidence to prove that those substances are safe or, in the case of health claims, are backed by sound science.

Scientific opinions and advice

Food ingredients and packaging: EFSA started work on the re-evaluation of consumer safety of bisphenol A (BPA) by setting up a working group to develop the hazard assessment protocol. EFSA revised its statement regarding theexposure assessment of food enzymes, following a public consultation.

The Authority continued its work on the re-evaluation of food flavourings and assessed applications for new flavouring substances and smoke flavourings. EFSA completed its re-evaluation of food colours and continued with the re-evaluation of food additives. The Authority published a concept paper ahead of the revision of guidance on nutrient source evaluations to gather feedback and suggestions from relevant stakeholders early on in the process.

Feed additives: EFSA adopted a large number of outputs on the re-evaluation of feed additives, the assessment of new feed additives or new uses of existing feed additives, and the modification of authorisations. EFSA also adopted the outcome of an 'Analysis of the need for an update of the guidance documents' in this area. The Authority endorsed a reply to a request for consultation on the amendment of Commission Regulation (EC) No 429/2008.

EFSA proposed modifications to the maximum levels of copper in feed for some animal groups. The recommended reductions of the maximum copper content in feed for most animals would reduce the amount of copper released into the environment, which could potentially play a role in reducing antimicrobial resistance.

Genetically modified organisms (GMOs): EFSA adopted scientific opinions related to applications for market authorisations of genetically modified (GM) plants, an environmental post-market monitoring report, and two cases of new sequencing information. EFSA held a public consultation and a stakeholder workshop on the draft guidance document for the allergenicity assessment of GM plants. The increased stakeholder participation in the development of the guidance document, led by a dedicated focus group, was part of the TERA project aiming to achieve more transparency and openness.

EFSA conducted a first consultation with Member States on the guidance on low-level presence of GMOs. EFSA provided advice to the European Commission on the prolongation of prohibition of several GM oilseed rapes, and in relation to newly

published scientific information on Bt crops. In close cooperation with EMA, EFSA also provided advice on the potential integration of a DNA plasmid vaccine into the salmon genome.

Nutrition: EFSA has updated its general scientific advice for health claims applicants, taking into consideration lessons learned from past experience and from an exchange of views with stakeholders. Following the adoption of the new European Regulation on novel foods in November 2015, EFSA published two guidance documents on novel food and traditional food from third countries, advising applicants on the data needed for the safety assessment. EFSA developed a scientific and technical guidance document to advise applicants on applications for the authorisation of infant formulae and/or follow-on formulae manufactured from protein hydrolysates.

Pesticides: EFSA finalised a new guidance document on evidence for toxicity and genotoxicity of pesticide metabolites. The Authority adopted a scientific opinion investigating experimental toxicological properties of plant protection products having a potential link to Parkinson's disease and childhood leukaemia. EFSA also continued the methodological updates to address the risks in complex environmental media such as sediment and soil.

EFSA continued with its peer-review for new pesticides and for the third renewal group (AIR-III) of active substances. The Authority further explained the 2015 assessment of glyphosate and, following a request for access to documents, made available the raw data used by EFSA for the safety evaluation of the substance.

EFSA implemented the backlog reduction plan for MRLs and responded to urgent ad-hoc requests from the European Commission. The yearly summary report on pesticide residues was published in October. The report results from the analysis of about 83 000 food samples from the 28 EU Member States. In connection with new mandates for the evaluation of three neonicotinoids, i.e. clothianidin, thiamethoxam and imidacloprid, EFSA published technical reports and conclusions on confirmatory data for clothianidin and imidacloprid.

EFSA and its European partners took a major step forward in their work on assessing the cumulative risks from exposure to pesticides. A software tool was developed to carry out exposure assessments.

EFSA hosted a conference on the EU regulatory framework for pesticides and on achievements in the area of environmental risk assessment for pesticides. EFSA and the OECD co-organised a workshop to facilitate the development and regulatory use of non-animal test methods for developmental neurotoxicity .

Supporting applicants

In 2016, EFSA processed 483 applications through its paperless submission system. The Applications Helpdesk replied to 303 information requests.

EFSA continued to implement support initiatives to increase the efficiency and predictability of the administrative workflow for both EFSA and applicants. EFSA published its updated catalogue of support initiatives for regulated products, strengthening engagement with applicants and other interested parties. The catalogue was also presented by means of a webinar. EFSA organised an additional webinar on scientific aspects to consider when preparing a health claim application. The success of EFSA webinars as a new support initiative for applicants confirmed the great potential of this channel to reach large audiences.

EFSA held a roundtable with industry associations to increase dialogue and stakeholder engagement during risk assessment. With the same purpose, EFSA organised four info sessions on applications for food enzymes, feed additives, GMO and pesticides.

2.2.2. *Key performance indicators and resources*

Table 15: Key performance indicators for Activity 2

Objective	Indicators	Achieved 2015	Target 2016	Achieved 2016
Ensure effective delivery of work programme	Number of scientific outputs adopted	306	265	259[a]
	Number of technical reports finalised[b]	-	47	62[c]
	Number of closed scientific questions[d]		413	382[e]
	Reduction of backlog of reasoned opinions on MRLs (backlog elimination by end of 2019)		Planned to be reduced to 237	Reduced to 221
Improve the timeliness of scientific advice	Proportion of scientific outputs adopted within deadline	84%	90%	75%[e]
	Proportion of scientific questions adopted within deadline		90%	75%[e]
Ensure full compliance with EFSA's Policy on Independence	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	100%	100%	100%
Ensure effective use of financial resources	Proportion of original budget for Activity 2 committed/paid at year end[g]	99.9% 91.8%	100% 90%	100.8% 89.5%

a) The result is mainly related to applications for new food flavorings, where requests for additional clarification have led to a clock-stop for some FIP opinions.
b) Technical reports (reports that EFSA issues at the request of the Commission, on its own initiative or as envisaged in relevant sectorial legislation) are, as a general rule, prepared by an EFSA working group and/or by EFSA scientific staff and were previously reported under Activity 3. From 2016 onwards, technical reports are reported under the different Activities (1, 2 and 3).
c) ESFA finalised more technical reports than targeted, mainly in pesticides area (peer review), where 40 technical reports were produced instead of 24 initially planned.
d) Scientific questions are specific questions that are contained in the official requests received from the European Commission or from Member States. A request can contain many questions. Scientific outputs can answer one or more scientific questions.
e) Discrepancy due to clock-stop on some FIP opinions following additional clarification requests, excluding questions already overdue at the beginning of the year.
f) Results for timeliness are mainly due to workload continuously accumulated over the years, and the complexity of opinions.
g) Including staff and infrastructure cost.

Regarding the reduction of the MRL backlog, the unit was able to fulfil the targets for 2016, finalising reasoned opinions and statements planned for adoption in the reporting period. The resources hired to absorb the backlog were not fully available during the year and some assessments were delayed postponing adoption by one year. The MRL backlog reduction plan was updated according to the availability of relevant resources, and the backlog is expected to be absorbed by 31/12/2021.

Table 16: Resources allocated to Activity 2

	Executed 2015		Plan 2016		Executed 2016	
	M€	FTE[a]	M€	FTE[a]	M€	FTE [a]
A2 Evaluation of regulated products	20.04	135	20.57	131	20.74	136
% Total EFSA	**25**	**30**	**26**	**29**	**26**	**29**

a) Actual available FTE.

2.3. Activity 3: data collection, scientific cooperation and networking

2.3.1. *Overview of the activity*

To carry out their risk assessments, EFSA and the 28 EU Member States rely on shared expertise, methods and data. EFSA encourages scientific debate to harmonise risk assessment approaches through many cooperation activities with European and international partners. Pooling Europe's and international scientific and technical capacity ensures a more efficient use of limited resources and coherence of scientific conclusions, enhancing food safety for the benefit of consumers.

Scientific cooperation at the heart of EFSA

EFSA's Scientific Cooperation Roadmap 2014-2016 shaped a new partnership approach to scientific cooperation involving Member States, neighbouring countries and international partners. Through its Advisory Forum, EFSA developed the EU Risk Assessment Agenda, which is based on common risk assessment priorities. It is presented in the form of a catalogue of projects to guide work planning and agreement on joint risk assessment activities among Member States and EFSA. The Members of the Advisory Forum signed a Declaration of Commitment and agreed to collaborate on a range of activities to meet future challenges.

The Focal Points network focused on the coordination and management of EFSA's scientific networks, the renewal of framework partnership agreements for 2016, and the preparation for the launch of the fellowship programme EU-FORA. EU-FORA is aimed at early- to mid-career scientists working in food safety organisations across Europe (Article 36 organisations) who will have the opportunity to complete a one-year placement in a competent authority. A dedicated page was created on the EFSA website to provide detailed information.

EFSA's Executive Director paid visits to nine countries to discuss opportunities for collaboration. This included the signing of framework partnership agreements with Germany, Spain and the Netherlands, also involving partners in other Member States. Discussions also focused on the organisation of international workshops on food-borne viruses, the cumulative risk assessment of pesticides, benchmark dose modelling, antimicrobial resistance in *Campylobacter*, crisis preparedness, dietary exposure assessment, use of the ImproRisk model, and lumpy skin disease.

A cooperation project on ciguatoxin food poisoning, involving 13 organisations from six Member States and EFSA, is taking shape. In April 2016, representatives of Spain and EFSA signed a Framework Partnership Agreement to carry out a four-year project on the risk characterisation of ciguatera food poisoning in Europe.

In May 2016, experts from the EU neighbourhood and pre-accession countries contributed to a workshop organised by EFSA and the European Commission on lumpy skin disease to discuss the epidemiological presence of the disease throughout the Middle East and Europe.

Through co-organised regional workshops, EFSA provided opportunities to enlarge expert networks and to share data and risk assessment methodologies. 24 new organisations were added to EFSA's Article 36 list, now including 351 organisations from 30 countries.

EFSA awarded new thematic grants to a total of 18 organisations from nine Member States in three projects. The Executive Directors of EFSA, ECHA and ECDC shaped the agenda of the EU Agencies Network on Scientific Advice (EU-ANSA), with a particular focus on data exchange.

On the international front, EFSA continued to support EU delegations in CODEX meetings in the area of pesticide residues, nutrition, veterinary drug residues and emerging risks, and submitted data in response to calls for data from CODEX and the Joint FAO/WHO Secretariats to JECFA. EFSA also contributed to the harmonisation of risk assessment methodologies through its participation: in the International Liaison Groups on chemical and microbiological food safety, and health claims; in networks run by WHO on chemical risk assessment, and by OECD on pesticides and developmental neuro-toxicity; as well as at the Global Summit on Regulatory Science 2016.

EFSA played a very active role in building international risk assessment capacity by participating in seminars on accelerating risk assessment, organised by the U.S. Environmental Protection Agency (USEPA); on trends and developments in risk assessment of chemicals, pesticides and novel foods, by the Chilean Agency for Food Safety (ACHIPIA); and on pesticides, by the EU-India Dialogue. EFSA also facilitated training opportunities on antimicrobial resistance, and its latest guidance on novel foods (in Thailand), and took part in the celebrations of the 25th anniversary of Food Standards Australia New Zealand (FSANZ).

Data collection and monitoring

EFSA supported the implementation of the food classification and description system (FoodEx2) by Member States and international organisations. The Authority delivered scientific reports on non-dietary exposure (mapping out different approaches used to estimate non-dietary exposure to chemical substances in consumers), as well as on dietary exposure to *Alternaria* toxins and to pyrrolizidine alkaloids.

The first pilot of the standard sample description (version 2.0) involving Member States was completed, providing input for the parallel pilot study to test electronic data transmission of the new sample-based data collection of annual veterinary drug residues.

