

2021

Adopted by written procedure on 24 March 2022 For EFSA's Management Board [SIGNED] Aivars Bērziņš **Chair of the Management Board**

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Legend

Status ¹ Symbol		Threshold		
Over-achieved	0	Actual/Target more than 105 %		
Achieved	0	Actual/Target between 95.1% and 105%		
Partially achieved	0	Actual/Target between 75.1% and 95%		
Not achieved	0	Actual/Target less or equal than 75 %		
N/A	0	Indicator not measured		

¹ In case of indicators not planned to be measured in 2020 (e.g.: frequency of measurement is not annual), their most recent result is showed in the "ACTUAL 2020" column and the most recent status has been carried over to 2020. By contrast, in case of indicators that were expected to be measured in 2020 but for which the measurement is not available, their most recent result is showed in the "ACTUAL 2020" column but their performance has not been considered (and their status is marked in grey).

List of abbreviations

AF	EFSA Advisory Forum
AHAW Panel	EFSA Panel on Animal Health and Welfare
Al	Artificial Intelligence
ALPHA	EFSA Animal and Plant Health Unit
AMR	antimicrobial resistance
AMU	EFSA Assessment and Methodological Support Unit
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail ²
APDESK	EFSA Applications Desk Unit
ART	Architecture Transformation Programme
ASF	African Swine Fever
BfR	Bundesinstitut für Risikobewertung ³
BIOCONTAM	EFSA Biological Hazards and Contaminants Unit
BPA	Bisphenol A
BSE	Bovine Spongiform Encephalopathy
BUS	Business Services Department
Col	Conflict of Interest
CORSER	EFSA Corporate Services Unit
CRA	Cumulative Risk Assessment
DATA	EFSA Evidence Management Unit
DG DIGIT	Directorate-General for Informatics
DG SANTE	Directorate-General for Health and Food Safety
Dol	Declaration of Interest
doi	digital object identifier
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EEA	European Environment Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EMAS	Eco-Management Audit Scheme certification
EMP	Expertise Management Programme
ENCO	EFSA Engagement and Cooperation Unit
ENP	European Neighbourhood Policy
ERA	Environmental Risk Assessment
EREN	Emerging Risks Exchange Network
ERI	Emerging Risks Identification
EU	European Union
EUAN	EU Agencies Network
F2F	European Commission's Farm to Fork Strategy
FAO	Food and Agriculture Organisation of the United Nations
FCM	Food Contact Materials

The French Agency for Food, Environmental and Occupational Health & Safety.

The German Federal Institute for Risk Assessment.



FEED	EFSA Feed Unit
FIN	EFSA Finance Unit
FIP	EFSA Food Ingredients and Packaging Unit
FTE	full-time staff equivalent
GDPR	General Data Protection Regulation ⁴
GMO	Genetically Modified Organism / EFSA GMO Unit
IARC	International Agency for Research on Cancer
IAS IMS	Internal Audit Service of the European Commission
IPCHEM	Integrated Management System European commission Information Platform for Chemical Monitoring
ІРСПЕМІ	
IPA	Instrument for pre-accession assistance (abbreviation used for the "pre-accession" countries)
IUCLID	International Uniform Chemical Information Database
JRC	Joint Research Centre
LA	EFSA Legal and Regulatory Affairs Unit
MB	EFSA Management Board
MRL	Maximum Residue Level
MS	Member States
NUTRI	EFSA Nutrition Unit
OECD	Organisation for Economic Co-operation and Development
OIE	World Organization for Animal Health
OSOA	One Substance One Assessment
PAD	Public Access to Documents
PPPs	Plant Protection Products
PRES	Pesticide residues Unit
PREV	Pesticide peer review Unit
RA	Risk assessment
RAMPRO	Risk Assessment Methodologies Programme
RASA	EFSA Risk Assessment and Scientific Assistance Department
REPRO	EFSA Scientific Evaluation of Regulated Products Department
SC	EFSA Scientific Committee
SCER	EFSA Scientific Committee and Emerging Risks Unit
SEA	Stakeholder Engagement Approach
SPIDO	Science Studies and Project Identification and Development Office
SOP	Standard Operating Procedure
SPG	Specific Protection Goals
TR	Transparency Regulation
TS	Transformation Services
TSE	Transmissible Spongiform Encephalopathy
TTC	Threshold of Toxicological Concern
UK	United Kingdom
WG	Working Group
WHO	World Health Organisation

⁴ Regulation (EU) 2016/679 of the European Parliament and of the Council of 27 April 2016 on the protection of natural persons with regards to the processing of personal data and on the free movement of such data, and re-pealing Directive 95/46/EC

Foreword

This report is in many ways a remarkable document. For although the activities it records may appear routine, they were achieved – for the second year running – in the most trying circumstances.

Once again, in 2021 EFSA was running on virtual mode, with staff working from home, physical meetings banned and lockdowns and quarantines causing severe disruption to lives and work schedules.

Despite the grim backdrop of the ongoing SARS-CoV-2 pandemic, the Authority's staff and external experts delivered more than 700 scientific outputs with no or minimal deviation from planned outcomes. The Management Board highly appreciates and acknowledge this achievement and commends the dedication, resilience and commitment that made it possible.

But EFSA didn't just dig in last year; it looked ahead and prepared for a new future.

An amendment to the General Food Law came into effect in March 2021 that increases EFSA's responsibilities towards EU citizens. The new Transparency Regulation was introduced primarily to increase the transparency of risk assessment in the food chain, to strengthen the reliability, objectivity and independence of the studies submitted to EFSA, and reinforce the governance of EFSA in order to ensure its long-term sustainability.

The implementation of the regulation marks a significant change in the way EFSA works and interacts with other players in the food safety ecosystem. It has also involved plenty of hard work behind the scenes: adopting new procedures, revising guidance documents, developing dedicated IT tools, and communicating with stakeholders and partners about how the new processes will affect them. The Management Board received regular progress reports, presentations at MB meetings and was pleased to hear that the project had been successfully executed.

Another landmark was the adoption of the Strategy 2027, deferred from 2020 because of the pandemic. This is a crucial document for EFSA, not just because it was prepared in parallel to the implementation of the Transparency Regulation, but because of the wider context: EU-wide policy developments, such as the Green Deal actions and in particular the Farm to Fork Strategy, the Chemicals Strategy for Sustainability and the Biodiversity Strategy.

The Strategy 2027 sets out how EFSA will respond to this changing environment, while continuing to serve to its customers, partners, stakeholders, and the public at large.

Amidst the strategic and organisational development, serious scientific work continued to be carried out. Important annual data reports on pesticides, zoonotic diseases and antimicrobial resistance were produced; work began on a significant package of mandates that will support the European Commission's plans to overhaul animal welfare legislation; important outputs helped risk managers to design strategies for coping with animal diseases such as African swine fever and avian influenza. Not to mention the rapid foodborne outbreak assessments, the continued support provided in collaboration with ECDC with regards to the SARS-CoV-2 in mustelids, the ongoing programme of regulated product assessments, the new framework for assessing the risks to bees from pollinators. It's a long list.

A welcome innovation was the creation of the Science Studies and Project Identification and Development Office (SPIDO), whose key tasks are to identify and initiate forward-looking thematic scientific projects and to coordinate their outsourcing. SPIDO will enable EFSA to build new and strategically important partnerships with other European institutions, sister agencies, international partners and Member States. Together with Strategy 2027, it will help ensure that EFSA is well positioned to meet the challenges and exploit the opportunities that lie ahead.

Aivars Bērziņš, Chair of the EFSA Management Board



Introduction

EFSA's work in 2021 was once again carried out against the backdrop of the SARS-CoV-2 pandemic, with homeworking and online meetings the norm for staff and external experts alike. But, as in 2020, we performed impressively – a total of 704 scientific questions were closed across all areas, 81 fewer than the planned 785 but in line with 2020 (697 questions closed). Of course, this is down on previous years but, given the extraordinary circumstances, I am immensely proud of the dedication and effort demonstrated by the EFSA family.

It is all the more laudable given the additional pressures under which we operated in 2021.

In March, the Transparency Regulation came into effect, a game-changing milestone for our organisation. To prepare for this generational change to the way we work we committed considerable investment to develop new processes, review our organisation design, and leverage technology and information management capabilities. Some of this preparatory work had originally been slated to be carried out in 2020 but had to be deferred in the face of the breaking pandemic. This meant devoting substantial resources in 2021 to development projects and areas such as talent selection, procurement, engagement and communication.

This was a challenging but essential exercise. Essential because the ultimate goal of these changes is to reinforce trust in EFSA and the EU food ecosystem by increasing the transparency of our work, improving the reliability of studies used in the assessment of regulated products, and making EFSA's operations more sustainable through wider sourcing from Member States and more coordinated communication. Our new capabilities were delivered to deadline and we look forward to reaping the benefits in the coming years.

The workplan for 2021 was executed under the Strategy 2020, which the Management Board decided to extend for an additional year due to the SARS-CoV-2 pandemic. Our new Strategy 2027 was adopted last year, following the environment scan performed in 2019 and 2020, and is focused sharply on delivering EFSA's mandate within the context of broader EU priorities, particularly the European Green Deal and the Farm to Fork strategy.

All these "backstage" initiatives are important only to the extent that they facilitate the main event: the delivery of high-quality, independent advice to risk managers in the EU. And in this respect our scientists excelled themselves once again.

You can read in detail about the various outputs that were delivered across EFSA's remit in the following pages. Two highlights that stand out are, firstly, the beginning of work on a significant batch of mandates related to animal welfare, particularly animal transport, that will underpin new legislation being developed in this area. Secondly, last year EFSA published its scientific opinion on multiple stressors in honey bees, which sets out an integrated framework for the risk assessment of pesticides in interaction with other stressors for honey bee colonies. This opinion, requested by the European Parliament, advances our knowledge in this crucial area for risk assessors and has produced new tools and models that could transform the future prospects for our domestic and wild bees.

Back with the human species, we said a fond farewell to Raymond O'Rourke, a stalwart of EFSA whose term as a member of our Management Board expired in June after eight years of service. We thank Raymond and wish him all the best for the future. The restructuring of our Management Board in 2022 will be another step towards a new EFSA in what promises to be another challenging but exciting year.

Bernhard Url, Executive Director

Management Board assessment

The Management Board,

having regard to Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002, as amended by Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain,

having regard to the Financial Regulation applicable to the budget of the European Food Safety Authority and in particular Article 47 thereof,

having regard to the EFSA Strategy 2020 adopted by the Management Board in March 2016,

having regard to the 2021-2023 Programming Document of the Authority adopted by the Management Board in December 2020,

- 1. Appreciates that, through pro-activeness and resilience, EFSA has minimised the impact on its productivity and taken care of the wellbeing of its staff during the SARS-CoV-2 crisis also in 2021.
- 2. Welcomes a sixth (and final) year of implementation of the Strategy 2020, with relevant progress made across all strategic objectives, and a sound performance across the various indicators, albeit a few deviations.
- 3. Notes the challenges faced in 2021, particularly with the entry into application of the Transparency Regulation and the related considerable investment on organisational changes and appreciates the successful safeguarding of EFSA's core business.
- 4. Appreciates the achievements in the area of general risk assessment and regulated products and the significant efforts made to improve risk managers satisfaction with fit for purpose, timely and independent scientific advice.
- 5. Welcomes the different risk communication activities in its area of competence and stresses especially the increasingly successful EFSA Journal.
- 6. Notes the productivity of the Authority in the finalization of 704 questions via scientific outputs and technical reports in a timely manner, with a point of attention on the challenges faced in a small number of regulated product areas.
- 7. Welcomes the strengthened work in the area of plant health on the assessment of risks from new and emerging plant pests (invertebrate and microorganism agents) on a wide range of plants and notes the continuous activities on horizon scanning and surveillance; also appreciates the efficiencies achieved in the areas of feed additives and food contact materials, the improved results in the area of pesticide MRLs and the timely finalisation of the Annual Report on Pesticide Residues.
- 8. Appreciates the coordinated and timely assistance provided to the Commission and Member States through different rapid foodborne outbreak assessments and the continued support provided in collaboration with ECDC with regards to the SARS-CoV-2 in mustelids.
- 9. Welcomes the commitment and attention to public opinion and perceptions via the integration of social science into food safety risk assessment; commends the reports published in response to the EC mandate on the science of Risk Communication; and acknowledges the impact of the pan European communication campaigns.



- 10. Appreciates the on-going work to engage with stakeholders for improved dialogue and enhanced quality of science, including the establishment of a new engagement framework, and the efforts to guarantee access to data and information and the sharing of scientific documents and tools through open repositories.
- 11. Notes the continuous collaboration with Member States, that has been instrumental in strengthening the identification of common priorities in EFSA's work-programme, and welcomes the initiative to explore ways to increase Member State engagement in partnership schemes and improve the sustainability of the risk assessment system.
- 12. Notes the efforts for strengthening cooperation with EU sister agencies, and particularly with the successful initiative with ECHA, preparing the field for more strategic partnerships around the "One Health" goals, and the implementation of the Chemical substances strategy and the One Substance-One Assessment approach in the context of the EU Green Deal and the Farm to fork strategy.
- 13. Appreciates the efforts made towards preparedness, and in particular the involvement of EFSA's Focal Point Network in order to improve collaboration and exchange information and knowledge, and the continuous investment in improving the organisation internal awareness regarding procedures for responding to urgent advice needs and communication strategies to use during a crisis.
- 14. Welcomes the close cooperation of EFSA with its partners towards the finalisation of the new Strategy 2027, driven by the results of the environment scan and its update in 2020 taking stock of the new policy agenda of the Commission, the midterm evaluation of the Strategy 2020 and the requirements of the Transparency regulation.
- 15. 15. Appreciates the continuation of the work, in close collaboration with DG SANTE, to support the new processes addressing the requirements of the Transparency regulation; also notes the importance of this collaboration considering that the new rules and measures specified in the Transparency Regulation will affect stakeholders' interaction with EFSA during the risk assessment process, especially in the areas of proactive transparency, confidentiality, notification of studies, pre-submission advice and consultation of third parties, as well as the processing of applications for access to documents held by EFSA.
- 16. Welcomes the positive outcomes achieved in developing an environment focused on improving organisational performance and capabilities, such as the ISO 9001:2018 Quality re-certification with no highlighted non-conformities; the confirmation of EFSA's certification in the field of health and safety management standard ISO 45001:2018, and the registration to Eco-Management and Audit Scheme (EMAS) registration. Appreciates the efforts for the integration of EFSA's management systems towards improving efficiency, relevance and clarity in the steering of the organisation.
- 17. Notes the achievements in the internal control area and the continued outstanding budget implementation; welcomes the fact that EFSA did not have to transmit or follow-up on any suspicion of fraud cases to OLAF.
- 18. Welcomes the audit results by the Internal Audit Service and the European Court of Auditors.

Adopted by written procedure on 24 March 2022 For the EFSA's Management Board

Aivars Bērziņš Chair of the Management Board

Executive Summary

EFSA in brief

Mission

The European Food Safety Authority (EFSA) is an integral part of the EU's food safety system. As outlined in its founding regulation (Regulation (EC) No 178/2002), the Authority's mission is to contribute to the safety of the EU food and feed chain, mainly by:

- providing EU risk managers with independent, up-to-date and fit-for-purpose scientific advice on questions related to food and feed safety, animal health and welfare, plant health, nutrition and environmental issues specific to the above (5);
- communicating to the public on its outputs and the information on which they are based;
- developing and applying uniform methodologies for fit-for-purpose scientific advice on questions related to food safety;
- collecting and analysing data to allow the identification, characterisation and monitoring of current risks that have a direct or indirect impact on food safety;
- cooperating with Member States, institutional partners and other interested parties/stakeholders (6) in the EU to promote coherent advice and increase trust in the EU food safety system;
- identifying emerging risks to food safety and contributing to a high level of protection of human life and health.

Vision

Trusted science for safe food.

General context

EFSA's landscape changed considerably in 2021, bringing new challenges but also exciting opportunities. In March 2021, EFSA celebrated the entry into force of the Transparency Regulation, which necessitated considerable investment for the development of new processes, the review of EFSA's organisation design, and the leveraging of its technology and information management capabilities. The ultimate goal of these changes is to strengthen trust in EFSA and the EU food ecosystem by increasing the transparency of EFSA's work, improving the reliability of studies in the context of the authorisation of regulated products, improving the sustainability of EFSA's operations by wider sourcing from Member States competent organisations and a more coordinated communication with EU Institutions and Member States.

EFSA, like other organisations, responding to the reality of the SARS-CoV-2 pandemic, continued largely operating by distance working, thanks to systems and technology in place allowing to switch from a physical to a digital working environment.

⁵ The phrase 'food safety' is used throughout the document as shorthand for 'food and feed safety, animal health and welfare, plant health, nutrition and environmental issues specific to the above'.

 $^{^{\}rm 6}$ $\,$ As defined in EFSA's founding regulation (Regulation (EC) No 178/2002), Article 3(13).



EFSA delivered its workplan implementing the Strategy 2020 for the last year of the strategy cycle, as the MB decided to extend the Strategy 2020 implementation until the end of 2021 due to the SARSCoV-2 pandemic. This approach ensured continuity of EFSA's activities as the strategy 2020 had already integrated the Transparency regulation requirements in the 2020-2022 draft Programming Document, and the Strategy 2027 has been designed as an evolution of the Strategy 2020, with the mid-term objectives focus on the implementation of the Transparency Regulation.

EFSA's strategy 2020⁷ outlines five strategic objectives (SOs) that guide EFSA in fulfilling its mission in light of the changing context described in the previous section while aiming to increase customer satisfaction and the trust of stakeholders in its scientific advice:

- SO1 prioritise public and stakeholder engagement in the process of scientific assessment;
- SO2 widen EFSA's evidence base and optimise access to its data;
- SO3 build the EU's scientific assessment capacity and knowledge community;
- SO4 prepare for future risk assessment challenges;
- SO5 create an environment and culture that reflect EFSA's values.

To implement its strategy, EFSA has designed a multiannual portfolio consisting of core processes and projects. The core processes represent the bulk of EFSA's work including the requests for scientific advice from the risk managers and supporting processes that deliver the outputs and results defined in EFSA's mission and strategy. As envisaged in the strategy implementation plan, projects have been included that will deliver benefits to EFSA's core processes, such as improved efficiency and quality, and will follow appropriate project governance.

- Ongoing and planned projects have been consolidated into four multiannual programmes. These
 programmes are identified in this document as the Architecture Transformation programme (ART), the
 Information Management Programme (IMP), the Risk Assessment Methodologies Programme (RAMPRO)
 and the Expertise Management Programme (EMP) and are set up to coordinate and align the projects in
 the respective areas. All four programmes are supported by a common transformation team.
- Each development project covers one or more aspects of the SOs, and together they maximise the strategic fit of the multiannual programme. The third external evaluation recommendations adopted by the MB in October 2018 enforced the transformation agenda envisaged within the ART programme and are integrated into the activities planned for 2019 and beyond. EFSA reported to the MB via regular progress reports.
- Annual and quarterly reviews of the strategy implementation allowed for adjustments of the resources dedicated to achieving the SOs through current and future processes and projects.

To ensure that EFSA's activities are focused on achieving the expected results as defined in its strategy, and to be able to monitor progress, EFSA has implemented its results-based orientation through the definition of an integrated framework founded on an intervention logic and a set of key performance indicators (KPIs). These are presented at impact, outcome, and input-activity-output level in the Part I Achievements of this document.

In 2021 EFSA's new Strategy 2027 was adopted, following the thorough environment scan analysis performed in 2019 and 2020, providing the strategic focus and ambitions for the coming years in the context of EFSA's mandate, and the evolving EU priorities—particularly the European Green Deal and farm to fork strategy.

⁷ EFSA strategy 2020, http://www.efsa.europa.eu/en/corporate/pub/strategy2020

Performance overview – The year in brief

Overall, EFSA registered a performance in line with the previous year.

If 2020 was affected by the SARS-CoV-2 outbreak, 2021 was a similarly challenging year, with the entry into force of the Transparency Regulation in March, the finalisation of a new Strategy 2027 and the progressive adaptation of EFSA's processes and operations to the new tasks and procedures.

Last year's de-prioritisation of some of the activities initially planned to make EFSA ready to the changes brought by the Transparency Regulation (such as the full revamp of EFSA's organisational structure and process architecture, or the finalisation of the new IT tools) was a necessary choice to safeguard the core business and the "must do" activities. This, however, created a backlog of activities that were carried to 2021 and that proved to be resource-intensive (estimated to approximately 67 FTEs considering development projects and support from areas such as talent selection, procurement, engagement and communication). Furthermore, the postponement of these activities caused delays in the generation of the efficiency gains expected by the full implementation of the ART Programme (which was set up to prepare EFSA for the requirements of the Transparency Regulation by driving all the needed changes and leaning EFSA's core and enabling processes). With the implementation of the new process architecture and the new organisation as of 01/01/2022, and the closure of the ART programme expected mid-2022, EFSA foresees to capitalise on the efforts in the coming years.

Overview of EFSA performance in 2021

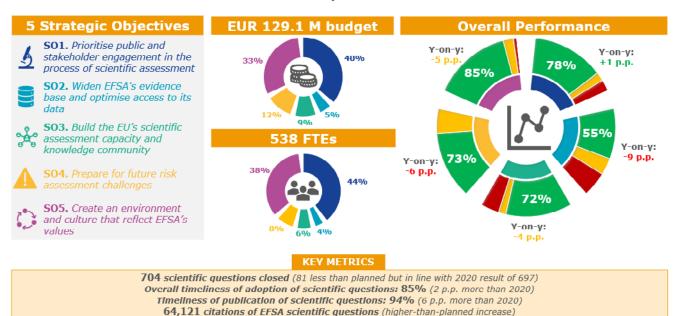


Figure 1. Overview of EFSA performance in 2021

Looking at the performance within each Strategic Objective, in **Strategic Objective 1** (78% of KPIs within the "on track" area or better) the results were in line with 2020 (when the result was 77%), with the metrics on EFSA's scientific Risk Assessment posting similar results y-on-y. The performance deviations in this area were due to the increased workload, the increasing complexity of scientific risk assessment, and delays in the reception of information needed for the risk assessment, as well as issues related with the adaptation to the changes brought as consequence of the Transparency Regulation. These are further explained below.

100% budget execution, despite budget increase of 19% (to EUR 129 M)



Positive performance is instead reported for the metrics in the area of communication, with the timeliness of publication on the EFSA Journal posting above-the-target results (more than 90% of EFSA's scientific opinions were published within 28 calendar days from their adoption), in line with the positive performance registered since 2018. Also the number of citations of EFSA's scientific outputs registered positive results, reaching almost 65,000 citations. This is a significant increase from the around 50,000 citations recorded as of December 2020, which is also due to the inclusion of the EFSA Journal in important abstract and citation databases.

Strategic Objective 2 registered the biggest difference year-on-year (-9 percentage points), with the proportion of KPIs reaching or surpassing targets decreasing from 64% to 55%. The reason of this drop is mainly related to the lower-than-planned production of scientific outputs in the area (9, vs a plan of 28), due to an initial overestimation in the planning (to contextualise, 15 questions were closed in 2020).

The remaining three Strategic Objectives registered deviations of a similar magnitude (around -5 percentage points year-on-year): in **Strategic Objective 3**, deviations are of diverse nature (for example the lower-than-planned number of applications to EFSA's calls is due to the combined effect of having calls of highly specialised scientific nature and the reduced potential pool of applicants after the entry into force of the withdrawal agreement of UK from the EU), whilst in **Strategic Objective 4** the deviations are due to the effect of the de-prioritisations in the area, especially the ones carried out in 2020 to safeguard the core business.

Finally, **Strategic Objective 5** registered a very positive performance despite the slight drop y-on-y, only due to the slower-than-planned recruitment of additional staff members in the context of the additional positions granted under the Transparency Regulation, (mainly requests of postponement of the start date). Looking in more detail at the performance of EFSA's **scientific production**, in 2021 a total of 704 scientific questions were closed across all areas, 81 less than the initial plan of 785 but in line with the 2020 performance (697 questions closed). This performance, however, was below the production registered in the previous years.

744 O 635 C 633 C of question 2019 2019 2021 2021 2021 2021 Reporting periods LEGEND

Number of questions closed over the last 5 years (SO1-SO4): actual vs plan

Questions closed Questions planned Positive deviation

Figure 2. Number of questions closed over the last 5 years (SO1-SO4): actual vs plan

The other key metric on EFSA's core business, the **timeliness of adoption of scientific questions**, closed the year at 85%, better than last year performance (83% in December 2020) and more in line with pre-pandemic

performance (Figure 3). In fact, if 2020 is not taken into account (due to the negative effect of the switch to virtual working conditions, increased delays in receiving data from applicants and effect of de-prioritisations in SO4), the 2021 performance follows the slight decreasing trend that can be seen in Figure 3 (90% in 2017, 87% in 2018, 86% in 2019 and 85% in 2021).

100% 95% 93% 92% 91% 91% Timeliness of adoption 90% 88% 88% 87% 87% 86% 86% 86% 85% 85% 83% 83% 83% 80% 75% P2 **P3** P2 P3 P2 P2 P3 P2 **P3** 2017 2017 2017 2017 2018 2018 2018 2018 2019 2019 2019 2019 2020 2020 2020 2020 2021 2021 2021 2021 Reporting periods

Timeliness of adoption over the last 5 years (SO1-SO4)

Figure 3. Timeliness of adoption over the last 5 years (SO1-SO4)

Overall, EFSA's performance in its key two metrics (number of questions closed and timeliness of adoption) remained in line with the results registered in 2020 and registered a drop-off compared to 2019 and previous years. This is compatible with the significant changes (implementation of the Transparency Regulation) and hurdles (SARS-CoV-2 pandemic) that EFSA faced in the past two years, as well as with the issues of increased workload (large batches of work and the arrival of several new tasks since 2017), increased complexity of EFSA's Risk Assessment (on the data and information to be processed, on the methodological rigour to be applied and the multidisci-plinary and/or novelty of the issues to be addressed) and need for greater transparency and en-gagement with society⁸. In fact, incremental decreases in performance, yet smaller, can be ob-served also from 2017 to 2019 for both metrics, corroborating the effect of the latter three drivers.

Main scientific achievements

Among the most notable achievements, there is the continuous work carried out in the context of the **African Swine Fever (ASF)** both at scientific level, with the finalisation of an opinion summarising the findings and assessing the factors to establish an ASF exit strategy, and at communication level, expanding in new EU countries the campaign to raise awareness on this deadly viral disease of pigs and wild boars. Further improvements were also carried out in terms of data collection, for example with the adoption of a new set of data standards to collect livestock data and the development of a web application for the automated translation and standardisation of national data.

⁸ More detailed information is available in the EFSA Single Programming Document 2021-2023 (Human and Financial resources – outlook chapter)



EFSA also continued is work on **Avian Influenza (AI)**, publishing a report that validates, analyses, and summarises the data resulting from AI surveillance programmes carried out in the EU. Similarly, EFSA continued the regular monitoring of the disease, in cooperation with the European Centre for Disease Prevention and Control (ECDC) and the EU Reference Laboratory on Avian Influenza.

Further notable achievements were reached in the area of biological hazards, with a new guidance to help food suppliers decide what information to give consumers about **storing food** and **time limits for consumption**. This guidance followed the tool developed already in 2020 to help food business operators decide when to apply the *use by* or *best before* date to their products.

In the area of plant health, further work was carried out on the **evaluation by commodity risk assessment of high-risk plants and derogation dossiers for the EU Plant Health Law**⁹, which gathered pace in 2020-2021 with 20 dossiers fully evaluated so far, an effort that well fit into the spirit and the initiatives that took place in the context of the International Year of Plant Health, which was celebrated in 2020.

EFSA also finalised, in collaboration with ECDC, the **European Union Summary Report on Antimicrobial Resistance in zoonotic and indicator bacteria from humans, animals and food** in 2018/2019, highlighting how a sizeable portion of *Salmonella* and *Campylobacter* bacteria is still resistant to antibiotics commonly used in humans and animals

Another annual report finalised by EFSA is the one on **Pesticides Residues** regarding the year 2019, which showed that 96.1% of the samples analysed were below the maximum residues levels set. Based on these data and on the current scientific knowledge, EFSA concluded that acute and chronic dietary exposure to pesticide residues is unlikely to pose concerns for consumer health.

The work carried out in 2021 in the area of **bee health** is also worth a mention. In particular, EFSA finalised its scientific opinion on "A systems-based approach to the environmental risk assessment of multiple stressors in honey bees" which sets out an integrate and holistic framework for the risk assessment of pesticides in interaction with other environmental stressors for honey bee colonies. Alongside this opinion, EFSA reviewed its guidance on the risk assessment of pesticides on bees and finalised two additional scientific opinions to support risk managers in the definition of specific protection goals for bees.

Finally, EFSA has continued its work related to the **SARS-CoV-2 virus in mustelids**, publishing in early 2021 a report that recommends the early detection of SARS-CoV-2 as a priority for monitoring activities at mink farms in the European Union. This report followed the contribution to a rapid assessment on the risks to human health from the new SARSCoV-2 variants related to mink, published in November 2020 by ECDC.

Entry into force of the Transparency Regulation

The 27th of March 2021 was a landmark day for EFSA, as the new provisions of the General Food Law entered into force. The new provisions are part of a new Regulation on the transparency and sustainability of the EU risk assessment in the food chain that was formally adopted by the European Council on the 13th of June 2019. This new regulation was developed in response to a European Citizens' Initiative on pesticides and the findings of the review of the General Food Law Regulation that was completed in January 2018.

"This is a pivotal moment for the assessment of risks in the food chain in the EU. EFSA is grateful to the European Parliament, to the European Commission and to the EU Member States for giv-ing us this opportunity to bring citizens and stake-holders closer to our work and to benefit from greater scrutiny of our working processes and prac-tices."

Bernhard Url, EFSA's Executive Director

Among other things, the new regulation is:

⁹ Regulation (EU) 2016/2031 of the European Parliament of the Council of 26 October 2016 on protective measures against pests of plants (https://eur-lex.europa.eu/eli/reg/2016/2031/oj)

- ensuring more transparency, allowing citizens access to scientific studies and information submitted to EFSA by industry early in the process of risk assessment
- strengthening the governance and the scientific cooperation, as Member States, civil society and European Parliament will be involved in the governance of the Authority by being duly represented in its Management Board. Member States will foster the Authority's scientific capacity and engage the best independent experts into its work
- increasing the completeness of the information that EFSA receives, with the Authority being notified of all". Moreover, it gives the European Commission the option of asking EFSA to procure additional studies
- **supporting the development of a comprehensive risk communication plan**, with a general plan ensuring coherent risk communication strategy throughout the risk analysis process, combined with open dialogue amongst all interested parties, for example embedding public consultations in the process for assessing applications for the approval of regulated products.



Figure 4. Transparency Regulation's initial roadmap

EFSA started working on these changes as early as March 2019 by setting up a dedicated programme, called ART, to drive the implementation of the Transparency Regulation (both getting ready for the mandatory provisions as well as updating its processes, tools, and organisation to support the changes). The ART programme delivered as planned, despite the disruption caused by the SARSCoV2 pandemic, which forced EFSA to postpone some nonmandatory activities expected to be completed in 2020 to 2021.

Budgetary Implementation

On the 29th of April 2021, EFSA achieved a clean discharge from the European Parliament on the implementation of the 2019 budget, confirming ex post that the implementation of EFSA's budget was in accordance with relevant rules and principles of sound financial management.

The 2021 performance of the budgetary indicators registered excellent results, in line with (in case of the commitment execution and of the payment of differentiated credits, at 100%) or close (in case of the payment



execution of non-differentiated credits, 87% vs 90%) to the plan, thus setting the basis for another positive assessment of EFSA's management of financial resources. It is to be highlighted that, as part of the Transparency Regulation, EFSA received an additional \leq 21 million in 2021 (an increase of around 20% compared to 2020 initial budget of \leq 108 million).

Key conclusions (Part I, II and III)

Overall, EFSA's performance was satisfactory, being was able to safeguard its core business; a total of 704 scientific questions were closed across all areas, 81 less than the initial plan of 785 but in line with the updated forecast in of October. Very positive results were registered in the area of communication of findings, with the timeliness of publication on the EFSA Journal keeping the positive performance registered in the past two years. EFSA was successfully prepared for the entry into force of the Transparency Regulation.

EFSA budgetary implementation achieved excellent results. EFSA addressed all accepted audit recommendations by proportionate action plans and monitored their implementation regularly. EFSA's implementation of audit recommendations was in general assessed as positive, auditors found EFSA's actions appropriate and did not report any improper delays.

EFSA assessed its internal control systems for the reporting year and concluded that overall, all internal control components and principles were present and functioning as intended. In addition, measures are under way to further strengthen the management of sensitive information, and to ensure fit for purpose risk management, internal control mechanisms for the increased funds as a result of the Transparency Regulation. This will be achieved in parallel with the ongoing integration of EFSA's management systems providing assurance towards legality and regularity, quality and performance, and health, safety, security and environment.

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary corrective action is being implemented.

Part I. Achievements of the year

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

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

EUR 52.25 M budget 33% 40% 237 FTES 38% 44%

Overall 2021 performance in Strategic Objective 1

Figure 5. Overall 2021 performance in Strategic Objective 1

Looking at the overall performance of the KPIs in the Strategic Objective 1, 78% of the measured indicators reached or surpassed their initial targets, in line with the performance from 2020 (77%). This result is below the last pre-SARS-CoV-2 performance (84%, in 2019) and this is a reflection of increased complexity of EFSA's RA and increased workload, as well as of issues in the data received and the effect of the adaptation to the new provision of the Transparency Regula-tion, also in terms of target setting (such as the overestimation of the targets related to the met-rics on public consultations, see tables 6 and 7 in the next pages).

In terms of input invested in SO1, 237 FTEs (44% of EFSA's total workforce for 2021) were allo-cated in 2021, about 21 FTEs more compared to 2020 (216 FTEs, 40% of EFSA's total for 2020). This increase of FTEs was allocated almost completely to activities connected with the Scientific Risk Assessment, including the new and incremental tasks introduced by the amendment of the General Food Law (such as offering pre-submission advice to applicants, or carrying out a more extensive sanitisation of the dossiers used for the Risk Assessment).



In terms of budgetary inputs, € 52.25 million were invested in 2021, which accounts for around € 9 million more year-on-year.

1.1. Fit-for-purpose scientific production

The comprehensive bi-annual survey that EFSA carries out with its interested parties was originally scheduled for the first half of 2021 but it was decided to postpone it to 2022 to align it with the end of the EFSA Strategic cycle (see Table 1 for the latest available results, gathered in 2019).

The annual feedback exercise that EFSA carries out with DG SANTE, instead, took place as planned. The 2020/2021 customer feedback exercise was finalised at the beginning of 2021, and the closing report was shared with EFSA's and SANTE's senior management. As per previous ex-ercises, the overall feedback received was positive, with some areas for improvement also identi-fied. Praise was given by both sides to the good collaboration, the readiness to negotiate dead-lines and the mutual understanding of priorities considering the workload. The open communica-tion between EFSA and SANTE was considered an asset and crucial when negotiating deadlines and developing fit for purpose opinions.

Table 1. Intermediary impact indicators for SO1 – Satisfaction on scientific outputs and the scientific assessment process

КРІ		Baseline	Target 2020	Executed 2020	Status
Intermediary impact: Increased sati managers and stakeholders) and the		g EFSA's scienti	fic outputs (for (Commission/Mei	mber State risk
Satisfaction via feedback surveys:	Risk managers (EC/MS)	81.6% <i>(2017)</i>	N/A in 2021	86.6% (2019)	O
manistica and valation accelisation		74.7% (2017)	N/A in 2021	78.1% (2019)	O
	Applicants	78.3% (2017)	N/A in 2021	78.6% (2019)	O

1.1.1. General risk assessment

In the area of general risk assessment, EFSA received about 250 questions and closed 244 in total (228 through scientific outputs and technical reports and 16 through external reports), slightly below the initial plan of 268 questions (see Table 2 and Figure 8), but higher than the results in 2020 (209) and 2019 (195).

The increase with respect to 2020 can however be explained by the postponement, in agreement with DG SANTE, of the adoption of about 40 questions linked to the scientific report to derive a common EU position in the Codex meeting (CCPR); on the other hand, some scientific areas suffered deviations compared to the initial plan.

Additional details on questions closed per Unit and food sector area can be found in Annex I Core business statistics (a) Questions closed in 2021.

Table 2. Activity and outputs indicators for SO1 — General risk assessment

ACTIVITY - OUTPUT INDICATORS						
General risk assessment						
Indicator	Executed 2020	Target 2021	Executed 2021	Status		
Number of questions delivered for scientific outputs and technical reports	194	253	228	o		
Number of questions delivered for 'other publications' (external reports, event reports)	15	15	16	O		
Proportion of scientific/technical questions adopted within deadline	98%	100%	98.7%	O		

In terms of timeliness of adoption, the result can be considered on track, at 96% versus a target of 100%.

Number of questions closed in general risk assessment area (2021 actuals vs 2021 plan compared with 2019 and 2020 actuals)

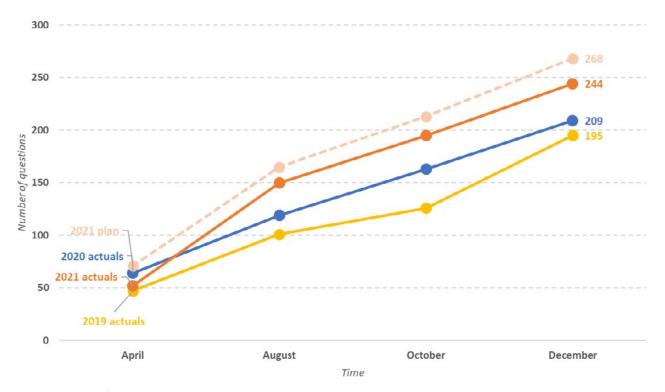


Figure 6. Number of questions closed in the General Risk Assessment area

The following achievements can be highlighted in the specific areas of work:

Plant health

In the area of plant health, work continued for plant pests surveillance, but with a reduction in the production of the pest survey cards with respect to the plan, which was due to the decrease in workforce available in



Member States via tasking grants and to a partial re-deployment of EFSA resources to meeting with and training Member States in the use of the EFSA surveillance tools; in the same area, literature and media monitoring newsletters were instead delivered as planned. A review of ranking systems for new plant threats in the EU and third countries was also finalised.

A production lower than the plan can also be observed for pest risk assessment and categorisation opinions: in this area the work started later than expected due to the delayed reception of the official mandate and was further held up by the technical issues experienced by EFSA with the Dol tool, together with resources shortage, since resources were re-deployed to address unforeseen F2F mandates in the animal welfare area.