The molecular typing project, developed in collaboration with ECDC, is now operational. A network for veterinary drug residue data collection was established to support the transmission of sample-based data on veterinary drugs from Member States to EFSA. In addition, on-site training was delivered in 17 Member States to support the transmission of zoonoses monitoring data to EFSA using the data collection framework's web-based data transmission tool.

EFSA published a web-based version of the Compendium of botanicals in its scientific data warehouse. The compendium is a database of botanicals that are reported to contain naturally occurring substances of possible human health concern when present in food. It is intended to help with the safety assessment of botanicals and botanical preparations that may be used in food, including supplements, by facilitating hazard identification.

After more than five years of preparation, the chemical hazards database (OpenFoodTox) was finalised and uploaded into the scientific data warehouse. The searchable database provides instant access to over 1 650 EFSA scientific outputs with information on the toxicity of over 4 400 chemicals found in the food and feed chain, with information on their critical effects, safe levels set by EFSA, links to EFSA outputs and related EU legislation.

2.3.2. *Key performance indicators and resources*

Table 17: Key performance indicators for Activity 3

Objective	Indicators	Achieved 2015	Target 2016	Achieved 2016
Ensure effective delivery of work programme	Number of scientific outputs/questions[a] adopted	6	6	9[b]
	Number of technical reports finalised[c]		13	28[d]
	Number of other publications (external scientific reports and event reports)[e]		45	72(f)
Improve the timeliness of scientific advice	Proportion of scientific outputs adopted within deadline	100%	100%	89%[g]
Ensure full compliance with EFSA's Policy on Independence	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	100%-	100%	100%
Ensure effective use of financial resources	Proportion of budget for Activity 3 committed/paid at year end(h)	98.9% 93.1%	100% 90%	98.9% 92.0%
Effective execution of grants and procurement programme	Proportion of original grants and procurement budget for Activity 3 committed/paid at year end	100% 99.1%	100% 100%	105% 105%

a) The number of questions and the number of outputs under Activity 3 is usually the same.
b) Compared to the initial work plan, some units delivered a higher number of scientific reports.
c) Following EFSA's project approach, intermediate reports formerly counted as distinct outputs under Activity 3 are now integrated into outputs of Activities 1 and 2.
d) The number of 28 technical reports is due to the re-allocation of technical reports from Activity 1 (see Table 13, footnote b).
e) In 2015, event and technical reports linked to scientific cooperation activities as well as annual network reports were reported together. From 2016 onwards, technical reports are reported under the different activities (1, 2 and 3).
f) This includes 65 external scientific reports and 7 event reports. The discrepancy between the planned target and the final result is mainly due to the carry-over of the scientific cooperation work programme.
g) The 89% result is due to the delayed approval of one EFSA scientific report.
h) Including staff and infrastructure cost.

Table 18: Resources allocated to Activity 3

	Executed 2015		Plan 2016 (b)		Executed 2016	
	M€	FTE[a]	M€	FTE[a]	M€	FTE [a]
A3 Data collection & scientific cooperation	22.88	99	22.53	92	22.28	91
% Total EFSA	**29**	**22**	**28**	**21**	**28**	**20**

a) Actual available FTE.

2.4. Activity 4: communication and dialogue

2.4.1. *Overview of the activity*

Communicating changing dynamics in science and risk assessment

EFSA's mission in risk communications is to provide appropriate, consistent, accurate and timely communications on food safety issues to interested parties, stakeholders and the public at large, based on the Authority's risk assessments and scientific expertise. Effective risk communication requires partnership with Member States, engagement with institutional and external stakeholders, and a high level of trust in EFSA's expertise and independence. EFSA aims to support and facilitate scientific cooperation activities with and among European and international partners to harmonise risk assessment approaches. EFSA also strives to build scientific and technical capacity to ensure efficient use of limited resources, enhancing food safety for the benefit of consumers.

In 2016, the focus of the three units in the Communications and External Relations Department was on improving the clarity, impact and reach of its materials; strengthening relationships with Member States, institutional and external stakeholders; and developing European and international mechanisms and networks for capacity building and harmonisation of risk assessment methodologies.

The activities listed in the following subsections show the breadth and depth of EFSA's work in communications, external relations and scientific cooperation. Over the past year, EFSA continued to invest resources and effort in building stronger partnerships with Member States and international partners through meetings and activities of the Advisory Forum, the Focal Point Network and the Advisory Forum Communications Working Group, as well as through international events and working groups. In 2016, EFSA reviewed its stakeholder consultative platform, which was disbanded to make place for a new stakeholder engagement approach.

A team of editors worked closely with in-house scientists and designers to produce more than two-hundred news and multimedia items, explaining complex scientific and technical issues and providing visuals and videos to support understanding and dissemination of content. These included topics such as antimicrobial resistance (AMR), bees, *Xylella fastidiosa*, vitamin D, palm oil, novel foods, molecular typing, lumpy skin disease and micro-plastics in seafood. Web and multimedia tools were used to highlight scientific initiatives such as the data warehouse collections on contaminants, botanicals and zoonoses, as well as key methodology developments such as Prometheus, Knowledge Junction and uncertainty assessment.

Media coverage of EFSA's scientific opinions and outputs resulted in over 17 000 articles in EU, international, national and specialist print media. EFSA's press office dealt with approximately 550 enquiries.

The migration of the EFSA Journal to a professional publisher (Wiley) improved the consistency and rigour in applying editorial standards and conventions, and overall improved the presentation of and access to EFSA's scientific work.

In summary, the work delivered in 2016 supported the organisation's journey towards an Open EFSA 2020, based on clear communications, genuine dialogue and fruitful scientific cooperation. The forthcoming year will be driven by the ambition to build on EFSA's reputation and visibility within and outside Europe to increase trust in the organisation and its scientific outputs.

Developing online tools towards more efficient communication

Website development – improving usability, boosting efficiency: in 2016, a number of enhancements were added to EFSA's website, following its successful redesign in 2015. The range of usability improvements included a new events calendar, a newsletter

design, and the rationalisation of metadata for the search function, as well as the introduction of a series of performance and security upgrades. Yearly savings of 65 000 EUR were achieved through the migration of the website-hosting to a centralised service coordinated by the European Commission.

Social media: EFSA further developed its approach to social media in 2016. The Authority launched its first thematic Twitter accounts: @Plants_EFSA and @Methods_EFSA (the latter also on LinkedIn); piloted personal accounts for EFSA's Executive Director and other senior management; exceeded 16 500 and 20 500 followers on Twitter and LinkedIn, respectively; and launched the #Efsa4Bees website on EFSA's work on bee health, including EFSA's first official interactive science blog. As part of the European Antibiotic Awareness Day, EFSA took part in its fourth Twitter chat in cooperation with DG SANTE, ECDC, EMA and WHO.

Building resilience in handling and communicating complicated scientific issues

More focus on the science of communication: the Advisory Forum Communications Working Group (AFCWG), which will become the Communications Expert Network (CEN) in 2017, produced jointly with Member States the document 'Best practice for crisis communications'.

Developing targeted risk communications campaigns: in 2016, EFSA also carried out target audience research in 12 Member States, and produced a report related to the perception of human health risks from antimicrobial resistance in food producing animals.

Improving preparedness at a global scale: a steering group consisting of WHO, FAO, the World Organization for Animal Health (OIE) and other international and Member State organisations contributed to the terms of reference for an International Risk Communications Liaison Group (IRCLG), which will focus on strengthening consistency, and improving preparedness at a global scale in the area of food safety risk communications.

Supporting transparency, cooperation and innovation

Video news from open meetings: for the first time, EFSA published a series of 'flash' video reports on the outcomes of its open plenary meetings immediately after the events as part of the Authority's commitment to make its scientific work more open and transparent.

Strengthening outward communications: EFSA joined the Troika of the EU Agencies Network and will take over its chairmanship in 2017. EFSA's contributions to the network were influential in defining the work programme to strengthen outward communications, including developing messaging and a themed approach to promote the agencies' added value.

Towards a new stakeholder engagement framework

In June 2016, EFSA's Management Board endorsed the Authority's new approach to stakeholder engagement, following a consultation process with Board members and EFSA stakeholders. The new approach ensures that the engagement channels EFSA uses are appropriate and useful to stakeholders, and that relevant stakeholders are able to interact with the Authority according to their specific interests in its work. By November, EFSA had received over 80 applications from organisations interested in becoming registered stakeholders.

EFSA's Executive Director took part in a number of bilateral meetings with stakeholders, including the European Consumer Organisation (BEUC), Foodwatch, the European Environmental Bureau, Friends of the Earth Europe, Corporate Europe Observatory (CEO), European Crop Protection (ECPA), Food and Drink Europe (FDE), the European Feed Manufacturers' Federation (FEFAC) and Copa-Cogeca. EFSA also welcomed a

delegation from Greenpeace and exchanged views on bee health, neonicotinoids, access to data and EFSA's MUST-B project.

Nurturing organisational relationships

Vytenis Andriukaitis, EU Commissioner for Health and Food Safety, paid his first visit to EFSA's premises in Parma, Italy, to learn about the Authority's work, its achievements and future challenges. Topics discussed included the selection of experts, latest improvements to EFSA's independence policy, the need to attract young talent to the pool of scientific experts, the collection of and open access to data, and the importance of public engagement in the development of EFSA's scientific opinions.

EFSA continued to work closely with its institutional partners (European Commission, European Council and European Parliament) on a host of corporate and scientific topics. Notable encounters included a series of regular meetings with the European Commission's DG SANTE and its senior management as part of the strategic and operational dialogue. Regular activities with the European Parliament included interactions in the context of the budgetary discharge 2014, which was successfully granted in April 2016, as well as the launch of new initiatives with MEPs in the areas of bee health, food contact materials and pesticides. EFSA also welcomed individual MEPs to its premises, who visited the Agency as part of their constituency activities, and participated in the Presidencies' programmes with activities on antimicrobial resistance (under the Dutch Presidency) and on animal health and welfare (Slovak Presidency).

Beyond the media to the general public

The main trigger for media coverage in the first part of the year was the reauthorisation process for glyphosate led by the European Commission, and pesticides in general remained in the media throughout the year, examples being coverage on the safety of dimethoate in cherries, risks posed by neonicotinoids to pollinators, and pesticide residues in food.

The press also widely reported on EFSA's opinions on *Xylella fastidiosa* and on processed contaminants in vegetable oils, in particular in Italy. Antimicrobial resistance was another recurrent theme in the media, to which EFSA contributed through articles in specialised magazines and a series of interviews with scientific officers.

Europe Day and related events organised by EFSA received wide and positive coverage by Italian national and local media.

The Authority dealt with 130 public access demands, consisting in the disclosure of 2,767 documents. The evolving case law on public access to documents and transparency and confidentiality requirements impacted substantially on the way EFSA handles this aspect of stakeholders engagement and communication together with its institutional partners, and on the consequent deployment of resources needed to adapt its internal processes.