Work continued also regarding *Xylella fastidiosa* for which EFSA finalised two new releases of the host plants database and co-organised, together with XF-ACTORS¹⁰ and other partners such as EU research projects and the Euphresco Network of Plant Health organisations¹¹, the 3rd European Conference: the event, held online in April, was attended by scientists, academics and interested stakeholders from more than 60 countries, and highlighted the progress that has been made in areas such as identifying resistant and substitute crops, and developing control measures and treatments for the pathogen, but also the need to accelerate the process of transferring research results into practical assistance for stakeholders.

Animal health

The scientific production in the area of animal health law (Regulation (EU) 2016/429) and related control measures for Category A diseases registered good performance, with more opinions finalised than originally planned (one scientific opinion per disease as well as the methodology applied for each disease).

Further work was also carried out with regards to African Swine Fever (ASF), in reply to both the European Commission requests for an EFSA opinion on the studies needed to fill the research gaps to facilitate evidence-informed decision making on ASF prevention and spread, and for an opinion summarising the findings and assessing the factors to define an ASF exit strategy, which provides an evaluation of the proposed exit strategy criteria and recommendations for further research.

Activities on Avian Influenza (AI) also continued, with the publication of the second report which validates, analyses and summarises the data resulting from AI surveillance programmes carried out in the EU, and with the continued monitoring carried out jointly with the European Centre for Disease Prevention and Control and the European Union Reference Laboratory for Avian Influenza.

In addition, EFSA continues the monitoring of SARS-CoV-2 in mustelids in collaboration with ECDC: a report finalised at year start recommends that early detection of SARS-CoV-2 should be a priority for monitoring activities at mink farms in the European Union. The report proposes options for monitoring strategies to help preventing and controlling the spread of the disease.

Animal welfare

EFSA is continuing its work with regards to animal welfare, in particular in relation to the advice requested by the European Commission in the context of the Farm to Fork (F2F) strategy. Work progresses with the regards to the scientific opinions for the protection of pigs, laying hens, broilers, calves and transport of animals. In the context of welfare assessment on the stunning and killing of animals, the scientific opinion covering the welfare of sheep and goats at slaughter was finalised in the period. In the context of F2F strategy and the End of Cage age initiative, two new mandates were received during the year specifically on the assessment and protection of dairy cattle and protection of ducks, geese, and quails.

https://www.xfactorsproject.eu/

¹¹ https://www.euphresco.net/

In addition, a public consultation was undertaken in April in order to support the development of a scientific opinion on the welfare of animals during transport in the EU; the consultation, launched early during the process, aimed at gathering any available data and information on the topic, as well as at obtaining stakeholders' views on whether the mandate and EFSA's interpretation of it cover relevant transport practices and areas of concern, and at collecting feedback on the practical obstacles. In total 31 comments were received from 6 Member States and stakeholders.

At the request of the special enquiry committee on the protection of animals during transport set up by the European Parliament (ANIT Committee), EFSA has been supporting the activities of the Committee by participating at public hearings and exchanges with rapporteurs MEPs. A mandate by the European Parliament was received in autumn to deliver a scientific opinion on AMR during animal transport, which will support upcoming work in the area of animal welfare and F2F strategy.

Chemical hazards

The "Report for 2019 on the results from the monitoring of veterinary medicinal product residues and other substances in live animals and animal products" was finalised and published, showing high rates of compliance with safety levels set by the European Union. A total of 671,642 samples were reported by Member States, Iceland and Norway, with a percentage of samples that exceeded maximum levels at 0.32%, a figure within the range of reported over the previous 10 years. The data are available on EFSA's curated repository Knowledge Junction.

The work on BPA further progressed: the draft opinion was endorsed by CEP Panel and proposes to considerably lower the tolerable daily intake (TDI) compared to EFSA's previous assessment in 2015, when a temporary TDI was set due to uncertainties and the need to fill data gaps was highlighted. A public consultation on the draft opinion was launched in December 2021, with the aim to finalise the opinion in 2022.

Biological hazards

In the area of biological hazard EFSA finalised a number of opinions higher than expected, since the mandate from the European Commission as regards specific maximum levels of cross-contamination for 24 antimicrobial



Figure 7. Defrosting food safely

active substances in non-target feed was split in 13 opinions according to the microbial classes. The assessments were carried out in collaboration with EMA.

EFSA has also finalised a new guidance to help food suppliers decide what information to give consumers about storing food and time limits for consumption, as a follow up of the tool developed already in 2020 to help food business operators decide when to apply the 'use by' or 'best before' date to their products. Once food packaging has been

opened, bacteria can be transferred to food by contaminated hands, surfaces, or equipment. Setting a time limit for consumption is complex, but the tool developed by EFSA's experts assists food suppliers in deciding whether it is appropriate to give consumers other instructions in addition to the 'use by' or 'best before' dates. The opinion also includes advice on good practices for defrosting food safely, for which an <u>infographic</u> was also developed and published on EFSA website.



Zoonoses, TSE and antimicrobial resistance monitoring

The European Union Summary Report on Antimicrobial Resistance in zoonotic and indicator bacteria from humans, animals and food in 2018/2019 was finalised as planned in collaboration with ECDC, and shows that a sizeable proportion of Salmonella and Campylobacter bacteria is still resistant to antibiotics commonly used in humans and animals; on the positive side, over the period 2015-2019, a decline in resistance to ampicillin and tetracyclines has been observed in Salmonella isolates from humans, and a decreasing trend has also been observed in the prevalence of extended-spectrum β -lactamase (ESBL)- producing E. coli in samples from food producing animals, while combined resistance to two critically important antimicrobials – fluoroquinolones and third generation cephalosporines in Salmonella and fluoroquinolones and macrolides in Campylobacter – remains low.

The "Third joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimicrobial resistance in bacteria from humans and food-producing animals in the EU/ EEA" was also finalised, in the spirit of the "One Health" approach, in collaboration with EMA and ECDC, and highlights that the use of antibiotics has overall decreased and is now lower in food-producing animals than in humans, which suggest that the measures taken at country level to reduce use are proving to be effective, despite the fact that the situation varies significantly by country and by antibiotic class.

EFSA also delivered the "European Union One Health 2020 Zoonoses Report", again in collaboration with ECDC, which highlights a drop in reported zoonotic diseases in humans and foodborne outbreaks; the drop is deemed to be related to the impact of the SARS-CoV-2 pandemic and the subsequent changes in health seeking behaviour, restrictions on travel and on events, the closing of restaurants, quarantine, lockdown, and other mitigation measures such as the use of masks, physical distancing and hand sanitisation.

Urgent response on biological hazards

Three joint EFSA-ECDC rapid outbreak assessments were carried out in 2021: on *Salmonella Enteritidis* infections presumably linked to consumption of frozen poultry products, on *Salmonella Braenderup* ST22 presumed to be linked to imported melons and on *Salmonella Enterica* serotypes linked to imported sesame-based products. In addition, EFSA delivered five Joint Notification Summaries (JNSs): *Salmonella* Enteritidis in bovine meat, *Listeria monocytogenes* in soft cheese, *Salmonella Mbandaka* and *Havana* in tahini, *Listeria monocytogenes* in smoked trout (2 JNSs).

Nutrition

In the area of Nutrition, EFSA finalised the scientific opinion on the Tolerable Upper Intake Level of dietary sugars, following an extensive literature screening (more than 30,000 publications), a public consultation for which more than 700 comments were received and a stakeholders' event held in September. The EFSA opinion concluded that intakes of added and free sugars should be as low as possible as part of a nutritionally adequate diet, which is in line with current recommendations; however, the scientific evidence did not allow to set a tolerable upper intake level for dietary sugars. An infographic and a plain-language summary were also published along the scientific opinion.

1.1.2. Regulated products

In the area of regulated products, EFSA received about 410 applications, just slightly above those received in 2020 (almost 400), and closed a total of 383 questions12 (381 through scientific outputs and technical reports and 2 through external reports), a result which is slightly below the plan of 405 questions (see Table 3 and

¹² The numbers reported here refer to the total of the questions in table 3: number of questions delivered for scientific outputs and technical reports and number of questions delivered for other publications.

Figure 10). Note that this is below the results of 2020 (424) and 2019 (546)13. It should also be noted that the number of applications received saw an increase in the first half of 2021, particularly right before the entry into application of the Transparency Regulation; this implied some difficulties in handling the intake phase.

Additional details on questions closed by Unit and food sector area can be found in Annex I Core business statistics (a) Questions closed in 2021.

Table 3. Activity and output indicators for SO1 — Regulated products evaluation

ACTIVITY - OUTPUT INDICATORS							
Regulated products evaluation							
Indicator	Executed 2020	Target 2021	Executed 2021	Status			
Number of questions delivered for scientific outputs and technical reports	422	400	381	O			
Number of questions delivered for 'other publications' (external reports, event reports)	2	5	2	0			
Number of questions in backlog in PRAS (Art. 12 only) delivered	33	2814	28 ¹⁵	O			
Proportion of scientific/technical questions adopted within deadline	76%	90%	75%	o			

¹³ The expected number of questions to be closed as of 2020 for regulated products has decreased compared to the previous years mainly as a result of a technical adjustment implemented to properly reflect the architecture of EFSA's processes.

¹⁴ 20 planned to be closed via Reasoned Opinions, 3 via Conclusions, 5 via Statements of EFSA.

¹⁵ 17 closed via Reasoned Opinions, 5 via Conclusions, 6 via Statements of EFSA.



Number of questions closed in the regulated products area (2021 actuals vs 2021 plan compared with 2020 and 2019 actuals)

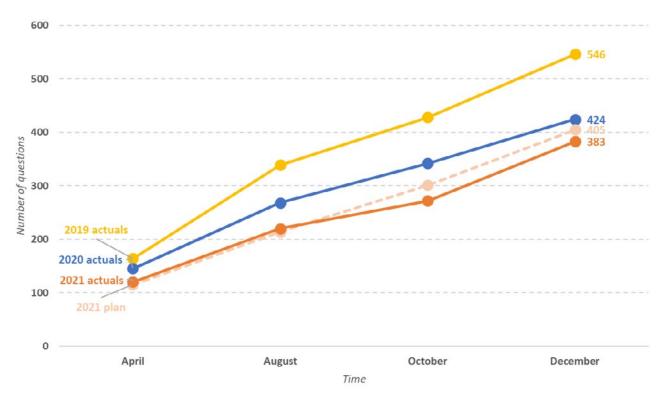


Figure 8. Number of questions closed in the Regulated Products area

In terms of **timeliness of adoption**, the index stood at 75%, below the target of 90% and below the results of the past two years (82.8% in 2019 and 76% in 2020).

The following achievements can be highlighted in the specific areas of work:

Novel foods

In the area of novel foods the number of submitted applications and notifications on traditional foods has seen an increase of about 45% compared to 2020; the number of questions closed has also increased by about 60% but is still below the planned target. In this respect, the effects of the SARSCoV-2 pandemic still play a role in delaying the process, but it should also be noted that the suboptimal quality of the information received from the applicants results in delaying the risk assessment process. In light of the large number of applications being received, a grant call is currently ongoing with the aim to secure Art .36 organization's support to the process.

Feed additives

In the area of feed additives applications, the number of questions closed is above the plan and slightly above that of 2020 (109 for 2020 vs 116 for 2021), confirming efficiency gains already observed in the past years, while also the number of submitted dossiers is above that of 2020 (more than 140 applications received in 2021, about +20% with respect to the previous year). The timeliness of adoption is however below target but stable compared to past years, due to the significant backlog and stock of ongoing dossiers that EFSA is

facing in this area. Despite the increased adoption rate, the backlog is reduced at a very slow pace, given the increased number of submitted applications.

Food ingredients and food contact materials

In the areas of food ingredients an under-execution can be observed with respect to flavourings completion of the evaluation, because of the postponement of the SC Guidance on Aneugenicity which implied a postponement of adoption of 19 question numbers. A lower number of questions closed with respect to the target is also observed for food additives re-evaluation, since the finalisation of the opinions on sweeteners had to be postponed because the need for newly generated experimental data on genotoxicity was identified for 9 out of the 15 substances under re-evaluation; a call for data was therefore launched in 2021. For what concerns food enzymes, the number of questions closed is slightly above the set target, and EFSA has also started to receive a higher number of new applications in the area.

With regards to food contact materials, EFSA has received an increased number of dossiers for recycling processes and this trend is expected to continue in the next years; the questions closed were well above the set target, which was possible thanks to the implementation of alean approach (including the grouping of similar dossiers).

Pesticides

In the pesticides area, the reduction of the MRL Art. 12 bulk evaluation reached the target in 2021, with 28 questions closed. An improved result was also reached for the MRL Art. 10 applications process, for which 52 questions were closed against a plan of 55 and against an execution of 48 questions closed in 2020. The timeliness of adoption however is low, which is due to the high complexity of applications, as well as to the switch of resources to other high priority activities agreed with DG SANTE, including tasks related to TR provisions implementation. It is however noted that, already as of 2020, corrective actions implemented after a lean project were applied to the MRL Art. applications, which helped to reduce by more than 50% the delays for reasoned opinions adopted after the DL and showed an increased number of opinions adopted within the legal DL for applications received as of 2020.

EFSA has also completed its assessments of 17 emergency authorisations granted by 11 EU Member States for the use of neonicotinoid-based insecticides on sugar beet in 2020 and 2021. EFSA has assessed the emergency authorisations using a protocol developed in 2017 and has concluded that in all 17 cases authorisation were justified, either because no alternative products or methods – chemical or non-chemical – were available or because there was a risk that the pest could become resistant to available alternative products. An information session to present the work carried out on the emergency authorisations was held in November 2021.

EFSA published the 2019 Annual Report on Pesticide Residues by its legal deadline. The data show that 96.1% of the overall 96,302 samples analysed fell below the maximum residue level (MRL) of pesticides. As part of this report, EFSA performs an acute (short-term) and chronic (long-term) dietary risk assessment; using the 2019 data, EFSA concluded that, according to current scientific knowledge, acute and chronic dietary exposure to pesticide residues is unlikely to pose concerns for consumer health.

1.1.3. Engagement with stakeholders

With interested parties

The EFSA Stakeholder Engagement Approach (SEA) registered good results in terms of feedback from its members on the effectiveness of its activities (Table 4); in the spirit of continuous improvement, it went through a review process which addressed the improvement requests put forward by the registered stakeholders. EFSA



organised a series of co-design workshops where stakeholders formulated specific enhancement proposals to develop a more flexible, targeted, topic-based and purpose-driven engagement approach, and clearer communication on how their input is considered by EFSA in its risk assessments. A blueprint for advancing the SEA was endorsed by the Management Board in October, to be rolled out as of January 2022. In addition, in 2021 EFSA finalised the Large-Scale Engagement (LSE) Project, which aimed at innovating the catalogue of EFSA's engagement methodologies and piloting new formats.

Table 4. Outcome indicators for SO1 – Increased engagement of stakeholders in scientific activities

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: Increased engageme	ent of stakeholders in scientific activities				
5 5	Survey feedback from SEA-registered members on the effectiveness of EFSA's stakeholder engagement activities	POSITIVA	90%	90%	•

In 2021, the pool of EFSA registered stakeholders counted 134 registered entities, in line with the forecast of 135 and up from the 124 entities registered at the end of 2020 (table 5). Their feedback on EFSA's engagement activities, gathered via a survey launched at year end, was very high at 96% (+3 p.p. y-on-y).

The 2021 Stakeholder Forum was held on 9 and 10 November, it attracted 50 representatives of EFSA's registered stakeholders, and focused on how EFSA's engagement with food chain stakeholders will evolve in the future. The first day covered the improvements to the Stakeholder Engagement Approach (SEA) including the new online stakeholder community platform for registered stakeholders. The second day was dedicated to the complexity of the ecosystem we are operating in and saw the participation of speakers from European Commission, the Joint Research Centre (JRC) and FAO.

A tailored-made engagement plan linked to the implementation of the TR was fully deployed in 2021, in close liaison with the EC DG SANTE. Activities were carried out via a Sounding board and technical groups on technical matters that were operating until mid-year. Since the entry into application of TR in March, the engagement process continued via dedicated Hypercare service, technical groups on IUCLID, trainings, webinars and targeted initiatives to users/applicants, notably linked to the new requirements and new digital tools in place. A detailed questions and answers document concerning the EFSA Practical Arrangements on pre-submission phase and public consultations and concerning transparency and confidentiality was prepared in close collaboration with EC DG SANTE.

Collaboration with all ecosystem actors is very important to ensure EFSA's continued relevance and preparedness to address present and future challenges and provide high-quality and timely scientific outputs. The new engagement approach will focus on efficient topic-based collaboration and support EFSA's scientists by bringing relevant information, data, and methodology from EFSA's ecosystem.

The commitment of EFSA in engaging its interested parties involves also the general public, with 99% of the requests received addressed within 15 working days (see Table 5). 1118 queries on general matters were processed in 2021, a number which has almost doubled compared to 2020 (543). At the end of January 2021, the new Connect.EFSA portal was launched, which provides a single access point for interactions with EFSA on general matters, regulated products, public access to documents (PAD) and human resources.

Table 5. Activity and outputs indicators for SO1 —Stakeholders' engagement

ACTIVITY - OUTPUT INDICATORS						
Communication and engagement						
Indicator	Executed 2020	Target 2021	Executed 2021	Status		
Number of stakeholder enquiries addressed within agreed deadlines	99%	97%	99%	O		
Percentage of positive feedback from engagement activities carried out with registered stakeholders	93%	90%	96%	O		
Total number of registered stakeholders	124	135	134	O		

In 2021, EFSA was expected to increase the number of public consultations launched, as part of the provisions of the Transparency Regulation. 106 public consultations were concluded in 2021, a marked increase compared to the 20 launched the year before but well below the expected 450 (Table 6).

Table 6. Activity and Output indicators for SO1 – Increased engagement of stakeholders in scientific activities

ACTIVITY - OUTPUT INDICATORS						
Communication and engagement						
Indicator	Executed 2020	Target 2021	Executed 2021	Status		
Number of public consultations on EFSA outputs	20	450	106	o		

The public consultations launched generated around 2900 comments from contributors. This is a result well below the target of 14,400, which can be explained by the lower-than-planned number of public consultations launched and also by the fact some type of public consultations, in particular the ones for notification of studies, are generating a limited number of comments, whilst more interest is observed in the consultations connected to the generic mandates.

Table 7. Outcome indicators for SO1 – Increased engagement of stakeholders in scientific activities

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: Increased engageme	ent of stakeholders in scientific activities				
	Number of contributions received — total and by stakeholder group	1,795 (2017)	14,400	2,924	0



With applicants

Regarding the efforts put in place by EFSA to support its applicants during the submission and risk assessment process, 136 support initiatives were organised in 2021, a figure in line with the annual target of 135 and higher than what registered in 2020 (123 support initiatives) (see Table 8), with the increase linked also to the entry into force of the Transparency Regulation on the 27th of March 2021. The service most frequently requested by applicants, as for past years, is the clarification teleconference during risk assessment, which covers 45%, followed by clarification teleconference during completeness check (25%).

Regulated products: webinar series to support applicants

Published: 20 May 2021

WEBINAR

Figure 9. Question closed in General Risk Assessment area

Until 2020, EFSA was measuring applicants'

satisfaction specifically on regulated products opinions, via a dedicated survey addressed to single applicants after the adoption of the output. The low response rate¹⁶ did not allow EFSA to consider the results obtained (see Table 8) as fully representative, and the metric the discontinued in 2021. The feedback from applicants remains an important element for EFSA, however, and it will be part of the new Performance Framework using a different typology of survey.