2.4.2. *Key performance indicators and resources*

Table 19: Key performance indicators for Activity 4

Objective	Indicators	Achieved 2015	Target 2016	Achieved 2016
Improve EFSA's visibility and outreach	Traffic to EFSA's web content (web metrics)	2.7 M	2.7 M	2.9 M
	Total number of subscribers to online subscription products (newsletter and alerts)	36 000	36 000	33 934
	Impact score of articles dedicated to EFSA[(a)]	12	5	24

Objective	Indicators	Achieved 2015	Target 2016	Achieved 2016
Improve EFSA's social media reach	Increase followers from social media platforms where EFSA is active (Twitter, Linked In, YouTube)	+21%	Baseline +10% (27 730)	+46%[b] (40 742)
	Traffic to EFSA web content from social media	2.1%	2% of traffic from SoMe. (baseline +0.24%	2.6%
Improve timeliness	Proportion of press releases/web news items accompanying scientific outputs delivered within 28[c] working days of adoption	91%	95%	63%
Improve coherence and preparedness for risk and crisis communications	Produce crisis communication guidelines in 2016	-	100% finalised	100% finalised[d]
Ensure effective use of financial resources	Proportion of original budget for Activity 4 committed/paid at year end[e]	97.3% 79.5%	100% 90%	91.3% 69.7%[f]

a) In 2014, EFSA developed an in-house methodology for media analysis. The approach is based on a system that multiplies the 'weight' of the media mentioning EFSA with the favourability of the article in question to give an impact score. Media are weighted by the type of publication (e.g. national daily, regional broadcast, etc.) and also by country. The favourability of an article is determined using a scale that takes account of information such as balance of the article, third party endorsement, severity of criticism, etc. The impact score can range from -100 (reflecting extremely negative media coverage) to +100 (reflecting extremely positive media coverage). An average impact score of between 5 and 20 reflects a 'neutral' coverage.
b) The initiatives taken by EFSA in terms of social media positively increased the number of followers. LinkedIn contributed the most to this increase.
c) As of April 2016, with the introduction of the Wiley process, the previous 20 working days of adoption were extended to 28. It was impossible for EFSA to respect the previous deadlines with the new process.
d) Published on the EFSA website in March 2016.
e) Including staff and infrastructure cost.
f) The low payment performance is mainly related to the late invoicing for outsourced services provided by Wiley for the EFSA Journal.

Table 20: Resources allocated to Activity 4

	Executed 2015		Plan 2016		Executed 2016	
	M€	FTE[a]	M€	FTE[a]	M€	FTE [a]
A4 Communication and dialogue	7.05	36	6.74	38	6.15	37
% Total EFSA	**9**	**8**	**9**	**8**	**8**	**8**

a) Actual available FTE.

2.5. Activities 5, 6 and 7: governance, support and coordination

2.5.1. *Overview of the activities*

Following the adoption of the strategy document in March, EFSA successfully delivered its first draft corporate performance dashboard. The dashboard provides strategic KPIs to guide the implementation of EFSA's strategy during 2016-2020, and represents the basis for the monitoring and reporting of data, thus strengthening a results-based management culture within the organisation.

As a result, in 2016, EFSA started to develop a system (organisation, processes and technology) that is capable of translating EFSA's values into concrete processes and practices, coherent with integrated risk management and quality management systems. As part of this move, assurance began being reorganised in an overall accountability framework, encompassing four pillars: results-based management, assurance, governance and decision-making, as well as quality and improvement. Regarding the assurance function, EFSA invested in *ex-ante* risk prevention by further developing audit consulting and integrating its input into the design of processes and procedures, and outsourcing the assurance audits as necessary.

Management Board activities

EFSA's Management Board continued to ensure compliance of EFSA's operations with the regulatory framework and provided strategic guidance. The Board adopted the EFSA Strategy 2020, which identified EFSA's overarching strategic objectives and will drive the Authority towards 2020. With the adoption of the Programming Documents for 2017-2020, the Board endorsed the multi-annual work programme pursuing the strategy objectives in the short- and medium-term.

The decisions on EFSA's stakeholder engagement approach and on the revision of the Advisory Forum operational procedures paved the way for a more structured dialogue with interested parties and strengthened cooperation with the Member States.

Promoting increased efficiency of organisational processes, the Board expressed its support for the re-organisation of the Internal Audit Capabilities functions. This also entailed the revision of the Management Board Audit Committee Charter. The Audit Committee guaranteed continuous assistance to the Board in identifying and dealing with organisational audit needs.

An ad-hoc working group was established to support the Board with activities around the revision of EFSA's Independence Policy. Another ad-hoc working group was created to focus on the process for the third external evaluation of EFSA.

In June, the Council confirmed Jaana-Husu-Kallio and Michael Winter for a second term as members of the Management Board and appointed five new members: Zita Čeponytė, Aivars Bērziņš, Didier Houssin, Giuseppe Ruocco and Andrej Simončič. The Board elected Jaana Husu-Kallio as chair, and Robert Van Gorcom and Raymond O'Rourke as vice-chairs. The Audit Committee was renewed in October with the appointments of András Székács and Andrej Simončič as chair and vice-chair, respectively.

Information technology

The IT roadmap, an integral part of EFSA's strategy, continues to drive progress in the area of standardisation and efficiency. It simplified the number of business applications to a few integrated solutions, and achieved a 24% rationalisation of software systems. This is on track with the 56 software systems expected to be rationalised by 2016 and an important step toward the 2020 objective of 33 software systems supporting all EFSA processes. The rationalisation of software systems helps streamline and modernise EFSA's business processes and deliver improved efficiencies, translated into another 3% efficiency gain in 2016.

In terms of IT support to projects, running costs were kept stable in order to fund increasingly important aspects in the digital era, such as cyber security, improved solutions for collaboration and productivity, modernising computing and mobility devices, and supporting EFSA's scientific units with real innovation, helping them visualise and communicate their scientific work in a better and easier ways.

The stable budget of EUR 4.7 million, or half of the total technology budget, left a full 50% of all technology expenditures spent for supporting the strategic objectives through transformation projects.

While project execution was below target for the year, based on the full-year result of all projects, the significantly increased involvement of EFSA's senior managers and unit heads in the governance of transformation programmes, including their technology, was used to mature project management practice and to focus on projects supporting EFSA's strategy. For the strategic subset of the 2016 portfolio, project performance improved by 50% during the period March through December 2016.

IT service delivery, outsourced since 2015, saw a 22% improvement this year, which is 18% above the 2016 target set on the continued journey toward world-class service delivery.

The first EFSA innovation prize was awarded in June, when candidates presented their mobile applications aimed at giving access to EFSA's work on mobile devices in an easy and user-friendly way. The winning app 'EFSA to the people' provides pocket news, event info, and links to EFSA publications to citizens across Europe. They can also check, via an interactive charts feature, which outputs have been completed, what EFSA is working on, and in which scientific areas it is concentrating its efforts.

Legal and regulatory affairs

EFSA continued providing legal steering in improving operations while containing legal risk, and centralised the management of legal administrative procedures, pre-litigation and litigation dossiers.

It was another year of dynamic case law[3], in particular as regards the areas of transparency and confidentiality, with important cases adjudicated in the area of pesticides.[4] In an overall context characterised by the increasing demand for transparency and public engagement, the Authority dealt with 130 public access requests, resulting in the disclosure of 2 767 documents amounting to a total of more than 10 million pages. Reflections on the process redesign have started, and a standard operation procedure (SOP) on public access to documents has been in force since January 2016.

Addressing feedback from the European Parliament, the centralisation of the validation procedure for the assessment of annual declarations of interests was completed in June. A new SOP on the management of competing interests is in force as of May.

The first review of the corporate repository of governance document was carried out over the summer. Also in this area, a revised standard operating procedure (SOP) is in force as of May.

The data protection function supported corporate compliance with the relevant EU legal framework. Since March, a SOP on data protection compliance support has been in force.

Three additional SOPs took effect in 2016: management of Ombudsman complaints, provision of legal and regulatory advice, and handling complaints by whistle blowers. All activities aimed to pursue objectives of EFSA's anti-fraud strategy were carried out in accordance with the established action plan.

Human resources

In 2006, EFSA launched a comprehensive Expertise Management Program (EMP) with the ambition to source and select the best available expertise in the area of risk assessment in Europe and to streamline processes with the support of best-of-breed technology. As part of this programme, the Talent Management Project reached a major milestone delivering a new recruitment solution designed to facilitate the selection process for applicants and managers. Building on this IT tool and thanks to an extensive dissemination campaign, EFSA benefits now from a recruitment database with 23,800 potential candidates registered. The programme will also support the panel renewal process starting in 2017. To support the efficient and effective assessment of experts, EFSA has started developing a scientific competency library in line with the European Skill Competencies and Occupation (ESCO) framework.

[3] Details are available on the EFSA website, in the Progress Reports prepared for Management Board meetings.
[4] E.g. Order of the President of the Court of 14 June 2016 in case C-134/16 P(R), Chemtura Netherlands B.V. v. EFSA; Judgment of the Court (Fifth Chamber) of 23v November 2016, Commission v Stichting Greenpeace Nederland and PAN EuropeC-673/13 P, Commission v Stichting Greenpeace Nederland and PAN Europe; Judgment of the Court (Fifth Chamber) of 23 November 2016 in case C-442/14, Bayer CropScience SA-NV and Stichting De Bijenstichting v College voor de toelating van gewasbeschermingsmiddelen en biociden.

As regards recruitment, a total of 43 new contracts were offered allowing for a significant improvement in the statutory staff occupancy rate (96.7% at end of 2016 and 95.3% as year average vs. a target of 95%) as well as a reduction in the time-to-hire (over 20% vs. the baseline). Over 2,000 applicants responded to the 2016 traineeship call that was launched in June with about 50 new trainees joining EFSA in 2016. Significant improvements were made as regards talent attraction with, for example, EFSA's career page on LinkedIn reaching over 20,800 followers. The Establishment Plan 2016 has been adjusted to reflect the required post reduction.

As a result of the 2015 Staff Engagement Survey, several areas had emerged as critical in the area of talent management, i.e. communication, leadership and decision making. To tackle these issues in a structured and holistic manner, various development initiatives addressing the three managerial layers of EFSA were developed with a focus on management and leadership development. These initiatives included the development of a Management Development Programme, the setting-up of a managerial pipeline, high profile courses as well as stretch assignments to train, grow and strengthen specific competencies. The end-of-year response rate for the 2016 management feedback survey (with an 80% response rate, +41% vs. the previous one) showed an improvement in the previously mentioned areas. A number of resources and activities for managers were also designed and implemented such as the e-Book, a performance dialogue toolkit, succession planning and the people's managers' forum. All these measures contributed to a continuous organisational effort to build a high-performance culture.

EFSA has furthermore adopted a new approach in terms of learning and development, moving towards a learning organisation with a number of actions including new learning offers, the re-establishment of the 70/20/10 model, the design of the new learning and development roadmap fostering the creation of communities of knowledge across and beyond the organisation, and an enhanced process to identify and analyse strategic learning needs.

Site management and events

In light of international security threats, EFSA's internal security procedures were re-assessed and measures heightened. In the context of the Plan-Do-Check-Act lifecycle, EFSA updated its business continuity plan to ensure timely reactivity of critical processes via the definition of alternative sites and resources.

The EFSA 2020 Strategy envisages the establishment of corporate business control functions. EFSA was tasked to establish and implemented a management system able to ensure appropriate control of the environmental impact linked to EFSA's business, as well as of occupational health and safety.

In 2016, EFSA successfully implemented a management system compliant with applicable international standards (ISO 14001), and in accordance with regulation EC 1221/2009 (Eco-Management Audit Scheme – EMAS). In 2016, EFSA obtained the ISO 14001 certification and submitted its application for the EMAS registration, which will be concluded in 2017 together with the Occupational Health and Safety Assessment Series (OHSAS) certification.

EFSA continued its outreach activities through the organisation of 26 public events involving over 1 000 participants, of which 48% were first-time attendees. The portfolio of events was broadened by assuming the organisational lead for EFSA's webinar services.

The increase of the outreach portfolio of both activities and tools led to the creation of the Events Governance Board. In this context the Board represents an essential step to guarantee that the outcome of the decision-making process is fully in line with strategic priorities and objectives of the organisation.

Financial operations

The full centralisation of procurement and grants management, and in particular the monitoring of the scientific cooperation programme, lead to a better anticipation and smooth launches of calls throughout the year. The programme exceeded its target, and the financial resources allocated to it were consequently increased by 5%.

The procurement programme was successfully implemented with a major breakthrough in terms of shared inter-agency services. EFSA lead an inter-agency tender for cloud services, in which 20 EU agencies participated. The benefits of the call were manifold and allowed the participating agencies to have access to best-in-class cloud services at highly attractive financial conditions, while saving resources in market investigations, specifications drafting, tendering and awarding steps of the procedure.

The envelope of the resulting framework contract is of €66 million and it is estimated that, by launching this join tender, the agencies saved €2.5 million in FTEs.

This coordinated inter-agency approach will be further promoted in 2017 with EFSA taking over the Chair of the EU Agencies Network.

The paperless approach and document management for the financial processing of experts and staff on mission payments was successfully implemented while generating time savings in the scientific units. The new approach was welcomed by experts and staff. The rate of invoices directly inserted in the financial system by suppliers having framework contracts with EFSA increased from 11% in 2015 to 22% in 2016.

Timeliness of payments was more efficient than planned, with an average of 17 days for payments to experts (target < 45 days), and 19 days on average for invoice payments (target < 30 days).

2.5.2. *Key performance indicators and resources*

Table 21: Key performance indicators for Activities 5, 6, 7

Objective	Indicators	Achieved 2015	Target 2016	Achieved 2016
Effective use of EFSA financial resources	Commitment credits executed	99.8%	100%	100.0%
	Payment credits executed	90.1%	90%	89.7%
	Carry-forward of payments[(a)] to following year	10.8%	10%	11.8%[(b)]
IT governance	IT governance	89%	89%	93%
	IT execution	73%	75%	67%
	IT satisfaction	73%	77%	64%
Ensure best management of staff	Average statutory staff occupancy rate[(c)]	94.7%	95%	95.3%

a) Non-differentiated payment appropriations.
b) The increase compared to the previous year is around EUR 0.7 million, mainly due to cost in the areas of IT operations, risk communication, and operational development. This also explains the minimal under-execution (0.3%) in payment credits.
c) Not including short-term contract agents.

The IT governance results lagging behind plan are due to the following indexes still below target: the on-time business project delivery, and the customer satisfaction index related to software-enforcing corporate policy.

IT governance performance continues to achieve the multi-annual performance targets set in 2013 for 2016 through 2020. IT governance is over the target due to increased involvement of the senior and middle management in project and quality practices implemented during the year.

The IT execution measures: service delivery, project delivery and financial stability. This is slightly below target by 8%. The underachievement is due to: service delivery quality (+18%), project timeliness (-19%), delays introduced by planning EFSA's strategy 2020 and adjusting the 2016 work programme during the year.
Customer satisfaction with all aspects of business projects and IT services is 13% below target due mainly to overachievement of end user services satisfaction (+10%), compensated by a reduced satisfaction of middle management with the speed of and engagement with the IT transformation (-17%) and the change management and communication activities of the projects (-22%).

Table 22: Resources allocated for Activities 5, 6, 7

	Executed 2015		Budget 2016		Executed 2016	
	M€	FTE[a]	M€	FTE[a]	M€	FTE [a]
A5 Coordination	2.32	16	1.53	11	1.75	14
A6 Administration	12.15	74	11.38	70	11.96	80
N7 Neutre	2.94	26	3.33	30	3.09	29
Total support activities	**17.41**	**116**	**16.24**	**111**	**16.80**	**123[b]**
% Total EFSA	**22**	**26**	**20**	**25**	**21**	**26**

a) Actual available FTE.
b) FTEs are calculated on the basis of the hours registered by EFSA staff for the process/project codes classified under the different activities. Hours tracked are converted into FTEs using a standard rate, with 1 FTE equalling 1 520 hours. A better occupancy rate (establishment plan posts filled) or a higher than standard amount of hours tracked in a year have the effect to increase the global amount of hours worked and, consequently, the number of FTEs. The amount of actual available FTE in 2016 is higher than planned because of a better occupancy rate and because of a higher amount of working hours per headcount than initially planned.

Section II – Management of resources

1. Budgetary and financial management

2016 was the third year of operation under the EU Multi-annual Financial Framework. The elimination of seven establishment plan posts (2% reduction) forced EFSA to continue its efforts for more efficient and effective procedures.

The execution of budgetary commitments was 100.0% of the €79.49 million budget[5]. Interests generated in EFSA's bank accounts (€0.08 million) became revenue.

The main drivers of expenditure were staff costs (€40.50 million), scientific cooperation activities (€10.27 million), IT investments (€8.59 million) and scientific meetings (€8.30 million) and building costs (€5.43 million).

Execution of payment appropriations was 89.66% of €79.32 million, mainly representing staff costs (€39.62 million), scientific cooperation activities (€10.09 million) and scientific meetings (€7.99 million) and building costs (€4.47 million).

Budget transfers

In the course of the year, a net transfer of €0.3 million was made from Title II (infrastructure) to Title I (staff costs) to cover a considerable shortfall in staff salary costs (€0.99 million), a result of a higher increase of basic salaries (2.4% vs 1% expected) and a higher occupancy rate (95.3% vs 95% planned).

An amount of €0.6 million was transferred within Title I, mainly into interim services, and to EU school contributions. Within Title II, transfers amounting to €0.5 million have been mainly done from telecommunication, administrative and building expenses to cover IT costs.

Within Title III, €2.3 million have been transferred, mainly from operational IT, risk communication and conferences and events costs, to cover shortfalls under scientific cooperation and operational development & control.

Out of 41 debit notes issued in 2016, 40 were effectively recovered to the amount of €79.3 million. This amount includes the EU budget contribution (€79.2 million). Two debit notes remained open at the end of the year to the amount of €0.03 million. One of these, to the amount of €0.02 million, was issued in previous years and is in litigation before the courts.

[5] Appendix B.

Budget execution by activity pillars

The budget distribution per activity was in line with the annual management plan 2016.

Table 23: Budget execution per activity

	Executed 2015		Budget 2016[a]		Executed 2016	
	M€	%	M€	%	M€	%
A1 Provision of scientific advice and risk assessment approaches	12.12	15	13.33	17	13.52	17
A2 Evaluation of regulated products	20.04	25	20.57	26	20.74	26
A3 Data collection & scientific cooperation	22.88	29	22.54	28	22.28	28
A4 Communication and dialogue	7.05	9	6.74	9	6.15	8
Total operational activities	**62.09**	**78**	**63.17**	**80**	**62.69**	**79**
A5 Coordination	2.32	3	1.53	2	1.75	2
A6 Administration	12.15	15	11.38	14	11.96	15
N7 Neutre	2.94	4	3.33	4	3.09	4
Total support activities	**17.41**	**22**	**16.24**	**20**	**16.80**	**21**
Total EFSA	**79.50**	**100**	**79.41**	**100**	**79.49**	**100**

a) Current budget after budget transfers.

2. Human resources management

On 31 December 2016, 450 of the available 470 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), the posts occupied on 31 December were 440 of the available 455 (96.7%). The yearly average occupancy rate was 95.3% versus a target of 95% (on average, around 433.5 of the available 455 posts were occupied throughout 2016).

Table 24: Staff availability per activity

	Executed 2015		Budget 2016		Executed 2016	
	FTE[a]	%	FTE[a]/Posts	%	FTE[a]	%
A1 Provision of scientific advice and risk assessment approaches	66	14	75/79	17	77	17
A2 Evaluation of regulated products	135	30	131/138	29	136	29
A3 Data collection & scientific cooperation	99	22	92/97	21	91	20
A4 Communication and dialogue	36	8	38/40	8	37	8
Total operational activities	**336**	**74**	**336/354**	**75**	**341**	**74**

	Executed 2015		Budget 2016		Executed 2016	
	FTE[a]	%	FTE[a]/Posts	%	FTE[a]	%
A5 Coordination	16	4	11/12	2	14	3
A6 Administration	74	16	70/74	16	80	17
N7 Neutre	26	6	30/31	7	29	6
Total support activities	**116**	**26**	**111/116**	**25**	**123**	**26**
Total EFSA	**452**	**100**	**447/470**	**100**	**464[b]**	**100**

a) Actual available FTE.
b) The amount of actual available FTE in 2016 was higher than planned. This is mainly due to a higher occupancy rate and a higher amount of working hours per headcount than initially planned.

2.1. Resource optimisation and efficiency gains

The EU multi-annual financial framework 2014-2020 has caused EFSA a reduction of 2% of the establishment plan posts in 2016 (i.e. 7 out of the 36 posts in the period 2013-2018) even though EFSA is considered as a 'cruising speed agency' with a stable budget. In addition, the human resource demand further increased in 2016 (estimated at 13 FTEs), as a result of the continuous increase of complexity of the scientific work, the demand for improved transparency and stakeholder engagement, and increased workload, such as the coordination of the EU agencies network and the inherited backlog of evaluations in the area of regulated products - particularly pesticides, which is progressively being absorbed with the help of the additional short term resources that only arrived between 2015 and 2016. In order to continue fulfilling customer and stakeholder expectations and keep EFSA a relevant global risk assessment player, EFSA's increasing human resource demands requires the implementation of continuous resource management optimisations.

The improvement of the statutory staff occupancy rate (+0.6% average compared to the previous year, or 7 FTEs) allowed a partial compensation of the above mentioned resource challenges. In addition, EFSA has implemented several activities aiming at optimizing work processes to use fewer resources. The overall efficiency gains implemented in the year are estimated to be around 7 full time equivalents (FTEs), stemming from:

- The outsourcing of the EFSA Journal that will be fully deployed in 2017.
- The upgrading to a more efficient EFSA web site.
- The deployment of the scientific data warehouse.
- The centralisation of services in the area of transaction processing, sourcing, planning, monitoring and reporting under the "Step 2018" project.

The saved resources have largely absorbed the increased capacity needs mentioned above, leaving however an estimated 6 FTEs in negative balance, which EFSA tried to cover via an increased investment in interim staff and trainees (€0.4million increase).

The estimated resources gap (FTEs) is estimated to increase to around 20 FTEs per year in the coming three years, determined by a further reduction of the establishment plan (-2% in 2017 and -1% in 2018) on the one hand, and the expected further increase of workload due to new tasks in certain core activities such as novel foods, pesticides and plant pest categorisation and surveillance.

EFSA will continue its efforts towards further efficiency gains and will work closely with the European Commission and the budgetary authorities to ensure that the necessary resources are provided. This would mitigate the potential risk of not fully achieving its obligations and objectives.

3. Follow-up of observations from the discharge authority (European Parliament)

On 28 April 2016, in the context of the budgetary discharge procedure relating to the implementation of EFSA's budget for the financial year 2014, the European Parliament adopted a decision granting the Executive Director discharge and approving the closure of the Authority's accounts for that year. This decision was accompanied by a resolution including 35 observations.

20 of these were recommendations calling for comments and sometimes specific actions from EFSA, including on EFSA's policy on independence and the prevention and management of conflicts of interest, as well as on transparency and openness. A letter was sent to the discharge authority on 17 October 2016, including a table outlining the actions already taken or was in the process of implementing in respect of each recommendation.

4. Competing interest management

EFSA's Policy on independence and scientific decision-making processes, adopted by the Management Board in December 2011, is the main text informing the Authority's approach to independence. In 2016, the function ensuring the centralised handling of competing interest management within EFSA's Legal and regulatory affairs Unit became fully operational.

In line with its policy of continuous improvement, EFSA initiated a comprehensive review of its 2011 policy and related implementing rules. This comprises an *ex-post* evaluation of the measures put in place by EFSA in terms of efficacy, efficiency and sustainability, and the establishment of a reflection group composed of Board members.

Regarding the screening of Declarations of Interest (DoI), EFSA kept implementing its 2014 rules on Declarations of Interests, processing a number of DoIs in line with the previous years. The figures of prevented conflicts of interest show a slight increase in the number of conflicts prevented by specific DoIs and a decrease in the number of conflicts prevented by annual DoIs, year on year. This is also due to a more regular recourse to hearing experts, which in 2016 represented more than 10% of the total number of annual DoIs processed by the Authority.