Table 8. Activity and output indicators for SO1 — Engagement with applicants

ACTIVITY - OUTPUT INDICATORS						
Regulated products evaluation						
Indicator	Executed 2020	Target 2021	Executed 2021	Status		
Number of service catalogue activities with applicants (meetings, webinars, info sessions etc.)	123	135	136	O		
Percentage of positive feedback on regulated products opinions from applicants	78%	54%	78% (2020)	o		

With the entry into application of the Transparency Regulation, EFSA fully implemented the electronic submission and handling of dossiers and established a temporary dedicated support for applicants and other external users on matters related to the submission of applications.

In the same spirit, EFSA also finalised the update and revision of several guidance documents for regulated products, including the EFSA's Catalogue of support initiatives during the life cycle of applications for regulated products. In addition, EFSA has also held a series of webinars on applications procedures and launched a LinkedIn group meant for applicants to remain updated on news and development and exchange knowledge and experience.

EFSA also held the annual roundtable with industry associations as online meeting on the 16th of June 2021. With 40 associations participating, the event also focused on the new requirements of the Transparency

Feedback based on 40 replies in 2020

Regulation. 1480 requests for information on regulated products matters were received and processed during the year, an increase of about 240% with respect to 2020 (436 requests received) with about 50% of the received requests related to the Transparency Regulation.

The KPIs related to the full availability of documentation relevant to EFSA's outputs could not be measured in 2021; however, EFSA started systematically implementing the proactive disclosure requirements set out in its Founding Regulation, as amended by the Transparency Regulation. As a result, currently all dossiers declared valid or admissible are made publicly available on the Open.EFSA platform, with the exception of confidential information as per Articles 38-39 of this Regulation.

Table 9. Outcome indicators for SO1 – Full availability of documentation relevant to EFSA's scientific outputs

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status	
Outcome: Full availability of documentation relevant to EFSA's scientific outputs						
Availability of documentation used in EFSA's scientific outputs		N/A	N/A	N/A	•	
	Proportion of EFSA's scientific outputs ¹⁷ providing direct access (links) to datasets and metadata	11.8% (2018)	50%	39% (2020)	0	

1.2. Enhanced outreach of communication

In the first quarter of 2021, EFSA finalised four reports aimed at supporting the development of a future EU-wide food safety *General Plan on Risk Communication* (GPRC) for EU food safety. This addresses the provision for an integrated framework for risk communication by EU food safety risk assessors and risk managers that was introduced by the Transparency Regulation. The GPRC aims at providing an assessment of risk communication theory and best practice to "support food safety authorities in Europe to better coordinate their respective risk communication tasks, and provide more consistent advice and information for the benefit of EU consumers and food safety stakeholders"

The four reports were developed jointly by EFSA, academic experts and partner organisations in the Member States:

- Scientific report of EFSA on Technical assistance in the field of risk communication
- Mapping the coordination and cooperation mechanisms of risk communication on feed/food safety in the EU
- Catalogue of Communication Tools and Dissemination Guidelines: Benchmarking current practice in EU and Members State bodies
- Engagement Toolkit: Methods, tips and best practices to design effective participatory processes

EFSA has started reviewing the rich array of findings coming from the reports with a view to improving our working practices and to updating our best practice Risk Communication Handbook, related materials and training programmes.

¹⁷ Scientific outputs published in EFSA Journal, excluding outputs linked to questions types public consultation, assistance (because they are merged in the main output, so it would be a duplication), Art. 31 when in combination with Unit PRES and Food sector area MRL Art. 10 and MRL Art 12, external scientific report and event report. The measurement is done through Knowledge Junction unique uploaded dois (digital object identifiers).



EFSA reports set to inspire future risk communications in Europe

Published: 29 April 2021

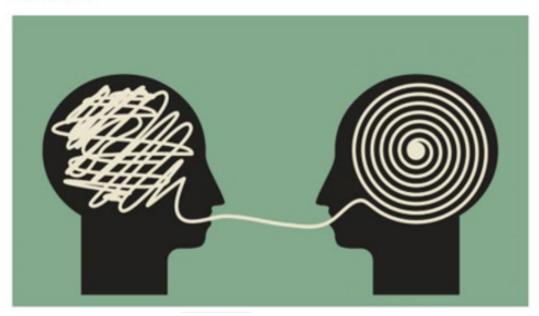


Figure 10. EFSA publishes 4 reports on the future of Risk Communication in Europe

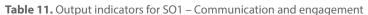
No comprehensive bi-annual satisfaction survey was launched in 2021, as it was decided to postpone it to align with the end of the EFSA Strategy. The most recent results are shown in the first row of table 10.

Table 10. Intermediary impact indicators for SO1 – Satisfaction on communication tools and materials and media coverage

КРІ	Baseline	Target 2021	Executed 2021	Status
Intermediary impact: Increased satisfaction of stakeholders regarding EFSA's scientific outputs (for Commission/Member State managers and stakeholders) and the scientific assessment process				
User satisfaction rating of communication tools and materials	76.9% (2017)	N/A in 2021	73.6% (2019)	0
Impact of media coverage (EFSA's coverage in the media, including the favourability of articles)	18 <i>(2017)</i>	16	16	O

Overall,2021 was a positive year for EFSA in the media, as demonstrated by the **media coverage index** (measuring the tone of media coverage mentioning EFSA). This is calculated by analysing articles that mentioned EFSA and its work in 2021. The index score remained in the neutral/slightly positive area for 2021 as per the target (Table 10).

In 2021 EFSA managed to address 99% of media enquiries in a timely manner, above the target and the level of 2020 execution, both 95% (table 11).



ACTIVITY - OUTPUT INDICATORS						
Communication and engagement						
Indicator	Executed 2020	Target 2021	Executed 2021	Status		
Number of media enquiries addressed within agreed deadlines	95%	95%	99%	O		

In 2020 EFSA launched a wide-ranging communication campaign in nine South-Eastern European countries to raise awareness about African Swine Fever (ASF). The campaign, which was carried out with competent authorities and interested parties throughout the region, was designed to provide hunters, farmers, and travellers with practical advice about how to stop the spread of the disease. The contribution of IPA competent authorities and stakeholders in the region were key success factor for the campaign results.

In 2021 the campaign was extended to an additional nine countries (Bulgaria, Czechia, Lithuania, Latvia, Poland, Slovakia, Estonia, Hungary, and Romania), aiming primarily at farmers.

The campaign produced a suite of communication materials (all available through a dedicated website¹⁸) that were disseminated simultaneously to target audiences using a combination of online, offline, direct, and indirect channels.

EFSA was awarded the prestigious EU Ombudsman award for Good Administration ("Excellence in Communication" category) in 2021 for its campaign on ASE

"Last year we decided to take our science out into the field and show that EFSA is committed to helping farmers and others who are living in the shadow of this terrible disease. The cam-paign was well received in the first wave of countries and now we are going further afield with our message to detect, prevent and report."

Nikolaus Kriz, Head of EFSA's Animal and Plant Health Unit

On 7th June 2021, EFSA joined the celebrations for the third World Food Safety Day (WFS) with the launch of its **#EUChooseSafeFood** communication campaign, which lasted the whole summer. The campaign aimed to raise awareness about the science behind our food and tell the story of the scientists who work to make sure it's safe. Its overall goal was to encourage citizens to think critically about their everyday food choices.



Figure 11. #EUChooseSafeFood communication campaign

The campaign was a joint effort between EFSA and the Member States, represented by its Communications Experts Network. Media and social media activities were carried out in six Member States, including partnerships with print and online publications and social media influencers. Results from the campaign were positive overall. For example, 32% of those who came into contact the with communication materials were able to recall the

campaign messages (exceeding the target of 1520%) and 10% of people registered an increase in awareness of food safety as a result of being exposed to the campaign (against a target of five to seven %).

¹⁸ https://www.efsa.europa.eu/en/StopASF#/



1.2.1. Communication of findings

The perceived usefulness of the EFSA Journal remained very high (98% according to the survey run by EFSA Journal among its users), in line with the results registered in the past two years.

Table 12. Intermediary impact indicators for SO1

КРІ		Baseline	Target 2021	Executed 2024	Status		
Intermediary impact: Increased satisfaction of stakeholders regarding EFSA's scientific outputs (for Commission/Member State risk managers and stakeholders) and the scientific assessment process							
User satisfaction rating of communication tools and materials	EFSA Journal	85% (2016)	> 80%	98%	0		

Since the full implementation of its enhanced publishing model, EFSA has increased its ability to publish its scientific outputs in a timely manner, as also shown in the graph Figure 11.

Progression of timeliness of publication in the EFSA Journal (2017-2021)

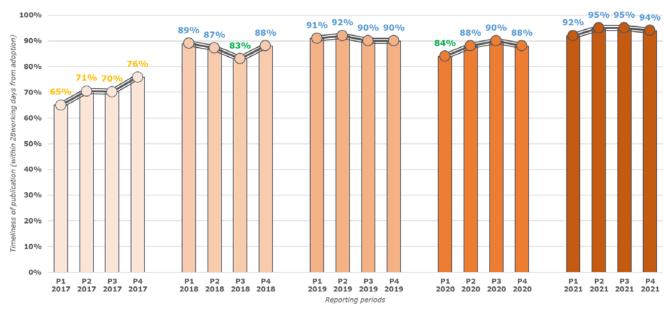


Figure 12. Progression of timeliness of publication in the EFSA Journal (2017-2021)

In 2021, the publication of scientific outputs in the EFSA Journal took place within 28 working days from the day of the adoption in 94% of the cases, a result considerably higher than the target of 82.5% set for the year and higher also that the already very positive results achieved since 2018 (see also Table 13).

Table 13. Activity and outputs indicators for SO1 — Communication

ACTIVITY - OUTPUT INDICATORS							
Communication and engagement							
Indicator	Executed 2020	Target 2021	Executed 2021	Status			
Proportion of scientific outputs delivered within 28 working days of adoption (%)	88%	83%	94%	o			

The positive findings in the survey are translated into **increased visibility of EFSA's scientific outputs**. In 2021, the EFSA Journal registered more than 4 million views, a figure higher than the planned target of 3.8 million and higher than the figure registered in 2020 (3.8 million) and 2019 (3.5 million). Similar results were also registered for the number of downloads from the EFSA Journal (4 million versus a target of 3.5 million and a 2020 performance of 3.5 million) and for the number of citations, which reached a cumulative number of almost 65,000 (against a target of 58,000 and a 2020 performance of 50,738, see Table 14).

Table 14. Outcome indicators for SO1 – Enhanced outreach of communication – EFSA Journal

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: Enhanced outreach of co	ommunication				
	Access	3,162,974 (2018)	3,800,317	4,158,904	O
Impact, visibility and discoverability of EFSA's scientific	Downloads	2,306,925 (2018)	3,400,000	4,088,675	O
outputs	Citations	18,347 (2018)	58,000	64,121	O

Progression of number of citations of EJ articles (2020-2021)

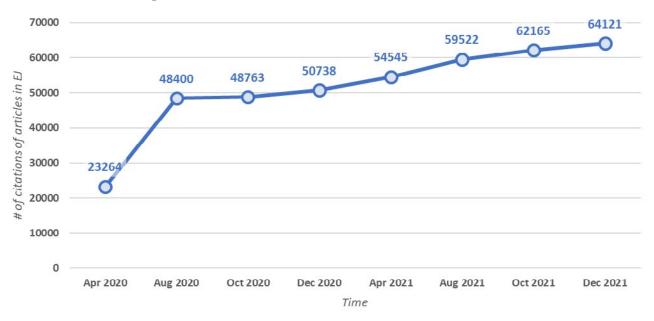


Figure 13. Progression of number of citations of EJ articles (2020-2021)



These positive results are also linked to the inclusion of the EFSA Journal in PubMed since April 2020, which, alongside acceptance for indexing in Scopus and Expanded Science Citation Index that took place in 2019, has created a good foundation for improving the visibility of EFSA's outputs (graph 13).

1.2.2. Social media presence

EFSA's **social media presence** achieved good results throughout 2021. Overall, the number of followers of the EFSA's social media accounts grew by around 25% compared to the previous year, reaching almost 200,000 followers in total (up from almost 160,000 in 2020). This increase led to a surge of the number of interactions through social media registered in 2021 (104,064), surpassing the planned target by 50% and registering a marked increase compared to 2020(89,20).

The figure on the traffic to EFSA web content promoted from social media is not available, as the measurement was stopped due to a change in the tool. The last available result was gathered in August 2020 (Table 15).

Table 15. Outcome indicators for SO1 – Enhanced outreach of communication – Social media

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: Enhanced outreach of	communication				
Social media effectiveness	Increase followers from social media platforms	40,742 (2016)	173,235	198,264	0
	Social interactions	14,881 <i>(2016)</i>	66,400	104,064	0
	Traffic to EFSA web content from social media	63,464 (2016)	73,404	71,102 ¹⁹ (2020)	0

Finally, in terms of online presence, EFSA closed the year with lower-than-planned results in terms of visits to the EFSA website (see Table 16). The reason for this result is that in 2020 EFSA moved to a new IT system to ensure compliance with the General Data Protection Regulation (EU) 2016/679 (GDPR), which tracks visits only after the user's explicit consent. However, the figures registered at year end are in line with the internal forecast calculated in April 2021, which was for 728,519 sessions.

The indicator on the number of subscribers to online subscription products (such as newsletters and alerts) surpassed the planned target at year-end (almost 25,000 versus a target of almost 20,000).

Table 16. Outcome indicators for SO1 – Enhanced outreach of communication – online products

КРІ	Indicator	Baseline	Target 2021	arget 2021 Executed 2021				
Outcome: Enhanced outreach of communication								
Traffic to EFSA's web content (v sessions	web metrics): number of	3,184,611 <i>(2016)</i>	3,875,045	735,467	O			
Number of subscribers to onlir (newsletter and alerts)	ne subscription products	33,934 (2016)	19,677	24,920	0			

¹⁹ Actual reported in from 31/08/2020

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

EFSA aims to enhance the quality of its outputs by giving direct access to data and promoting the development of collaborative platforms in Europe and internationally, as well as fostering data re-use and innovation. EFSA advocates for openness by working with data providers and organisations and adopting open data concepts and standards, by gaining better access to, and making better use of, data from a wider evidence base that, where possible, follows international quality standards. In doing so, exploring the use of innovative sources of information, such as social media. By the end of 2020 more than 200 million chemical monitoring data were publicly accessible on the IPCHEM (European commission Information Platform for Chemical Monitoring) portal.

Adopting an open data approach has been a key objective of EFSA's 2020 strategy (SO2). Through a partnership with the JRC and DG ENV on the IPCHEM portal, EFSA greatly improved the discoverability of European chemical monitoring data for re-use by interested parties with some 200 million analytical records in the public domain on the IPCHEM portal. EFSA will expand its data coverage on IPCHEM through an automated publication process that was co-developed by EFSA and the JRC.

EUR 6.66 M budget 33% 40% 20 FTEs 38% 44%

Overall 2021 performance in Strategic Objective 2

Figure 14. Overall 2021 performance in Strategic Objective 2

Looking at the overall performance of the KPIs in the Strategy Objective 2, 55% of the measured indicators reached or surpassed their initial targets, a performance below what was registered in 2020 and in 2019 (64% in both cases, as this area was only marginally impacted by the effects of the SARS-CoV-2 outbreak). This decrease is mainly due to erroneous planning for what concerns the number of scientific questions to be closed, which was higher than it should have been.

In terms of input invested in SO2, in 2021 20 FTEs were allocated to this area of work, four less than in 2020 (24 FTEs). In terms of budget, \in 6.66 million were invested in 2021, higher than the plan of \in 6.52 million and also higher than the 2020's investment of \in 4.68 million. This difference is due to the increased investments



in development activities aimed at upgrading EFSA's data management capabilities, targeting a coherent, scalable integrated architecture to store/access any type of data and improvement on the delivery of data services, as well as of other commitments made under the Information Management Programme.

No new data are available for what concerns the satisfaction of EFSA's interested parties in this area, as EFSA's comprehensive bi-annual survey, planned to be launched in 2021, was postponed to 2022 (see Table 17 for 2019's results).

Table 17. Intermediary impact indicators for SO2

КРІ		Baseline	Target 2021	Executed 2021	Status		
Intermediary impact: Increased satisfaction of stakeholders regarding EFSA's evidence management services and fostered innovative reuse of data							
Satisfaction via feedback surveys: poimprovement (with regards to follow	57.8% (2017)	N/A in 2021	54.8% (2019)	0			
Use and reuse of EFSA's accessible data and evidence	Data/evidence reused by stakeholders via citation/ statistics	N/A	N/A	N/A	0		

2.1. Improved access to data, wider data coverage and support to data collections

EFSA is sharing its evidence in different domains, mainly through the **Scientific Data Warehouse** and the **Knowledge Junction platform**, the European Commission IPCHEM Portal, and the Global Portal to Information on Chemical Substances (eChemPortal).

In 2021, no measurement of the number of registered users in the **Scientific Data Warehouse** was carried out, as the metric was discontinued since no significant trend emerged in the past years. However, the figure from 2020 showed that there were 1,125 registered users, around 30% more of what EFSA was targeting (Table 18).

A boost to wider data coverage was partially achieved from the work carried out in the context of the EFSA's EU Menu project (2011-2023), which aims at gathering high-quality, harmonised data from Member States

Published date: 3 March 2021

What and how much do Europeans eat and drink? Food consumption data are essential for assessing how exposed people are to potential risks in the food chain

RISK ASSESSMENT

RISK ASSESSMENT

CONTAMINATION

European Food Safety Authority

presents

understanding

SCIENCE

CAMPYLOBRATER

Figure 15 Food consumption data

on food consumption, covering all age groups from three months to 74 years.

EFSA has launched a call to update the guidance on the EU menu methodology that was previously endorsed by the EFSA Network on Food Consumption Data which consists of representatives from EU institutions responsible for the collection of dietary data.

In 2021, the DAMA project increased the security and the performance of the EFSA Data Analytics applications (based on SAS and Microstrategy), already moved to the Cloud in 2020. In line with the EFSA 2027 strategic roadmap, the project for the implementation of the new EFSA Data Science platform (DAMA2) was started in the last quarter.

Also the KPI connected to the usage of the **Knowledge**

Junction platform (a curated, open repository for the exchange of evidence and supporting materials used in food and feed safety risk assessments) was not measured in 2021, since the Transparency Regulation has established that EFSA has a legal obligation to publish data used in its assessments on the dissemination portal. Therefore, EFSA will re-evaluate the value of trying to reach incremental targets for the number of

digital objects. The latest available measurement, carried out in December 2020, was showing that 397 digital objects (evidence) were uploaded to the platform.

Table 18. Outcome indicators for SO2 – Wider data coverage

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status	
Outcome: Wider data coverage						
User statistics from the da	ta warehouse	421 (2017)	N/A in 2021	1,125 (2020)	O	
Number of digital object repository	ts (evidence) uploaded to EFSA's open	500 (2017)	N/A in 2021	397 (2020)	o	

Regarding the efforts in improving the accessibility of its data, EFSA published 9 publicly accessible data collections with no data aggregation from EFSA, in line with the target of 9, whilst the number of data collections dashboards/aggregates was not measured in 2021, as the indicator was not considered strategic anymore in the review carried out last year (Table 19). Regarding the metric on the timeliness on data quality, the result was 93% (against a target of 90% and a 2020 result of 80%), showing a very good performance in terms of timely submission and confirmation of data records in the scientific data warehouse (Table 19).

Table 19. Outcome indicators for SO2 - Improved access to data & Improved quality of data

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status		
Outcome: Improved acco	Outcome: Improved access to data						
Data accessibility index	Number of publicly accessible data collections published with no data aggregation from EFSA	1 (2016)	9	9	0		
·	Number of data collection dashboards/aggregates published	11 <i>(2017)</i>	N/A in 2021	20 (2020)	o		
Outcome: Improved quality of data							
Data quality index		46% (2018)	90%	93%	O		

To improve its data management architecture, in 2021 EFSA carried out the implementation of the Transparency Regulation's security requirements, as well as proceeded on upgrading some of the tools used for data analysis.