Table 25: Key performance indicators for compliance with independency policy

Objective	Indicators	Achieved 2015	Target 2016	Achieved 2016
Ensure full compliance with EFSA's policy on independence	Proportion of experts with approved annual declarations of interest before first meeting invitation	99.8%	100%	100%
	Proportion of experts with approved specific declarations of interest before participation in an EFSA meeting	99.7%	100%	99.9%

The following table provides updated figures on the implementation of EFSA's DoI assessment and validation processes for the reference year.

Table 26: Independence-related figures for 2016

DoIs screened	Meeting agenda items scrutinised	Potential conflicts prevented	Breach of trust procedures	Staff members leaving EFSA
4 319 sDoIs 3 148 aDoIs	29 080	sDoIs: 99 agenda items 8 aDoIs rejected	0	Total: 17 Private sector:3 Restrictions: 2

Of the 17 statutory staff members that left EFSA in 2016, one moved to the non-profit sector promoting social awareness about food waste; one to the consulting sector on food enzymes; and one to the food industry sector. In two cases restrictions were applied. The restrictions referred to preventing the individuals from becoming contact points between EFSA and their new employer, exercising lobbying activities, and performing activities related to on-going EFSA files.

Section III – Management assurance

1. Review of the elements supporting assurance

The reliability of the information contained in this report is supported by the following building blocks of assurance:

- Risk management;
- Annual review of internal control standards ;
- Quality management annual report;
- EFSA exception reports and analysis;
- Results of evaluation activities;
- Compliance and veracity checking of DoIs;
- Internal audit conclusions;
- EFSA Provisional Accounts drawn by the Accounting Officer and the certification by the Accounting Officer of EFSA final accounts 2015;

The information provided by the various building blocks gives reasonable assurance that the information therein is complete and reliable.

1.1. Risk management

EFSA held a risk management workshop with stakeholders for the first time. Having stakeholders share their views on the risks EFSA is facing enabled the Authority to complete the risk spectrum that it had already identified and develop respective mitigation measures. This was very much welcomed and appreciated by the stakeholders.

The stakeholders identified three new risks: 'communication with citizens', 'being slow' and 'being less inclusive'. The responses to these risks proposed by the stakeholders, or identified by EFSA, were linked to the activities and outputs outlined in the implementation plan of EFSA's strategy. It is important to integrate the monitoring of corporate risks in the strategy and verify whether activities envisaged there are sufficient to adequately mitigate the risks, or need to be adapted.

From the stakeholders' point of view 'reputation' is by far the most sensitive risk. On the other hand, stakeholders place the risk of 'being static' at the end of the spectrum, not considering it a risk for EFSA at all. While stakeholders considered the risks already flagged by EFSA as mid-range, they identified the three additional risks ('communication with citizens', 'being slow', and 'being less inclusive') as relatively low.

Risk owners reviewed these risks and their criticality as well as the associated mitigating activities and outputs contained in the strategy implementation plan. The purpose of this review is to ensure that the response to these risks is adequate or, if proved insufficient, that additional mitigation measures are considered.

Whereas none of the risks identified is considered 'critical', taking into account the envisaged mitigation actions, three risks remain 'significant':

- 'Being inefficient'

  This risk has two facets, concerning inefficiencies related to internal organisational changes and developments that would create inefficiencies during their implementation. they concern inefficiencies related to scientific methodologies processes. Whereas the first reflects EFSA's own assessment, the second one was highlighted by the stakeholders. The risk is kept at 'significant' level even if the activities envisaged in the strategy are deemed to be proportionate and relevant to adequately respond to the risk.

- 'Being inept'

  The activities identified in the implementation plan, and in particular those foreseen under the Talent Management Project and Expertise Management Program, are considered essential to properly continue mitigating the risk. Also important are the activities related to the fellowship programme, PhD programme and collaboration with universities, which are intended to foster a better understanding of EFSA's activities and mission, thereby triggering an increased interest in active participation in EFSA's work. The risk level is nonetheless kept 'significant'.

- 'Reputation risk'

  The reputation dimension is high on EFSA's agenda. The strengthening of the process dealing with 'reputation' is in progress. In this regard, the stakeholder mapping was extended to national authorities. Also, every event is exploited to consolidate the concept of 'Trusted science for safe food'. Additional resources are invested that go beyond the activities already envisaged in the implementation plan of EFSA's strategy. Considering the high attention and sensitivity of stakeholders to the 'reputation' risk, this risk is upgraded to 'significant' as it requires constant vigilance.

1.2. Annual review of internal control standards

Internal controls are all measures the management takes to ensure that operational activities are effective and efficient, rules and regulations are met, and financial and other management reporting is reliable. EFSA regularly reviews the implementation of the Internal Control Standards (ICS).

The review conducted in 2016 was assessed by implementing the action plans included in the 2015 IAC Audit Report on the ICS implementation. The assessment concluded that EFSA implements the ICS effectively. The action plans for the standards concerning ethical and organisational values, staff evaluation and development, operational structure and business continuity were implemented. Measures will be taken to further improve the efficiency and application of the ICS 14 concerning the evaluation of activities.

1.3. Quality management annual report

In 2016, EFSA has made great process towards implementing a robust quality management system (QMS) in the organization. In November 2016, EFSA obtained the ISO9001:2015 certification attesting that the current EFSA QMS is considered robust, well established and in compliance with international recognised standards. Furthermore, there is ample evidence of documented information related to monitoring, analysis and evaluation of the QMS performance which demonstrates EFSA's excellent capability to control, maintain and review, as necessary, its QMS to ensure its continuous fit for purpose.

EFSA again received very positive feedback from the European Commission (DG SANTE) as part of the established customer feedback exercise. The quality of EFSA's work was

rated as high by all the DG SANTE staff members interviewed and it was confirmed that the majority of EFSA's outputs have been used effectively for risk management decisions.

In 2016, EFSA successfully implemented a management system compliant with applicable international standards (ISO 14001) and in accordance with regulation EC 1221/2009 (Eco-Management Audit Scheme (EMAS). EFSA obtained the ISO:14001:2004 certificate attesting that EFSA's eco-management system is effective. The certificate provides assurance to the management and external stakeholders that the EFSA environmental impact is being measured and continuously improved. EFSA submitted its application for the EMAS registration which will be concluded in 2017 together with the Occupational Health and Safety Assessment Series (OHSAS) certification.

Table 27: Quality certifications target

Target 2016	Achieved
ISO 9001:2015 compliance for enabling activities	Full ISO 9001:2015 certification. Training on ISO 9001:2015 principles rolled out to all EFSA's staff. Full ISO: 14001:2004 certification

1.4. Exception reporting and analysis

In 2016, the number of deviations increased by 17%, mainly due to a higher number of non-compliance events. 150 deviations, representing about 2% of the 7 000 transactions processed, were recorded. Nearly 70% of the recorded deviations concerned exception requests approved ex-ante, whereas 30% concerned non-compliance events noted ex-post, meaning that, in these latter cases, there was no awareness of the deviation when it occurred[6]. The financial value of the deviations has been stable since four years at EUR 261 000[7]. The approved exceptions mainly relate to expert reimbursements and missions. The revision of the expert compensation guide will ease the organisation of meetings and mitigate related deviations. The analysis showed that neither the number nor the amount or nature of the recorded deviations represent a matter of concern.

1.5. Results of evaluation activities

Article 29 (5) of the EFSA Financial Regulation stipulates that the Authority shall undertake both ex-ante and ex-post evaluations to assess the achievements and impact of activities and initiatives that entail significant spending on the basis of a set criteria and indicators. All proposals for activities or initiatives exceeding 5% of the annual operational expenditure of the Authority shall be the subject of an ex-ante evaluation. Interim and/or ex-post evaluations shall be implemented when the resources mobilised exceed 10% of the annual operational expenditure.

Since 2014, EFSA has implemented the requirements of the Financial Regulation by ensuring that all recurring risk assessment, risk communication and cooperation activities are chartered in a way that identifies the purpose and value of the proposed spend ex-ante. The activities carried out at portfolio management provide a decision step based on a business case before the start of a project. The method was implemented to improve the overall resource management and evaluation of initiatives below the threshold, allowing EFSA to meet the requirements of the regulation. EFSA started implementing ex-post assessments of the main organisational development projects by delivering and discussing closing reports in line with the project management methodology.

[6] Ideally, all deviations should be approved ex-ante.
[7] 0.3% of the EFSA budget.

1.6. Compliance and veracity checking

EFSA continued performing compliance and veracity checks on the DoI assessment and validation processes in line with Article 14(2) of its Decision on DoIs. This checking was carried out twice on DoIs of experts participating in a Scientific Committee, scientific panel or working group meeting within the reference period. For each reporting period, 15 experts were randomly selected and their annual Declaration of Interests (aDoI), the specific Declaration of Interests (sDoI) and oral Declaration of Interests (oDoI) were checked for compliance with the EFSA Decision on DoIs and veracity of the information contained. The compliance checks revealed that for 29 out of the 30 experts checked, the procedure for the evaluation of aDoIs, sDoIs and oDoIs had been followed correctly. For the remaining expert, it was found that a conflict of interest of a general nature had not been identified, which was related to the expert's ownership of shares in companies active in areas overlapping with the mandate of the EFSA working group, in which the expert participated. In view of the closure of the respective working group and the finalisation of the related scientific opinion, the importance of the expert's scientific expertise and lack of a suitable alternative expert, a retroactive waiver was granted. The veracity checks demonstrated that the aDoIs of 26 out of 30 experts were in line with EFSA's Decision on DoIs, while four omissions were identified. The aDoIs of two experts had to be updated and re-evaluated. In the resulting re-evaluation EFSA concluded that the omissions were of a minor nature and did not constitute a conflict of interest. The findings highlighted the need to continue investing in experts' awareness of DoI requirements.

1.7. Audit results during the reporting year

1.7.1. *Internal Audit Capability*

The work of the Internal Audit Capability (IAC) is performed under the authority of the Management Board through its Audit Committee. The IAC carried out the assurance engagements and other special tasks as envisaged in the IAC Annual Audit Plan approved by the EFSA Audit Committee. The audit engagements covered: the corporate governance audit on the role of the expert in the scientific decision-making processes; the validation of ABAC user access rights; two follow-up reports on outstanding audit recommendations by the IAC, the Internal Audit Service (IAS) and the European Court of Auditors (ECA); and the follow-up report on the action plans following the 2013 risk assessment. As a result, the IAC is of the opinion that the internal control system in place provides reasonable assurance regarding the achievement of the business objectives set for the processes audited. One 'very important' recommendation on improving the disclosure and transparency of the scientific decision-making processes was issued.

The IAC also provided assistance and coordination for the ECA financial audit, the ECA special audit on grant management, the IAS audit on IT governance and IT project management, and the IAS audit on the evaluation of regulated products and the assessment phase in pesticides authorisation.

1.7.2. *Internal Audit Service*

In November 2016, the IAS released the final report on IT governance and IT project management in EFSA, in which they concluded that the IT project management process at EFSA is, overall, adequately controlled.

As regards IT governance, however, the IAS identified weaknesses and issued the following 'very important' recommendations:

i. Revise the existing IT governance framework to ensure adequate business involvement and move the CBC function out of the Planning, transformation and technology Unit;

ii. Define and adopt a holistic IT-related risk management framework;

iii. Position the information security function outside the Planning, transformation and technology Unit;

iv. Revise the existing enterprise architecture framework and enhance business participation in Enterprise Architecture;

v. Define and adopt a business requirement management and IT solution identification and selection methodology supported by an organisation-wide process; and

vi. Define and adopt an IT strategy management process and re-assess the current IT strategy and related roadmaps, and ensure close and continuous alignment with business needs.

EFSA adopted an action plan addressing the accepted recommendations and will keep the Audit Committee informed on how the risks are covered for the recommendations that were not accepted. However, EFSA has partially rejected some of the IAS recommendations and, more in particular, EFSA considered that the holistic IT-related risk management framework, the business requirement management and IT solution identification and selection methodology are industry standard and fit for purpose. EFSA adopted an action plan addressing the accepted recommendations.

The IAS also performed the planning and fieldwork for the audit on the evaluation of regulated products, and the assessment phase in pesticides authorisation. The outcome of this audit will be reported in 2017.

1.7.3. *European Court of Auditors*

The ECA conducted its annual audit of the Authority's 2015 accounts, and adopted its report on 13 September 2016. The report contains the following statement of assurance:

Opinion on the reliability of the accounts: in the Court's opinion, the Authority's annual accounts present fairly, in all material respects, its financial position as of 31 December 2015 and the results of its operations and its cash flows for the year then ended, in accordance with the provisions of its financial regulation and the accounting rules adopted by the European Commission's accounting officer.

Opinion on the legality and regularity of the transactions underlying the accounts: in the Court's opinion, the transactions underlying the annual accounts for the year ended 31 December 2015 are legal and regular in all material respects.

1.7.4. *Internal audit conclusions*

At the end of 2016, no critical and two 'very important' audit recommendations stemming from IAS audits carried out up to 31 December 2015 were still open. They concerned the following audit observations: (1) a recommendation to define and adopt a comprehensive data management framework, resulting from the audit on scientific support to risk assessment and the evaluation of regulated products, with a focus on data collection and analysis; and (2) an observation on the monitoring of the performance appraisal process, from the audit on performance evaluation and career development. The action plans related to these observations are being implemented.

There were no outstanding recommendations from previous reports concerning the ECA.

At the end of 2016, there were no outstanding 'critical' or 'very important' IAC audit recommendations open from audits carried out up to 31 December 2015.

Based on the audits and reviews carried out in accordance with the IAC Annual Audit Plan approved by the EFSA Audit Committee, the IAC is of the opinion that the internal control system in place provides reasonable assurance regarding the achievement of the business objectives set for the processes audited. The IAC issued one 'very important'

recommendation on improving the disclosure and transparency of the scientific decision-making processes. Most of the actions related to the outcome of the audits have been or are being implemented as planned.

1.8. EFSA 2016 Provisional Accounts drawn up by the Accounting Officer

The 2016 EFSA Provisional Accounts were prepared by the Accounting Officer on 20 February 2017. The Accounting Officer has a reasonable assurance that in terms of reliability, the 2016 EFSA Provisional Accounts show a true and fair view of EFSA's financial position as of 31 December 2016.

1.9. Conclusions on assurance

Based on all the facts presented in the report, including the management of the control system, and in light of the opinions expressed by the ECA on the reliability of the accounts and on the legality and regularity of the transactions underlying the accounts, the Authority can conclude that the systems in place provide reasonable assurance that the resources under the responsibility of the Executive Director were used for their intended purposes and in accordance with the principles of sound financial management.

Taking into account the review of the elements supporting assurance, the Executive Director is of the opinion that the management and control systems in place at EFSA are working as intended, risks are being appropriately monitored and mitigated, and necessary improvements and reinforcements are being implemented.

Based on the above, the Executive Director sees no reason that would justify or require a reservation.

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 results of the self-assessment, the work of the Internal Audit Service, the work of the Internal Audit Capability, and the lessons learnt from the reports of the Court of Auditors for the years prior to the year of this declaration, and the reasonable assurance provided by the EFSA Accounting Officer regarding the reliability of the 2016 EFSA Provisional Accounts.

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

Parma, 10 March 2017

[Signed]

Bernhard Url

Management Board Assessment

Appendix A – Scientific outputs 2016

Table 28: Scientific outputs 2016

	REPRO						RASA					TOTAL
	APDESK	FEED	FIP	GMO	NUTRI	PRAS	ALPHA	AMU	BIOCONTAM	DATA	SCER	
A1 EFSA Scientific outputs – Provision of scientific advice and risk assessment approaches	-	-	1[8]	-	6	-	14[9]	-	18[10]	-	3	42
A1 Technical Reports – Provision of scientific advice and risk assessment approaches	-	-	-	-	6	-	-	-	-	-	3	9
A1 Total	-	-	1	-	12	-	14	-	18	-	6	51
A2 EFSA Scientific outputs – Evaluation of regulated products												
Of which:												
– Conclusion on pesticides peer review	-	-	-	-	-	37	-	-	-	-	-	37
– Guidance of the Scientific Committee / Scientific Panel	-	-	-	-	3	1	-	-	-	-	-	4
– Opinion of the Scientific Committee / Scientific Panel	-	67	46[11]	10	19	2	-	-	1[12]	-	-	145
– Reasoned opinion	-	-	-	-	-	60	-	-	-	-	-	60
– Scientific report of EFSA	-	-	-	-	-	3	-	-	-	-	-	3
– Statement of the Scientific Committee / Scientific Panel	-	1	2[13]	1	-		-	-	-	-	-	4

[8] 1 output from CEF Panel.
[9] Of which 3 outputs from AHAW Panel, 10 outputs from PLH Panel, and 1 scientific report of EFSA.
[10] Of which 8 outputs from BIOHAZ Panel, 8 outputs from CONTAM Panel, and 2 scientific reports of EFSA.
[11] Of which 21 outputs from ANS Panel, and 25 outputs from CEF Panel.
[12] 1 output from BIOHAZ Panel.
[13] 2 outputs from CEF Panel.

	REPRO						RASA					TOTAL
	APDESK	FEED	FIP	GMO	NUTRI	PRAS	ALPHA	AMU	BIOCONTAM	DATA	SCER	
– Statement EFSA	-	-	-	1	-	4	-	-	-	-	-	5
– Guidance of EFSA	-	-	-	-	-	1	-	-	-	-	-	1
A2 Technical reports – Evaluation of regulated products	1	-	2	12	7	40	-	-	-	-	-	62
A2 total	**1**	**68**	**50**	**24**	**29**	**148**	**-**	**-**	**1**	**-**	**-**	**321**
A3 EFSA scientific outputs – Data collection & scientific cooperation	-	-	-	-	-	-	-	2	3	3	1	9
A3 Technical reports – Data collection & scientific cooperation	-	-	-	1	-	-	1	1	7	12	6	28
A3 Total	**-**	**-**	**-**	**1**	**-**	**-**	**1**	**3**	**10**	**15**	**7**	**37**
Other publications (event reports and external scientific reports)	-	3	3	3	1	4	9	5	17	14	13	72[14]
Total outputs	**1**	**71**	**54**	**28**	**42**	**152**	**24**	**8**	**46**	**29**	**26**	**481**
A2 Total scientific questions 2016 (excluding technical reports & other publications)	-	73	80	12	22	194	-	1	-	-	-	382

[14] Comprising 65 external scientific reports and 7 event reports (4 from ALPHA, and 3 from SCER)

Appendix B – Financial performance

Budget execution

As of 31 December 2016

Table29: Budget execution per title

Title	Initial Commitment Appropriation	Current Commitment Appropriation	Δ*	Amount Committed	%	Payment Appropriation	Amount Paid	%
Personnel (Title I)	40,244,000	40,513,288	0.70%	40,513,288	100.00%	40,513,288	39,621,497	97.80%
Infrastructure (Title II)	9,915,666	9,725,323	-1.90%	9,725,259	100.00%	9,725,323	7,480,789	76.90%
Operations (Title III)	29,254,334	29,254,334	0.00%	29,252,110	100.00%	29,080,391	24,014,822	82.60%
Total	**79,414,000**	**79,492,945**	**0.10%**	**79,490,657**	**100%**	**79,319,002**	**71,117,107**	**89.7.**

Table30: Budget execution per activity

Activities	Initial commitment appropriation	Current commitment appropriation	Δ[(a)]	Amount committed	%	Current payment appropriation	Amount paid	%
A1 Provision of scientific advice and risk assessment approaches	13,330,777	13,519,477	188,700	13,519,407	100.00%	13,519,477	12,137,225	89.78%
A2 Evaluation of regulated products	20,568,398	20,743,347	174,950	20,741,261	100.00%	20,743,347	18,417,656	88.79%
A3 Data collection, Scientific cooperation and networking	22,534,092	22,277,797	-256,295	22,277,716	100.00%	22,103,854	20,574,256	93.08%
A4 Communication and dialogue	6,739,748	6,150,193	-589,555	6,150,159	100.00%	6,150,193	4,699,208	76.41%
A5 Coordination	1,528,504	1,751,992	223,488	1,751,990	100.00%	1,751,992	1,574,616	89.88%
A6 Administration	11,382,292	11,960,985	578,693	11,960,974	100.00%	11,960,985	10,828,047	90.53%
N7 Neutre	3,330,189	3,089,153	-241,036	3,089,149	100.00%	3,089,153	2,886,100	93.43%
Total	**79,414,000**	**79,492,945**	**78,945**	**79,490,657**	**100.00%**	**79,319,002**	**71,117,107**	**89.66%**

(a) Difference between initial commitment appropriations approved for Budget 2016 and current commitment appropriations.

Table 31: Budget execution per budget lines

	Budget line	Initial commitment appropriation	Current commitment appropriation	Executed commitment	% Committed	Payment appropriation	Executed payment	% Paid
1	STAFF							
11	STAFF IN ACTIVE EMPLOYMENT							
1100	Basic salary	€ 21,255,000	€ 22,252,042	€ 22,252,042	100.00%	€ 22,252,042	€ 22,252,042	100.00%
1101	Family allowance	€ 2,950,000	€ 2,926,325	€ 2,926,325	100.00%	€ 2,926,325	€ 2,926,325	100.00%
1102	Transfer and expatriation allowance	€ 2,479,000	€ 2,424,459	€ 2,424,459	100.00%	€ 2,424,459	€ 2,424,459	100.00%
1103	Secretarial allowance	€ 15,000	€ 11,840	€ 11,840	100.00%	€ 11,840	€ 11,840	100.00%
1113	Stagiaires	€ 716,000	€ 534,700	€ 534,700	100.00%	€ 534,700	€ 529,606	99.05%
1115	Contract staff	€ 5,555,000	€ 5,579,615	€ 5,579,615	100.00%	€ 5,579,615	€ 5,579,615	100.00%
1130	Insurance against sickness	€ 770,000	€ 794,456	€ 794,456	100.00%	€ 794,456	€ 794,456	100.00%
1131	Insurance against accidents and occupational disease	€ 113,000	€ 116,958	€ 116,958	100.00%	€ 116,958	€ 116,958	100.00%
1132	Unemployment insurance for temporary staff	€ 278,000	€ 293,315	€ 293,315	100.00%	€ 293,315	€ 293,315	100.00%
1140	Birth and death allowance	€ 5,000	€ 1,785	€ 1,785	100.00%	€ 1,785	€ 1,785	100.00%
1141	Annual leave travelling expenses	€ 306,000	€ 277,292	€ 277,292	100.00%	€ 277,292	€ 277,292	100.00%
1147	Call on duties	€ 70,000	€ 66,583	€ 66,583	100.00%	€ 66,583	€ 66,583	100.00%
1149	Other allowances and repayments	€ 55,000	€ 14,498	€ 14,498	100.00%	€ 14,498	€ 14,498	100.00%
1171	Translation and interpretation	€ 60,000	€ 47,722	€ 47,722	100.00%	€ 47,722	€ 47,722	100.00%