Finally, the assessment done by EFSA on its **data interoperability capabilities** (using the EIF/IMM index²⁰) was not carried out in 2021, hence the figure referring to 2020 is reported (see Table 20).

²⁰ European Interoperability framework for European public services/Interoperability maturity model. The index was drafted based on the European Interoperability Framework recommendations developed by the ISA2 programme (interoperability solutions for public administrations, businesses, and citizens). The index was calculated averaging the score registered by selected projects in a set of dimensions. The EIF/IMM index has 5 stages of maturity (1Initial, 2Managed, 3Defined, 4Quantitatively Managed, and 5Optimising)



Table 20. Outcome indicators for SO2 - Increased standardisation and interoperability of data

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status	
Outcome: Increased standardisation and interoperability of data						
Share of regulated produc	t areas covered by structured data	0	N/A	N/A	O	
Increased maturity data in	nteroperability - EIF/IMM index	1.3 (2018)	3.1	2.7 (2020)	O	

In terms of related EFSA scientific production, the number of questions closed in SO2 was 9, below the set target (table 21); the discrepancy refers mainly to the SIGMA project, for which the plan of questions to be closed was likely overestimated.

In 2021 the SIGMA project however still delivered on time all planned objectives. Among those achievements, the most important are: (i) the adoption by EFSA of a new set of data standards to collect livestock data; (ii) the tailoring of the SSD2²¹ to the needs of the surveillance activities conducted on animals; (iii) the development of a web application for the automated translation and standardisation of the national data; (iv) the realisation of a validation dashboard for the data providers. The new approach for collecting data was validated in occasion of the African Swine Fever data collection, proving to be able to gather data of higher quality and with higher standards and level of detail. The SIGMA approach is now being run in process mode and has proven to be completely sustainable.

EFSA also finalised a statement on the "Requirements for the whole genome sequencing and analysis for micro-organisms". Given that, in some regulated products areas, the use of whole genome sequence-based data has been established as a requirement for the risk assessment, this document provides recommendations to applicants on how to describe the process and results which should be provided to the risk assessor in the context of an application for market authorisation of a regulated product. Indications are given on how to perform WGS and the quality criteria/thresholds that should be reached as well as the data and relevant information that need to be sent along whenever such kind of data are required.

The timeliness of adoption for Strategic Objective 2 was on time as all the questions closed did comply with the agreed deadline. The number of new (dietary exposure) tools developed, instead, was one, against a target of 2, due to delays in one of the tools initially planned to be developed (on the feed enzymes intake model - FEIM).

Table 21. Activity and output indicators for SO2

ACTIVITY - OUTPUT INDICATORS							
Indicator	Executed 2020	Target 2021	Executed 2021	Status			
Number of questions delivered for scientific outputs and technical reports	9	8	5	O			
Number of questions delivered for 'other publications' (external reports, event reports)	6	18	4	o			
Proportion of scientific/technical questions adopted within deadline	100%	100%	100%	O			
Number of new tools	3	2	1	O			

²¹ Standard sample description, version 2

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

In the area of capacity building and capacity sharing EFSA has two Operational Objectives under Strategic objective 3, namely to:

- a. Strengthen capacity building and capacity sharing and foster growth of the RA community with international organisations
- b. Review and further develop EFSA's scientific assessment model

To fulfil its objectives in this area, EFSA works towards setting up cooperation initiatives that make the best use of expertise for scientific assessment through a partnership between EFSA staff, scientific experts, Member States, and international organisations. EFSA invests in competence development and capability transfer, common programming, and work-sharing to grow EU and international expertise, thus increasing the EU's scientific assessment capacity and efficiency. EFSA is taking stock of best practices internally and elsewhere (other EU agencies and international bodies), and optimises its workforce model (tasks, roles and working methods), making the best possible use of available capacities and getting timely access to the necessary expertise. EFSA is strengthening multi-and inter-disciplinary working, and harmonisation and exchanges across different areas/panels, while exploring innovative ways of increasing risk assessment capacity, such as via crowdsourcing and cognitive computing. Parallel to these, EFSA is advancing on discussions with the Member States (via the Advisory Forum) and EU Agencies to identify ways that will further expand scientific cooperation under partnership schemes and establish those as an effective, trusted, and sustainable way to perform risk assessment.

Overall 2021 performance in Strategic Objective 3

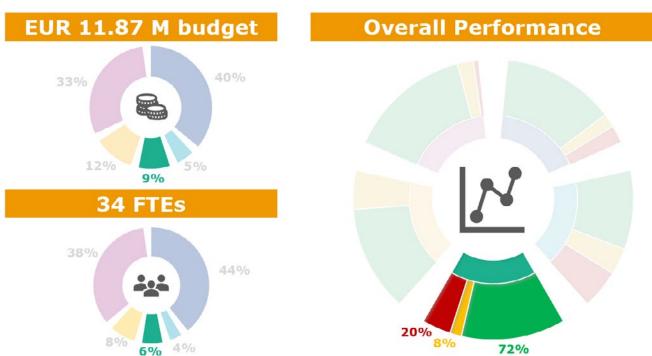


Figure 16. Overall 2021 performance in Strategic Objective 3

Looking at the overall performance of the KPIs in the Strategy Objective 3, 72% of the measured indicators reached or surpassed their initial targets, a performance slightly lower than the result registered in 2020 (76%).



In terms of input invested in SO3, 34 FTEs were allocated to this Strategic Objective in 2021, an increase compared to the 31 FTEs allocated in 2020, while the budget invested increased to € 11.87 million (from € 8.91 million in 2020), due to EFSA's increased focus in cooperation and capacity building.

No new data are available for what concerns the satisfaction of EFSA's interested parties in this area, as EFSA's comprehensive bi-annual survey, planned to be launched in 2021, was postponed to 2022 (see Table 22 for the most recent results from 2019).

Table 22. Intermediary impact indicators for SO3 – Satisfaction for capacity building and sharing of risk assessment capacity

КРІ		Baseline	Target 2021	Executed 2021	Status		
Intermediary impact: Increased satisfaction of MS, EU, and international partners with regards to the building and sharing of risk assessment capacity and a knowledge community at organisational and individual level, in general and via specific tools (e.g. grants)							
Satisfaction — general satisfaction with and usefulness of joint outputs		56.9% (2017)	N/A in 2021	70.9% (2019)	O		
— via feedback surveys: positive and relative qualitative improvement (with regards to follow-up actions)		72.0% (2017)	N/A in 2021	58.8% (2019)	<u></u>		

3.1. Strengthen capacity building and capacity sharing

Cooperation activities allow to make the best possible use of the expertise for scientific assessment available in the EU and worldwide and, in the area of **cooperation with the Member States**, the work with the Advisory Forum and the Focal Points is instrumental in the achievement of these results.



In 2021, four Advisory Forum meetings were held, all virtually to comply with the restrictions linked to the ongoing SARS-CoV-2 pandemic and in line with a multiannual rolling plan including contributions from MSs, EU Agencies and EC services. Member States proactively presented initiatives led by national authorities and exchanged information on planned risk assessment mandates in an effort to identify areas for collaboration. During these four meetings participants regularly discussed the progress made by EFSA in implementing the provisions of the Transparency Regulation, as well as opportunities for long-term partnerships under broad themes such as Healthy Diets from Sustainable Food Systems, the Chemicals Strategy for Sustainability and the "One Substance - One Assessment" approach, and European Partnerships under Horizon Europe.

Overall, EFSA carried out 103 MS cooperation activities in 2021, a result that is well above the yearly target (set at 50, Table 23), as some of the activities postponed in 2020 due to the pandemic were carried out in 2021, and MS reported a higher number of cooperation activities.

Table 23. Activity and output indicators for SO3 – EU cooperation activities

ACTIVITY - OUTPUT INDICATORS				
Indicator Executed Target Executed St				
Number of MS cooperation activities (network meetings, national FP events/workshops)	74	50	103	O

In the context of the participation of MS organisations to the implementation of EFSA's work programme, the results of the **outreach of grants and procurements supporting publications** exceeded the set targets in terms of access to publications, downloads, and citation index (Table 24). This outcome suggests the interest of the scientific community in the outputs of EFSA's projects and initiatives developed with contractors or Art. 36 List organisations, as EFSA's grants beneficiaries.

Table 24. Intermediary impact indicators for SO3 – Satisfaction for capacity building and sharing of risk assessment capacity – Outreach of reports

	КРІ	Baseline	Target 2021	Executed 2021	Status	
Intermediary impact: Increased satisfaction of MS, EU, and international partners with regard to the building and sharing of risk assessment capacity and a knowledge community at organisational and individual level, in general and via specific tools (e.g. grants)						
	Number of page visits (visibility)	213,048 <i>(2018)</i>	285,500	297,300	O	
Outreach of supporting publications on grants and procurements	Number of downloads (usage)	201,251 (2018)	267,500	283,278	o	
procurements	Number of citations (impact)	2.47 (2018)	3.65	4.1	O	

The **application rate for EFSA's open calls** was 3.1 applications/call on average, a result below the target of more than 4 applications/call. Similarly, also the index that monitors the absolute number of **Art. 36 organisations**²² that **applied to EFSA's grants** registered a deviation compared to the target (70 organisations, against a target of 90, Table 25). This divergence is largely due to the highly specialised scientific nature of some of the calls in 2021 which naturally reduced the potential pool of applicants to only those with the required expertise in those specific sectors, and not including any longer UK organisations. The applications/call on average would also be reduced where organisations have chosen, or have been encouraged, to apply in consortium. In addition, the entry into force of the withdrawal agreement of UK from the EU resulted in an overall reduction of organisations on the Art. 36 list, with UK entities no longer being eligible to receive EFSA grants. This also resulted in the pool of potential applicants for EFSA grants being reduced.

During 2021, 18 new competent organisations from 12 different countries were designated by their MS and included in the "Article 36 List", bringing the total to 308 competent organisations from 29 countries (EU27, Norway and Iceland), covering all the 13 main competence fields of EFSA's remit with over 2,100 contact person details per competences.

Following the survey to Article 36 competent organisations in Q4 2020, a detailed action plan was implemented during 2021. Improvements were made to the timing and level of detail provided in the procurement and grants plan which is shared with MSs to facilitate strategic alignment of EFSA and Article 36 activities. In Q4 2021, a live webinar on science outsourcing opportunities and tools was also organised by the outsourcing task force to improve dissemination of information about forthcoming outsourcing opportunities. A thorough

²² Article 36 of EFSA's Founding Regulation calls for promoting the European networking of organisations operating in the fields within EFSA's mission. To this purpose, Member States can designate their organisations for inclusion in the List, which is drawn up by EFSA's Management Board. Organisations included on the List may assist EFSA in its mission, individually or in networks.



review was undertaken of the documents necessary to apply for grant calls, with improvements and leanings made in order to reduce the administrative burden for grant applicants. A leaner application process will also be facilitated by onboarding with the e-grants tool of the Commission in 2022, for which EFSA carried out a feasibility study and initial onboarding meetings with DG-DIGIT in 2021.

Table 25. Outcome indicators for SO3 - Building and sharing capacity within the risk assessment community at organisational level

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: Building and sl	naring capacity within the risk assessmen	nt community at	organisational le	evel	
Participation of MS organisations to EFSA's	Application rate for EFSA's open calls	2.15 (2017)	> 4	3.1	0
work programme (science grants and procurement)	Number of Article 36 organisations applying for EFSA grants	84 (2017)	93	70	0

In parallel, for what concerns the metrics monitoring potential duplications/divergences and the needed follow-up actions, they are fully on track as no cases were recorded in 2021. -The fact that 24 Member States were actively sharing their risk assessment plans (table 26), confirming the already positive outcome registered in 2019 and 2020, contributes to this result. In addition, also three PreAccession countries and the United Kingdom shared their risk assessment plans with EFSA.

Table 26. Intermediary impact indicators for SO3 – Increased efficiency of risk assessment at EU and international level

	КРІ	Baseline	Target 2021	Executed 2021	Status
Intermediary impact: Increased	d efficiency at European and internation	al level			
Identification of potential	Number of MS active in sharing risk assessment information	25 (2016)	25	24	0
incidents of duplication and divergence and resolution of issues when identified within	Potential duplication identified	100%	100%	100%	o
	before the adoption of an opinion	100%	100%	100%	o
of a database for sharing MS RA activities)	Follow-up actions within 10 days of identification of potential duplication/divergence	100%	100%	100%	o

The results of the indicators in the EU **risk-assessment agenda take-up** index are generally positive, with all the indicators meeting or exceeding their targets. The only exception was the "Number of joint projects awarded", which registered a deviation compared to the plan (4 vs 6) due to the fact that joint projects have progressively phased out as a result of the end of the cycle of visits of the Executive Director to Member States and as well possible ideas for thematic grants for 2021 being taken up under other types of projects and grant forms.

Table 27. Outcomes indicators for SO3 – Risk assessment agenda take-up

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status			
Outcome: Building and sl	Outcome: Building and sharing capacity within the risk assessment community at organisational level							
	Number of joint projects	13 <i>(2017)</i>	6	4	o			
	Number of priority areas covered	8 (2017)	2	2	o			
Risk assessment agenda take-up index	Number of partners (Member States) in joint projects	15 <i>(2017)</i>	8	11	O			
	Number of partners (other than Member States) in joint projects	29 (2017)	8	14	O			
	Number of projects non funded primarily by EFSA	0 (2017)	4	4	©			

In the area of **international cooperation**, EFSA exceeded the set target in terms of cooperation activities with organisations such as the WHO, FAO, IARC and the OECD, and risk assessments bodies from third countries (68 vs a target of 43, Table 28).

These figures highlight the efforts from EFSA, in alignment with DG SANTE, to continue building on a structured exchange with different international organisations and organisations in non-EU countries to align on data accessibility and sharing, methodology, expertise and engagement and communication.

In that context, on 9 December 2021 EFSA and the Scientific Research Centre of Agriculture (SRCA) of Georgia co-organised a workshop "ONE-Health Regional Workshop for East ENP countries". The workshop gathered around 40 participants from six East-ENP countries (Armenia, Azerbaijan, Belarus, Georgia, Moldova, and Ukraine) and additional invited speakers from Med-Vet-Net Association (MVNA), National Sanitary Veterinary and Food Safety Authority of Romania and Istituto Superiore di Sanita, Italy.

Among the most important activities carried out in this area was the work to inform international partners on the new Transparency Regulation and its impact on working relationships established through a variety of formal agreements with partners across the world (i.e. Exchange of Letters, Memoranda of Cooperation, Memoranda of Understanding). The TR might impact on these agreements so finding opportunities to inform partners was a necessary exercise. Furthermore, EFSA maintained regular contact with international partners and multilateral organisations on a variety of additional topics through various fora (such as cluster groups, bilateral meetings, workshops, trainings etc). EFSA's thinking on (virtual) staff exchanges was also shared in a number of meetings. Discussions continued during 2021 on several new potential agreements. However, no new cooperation agreements with international and third country organisations were signed in 2021, against an initial target of two, since the document template used as a basis for negotiating such agreements had to be adapted to reflect the changes that the Transparency Regulation introduced into EFSA's Founding Regulation, e.g., with regards to the handling of confidential information. In addition, EFSA initiated the review of existing agreements that will require amendments.



Table 28. Activity and output indicators for SO3 – International cooperation activities

ACTIVITY - OUTPUT INDICATORS					
Indicator	Executed 2020	Target 2021	Executed 2021	Status	
Number of international cooperation activities (meetings, events, missions)	59	43	68	O	
Number of cooperation agreements with international and third-country organisations	0	2	0	O	

EFSA further developed awareness and understanding of its role and outputs at the EU Pre-Accession (IPA) beneficiaries' level and enhanced the credibility of the scientific basis for European measures taken in the areas covered by EFSA's remit.

The activities in 2021 focused on areas where the EC and EFSA have special interest, such as improving crisis preparedness capacity, animal health preparedness and animal welfare, areas which the National Food Authorities in the IPA beneficiaries concerned have already indicated as a priority for a collaborative and transdisciplinary (One Health) approach. The focus has also been on building further IPA's risk communication and assessment capacity; implementation of innovative technology to foster knowledge sharing within the digital ecosystem community; harmonisation with the EU/EFSA methodologies and standards; collaboration in data sharing and reporting opportunities and initiatives, enhancing the visibility of EFSA in the IPA beneficiaries. The contribution of IPA countries and local stakeholders were a key success factor of EFSA ASF campaign in those countries. IPA representatives have been participating in the Advisory Forum, Focal Points, Autumn Summer School, and scientific expert meetings.

All these initiatives led to 35 joint activities (e.g. joint projects, staff exchanges, etc) with international partners were carried out in 2021, in line with the plan of 34 but below the performance in 2020 (47) (Table 29).

Table 29. Outcomes indicators for SO3 – Risk assessment agenda take up

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status		
Outcome: Building and sh	Dutcome: Building and sharing capacity within the risk assessment community at organisational level						
	ties (staff exchange, joint projects/ ational partners under cooperation		34	35	0		

Strengthening cooperation with EU sister agencies

EFSA has continued to work together with the ENVI Agencies (ECDC, ECHA, EEA and EMA) at many different levels and activities, ranging from cooperation on the preparation of scientific outputs (such as the EU One Health Zoonoses report prepared in cooperation with ECDC or the JIACRA III²³ prepared together with ECDC and EMA), to support in preparedness activities (including but not limited to work for the identification of potential emerging risks) and sharing views and best practises in areas of common interest.

A Senior Management workshop between EFSA and ECHA took place in 2021, looking at the developments around the EC's Chemicals Strategy for Sustainability and exploring areas for further cooperation.

²³ Joint inter-agency report on integrated analysis of consumption of antimicrobial agents and occurrence of antimi-crobial resistance in bacteria from humans and food-producing animals in the EU/EEA

EFSA and the ENVI Agencies continued the practice of consulting each other on their work programmes. This allows the Agencies to identify synergies at an early stage.

Cooperation has also been established in the area of joint procurement. In 2021, out of a total of 18 interagency procurement calls, EFSA led 5 of those on topics of common interest.

In 2021, EFSA, the ENVI Agencies and the JRC piloted an inter-service newsletter, featuring news on scientific outputs, initiatives, training opportunities and calls, aiming at further inspiring the culture of cross-organisation cooperation across their staff. EFSA has also worked closely together with ECDC, ECHA, EEA, EMA and the JRC to shape the content of the ONE – Health, Environment, Society Conference, which will take place in June 2022.

Concerning the activities in relation to the **research agenda** take-up, during the year EFSA was involved in 30 projects at EU and international level, a figure which is above the target of 24 set for 2021 (see Table 30) and slightly lower than the figure from 2020. One of these projects (the OneHealth European Joint Programme) has nine daughter projects addressing EFSA needs where EFSA is following (on Zoonoses, AMR and emerging risks).

With the aim of increasing its participation in EU funded research activities, EFSA had planned to organise its second Risk Assessment Research Assembly (RARA) event in December 2021, after a first postponement from 2020 due to the impact of the SARS-CoV-2. However, also in 2021 the event had to be postponed because of the effect of the pandemic, this time to December 2022. The event aims to bring together EU and national research funders, policy/decision makers and leading researchers to discuss how food safety regulatory research can support the Sustainable Development Goals (SDGs) and relevant European policies and foster alignment of food safety research and innovation investments to support regulatory science outcomes.