	Budget line	Initial commitment appropriation	Current commitment appropriation	Executed commitment	% Committed	Payment appropriation	Executed payment	% Paid
1172	Payment for administrative assistance from the Community institutions	€ 266,000	€ 242,493	€ 242,493	100.00%	€ 242,493	€ 237,493	97.94%
1175	Interim services	€ 672,000	€ 1,185,171	€ 1,185,171	100.00%	€ 1,185,171	€ 854,037	72.06%
1176	Consultancy	€ 562,000	€ 144,604	€ 144,604	100.00%	€ 144,604	€ 78,228	54.10%
1177	Other services	€ 160,000	€ 156,155	€ 156,155	100.00%	€ 156,155	€ 140,065	89.70%
1180	Miscellaneous expenditure on recruitment	€ 142,000	€ 131,532	€ 131,532	100.00%	€ 131,532	€ 90,061	68.47%
1181	Travel expenses (including for members of the family)	€ 10,000	€ 10,766	€ 10,766	100.00%	€ 10,766	€ 10,766	100.00%
1182	Installation, resettlement and transfer allowances	€ 180,000	€ 180,964	€ 180,964	100.00%	€ 180,964	€ 180,964	100.00%
1183	Removal expenses	€ 100,000	€ 99,288	€ 99,288	100.00%	€ 99,288	€ 78,978	79.54%
1184	Temporary daily subsistence allowance	€ 67,000	€ 51,558	€ 51,558	100.00%	€ 51,558	€ 51,558	100.00%
1190	Salary weightings	€ 120,000	€ 6	€ 6	100.00%	€ 6	€ 6	100.00%
	Total Chapter 11	**€ 36,906,000**	**€ 37,544,127**	**€ 37,544,127**	**100.00%**	**€ 37,544,127**	**€ 37,058,651**	**98.71%**
13	MISSIONS AND DUTY TRAVEL							
1300	Mission and travel expenses	€ 170,000	€ 140,588	€ 140,588	100.00%	€ 140,588	€ 133,564	95.00%
1301	Shuttles for missions and duty	€ 65,000	€ 56,080	€ 56,080	100.00%	€ 56,080	€ 56,080	100.00%
	Total Chapter 13	**€ 235,000**	**€ 196,668**	**€ 196,668**	**100.00%**	**€ 196,668**	**€ 189,645**	**96.43%**

14	SOCIOMEDICAL INFRASTRUCTURE							
1400	Restaurants, meals and canteens	€ 58,000	€ 48,548	€ 48,548	100.00%	€ 48,548	€ 43,088	88.75%
1410	Medical service	€ 230,000	€ 246,769	€ 246,769	100.00%	€ 246,769	€ 176,419	71.49%
1420	Further training, language courses and retraining for staff	€ 850,000	€ 579,075	€ 579,075	100.00%	€ 579,075	€ 264,790	45.73%
	Total Chapter 14	**€ 1,138,000**	**€ 874,392**	**€ 874,392**	**100.00%**	**€ 874,392**	**€ 484,297**	**55.39%**
15	EXCHANGE OF OFFICIALS AND EXPERTS							
1520	Visiting experts, National Experts on Detachment	€ 850,000	€ 650,208	€ 650,208	100.00%	€ 650,208	€ 647,008	99.51%
	Total Chapter 15	**€ 850,000**	**€ 650,208**	**€ 650,208**	**100.00%**	**€ 650,208**	**€ 647,008**	**99.51%**
16	SOCIAL WELFARE							
1610	Social contacts between staff	€ 50,000	€ 26,187	€ 26,187	100.00%	€ 26,187	€ 22,631	86.42%
1630	Early childhood centres, other crèches and EU school contribution	€ 1,050,000	€ 1,211,772	€ 1,211,772	100.00%	€ 1,211,772	€ 1,211,772	100.00%
1640	Complementary aid for the handicapped	€ 10,000	€ 4,935	€ 4,935	100.00%	€ 4,935	€ 4,935	100.00%
	Total Chapter 16	**€ 1,110,000**	**€ 1,242,894**	**€ 1,242,894**	**100.00%**	**€ 1,242,894**	**€ 1,239,338**	**99.71%**
17	RECEPTION AND ENTERTAINMENT EXPENSES							
1700	Reception and entertainment expenses	€ 5,000	€ 5,000	€ 5,000	100.00%	€ 5,000	€ 2,558	51.16%
	Total Chapter 17	**€ 5,000**	**€ 5,000**	**€ 5,000**	**100.00%**	**€ 5,000**	**€ 2,558**	**51.16%**
	Total Title 1	**€ 40,244,000**	**€ 40,513,288**	**€ 40,513,288**	**100.00%**	**€ 40,513,288**	**€ 39,621,497**	**97.80%**

2	BUILDINGS, EQUIPMENT AND MISCELLANEOUS OPERATING EXPENDITURE LINKED TO THE AUTHORITY							
20	INVESTMENTS IN IMMOVABLE PROPERTY, RENTAL OF BUILDING AND ASSOCIATED COSTS							
2000	Rent	€ 15,000	€ 25,833	€ 25,833	100.00%	€ 25,833	€ 25,833	100.00%
2001	Acquisition	€ 1,920,000	€ 2,123,648	€ 2,123,648	100.00%	€ 2,123,648	€ 2,123,648	100.00%
2010	Insurance	€ 37,200	€ 30,269	€ 30,269	100.00%	€ 30,269	€ 29,869	98.68%
2020	Water, gas, electricity and heating	€ 555,500	€ 466,366	€ 466,366	100.00%	€ 466,366	€ 360,722	77.35%
2030	Maintenance	€ 347,000	€ 318,798	€ 318,798	100.00%	€ 318,798	€ 238,651	74.86%
2031	Cleaning	€ 293,200	€ 273,880	€ 273,880	100.00%	€ 273,880	€ 219,994	80.33%
2040	Refurbishment of premises/Fitting out	€ 353,500	€ 478,172	€ 478,172	100.00%	€ 478,172	€ 82,312	17.21%
2050	Security and surveillance of buildings	€ 746,900	€ 736,221	€ 736,221	100.00%	€ 736,221	€ 580,089	78.79%
2080	Preliminary to construction, acquisition or rental of immovable property	€ 333,000	€ 266,220	€ 266,220	100.00%	€ 266,220	€ 150,520	56.54%
2090	Other expenditure on buildings	€ 884,500	€ 717,311	€ 717,311	100.00%	€ 717,311	€ 661,439	92.21%
	Total Chapter 20	**€ 5,485,800**	**€ 5,436,717**	**€ 5,436,717**	**100.00%**	**€ 5,436,717**	**€ 4,473,077**	**82.28%**
21	EXPENDITURE ON DATA PROCESSING							
2100	Purchase/ maintenance of IT equipment	€ 382,824	€ 722,112	€ 722,048	99.99%	€ 722,112	€ 391,172	54.17%
2101	Purchase / maintenance of software	€ 489,657	€ 686,379	€ 686,379	100.00%	€ 686,379	€ 524,536	76.42%
2103	Software development	€ 1,508,291	€ 1,365,457	€ 1,365,457	100.00%	€ 1,365,457	€ 990,762	72.56%
2104	User Support	€ 842,000	€ 774,294	€ 774,294	100.00%	€ 774,294	€ 664,172	85.78%
	Total Chapter 21	**€ 3,222,772**	**€ 3,548,242**	**€ 3,548,179**	**100.00%**	**€ 3,548,242**	**€ 2,570,642**	**72.45%**

22	MOVABLE PROPERTY AND ASSOCIATED COSTS							
2200	Technical equipment and installations	€ 40,000	€ 34,000	€ 34,000	100.00%	€ 34,000	€ 27,200	80.00%
2210	Purchase of furniture	€ 25,000	€ 1,010	€ 1,010	100.00%	€ 1,010	€ 247	24.43%
	Total Chapter 22	**€ 65,000**	**€ 35,010**	**€ 35,010**	**100.00%**	**€ 35,010**	**€ 27,446**	**78.40%**
23	CURRENT ADMINISTRATIVE EXPENDITURE							
2300	Stationery and office supplies	€ 102,000	€ 52,000	€ 52,000	100.00%	€ 52,000	€ 45,485	87.47%
2320	Bank charges	€ 2,000	€ 300	€ 300	100.00%	€ 300	€ 90	30.00%
2330	Legal expenses	€ 235,000	€ 181,545	€ 181,545	100.00%	€ 181,545	€ 93,020	51.24%
2350	Miscellaneous insurance	€ 11,000	€ 11,150	€ 11,150	100.00%	€ 11,150	€ 7,832	70.25%
2390	Publications	€ 12,000	€ 1,121	€ 1,121	100.00%	€ 1,121	€ 0	0.00%
	Total Chapter 23	**€ 362,000**	**€ 246,116**	**€ 246,116**	**100.00%**	**€ 246,116**	**€ 146,427**	**59.50%**
24	POSTAL CHARGES AND TELECOMMUNICATIONS							
2400	Postal charges	€ 46,000	€ 23,700	€ 23,700	100.00%	€ 23,700	€ 14,997	63.28%
2410	Telecommunications subscriptions and charges	€ 335,000	€ 182,526	€ 182,526	100.00%	€ 182,526	€ 117,244	64.23%
2411	Purchase and installation of equipment	€ 297,000	€ 159,149	€ 159,149	100.00%	€ 159,149	€ 65,849	41.38%
	Total Chapter 24	**€ 678,000**	**€ 365,375**	**€ 365,375**	**100.00%**	**€ 365,375**	**€ 198,091**	**54.22%**

25	GOVERNANCE EXPENDITURE							
2500	Management Board meetings	€ 102,094	€ 93,862	€ 93,862	100.00%	€ 93,862	€ 65,105	69.36%
	Total Chapter 25	**€ 102,094**	**€ 93,862**	**€ 93,862**	**100.00%**	**€ 93,862**	**€ 65,105**	**69.36%**
	Total Title 2	**€ 9,915,666**	**€ 9,725,323**	**€ 9,725,259**	**100.00%**	**€ 9,725,323**	**€ 7,480,789**	**76.92%**
3	OPERATING EXPENDITURE LINKED TO THE AUTHORITY							
30	SCIENTIFIC EVALUATION OF REGULATED PRODUCTS							
3010	REPRO grants & procurement	€ 1,911,000	€ 1,739,655	€ 1,739,655	100.00%	€ 1,544,727	€ 1,544,726	100.00%
3020	REPRO expert meetings	€ 4,471,289	€ 4,467,550	€ 4,465,586	99.96%	€ 4,467,550	€ 4,279,440	95.79%
	Total Chapter 30	**€ 6,382,289**	**€ 6,207,205**	**€ 6,205,241**	**99.97%**	**€ 6,012,276**	**€ 5,824,166**	**96.87%**
31	RISK ASSESSMENT & SCIENTIFIC ASSISTANCE							
3110	RASA grants & procurement	€ 4,642,300	€ 7,004,950	€ 7,004,950	100.00%	€ 7,497,923	€ 7,494,365	99.95%
3120	RASA expert meetings	€ 3,824,000	€ 3,834,707	€ 3,834,707	100.00%	€ 3,834,707	€ 3,709,025	96.72%
3130	Crisis support	€ 10,000	€ 5,000	€ 5,000	100.00%	€ 5,000	€ 0	0.00%
3140	Quality management	€ 180,000	€ 107,930	€ 107,930	100.00%	€ 107,930	€ 60,665	56.21%
	Total Chapter 31	**€ 8,656,300**	**€ 10,952,587**	**€ 10,952,587**	**100.00%**	**€ 11,445,559**	**€ 11,264,056**	**98.41%**