Figure 17. EFSA Conference June 2022

In 2021 EFSA also progressed with the preparation of the 2022 EFSA Conference, which is expected to be held from the 21st to the 24th of June 2022 in Brussels. The scientific programme is summed up in the official name of the Conference: "ONE – Health, Environment, Society – Conference 2022". Food systems lie at the intersection of the many critical challenges facing us today, from fighting climate change, to halting biodiversity loss to reducing waste.

Meeting such challenges requires urgent action, as set out in the objectives for a sustainable future at the heart of the

UN Development Goals and the European Commission's Green Deal. The programme will be shaped in partnership with the European Centre for Disease Prevention and Control (ECDC), the European Chemicals Agency (ECHA), the European Environment Agency (EEA), the European Medicines Agency (EMA), and the European Commission's Joint Research Centre. EU Member States, EFSA's international partners and scientists will also be invited to co-develop the scientific programme.



Table 30. Outcomes indicators for SO3 – Research agenda take-up

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status		
Outcome: Building and sharing capacity within the risk assessment community at organisational level							
	Number of external research project outcomes taken up in EFSA's outputs ²⁴		N/A	N/A	0		
Research agenda take- up index	Number of research projects (EU and international) in which EFSA is participating (actively or passively)		24	30	0		

EFSA's activities towards **building and sharing of capacity within the risk assessment community** go beyond the cooperation among organisations, focusing and investing also **at individual level**, supporting the development of the appropriate expertise for the current and the future risk assessment needs. In this context, the fourth cycle of the **EU Food Risk Assessment Fellowship (EU-FORA)** saw 20 fellows successfully completing the cycle by the end of December, despite the challenges posed by the SARS-CoV-2 pandemic, with the start of the programme being postponed from September 2020 to January 2021, when it started with the regular three-week induction training held virtually for the first time ever. In 2021, all training modules had to be organised remotely, and in October 2021, a module on data collection and reporting, developed by a task force of Focal Points, was newly introduced.

EU-FORA is a fellowship programme with a focus on chemical and microbiological risk assessment. Until 2021, it targeted early to mid-career professionals from EU and EFTA countries, offering candidates the chance to widen their knowledge and hands-on experience of food safety risk assessment. It is aimed at professionals with a scientific background relevant to food safety and competent organisations with strong capacity in one or more areas of food safety risk assessment. The programme thus intends to increase the pool of food safety risk assessment experts available in Europe and stimulate the involvement of Member States in risk assessment work, all with the ultimate objective of building a common EU culture for risk assessment.

The ongoing fifth EU-FORA cycle started in September 2021, with a three-week virtual induction training. In November 2021, a 1-week training module was virtually held, with the participation of two different cohorts of fellows for the first time. This cycle is seeing 21 fellows being hosted in 14 different hosting sites from 8 different countries.

In 2021, EFSA also worked on an enhanced version of the EU-FORA, called EU-FORA 2.0, which introduces several significant changes based on five years of experience and that was developed with the aim of capitalising on the successful aspects of the current programme, while addressing those areas identified for improvement, and taking on board recognised mutual needs of EFSA and Member States (MS). In autumn 2021, the first Call for Proposals for the evolved programme was launched. In parallel, a new Call for Tender for the selection of a training contractor was initiated and webinar was organised in December 2021 to explain the changes to fellowship programme in EU-FORA 2.0 and the recently launched Call for Proposals to MS Focal Points and potential applicants.

EU-FORA 2.0 will start in September 2022, with the expected implementation of 15 work programmes in the first year. Unlike the previous programme, EU-FORA 2.0 targets mid-career professionals employed at competent organisations from EU MS, Iceland and Norway.

 $^{^{24}}$ In preparation for the next strategy cycle to elaborate on the methodology that would make it possible to properly monitor the indicator



Another activity carried out in the context of building and sharing of capacity within the risk assessment community at individual level was the sixth edition of the **Parma Summer School**, organised by EFSA, *the University of Parma*, *the School of Advanced Studies on Food and Nutrition*, and *the Catholic University of the Sacred Heart*. The Summer School was held between the 28th and the 30th of September 2021. Due to the challenges of the pandemic, also in 2021 the event was run virtually.



The relevance of the food safety issues, together with the technological innovation and the necessary adaptation of the risk assessment procedures, were addressed in the frame of food systems transformations involving complex interactions and feedback between bio-physical, political, and socio-economic drivers using different perspectives. The 2021 edition was organised around three case studies: *Biodiversity and Environmental Safety; Chemical Mixtures*; and *Novel Food and Technologies*. For the 300 available spots, EFSA received 1329 applications from 85 different countries, with the majority of the applicants from EU countries (more than 80%) and younger than 40 years old (80%). As expected, half of the applicants were coming from academia and research institutions, followed by applicants from Member States' national authorities and EU institutions other than EFSA.



95 EXPRESSIONS OF INTEREST



35 SELECTED ATTENDEES



13 INTERNAL & EXTERNAL SPEAKERS



7 BENEFICIARY COUNTRIES



2 DAYS OF MEETINGS

Figure 18. EFSA Autumn school statistics

Finally, the 2nd edition of the **EFSA Autumn School** was held on the 9th and 10th of November. This initiative organised under the framework of the EFSA's Pre-Accession Programme (IPA) 2019-2022 financed by the European Commission (EC), targeted young experts and scientists from the Pre-Accession countries. The Autumn School provides a solid knowledge of the EU food safety system and legislation related to EFSA. Scientific principles of food risk analysis, food risk assessment and communication were also covered. This annual event was also an opportunity to consolidate cross-team cooperation, with the participation of speakers from the Croatian Agency for Agriculture and Food (HAPIH) and the French Agency for Food, Environmental and Occupational Health Safety (ANSES).



3.2. Workforce model

In support of the implementation of the Transparency Regulation highlighting the support that Article 36 organisations could provide in the preparation and drafting of scientific opinions - to be peer-reviewed by the Scientific Committee and Panels before their adoption - EFSA is working on the establishment of a new framework that would facilitate the formation of partnerships and would be more open to ecosystem interactions. EFSA and the Advisory Forum have established an Advisory Forum Discussion Group to facilitate the development of such a framework by identifying ways or modalities that would make long-term partnerships with MS competent organisations more attractive, easier to form and more engaging. The Discussion Group has been providing regular input to the Advisory Forum and the work is expected to continue in 2022, with its outputs expected to contribute to the implementation of the framework.

Moreover, taking advantage of a Service Level Agreement with the DG-JRC of the European Commission, EFSA has started exploring the use of the JRC's Tool for Innovation Monitoring (TIM) as a source of intelligence of the scientific work in areas and topics relevant to EFSA's needs. This can be used to improve the outreach to experts or science organisations that could support EFSA's risk assessment work. The tool will be running on a pilot service mode provided by JRC to EFSA until September 2022 and will be primarily explored for competence mapping of organisations in support of future EFSA networking, engagement, partnership and outsourcing needs, ensuring a fit-for purpose Article 36 list of organisations, as well.

Finally, looking at the readiness of EFSA to retrieve timely the appropriate expertise for its scientific work, the indicator measuring the time to hire of working group experts²⁵, which had a target of 1.5 months after the positive performance of 2020 (1.4 months on average) was higher than expected, at 2.3 months, also due to the impact of the issues with the Declaration of Interest tool. This is, however, a better result than the baseline of 3 months measured in 2019 (Table 31). The indicators related to the renewal of the panel, instead, were not applicable this year as the activity is carried out every three years.

Table 31. Outcomes indicators for SO3 - Building and sharing capacity within the risk assessment community at individual level

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: Building and s	haring capacity within the risk assessme	nt community at i	ndividual level		
	Number of TOTAL applicants for panel renewals	1,150 <i>(2015)</i>	N/A	N/A	0
	Number of ELIGIBLE applicants for panel renewals	900 (2015)	N/A	N/A	0
la	Balance of applicants (total and eligible) for panel renewals, in terms of age (<40 years/40-55 years/>55 years)	23%/49%/28% (2017)	N/A	N/A	0
Increased common expertise pool coverage and availability index ²⁶	Balance of applicants (total and	5500/4500	N/A	N/A	0
	Balance of applicants (total and eligible) for panel renewals, in terms of geographic location (Mid-western Europe/Eastern Europe)	88%/12% (2017)	N/A	N/A	0
	Elapsed 'time to hire' for working group experts	3 months (2019)	1.5 months	2.3 months	0

²⁵ The index represents the average number of days that span from the approval date of a working group by the relevant Head of Unit and the hire date of an expert

²⁶ No target available for the indicators referring to panel renewals (first 5 indicators in the table), as the next panel renewal will be carried out in 2022. The targets listed in the Single Programming Document 2020 are to be considered not applicable

3.3. Strengthen capacity using innovative ways

To further build on the experience gained by machine learning feasibility studies already carried out by EFSA, and ultimately to achieve the implementation of artificial intelligence approaches at organisational level while exploring collaboration and sharing with EU partners, the project of Joining Forces at EU Level on Implementation of AI continued running in 2021.

Table 32. Outcomes indicators for SO3 - Strengthened capacity using innovative ways

KPI Outcome: Strengthened	Indicator capacity using innovative ways	Baseline	Target 2021	Executed 2021	Status
Number of innovative a computing, artificial into	approaches (crowdsourcing, cognitive elligence) included in EFSA's strategy iginal or revised) having been further	N/A	N/A	N/A	•

Finally, 8 questions were closed in the context of the Strategic Objective 3, overall in line with the plan but with small deviations with regards to the type of output: one less network technical report was closed, since the discussion and conclusions were instead published as meeting minutes. All the adopted outputs were delivered on time, therefore resulting in 100% timeliness of adoption (table 33).

Table 33. Activity and output indicators for SO3

ACTIVITY - OUTPUT INDICATORS					
Indicator	Executed 2020	Target 2021	Executed 2021	Status	
Number of questions delivered for scientific outputs and technical reports	3	4	3	0	
Number of questions delivered for 'other publications' (external reports, event reports)	4	4	5	O	
Proportion of scientific/technical questions adopted within deadline	100%	100%	100%	o	

An overview of the status of the ongoing projects under this strategic objective and their contribution to the expected results from the EFSA strategy implementation is given in Annex III.



4. Prepare for future risk assessment challenges

Anticipating risk assessment priorities and related methodology and evidence needs ensures that EFSA is prepared for present and new challenges in a dynamic food safety system, while driving harmonisation of methodologies to improve food safety across Europe. The preparation for potential future challenges and crises in food risk assessment encompasses the production of guidance documents and participation in crisis simulation exercises, and continuous update and creation of standardised guidelines or methodologies to assess risks in a consistent and harmonised manner.

EUR 15.18 M budget 35% 41% 43 FTES 38% 73%

Overall 2021 performance in Strategic Objective 4

Figure 19. Overall 2021 performance in Strategic Objective 4

Looking at the overall performance of the KPIs in the Strategic Objective 4, 73% of the measured indicators reached or surpassed their initial targets, a performance below the result registered in 2020 (79%). This discrepancy can be explained by the lingering effect of the re-prioritisation exercise run by EFSA in 2020 to react to the threat posed by the pandemic on its *business as usual*, as well as by the fact that this area has a limited number of indicators (hence changes in few indicators can have a significant impact in the overall performance). A positive note is the fact that in 2021 no KPIs have registered a relevant deviation (red area), compared to 14% registered last year.

In terms of human resources invested, 43 FTEs were initially allocated to this area, in line with 2020 (also 43 FTEs). In terms of budgetary inputs invested, € 15.18 million were spent in this area in 2021, around € 5 million more than 2020's investment of € 10.44 million, mainly due to the work carried out in establishing and running EFSA's Science Studies and Project Identification & Development Office (SPIDO). The SPIDO office aims at coordinating the identification of scientific themes and related roadmaps for actions to commission studies directed to fill data, knowledge, and communication gaps in regulatory science and ensuring preparedness for possible verification studies, using multi-annual, multi-partner and high-value grants and procurements projects. In 2021, 4 contracts for roadmaps in the area of artificial intelligence for evidence management, new

approach methodologies in risk assessment, risk assessment of combined exposure to multiple chemicals and a partnership for systems-based environmental risk assessment were signed and executed. In addition, two pilot projects in support of the ongoing roadmaps were initiated: a three-year project to explore the use of Artificial Intelligence approaches for extracting, analysing and integrating data obtained through New Approach Methodologies (NAMs) for chemical risk assessment, and a four-year study advancing the environmental risk assessment of non-target arthropods for plant protection products. The aim is to collect data and develop tools to provide the scientific ground to risk managers to support the definition of specific protection goals as well to develop risk assessment schemes fully compliant with the specific protection goal. In addition, several other scientific themes (omics, insect pollinators, animal welfare and communication science) were developed providing the foundation for future roadmaps.

No new data are available for what concerns the satisfaction of EFSA's interested parties in the Strategic Objective 4 area, as EFSA's comprehensive bi-annual survey, planned to be launched in 2021, was postponed to 2022 (see Table 22 for 2019's results).

Table 34. Intermediary impact indicators for SO4 - Increased satisfaction of stakeholders with regards to EFSA's preparedness, methodologies, and response (1/2)

	КРІ	Baseline	Target 2021	Executed 2021	Status
Intermediary impact: Increas	sed satisfaction of stakeholders with re	egards to EFSA's	preparedness, m	ethodologies, ar	nd response
, , , , , , , , , , , , , , , , , , ,	Risk managers (EU/MS)	66.6% (2017)	N/A in 2021	78.8% (2019)	0
surveys: positive and relative qualitative improvement (with regards to follow-up actions)	Stakeholders (general)	66.3% (2017)	N/A in 2021	70.1% (2019)	0
	MS, EU, international, non-EU country organisations	69.9% (2017)	N/A in 2021	71.4% (2019)	0

4.1. Effectiveness of EFSA's Preparedness and Response

EFSA preparedness to address requests from its customers remained high and in line with the targets set for 2021 for all three dimensions²⁷, all registering an increase year-on-year.

Moreover, the percentage of regular and urgent questions delivered within the initially agreed timelines (86%), below the target set (95%) and the 2020 performance (90.9%)²⁸ (see Table 35).

²⁷ Assessment based on 26 mandates

²⁸ Initially agreed versus updated deadline. Only applicable for negotiated deadlines, with the exclusion of regulated products applications and technical assistance.



Table 35. Intermediary impact indicators - Increased effectiveness of preparedness and response

КРІ		Baseline	Target 2021	Executed 2021	Status
Intermediary impact: Increa	sed effectiveness of preparedness and	response			
	% of questions for which data is readily available	79% (2018)	81%	90%	O
methods and expertise to	% of questions for which methods are readily available	88% (2018)	92%	95%	O
	% of questions for which expertise is readily available	91% (2018)	98%	96%	O
	% of questions (regular and urgent) delivered within the initially agreed timelines	94.3% (2018)	95%	86%	0

4.1.1. Emerging risks identification and crisis preparedness

Emerging risks identification

The activities of the emerging risks identification (ERI) process went according to the plan, with the final report of the Eurocigua (Risk characterisation of ciguatera poisoning in Europe) project, resulting from a partnership between EFSA and the Spanish Food Safety and Nutrition Agency (AESAN), published on 19 May 2021. Following up on a discussion with the EFSA Emerging Risks Exchange Network (EREN) on the possible risk of plastic soup for human health, EFSA organised on 6 and 7 May 2021 the 25th EFSA Scientific Colloquium for a coordinated approach to assess the human health risks of micro- and nanoplastics in food. In relation to an ongoing two-year project on identification of emerging risks related to circular economy, EFSA organised a stakeholder workshop on food and feed safety vulnerabilities in circular economy. This event, attended by 21 organisations, was the first step in a foresight participatory process where EFSA will engage with partners and stakeholders having an interest in this topic. Last but not least, EFSA organised on 20 May 2021, as part of the UN Food Systems Summit 2021 Dialogues, a discussion on "The European Green Deal: opportunities to anticipate and address emerging risks" The event involved EFSA's EREN network, the EFSA Stakeholders Discussion Group on Emerging Risks, and Representatives from DG SANTE; 39 participants discussed on the potential opportunities and challenges derived from the transition to sustainable food systems, and how to anticipate solutions on potentially related emerging risks.

Crisis preparedness and response

In the area of crisis preparedness, two workshops took place in 2021. The first workshop was a three-day (5-7 July) External Crisis Preparedness Training (ECPT) online workshop that was jointly devised, developed, and delivered by EFSA and the Istituto Zooprofilattico Sperimentale dell'Abruzzo e del Molise (IZSAM). The workshop focused on animal health crisis preparedness, specifically on Rift Valley fever (RVF). The overall training objective was to improve incident response collaboration between animal and public health authorities from multiple countries, using a 'One Health' approach. The content of the workshop was jointly developed by EFSA, IZSAM and Instinctif Partners, with input from ECDC, FAO, OIE, WHO and EC DG SANTE. Twenty-seven participants from 6 EU Member States and 3 EU candidate countries attended the training, as well as 12 observers from 3 EU MSs and 3 international organisations.

The second workshop was an Internal Crisis Preparedness Training (ICPT), which took place in November 2021. Using a repurposed version of the Rift Valley Fever scenario used in the July workshop, the focus of

²⁹ See https://summitdialogues.org/dialogue/18790/

the training was to plan and practise EFSA's management of risk communication, in conjunction with other European agencies, during a joint urgent response to a multi-country animal health/public health outbreak. Fourteen participants from EFSA, EFSA's Communications Expert Network (CEN) and the European Centre for Disease Prevention and Control (ECDC) attended the training, plus 13 observers from EFSA and the European Commission's (EC's) Directorate-General for Health and Food Safety (DG SANTE). A scenario exercise explored how EU agencies and DG SANTE would respond and collaborate if RVF entered the EU.

Concerning crisis response, EFSA participated to three meetings of the crisis coordinators on Ethylene oxide (EtO) organised by DG SANTE. Specific support was provided by answering an urgent request for a scientific statement on the Bundesinstitut für Risikobewertung (BfR) opinion on the "Health risk assessment of ethylene oxide residues in sesame seeds" (Opinion No 024/2021), taking into account the studies assessed in the frame of this opinion and any other relevant available studies on the toxicity of 2-chloroethanol (metabolite of EtO), not assessed by the BfR. EFSA was also asked to clarify under which circumstances the use of the MOE approach is considered appropriate.

4.1.2. Methodology development, harmonisation and accessibility of methods/tools

In the area of methodology development, the usage registered by EFSA's guidance documents met or surpassed the 2021 plan, with the indexes measuring the number of visits, the number of downloads, and the average number of citations/guidance documents registering all positive fig-ures (Table 36).

Table 36. Satisfaction of stakeholders with regards to EFSA's methodologies

	КРІ	Baseline	Target 2021	Executed 2021	Status	
Intermediary impact: Increased satisfaction of stakeholders with regards to EFSA's preparedness, methodologies, and response						
Use of EFSA's guidance (access, downloads, citations)	Number of page visits (visibility)	362,409 <i>(2018)</i>	435,000	451,479	O	
	Number of downloads (usage)	348,223 (2018)	410,000	430,727	o	
	Number of citations (impact)	2.97 (2018)	3.7	4.3	o	
Use of EFSA's methodologies (access, download, citations)		TBD	N/A	N/A	0	
Use of EFSA's tools (statistical models)		687 (2018)	2,407	4,100	o	

Regarding the accessibility of tools for external users, a substantially higher-than-planned num-ber of registered users in the R4EU platform was registered in 2021, while the indicator monitor-ing the accessibility of methods was not developed (see Table 37).



Table 37. Outcome indicators for SO4

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: Fostered use	e of new approaches and enhanced ability to	anticipate and r	espond to risks		
	included in EFSA's strategy implementation I) having been further developed ³⁰	0 (2016)	8	10 <i>(2019)</i>	0
Outcome: Accessibility of EFSA methods and tools					
Number of methods and tools readily accessible for use by external users (available in online repositories and on platforms)		TBD	N/A	N/A	0
Outcome: Harmonisation of risk assessment methodologies					
Increase in the use of or Panels	cross-cutting guidance documents by EFSA	TBD	N/A	N/A	0
Use of 'compulsory' gu groups	idance documents by panels and working	TBD	N/A	N/A	0

The volume of scientific production in this area was lower than expected, as 60 questions were closed in 2021 against a target of 78 (Table 38), because of the de-prioritisations in this area, in particular the one carried out in 2020 to counter the impact of the SARS-CoV-2 pandemic on EF-SA's operations. The 2021 performance, however, is better year-on-year, as in 2020 only 42 questions were closed in this area, mainly due to the combined effect of the re-prioritisation of activities agreed by EFSA to safeguard the scientific activities carried out in the Strategic Objec-tive 1 after the SARS-CoV-2 outbreak, and the delays registered in grants & procurements, as more than 25 deliverables (either intermediary or final) related to development projects were postponed to 2021 or had their scope reduced.

Additional details on questions closed by Unit and food sector area can be found in Annex IV. Questions closed in 2021.

The timeliness of adoption stands at 93.5%, so below the 100% target, but has seen a significant improvement with respect to 2020 when was at 73.9%.

³⁰ Further developed = moved at least one stage from non-explored to feasibility, piloting, guidance endorsed, training provided, application in risk assessment

Number of questions closed in Strategic Objective 4 (2021 actuals vs 2021 plan compared with 2020 and 2019 actuals)



Figure 20. Number of questions closed in Strategic Objective 4

Table 38. Activity and output indicators for SO4

ACTIVITY - OUTPUT INDICATORS					
Indicator	Executed 2020	Target 2021	Executed 2021	Status	
Number of questions delivered for scientific outputs and technical reports	23	40	31	o	
Number of questions delivered for 'other publications' (external reports, event reports)	19	38	29	O	
Proportion of scientific/technical questions adopted within deadline	73.9%	100%	93.5%	o	

An overview of the status of the ongoing projects under this strategic objective and their contri-bution to the expected results from the EFSA strategy implementation is given in Annex III.

From the overall scientific work delivered in the preparedness and harmonisation area, the follow-ing achievements can be highlighted in the specific areas of work.



Risk Assessment Methodologies Programme (RAMPRO)

Under the umbrella of the Risk Assessment Methodologies Programme (RAMPRO), the activities of identification, prioritisation and management of scientific projects continued in the areas of (i) chemical risk assessment for human and animal health, (ii) environmental risk assessment of chemicals, (iii) biological risk assessment, (iv) harmonisation of risk assessment methods. The programme's objective was to ensure the implementation of EFSA Strategy 2020, by increasing synergies amongst different projects developing new scientific methods and tools, and by fostering a harmonised use of EFSA's scientific solutions. The programme stimulated scientific cooperation across EFSA as well as between EFSA and centres of excellence in and outside the EU.

Overall, the programme delivered results in line with the business plan, with similar trends than in 2020 for all monitored dimensions: no deviation in scope, availability of resources (budget and staff), appropriate risk management, half of the projects slightly delayed by the SARS-CoV-2 crisis. Since the beginning of the programme, 27 projects were successfully closed including 12 in 2021: 6 projects on chemical risk assessment (e.g. impact of non-monotonic dose responses on EFSA's human health risk assessments, EFSA Guidance document on scientific criteria for grouping chemicals into assessment groups), 4 in environmental risk assessment (e.g. transition metals used as active substances in plant protection products), one in biological risk assessment (plant health horizon scanning) and one on the monitoring of the use of guidance documents (see below).

Cumulative risk assessment implementation

Developing the Cumulative Risk Assessment (CRA) methodology and assessing the CRA of pesticide residues for the consumers are requested by Regulations (EC) No 396/2005 and (EC) No 1107/2009.

Work has progressed in the CRA area, with the publication of the EFSA scientific report on "Cumulative dietary risk assessment of chronic acetylcholinesterase inhibition by residues of pesticides" and 3 external scientific reports: "Feasibility study Open MCRA", "Proposed prospective scenarios for CRA of pesticide residues" and "Potential impact of prioritisation methods on the outcome of the cumulative exposure assessment of pesticides".

Bee health and insect pollinators

As part of the ongoing review of the guidance on the risk assessment of pesticides on bees (see below in "Pesticides"), EFSA finalised two reports (the "Analysis of background variability of honey bee colony size" and the "Analysis of the evidence to support the definition of Specific Protection Goals (SPG) for bumble bees and solitary bees") to support risk managers in the definition of specific protection goals for bees. In relation to the report on honey bees, a Member State and Stakeholder consultation was held. In addition, under the umbrella of the EU Commission, an info session was given to Member States and Stakeholders regarding some pivotal methodological issues for the implementation of the SPG agreed by the Risk Managers.

EFSA also finalised, following a public consultation, its scientific opinion on "A systems-based approach to the environmental risk assessment of multiple stressors in honey bees" which sets out an integrate and holistic framework for the risk assessment of pesticides in interaction with other environmental stressors for honey bee colonies. The scientific opinion was produced under the multiannual project MUST-B which developed an agent-based model, ApisRAM to assess the risks of pesticides and multiple stressors. The opinion is based on modelling and monitoring systems to support the predictive and post-authorisation risk assessment of pesticides.

During 2021, the EU Bee Partnership (EUBP) has developed a prototype online platform to promote standardised data collection and sharing. The EUBP initiative is represented by stakeholders from different sectors – i.e. by

field practitioners from the beekeeping, veterinary and farming sectors, academia, business and food industry, NGOs, advocacy groups, and others – which have collaborated closely to develop the prototype platform. BeeLife European Beekeeping Coordination led the development of the platform, supported by a grant from EFSA. The ultimate goal is for the platform to become a hub that brings together all relevant information, knowledge and data collected by, and exchanged among, stakeholders on bee health, beekeeping and insect pollinators. The prototype will be further developed into an operational platform.

In September 2021, EFSA co-organised the EU Pollinator Week "A new deal for pollinators" with the Members of the European Parliament and in partnership with the European Commission, the Slovenian Presidency of the Council of the EU. The EU Pollinator Week brings together all relevant stakeholders to discuss ideas and promote policies and actions for sustainable and healthy populations of insect pollinators and pollination services in EU. A dedicated session was jointly organised between EFSA and ECHA on "Advancing environmental risk assessment to better protect insect pollinators".

With a view to address the issue of insect declines in EU, EFSA enlarged the scope of its activities from bees to insect pollinators and prepared a thematic paper on the ERA of chemicals to better protect insect pollinators (IPOL-ERA). This theme led to a call for tender in 2021 to define a roadmap of actions and prioritise research areas on this topic.

Wildlife surveillance

EFSA continued in 2021 its project with the publication of a scientific opinion on the Research priorities to fill knowledge gaps in wild boar management measures that could improve the control of African swine fever in wild boar populations" and two external scientific reports on the "update of model for wild boar abundance based on hunting yield and first models based on occurrence for wild ruminants at European scale" and "modelling and updating spatial distribution of wild boar, ruminants and carnivores". An application for mobile phones and computers for warning about found carcases of wild boar to inform institutions and veterinarian services was also delivered in December 2021.

Genetically modified organisms

EFSA finalised a scientific opinion on recommendations for future development of allergenicity risk assessment. The output, which also took into account the comments raised by a Stakeholder Consultative Group and the main outcomes of the Allergenicity Risk Assessment Workshop organised in June 2021 with the collaboration of the Stakeholder Group, recommends to continue investing resources in the modernisation of available tools to consider experience gained, current and new knowledge that could lead to increase the robustness, avoid inconsistences and lack of reproducibility of the assessments, and proposes a series of research priorities to address such purposes.

In the area of environmental risk assessment, EFSA also released a extension of the spatially- and temporally-explicit "briskaR-NTL" model to assess potential adverse effects of Bt-maize pollen on non-target Lepidoptera at landscape level.

Advanced toxicology and new approach methodologies (NAMs)

A scientific opinion on the development of integrated approaches to testing and assessment (IATA) case studies on developmental neurotoxicity (DNT) risk assessment was delivered. Two adverse outcome pathway (AOP) informed integrated approach to testing and assessment (IATA) case studies were developed to answer a developmental neurotoxicity (DNT) hazard identification and characterisation problem formulation that could support the regulatory decisions for the pesticide active substances deltamethrin and flufenacet. An external scientific report on the interpretation of data from the developmental neurotoxicity in vitro testing assays for use in IATA was also published.



EFSA published, in the annex of the OECD guidance document on the use of physiologically-based kinetic (PB-K) models in risk assessment, 3 case studies on the use of such PB-K models for humans, farm animals and fish. Such generic PB-K models have also been integrated in the TKPlate platform for a prototype has been shared with experts and national agencies for further testing before publication. An external scientific report has been published on the modelling of human variability in toxicokinetic (TK) and toxicodynamic (TD)processes using *in vitro* methods, bayesian meta-analysis and PB-K modelling. Two new procurement calls have been launched for the further development and integration of new models in the TKplate platform including models for farm animals, amphibians and reptiles for the risk assessment of single chemicals, mixtures as well as multiple stressors.

A scientific opinion on the impact of non-monotonic dose responses (NMDR) on EFSA's human health risk assessments was delivered. It assesses the biological relevance of the NMDR identified in a previous EFSA external report and proposes specific recommendations for identifying the plausibility and impact of NMDRs during the risk assessment process. It is completed with cases implementing these recommendations in EFSA assessments.

Guidance development

Cross-cutting guidance

EFSA published in December 2021 a new guidance which provides a framework for grouping chemicals for human risk assessment of combined exposure to multiple chemicals and methods for identifying low priority chemicals to reduce the number of chemicals in assessments. Input to the development of the guidance was also provided during a public consultation held on the draft output and in the context of an international workshop which targeted scientists working on methods for risk assessment of combined exposure to multiple chemicals, held in October 2021.

EFSA also adopted the "Statement on the derivation of Health-Based Guidance Values (HBGVs) for regulated products that are also nutrients", following a public consultation on the draft output. The statement describes the specific considerations that should be followed for establishing the HBGVs during the assessment of a regulated product that is also a nutrient. It also addresses the elements to be considered in the intake assessment and proposes a decision tree for ensuring a harmonised process for the risk characterisation of regulated products that are also nutrients.

Two new guidance documents finalised by EFSA in 2021 will help to further clarify how EFSA's scientists approach the assessment of nanomaterials in the food and feed chain: the "Guidance on risk assessment of nanomaterials in the food and feed chain: animal and human health", which provides a roadmap to progressively roll out and assist the assessment of nanomaterials, and the "Guidance on technical requirements for regulated food and feed product applications to establish the presence of small particles including nanoparticles", which relates to conventional materials that contain a fraction of small particles but do not meet the definition of engineered nanomaterial. Both documents also set down data and information requirements for applicants when submitting materials for assessment as part of EU market authorisation procedures, e.g. for use as novel food, feed additive, food additives or food contact materials.

Sectoral guidance

Food ingredients

In the course of 2021 both the "Scientific Guidance for the submission of dossiers on Food Enzymes" and the "Scientific Guidance for the preparation of applications on smoke flavouring primary products" were finalised

with updated information to assist applicants in the preparation of applications for regulated products. Both outputs underwent a public consultation before finalisation.

Pesticides

EFSA updated its "Guidance on the assessment of the exposure of operators, workers, residents and bystanders in risk assessment of plant protection products", which is designed to assist risk assessors and applicants when quantifying potential non-dietary, systemic exposures as part of regulatory risk assessment for plant protection products (PPPs). It is based on the Scientific Opinion on 'Preparation of a Guidance Document on Pesticide Exposure Assessment for Workers, Operators, Residents and Bystanders' developed by the EFSA PPR Panel in 2010. The updated guidance proposes a number of changes to the practices in use (i.e. use of deterministic methods for individual PPPs; need to perform an acute risk assessment for PPPs that are acutely toxic; use of appropriate percentile for acute or longer term risk assessments), and is complemented with online calculator which has been further developed compared to the 2010 opinion.

EFSA also finalised the "Statement of the PPR Panel on a framework for conducting the environmental exposure and risk assessment for transition metals when used as active substances in plant protection products", which outlines appropriate scientific methodology and limitations for assessing transition metals and their compounds used as active substances in PPPs and indicates possible solutions.



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

Since the adoption of the current Strategy in 2016, EFSA has been strengthening a culture based on its values of openness, innovation, cooperation, independence and scientific excellence among its experts, partners, and staff. In doing so, EFSA has implemented initiatives aiming to create an efficient, transparent, and responsive environment, (i.e. organisation, processes, and tools) that allow sustaining organisational performance improvements and delivering on its strategic objectives.

EUR 43.20 M budget 35% 41% 204 FTEs 38% 44%

Overall 2021 performance in Strategic Objective 5

Figure 21. Overall 2021 performance in Strategic Objective 5

Looking at the overall performance of the KPIs in the Strategy Objective 5, 85% of the indicators reached or surpassed their initial targets, a performance that is similar to last year's result (90%) and that can be considered positive.

In terms of input invested in SO5, 204 FTEs were allocated to this area in 2021, an increase compared to the previous year (192 FTEs), also consistent with the overall FTEs increase that took place in 2021. In terms of budgetary inputs, \in 43.20 million were invested in 2021, around \in 8 million more than in 2020 (\in 35.26 million) and more than the planned \in 38.60. These increases are mainly linked to expenditures connected to external services for the operation, implementation and maintenance of software and user support, and to purchase and maintenance of software, as well as to interim and consultancy support.

Similarly to 2020, 2021 was expected to be a year of transition for EFSA, with the entry into force of the new Transparency Regulation and the finalisation and adoption of the new EFSA 2027 Strategy. The nature of the Transparency Regulation, which focuses on transparency and reliability, co-design with Member States and partnership with EU institutions and Member States on risk communication, was seen as an enhancement of the current EFSA strategic objectives and a bridge towards the new ones, while enabling the implementation of the Board's recommendations following the 3rd external evaluation.

5.1. Staying relevant in an evolving strategic context

In the context of the preparation for the entry into application of the Transparency Regulation on the 27th of March 2021, EFSA countered the effects of the SARS-CoV-2 pandemic focusing its efforts on the delivery of the measures that were mandated by law, such as the set-up of the new tasks of presubmission advice, notification of studies, confidentiality assessment and content sanitisation.



Figure 22. Transparency Regulation entry into applications

Once the "must do" provisions of the Transparency Regulation were ensured by the entry into force of the new rules, EFSA focused on rolling out an organisation able to efficiently comply with the new tasks assigned and the new procedures in place. This meant that in June 2021 EFSA unveiled a new process architecture and a new organisational design, to be in place as of the 1st of January 2022. The work in this area is expected to continue also in 2022, when all the new EFSA processes are expected to be fully defined and functioning. The new processes and

organisation have been designed also to enable the implementation of the EFSA 2027 Strategy, which was formally adopted by EFSA's Management Board in June 2021.

The adoption of the Strategy follows two years of consultation with EFSA's partners, stakeholders, Management Board and the wider public, and takes into consideration the changing landscape in which EFSA operates, from the changes brought by the amendment to the General Food Law to the EU-wide policy developments, such as the Farm to Fork Strategy, as well as considering the lessons learnt from the pandemic on new ways of working.

The Strategy outlines three Strategy Objectives for EFSA to focus on:

- 1. delivering trustworthy scientific advice and communication of risks from farm to fork
- 2. ensuring preparedness for future risk analysis needs
- 3. empowering people and ensuring organisational agility.

The Strategy was complemented by a new Performance Framework, which includes the corporate indicators that will measure the performance of the organisation towards the achievement of the expected results. The new Performance Framework was discussed in the Management Board in December 2021 and included in the Programming Document 2022-2024.

5.2. Sound operational performance and assurance

Sound operational performance is globally measured through 'the clean budget discharge' and the 'proportion of KPIs of the programming documents having met their target' (see Table 39).

On the 29th of April, the European Parliament granted EFSA's Executive Director the discharge for the financial year 2019 and approved EFSA's accounts, hence closing the discharge procedure for that year.

The composite indices that are measuring the overall performance of EFSA's three "tiers" (intermediary impact-outcome-output) of performance indicators against their initial targets showed mixed results. In fact, while the index on the intermediary impact indicators, which measures the long-term effect of EFSA's activities,



registered positive results remaining in line with the performance registered in 2020 (80%), the indices on the outcome indicators (that measures the short-term results achieved by EFSA in the areas of interest) and on the output indicators (that measures the direct product of EFSA processes) were below their targets (90% and 95%, respectively) and below 2020 performance (88% and 68%). Given the nature of the indices, which are calculated based on the performance of all available indicators, the reasons for deviations are diverse and are explained throughout the document. The deterioration of two indices over the past years (in 2019 they scored 90% and 84%) can be seen as a reflection of the impact of the pandemic and the most intense phase of the TR preparation on EFSA's overall performance.

Table 39. Intermediary impact indicators for SO5 – Sound operational performance

	КЫ	Baseline	Target 2021	Executed 2021	Status
Intermediary impact: Sound o	perational performance				
Proportion of KPIs of the programming documents reaching targets	Intermediate impact	71% <i>(2017)</i>	80%	81%	0
		100% <i>(2017)</i>	90%	79%	o
	Activity/output	73.5% (2017)	95%	60%	O
	Discharge is granted	Yes	Yes	Yes	O
Clean discharge achieved	Accounts are closed	Yes	Yes	Yes	O
	Observations are followed up within the prescribed deadlines	100%	100%	100%	O

On the financial side, the three indicators measuring the budgetary performance of EFSA in 2021 registered positive results, both in terms of commitments and payments, with only a minor deviation connected to the payments of non-differentiated credits (table 40). Considering that in 2021 EFSA handled an initial approved budget of € 129 million in commitment appropriations, 19% more than 2020 initial budget due to the additional resources given in the context of the Transparency Regulation, these results are to be considered positive.

An overview of the status of the ongoing projects under this strategic objective and their contribution to the expected results from the EFSA strategy implementation is given in Annex III.

Table 40. Activity and output indicators for SO5 (1/2)

ACTIVITY - OUTPUT INDICATORS				
Indicator ³¹	Executed 2020	Target 2021	Executed 2021	Status
Commitment execution ³²	100%	100%	100%	0

³¹ The budget KPIs have been simplified compared to previous years in order to better represent global performance, simplify measurement and avoid overlapping KPIs. The following indicators are replaced: Proportion of original budget committed at year end — differentiated, Proportion of original budget committed at year end — non-differentiated, Proportion of original science grants and procurement budget committed at year end, Proportion of original budget paid at year end — non-differentiated, Proportion of original budget paid at year end — non-differentiated, Proportion of original science grants and procurement budget paid at year end, Carry-forward of payments to following year. The scientific grants & procurement are not measured separately anymore as they are covered by the indicator on differentiated credits. The measurement of the "Carry forward" is covered by the indicator "Payment execution of non-differentiated credits".

³² New indicator.

ACTIVITY - OUTPUT INDICATORS				
Indicator ³¹	Executed 2020	Target 2021	Executed 2021	Status
Payment execution – non-differentiated credits ³³	87%	90%	87%	0
Payment execution – differentiated credits ³⁴	100%	100%	100%	0

Accountability framework

Underpinning the sound operational performance of EFSA is the strengthened accountability framework based on its four pillars: governance and decision making, result-based management, quality & continuous improvement and assurance, highlights of which are provided below.