34	COMMUNICATIONS							
3410	Risk communication	€ 1,145,000	€ 942,296	€ 942,296	100.00%	€ 942,296	€ 272,075	28.87%
3420	External relations	€ 350,000	€ 189,437	€ 189,437	100.00%	€ 189,437	€ 80,315	42.40%
3430	Scientific cooperation meetings	€ 3,000	€ 1,300	€ 1,300	100.00%	€ 1,300	€ 1,072	82.43%
3431	Focal Point and grant agreements	€ 3,220,000	€ 1,520,784	€ 1,520,784	100.00%	€ 1,048,797	€ 1,048,797	100.00%
	Total Chapter 34	**€ 4,718,000**	**€ 2,653,818**	**€ 2,653,818**	**100.00%**	**€ 2,181,831**	**€ 1,402,259**	**64.27%**
35	HORIZONTAL OPERATIONS							
3500	Operational IT systems	€ 5,148,195	€ 4,661,797	€ 4,661,538	99.99%	€ 4,661,797	€ 1,777,971	38.14%
3511	Translation, interpretation, linguistic proofreading and editing	€ 110,000	€ 146,984	€ 146,983	100.00%	€ 146,984	€ 130,488	88.78%
3512	Library	€ 534,000	€ 534,000	€ 534,000	100.00%	€ 534,000	€ 467,274	87.50%
3513	Missions of staff related to operational duties	€ 860,000	€ 866,085	€ 866,085	100.00%	€ 866,085	€ 806,982	93.18%
3514	Shuttles for experts and staff related to operational duties	€ 1,020,000	€ 1,030,000	€ 1,030,000	100.00%	€ 1,030,000	€ 951,443	92.37%
3520	Conferences and outreach	€ 970,550	€ 788,756	€ 788,756	100.00%	€ 788,756	€ 676,666	85.79%
3530	Operational development & control	€ 855,000	€ 1,413,104	€ 1,413,103	100.00%	€ 1,413,104	€ 713,516	50.49%
	Total Chapter 35	**€ 9,497,745**	**€ 9,440,725**	**€ 9,440,465**	**100.00%**	**€ 9,440,725**	**€ 5,524,340**	**58.52%**
	Total Title 3	**€ 29,254,334**	**€ 29,254,334**	**€ 29,252,110**	**99.99%**	**€ 29,080,391**	**€ 24,014,822**	**82.58%**
	TOTAL Budget	**€ 79,414,000**	**€ 79,492,945**	**€ 79,490,657**	**100.00%**	**€ 79,319,002**	**€ 71,117,107**	**89.66%**

The carry-forward from 2015 to 2016 (carry-forward 2016) was utilised at 94.1% (93.4% in 2015).

The amount carried forward from 2016 to 2017 (carry-forward 2017) was EUR 8.20 million, higher than in the previous year (EUR 7.53 million).

Table 32: Carry-forward 2016 and 2017 (non-differentiated appropriations)

	Carry-forward 2016			Carry-forward 2017
Title	Commitment appropriation	Executed payment	%	Commitment appropriation
Personnel	968,427	851,088	87.9%	893,080
Infrastructure	2,682,853	2,576,415	96.0%	2,244,470
Operations	3,880,893	3,663,063	94.40%	5,059,788
Total	**7,532,173**	**7,090,566**	**94.10%**	**8,197,338**

Appendix C – Negotiated procedures and time to grant

Negotiated procedures

In 2016, 11 special negotiated procedures were concluded for a total amount of €4.3 million. This compares to 14 procedures concluded in 2015 for a value of €4.4 million, in a context where the value of outsourcing is increasing.

Table 33: 2016 negotiated procedures

	2016 negotiated procedures under Article 134 (1) a to f art 53 RAP			
Number	Procedure type	Contractor name	Procedure type	Contract value
1	Neg Art 134 1b	Bartlett Media Ltd	Subscription to EU Food Policy	20,000 €
2	Neg Art 134 1b	Croatian Food Agency	Update of the EFSA Comprehensive food consumption database Croatia 2011-12 to EFSA	46,000 €
3	Neg Art 134 1b	Elsevier B.V.	Purchase of access to and associated services for the SCOPUS database and the Embase database	162,000 €
4	Neg Art 134 1b	Thomson Reuters Scientific	Thomson database	79,911 €
5	Neg Art 134 1b	Institute of technology, Prague	Botanicals	130,000 €
6	Neg Art 134 1e	Techem	Art. 134(1)(e) RAP Amendment for repetition of services of FWC OC/EFSA/GMO/2013/01 Preparatory work on bio informatics for the evaluation of risk assessment of GMO dossiers	75,000 €
7	Neg Art 134 1e	DTU	Art. 134(1)(e) RAP Amendment for repetition of services of FWC OC/EFSA/FIP/2013/02 lot 1_Preparatory work for safety assessment of applications in the area of food flavourings	60,000 €

	2016 negotiated procedures under Article 134 (1) a to f art 53 RAP			
Number	Procedure type	Contractor name	Procedure type	Contract value
8	Neg Art 134 1e	ICF consulting Services limited/ Market opinion research international LTD	Negotiated procedure art134(1) (e) for repetition of services	300,000 €
9	Neg Art 134 e	Adecco	Negotiated procedure art134(1) (e) for repetition of services	1,300,000 €
10	Neg Art 134 e	Pomilio	Negotiated procedure art134(1) (e) for repetition of services	2,000,000 €
11	Neg Art 134 e	Medlavitalia	Negotiated procedure art134(1) (e) for repetition of services	170,000 €
Total				**4,342,912 €**

Time to grant

In 2017, 75 calendar days on average were needed to award a grant after receipt of the application. It took on average 18 calendar days from awarding the grant to having the grant agreement signed by both parties. This is significantly less than the legal limits of 180 and 90 days, respectively, and constitutes a significant progress compared to 2015 (118 and 52 days, respectively).

Table 34: 2016 average time to grant

Grant agreement	Deadline for application	Signature award decision	Signature grant agreement	Art 128 2 a	Art 128 2 b
Thematic grant 2016 Lot 3	06/10/2016	02/12/2016	09/12/2016	57	7
Genotoxicity study on Beauvericin and Enniatins in order to refine risk assessment	18/09/2015	11/01/2016	26/02/2016	115	46
Database of processing types and processing factors compatible with the EFSA food classification and description system FoodEx2	07/11/2016	30/11/2016	02/12/2016	23	2
Modelling human variability in the metabolism of chemicals using human in vitro systems and Bayesian meta-analysis	18/02/2016	22/06/2016	15/07/2016	125	23
Thematic grant 2016 Lot 2	06/10/2016	02/12/2016	15/12/2016	57	13
Average				**75**	**18**

Appendix D – Human resources

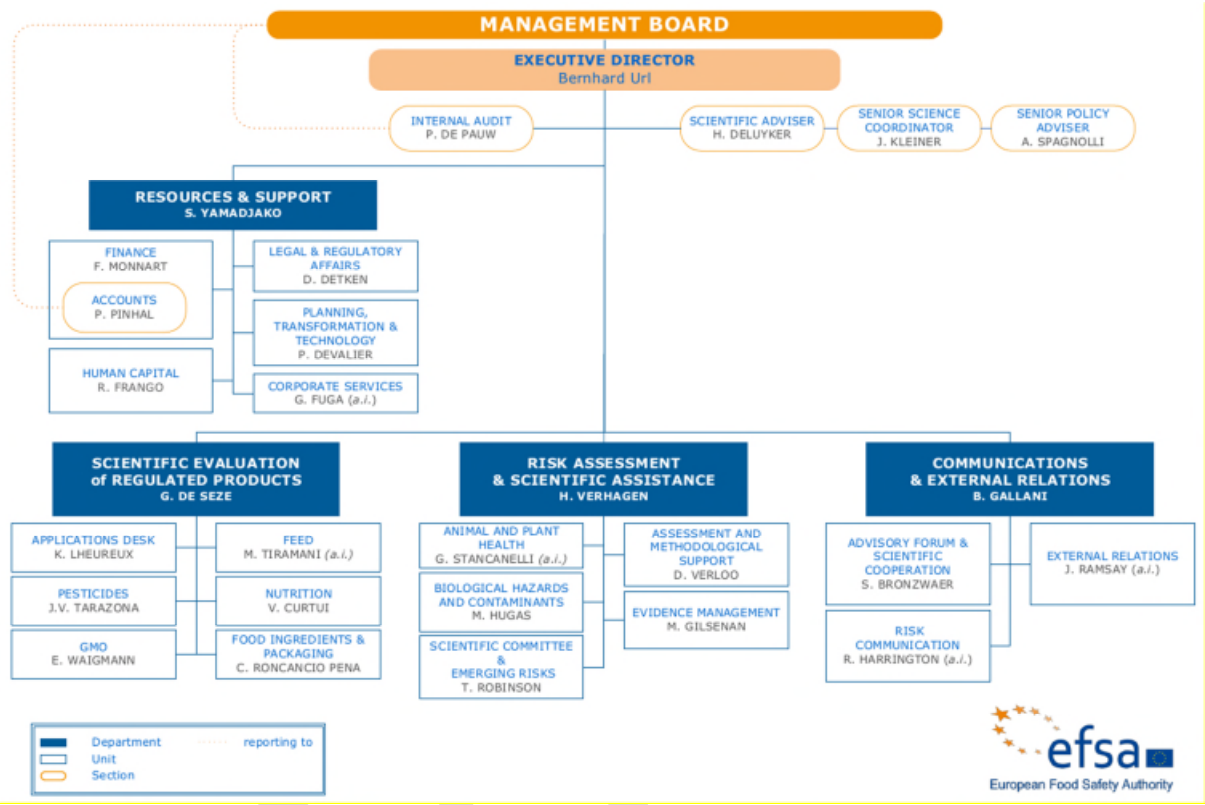

Figure 1 Organisational chart (1/12/16)

Table 35: Establishment plan 2016

Function group and grade	2016			
	Authorised under the EU Budget		Filled as of 31/12/2016	
	Permanent posts	Temporary posts	Permanent posts	Temporary posts
AD 16	-	-	-	-
AD 15	-	1	-	-
AD 14	-	2	-	1
AD 13	-	2	-	1
AD 12	1	15	-	6
AD 11	-	11	-	6
AD 10	1	16	-	11
AD 9	1	42	-	27
AD 8	-	54	-	54
AD 7	1	57	4	46
AD 6	1	17	1	43
AD 5	-	8	-	12
AD TOTAL	**5**	**225**	**5**	**207**
AST 11	-	-	-	-
AST 10	-	-	-	-
AST 9	-	-	-	-
AST 8	-	3	-	-
AST 7	-	4	-	2
AST 6	-	9	-	2
AST 5	-	30	-	15
AST 4	-	26	-	40
AST 3	-	25	-	17
AST 2	-	3	-	29
AST 1	-	-	-	3
AST TOTAL	**-**	**100**	**-**	**108**
AST/SC 6	-	-	-	-
AST/SC 5	-	-	-	-
AST/SC 4	-	-	-	-
AST/SC 3	-	-	-	-
AST/SC 2	-	-	-	-
AST/SC 1	-	-	-	-
AST/SC TOTAL	**-**	**-**	**-**	**-**
TOTAL	**5**	**325**	**5**	**315**
GRAND TOTAL		**330**		**320**

Table 36: Results of the benchmarking exercise in accordance with provisions of Art. 29 (3) Framework Financial Regulation and the Methodology for Agencies Job Screening[(a)]

Job type (sub) category	Year 2015	Year 2016
Administrative support and coordination	**21.4%**	**21.4%**
Administrative support	20.0%	19.7%
Coordination	1.4%	1.7%
Operational	**72.4%**	**71.6%**
Top-level operational coordination	2.8%	3.7%
Programme management and implementation	54.8%	54.9%
Evaluation & impact assessment	0.0%	0.0%
General operational	14.8%	13.1%
Neutral	**6.2%**	**7.0%**
Finance/control	5.7%	6.4%
Linguistics	0.5%	0.5%
TOTAL	**100%**	**100%**

(a) The benchmarking exercise methodology common to all EU agencies includes all staff categories: officials, temporary agents, contract agents, seconded national experts as well as visiting experts, interims, trainees, consultants and external service providers.