Pillar 1: Governance and decision making



Figure 23. Integrated management system

Following the decision taken in 2018, EFSA started working on having an Integrated Management System (IMS), with the aim of aligning and streamlining the implementation of EFSA activities dealing with the different management standards in an efficient way. The EFSA IMS was finalised in 2021, while the adoption of an overarching accountability policy steering EFSA's IMS over the years was postponed to 2022 as a result of re-prioritisations for the TR and Strategy 2027 activities.

Important progresses were achieved

in 2021 regarding the IMS, with the mapping of EFSA's Management Systems, the definition of integrated objectives, and the development of a roadmap for the full implementation of the IMS (with the plan of having an integrated external certification audit for all ISO standards by 2023). Some important actions were already implemented in 2021, such as the creation of a single/integrated audit checklist

to minimise overlaps and streamline audits, a process for the central management of normative documentation, as well as the further integration of the areas of health, safety, security and environment (HSSE)).

In the context of the revised EFSA process architecture and organisational design, EFSA started its work on the revision of its decision-making framework. Key principles include simplification, the strengthening of individual accountability, and the appropriate coverage of responsibilities across the process, information and technology dimensions of the IMS.

Pillar 2: Result-Based Management

Under the pillar of **results-based management**, the index that measures the overall performance of EFSA's projects registered a result below the target (80.5%, against a target of 90%), mainly due to delays and risks (of moderate entity in the vast majority of the cases) reported by the 84 projects active as of the end of December, while the other dimensions analysed (Scope, Budget, and FTEs) were instead on track.

 $^{^{\}rm 33}\ \ Indicator\ changed\ from\ "Proportion\ of\ original\ budget\ committed/paid\ at\ year\ end\ --non-differentiated".$

 $^{^{34}\ \} Indicator\ changed\ from\ "Proportion\ of\ original\ budget\ committed/paid\ at\ year\ end\ --\ differentiated".$



Regarding the allocation of the FTEs between operational and support activities, the metric has been frozen in 2021, since the change of IT tool used for time-tracking that took place in 2020; The 2020 figure is instead reported. The metric will not be included in the new performance framework of the EFSA Strategy 2027.

A new process performance metric was developed to replace the two indicators in Table 42 originally planned under the 2020 Strategy. The results show that 73% of the EFSA processes were on track at year end, a result lower than 2020 performance of 80%. The trend of this metric is in line with the other metrics on EFSA's overall performance. The 9% of processes with "not enough data" refers to processes that did not run in (either because not triggered or because not fully in place).

Performance of process metrics: 2021 vs 2020 comparison



Figure 24. Performance of process metrics

Table 41. Intermediary impact indicators for SO5 – Efficiency

	КРІ	Baseline	Target 2021	Executed 2021	Status
Intermediary impa	ct: Efficiency				
Improved ratio of activities	effort (FTE) spent in operational vs support	73.5/26.5 (2016)	Not measured in 2021	76/24 (2020)	o
	For mature processes: improved index (ratio of output and quality/satisfaction vs input)	TBD	N/A	N/A	0
Efficiency index in EFSA's activities	Process maturity index: percentage of mature vs total processes	TBD	N/A	N/A	0
	Projects: improved index (delivery on budget, on time, in scope or better)	77% (201 <i>7</i>)	90%	80.5%	<u></u>

In terms of capabilities, the maturity level of EFSA's performance-based management was not measured in 2021. Similarly, the IT maturity was not measured also in 2021 due to the closure of the IT Strategy in 2019. The most updated actuals are reported in Table 42.

Table 42. Outcome indicators for SO5 - Capabilities

КРІ	Baseline	Target 2021	Executed 2021	Status
Outcome: Capabilities				
Performance-based management maturity level	Between stage 2&3 <i>(2017)</i>	Between stage 3&4	Between stage 3&4 (2020)	0
World-class IT maturity level (PEMM model)	1.7 (2017)	N/A in 2020	2.4 (2019)	O

Pillar 3: Quality and continuous improvement

Under the pillar of **quality and continuous improvement**, the 2021 Annual Quality Management Plan implementation is on track, with around 80% of the yearly objectives being achieved by year end.

Monitoring of Annual Quality Objectives

Objective	Action	Status at year end
	Prepare for and run surveillance audit	Achieved
Maintain ISO 9001:2015 certification	Implement internal quality audit cycle	Achieved
	Customer feedback interviews with SANTE / Customer/stakeholder survey	Achieved
	Close gaps and lean process documentation (SOPs/WINs)	Achieved
	Update of EPA (EPA III) for the 2021 planning cycle	Achieved
QMS updated in line with TR measures and strategic needs	Update Quality roadmap in line with the Strategy 2027	Achieved
measures and strategic needs	Adopt Quality Policy	Achieved
	Adopt Accountability policy by year end	Postponed
Integration of management	Develop and implement EFSA's integration of management systems roadmap	Achieved
systems	Operationalise hierarchy and repository of normative documents implementation	Achieved
	Integrated indicators framework: review of KPIs and PPIs in line with strategy	Achieved
Implement Continuous	Run Process Improvement Initiatives (Lean), communicate results achieved	Partially achieved
Improvement Process	Deploy L&D plan on process management and lean	Partially achieved

Figure 25. Monitoring of Annual Quality Objectives

On the 25th and the 27th of October EFSA underwent its second ISO 9001:2015 Surveillance Audit after reobtaining the certification in 2019, with 10 Units directly involved. The assessment was positive, with no nonconformities identified, leading to the confirmation of EFSA's certification. All units showed that great effort was put in planning suitable actions to drive enhancements and improvements.

The annual 2019/2020 Customer feedback exercise with SANTE was finalised at the beginning of 2021, and the closing report was shared with EFSA's and SANTE's senior management. The overall feedback received was positive, with some areas for improvement identified by DG SANTE. The 2021/2022 Customer feedback exercise was carried out in December 2021.

In the context of the process of Continuous Improvement that EFSA kicked off since 2019, 9 new improvement initiatives were launched in 2021, while 11 initiatives were closed (4 started in 2021 and 7 carried over from 2020). The initiatives launched aimed at achieving different types of benefits, such as reducing cycle time of some activities (such as the reduction of the time needed to develop Standard Operating Procedures from 162 days to 92 days) increasing customer satisfaction, or generating efficiencies (such as the set of initiatives carried out in the area of Food Enzyme Risk Assessment, where the number of scientific opinions adopted per plenary meeting passed from 9 in 2017 to 24 in 2021, this to prepare the function to better deal with the



incoming workload in the area). Additionally, a strategic sourcing model and a new staff onboarding self-service process were defined and implemented.

Environmental sustainability is ensured

EFSA maintained the Eco-Management and Audit Scheme (EMAS) and the Occupational health and safety management systems (ISO 45001) certifications, which were confirmed after the external audits that took place in May and in October. Additional details are provided in Section III – Assurance and Annex VII – Environment Management.

Pillar 4: Assurance

Under the pillar of **assurance**, EFSA has adopted a new anti-fraud strategy in 2021 defining four main objectives focusing on enhancing an environment and culture that reflects EFSA's intolerance to fraud, strengthening fraud risk monitoring, maintaining a robust system for fraud detection and investigation, and, readiness in recovering damages and sanctioning fraudulent activities. In the reporting year, with EFSA receiving additional Transparency Regulation funds, a series of measures were put in place to safeguard the financial processes to ensure that funds are spent in compliance with rules and regulations and principles of sound financial management. The work in this area will continue in 2022 with focus on grants & procurement, IT financial and vendor management.

EFSA carried out the control activities as per control strategy with the *ex post* controls in the areas of independence, human resources, information management, finance and science; performed the overall assessment of the presence and functioning of the internal control principles and continuously monitored the functioning of the internal control system through the systematic registration of exceptions. In the reporting year EFSA extended the scope of the DMS annual review to include the management of access rights in Teams/ Sharepoint and the management of access rights to functional mailboxes. The review also specifically focused on the access rights management for sensitive information.

In April, the European Commission Internal Audit Service (IAS) issued the final audit report on the procurement and grant award processes in EFSA. Further details are provided in part II of this document.

The European Court of Auditors published the annual report on EU agencies for the financial year 2020, with EFSA receiving clean opinions on the reliability of its accounts and on the legality and regularity of its transactions. Further details are provided in part II of this document.

On 29 April 2021, the European Parliament (EP) granted to EFSA the Discharge in respect of the implementation of the budget for the financial year 2019. This is the final approval of the budget implementation and the closure of the 2019 annual accounts.

Overall, in terms of compliance monitoring, only one very important observation was registered in 2021, (Table 43). More details are available in the parts II, III, and IV of this document.

Table 43. Outcome indicators for SO5 - Compliance

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: Compliance					
Compliance index (to laws, regulations, decisions, standards, policies, and procedures applicable to EFSA)		4 (2016)	< 5	1	0

Public access to documents

For what concerns the activity of Public Access to Document (PAD), EFSA handled 232 PAD applications in 2021, out of which 186 were received between the 1st of January and the 31st of December 2021, with 46 applications carried forward. 2021 represented the year in which EFSA received the highest number of PAD applications ever. For some of these PAD applications only personal data was redacted with a view of protecting the privacy and integrity of individuals³⁵. For others, protection was (also) grounded on Article 4(2) of the PAD Regulation. In 2021 EFSA received 3 confirmatory applications challenging partial protection mainly based on the commercial interests' exception.

5.3. Enabling working environment

Measurements regarding the development of an enabling working environment properly supported by world-class IT tools that promote innovative collaboration methods are on track. Moreover, important developments were made in 2021 in the areas of the provision of transactional services, digital collaboration and EFSA's technology roadmap.

Enabling services

In the area of enabling services, EFSA made important progresses via its Enabling Services Project (ESP), one of the projects under the ART umbrella. The ESP was set up to ensure the development and the implementation of a model to effectively and efficiently deliver of all enabling services (such as transactional, administrative and scientific support services, competency management and the outsourcing of scientific activities), as well as technological and building upgrades.

In particular, EFSA set up a shared support office (SSO) to manage service delivery and incident for more than 30 services in the area of corporate services, finance, and human resources, as well as already setting up the basis for the adding additional services in the coming year.

EFSA also took advantage of the home-office situation to advance with the remodelling and the technological upgrade of many of EFSA's physical spaces and meeting rooms, with the aim of creating a comfortable and multi-functional working environment.

IT Operational Strategy & Technology Roadmap

EFSA's 2014-2020 technology strategy focused on fully modernising its technology infrastructure to put in place a cloud based, highly scalable, computational capability underpinning its data management, methodology and computation activities, such as bioinformatics and AI4EU. It also consolidated corporate processes in order to reduce the cost of information technology expense through standardisation and the adoption of shared services. In 2020 and 2021 EFSA focused on implementing the transparency regulation by extending the cloud solutions to cover the data and processing needs of applicants, staff and the citizen through three main portals delivering access to the transparency regulation outcomes.

In 2021 EFSA introduced its 2027 Digital Roadmap which supports the European Commission's Digital Strategy. The new Digital Roadmap identifies 8 digital capabilities that are necessary to digitalising EFSA's operations and to ensure the successful implementation of EFSA 2027 Strategy. Mapped against the 2027 Strategic Objectives and Expected Operational Results, these digital capabilities are combinations of process, culture, competence and supporting technologies which function together to satisfy the needs of the strategy and our customer:

³⁵ In accordance with Article 4(1)(b) of the Regulation (EC) No 1049/2001 ("PAD Regulation")



- 1. Access: creating and maintaining security profiles and usage rules for all information that flows through the organisation and for all of the people who use it.
- 2. Connect: enabling partners in an international public health ecosystem to publish and discover services and data EFSA can provide for the benefit of all members of its ecosystem.
- 3. Compute: a modern cloud-based way to compute scientific problems that can be scaled up or down in power and cost, as needed, and that allows data and computational capability to be used independent of the computing languages and data locations.
- 4. Collaborate: digital solutions that intelligently connect people across different communities by automatically making it easier to find, connect and engage with new knowledge communities.
- 5. Knowledge Capture: the capture of informal as well as formal information and data in such a way that intelligently digest information streams and propose relationships across both data pools and knowledge communities
- 6. Talent Management: enabling talent to create voluntary digital profiles of their competencies and capabilities, in order to facilitate machine-supported connection and collaboration
- 7. Ecosystem Management: digital representation of the capabilities and interactions of all ecosystem partners the Authority interacts with in order to enable intelligent recommendations on which ecosystem partners can collaborate on problems in public health.
- 8. Digital Dexterity: a focus on building the cultural traits and the people skills that are necessary to leverage the digital potential of EFSA's strategy, including learning-focus, multidisciplinary interaction, user-centricity, and agility.

Data and technology are at the heart of all EFSA's work. Going forward the outcome of all corporate and science projects will need to ensure they achieve expected operational results and are in turn compatible with the digital capabilities, leaving space nonetheless for innovation.

The IT investments carried out in the past Technology Roadmap proved to be important to support the EFSA journey towards a more modern and agile working environment, and they were key in avoiding severe disruptions in the Authority's work during the SARS-CoV-2 pandemic.

In this context, the Service delivery index, which is the metric that measures the satisfaction rate expressed by end-users about the IT support provided, closed the year at 82%, slightly above the target (80%) and 2020 performance (79.1%), while the Transformation performance index was not calculated in 2021 due to the closure of the IT Strategy in December 2019. The indicator registered a final score of 78%, in line with the target of 80% and registering a marked increase compared to the baseline of 67%. While EFSA successfully reduced its IT running costs in the 2013-2019 period, going from \leqslant 10.2 million to \leqslant 8.7 million, by simplifying and consolidating its IT architecture, the 2021-2027 period sees an increased investment in technology in order to support the Authority's and the Commission's digital agenda and its objectives.

Table 44. Output indicators for SO5 (2/2)

ACTIVITY - OUTPUT INDICATORS									
Indicator	Executed 2020	Target 2021	Executed 2021	Status					
Service delivery index ³⁶	79.1%	80%	81.8%	0					
Transformation performance index (development project execution index) ³⁷	N/A	N/A	78% (2019)	0					

Digital collaboration

With EFSA aiming at improving the exchange of knowledge and expertise within EFSA's networks of staff, experts, and interested parties through its Digital Collaboration project, 204 active social collaboration groups with EFSA's scientific experts and networks were active in 2021, above the target of 170 and above the 2020 result of 148 (see table 45).

Another area where the efforts in digitalisation have paid off is the setup of the meetings with EFSA's scientific experts, with EFSA supporting the increase of tele-meetings instead of physical meetings. The last prepandemic result (February 2020) showed that 39% of the meetings with experts were held as tele-meetings³⁸, a result well above the target of 25%. The indicator, that in December 2020 registered a score of 91%, was not measured in 2021 since all the meetings were expected to be held virtually due to the pandemic.

Table 45. Outcome indicators for SO5 – Enabling working environment

КРІ	Indicator	Baseline	Target 2021	Executed 2021	Status			
Outcome: Enabling work environment								
	% of tele-meetings (experts & networks) over total meetings (tele-meetings + physical meetings)	20% (2017)	Not measured in 2021	91% (2020)	o			
Innovative collaboration methods supported by world-class IT tools	Ratio of internal to external email traffic (staff, experts, networks)	95/5 (2017)	Not measured in 2021	55/45 (2018)	o			
	Social collaboration platforms (staff, experts, networks)	15 (2018)	170	204	o			

5.4. People and culture

The emergence of the SARS-CoV-2 pandemic has affected several workplaces across the world, and EFSA, also given the magnitude of the virus in Italy, had to face new challenges. The Authority swiftly acted to protect its workers and its operations, closing its premises at the beginning of March 2020, cancelling all physical meetings and missions, and adopting "smart working" measures, as well as setting up a Crisis Management

³⁶ For the subset of mature processes followed.

 $^{^{}m 37}\,$ For the subset of key projects followed.

³⁸ Percentages are referring to "expert days" (# of hours spent by experts in tele-meetings/# of hours spent by experts overall) and not to "number of meetings", this to avoid, for example, that a long meeting with a lot of participants would have counted as much as a small meeting with a lower number of participants.



Team (CMT). These measures and internal communication activities, developed in 2020 in the wake of the pandemic, were continued also in 2021.

Initiatives to support staff during times of hardship and uncertainty included, among others: a revised onboarding and induction project for newcomers, fully digitalised and integrated with a full relocation package; psychological support open to all staff with licenced psychologists throughout the pandemic; a home office support scheme to assist staff better equip themselves for home working; individual coaching opportunities for managers and staff in critical positions. 46 managers were supported with extra coaching sessions to strengthen resilience while 60 staff members attended the online course "Positive psychology foundations" which aimed at instilling a positive mindset during challenging times.

In addition, in 2021 EFSA continued offering to its staff an online mindfulness course, which won the European School of Administration L&D Awards for best activity to foster resilience in January 2021.

In line with the 3-step approach for a safe and gradual return to the office, in 2021 EFSA remained in the *Gradual Normalisation* step, where teleworking remained the primary working regime but EFSA premises were ready to host up to 50% of staff. EFSA continued however to allow its staff to telework 100% throughout 2021. From 1st September, telework was performed from the place of employment or from a distance allowing Parma to be reached within a reasonable time (a couple of hours).

EFSA has continued to assess how the lessons learnt during this period of virtual work can be translated and adapted into a post-SARS-CoV-2 scenario where the default is switched from physical to virtual, and that were used to support the definition of the EFSA 2027 Strategy.







Step 1 **Cautious** Return

Assumptions

Staff Measures

Other key medsures

- Likelihood of contracting the SARS-CoV-2 virus persists
 Mobility within national &
- European borders remains
- Protective & social distancing
- measures in force
 Teleworking recommended
 Schools & childcare services
 closed or unavailable

- Prolongation of existing teleworking measures
 Prolongation of existing flexible working measures until end June 2020
 Prolongation of special leave for staff taking care of children until end June 2020
 Prolongaton of special leave due to force majeure (serious illness of a spouse/partner, child or relative; incompatibility with teleworking: exceptional circumstances)
 Voluntary return to the office of up to a maximum of 10% of staff including SNEs, trainees, interim workers & consultants
 Provision of coaching, medical & psychological support
- & psychological support services
- Mandatory temperature measurement of all staff & contractors who enter EFSA
- premises

 Daily supply of surgical masks for staff to be worn at all times

 Supply of hand sanitisers on all floors and in key communal greats
- areas
 Regular cleaning & sanitisation of EFSA's
- premises

 Air conditioning operational with 98/99% new air

 Canteen and bar services remain closed

Step 2 Gradual Normalisation

- Likelihood of contracting the SARS-CoV-2 virus remains
- SARS-CoV-2 virus remains possible
 Travel across Europe possible
 Protective & social distancing measures remain desirable
 Schools & childcare services are available operating onsite and virtually
- Teleworking remains the primary working regime
 Voluntary return to the office of up to a maximum of 50% of staff including SNEs, trainees, interim workers & consultants
 Respect of care hours and
- Respect of core hours and established rules on flexitime and recuperation as of July
- 2020
 Development of digital social initiatives to support interaction amongst staff Continued provision of coaching, medical & psychological support services
- Mandatory temperature measurement of all staff & contractors who enter EFSA
- premises
 Daily supply of surgical masks
 for staff to be worn at all times
 Supply of hand sanitisers on
 all floors and in key communal
- areas Regular cleaning & sanitisation of EFSA's premises
- Air conditioning operational with 98/99% new air
 Canteen and bar services remain closed

Step 3 The "next normal"

- Sufficient degree of population immunity has been achieved via vaccination and
- disease exposure
 Likelihood of contracting the
 SARS-CoV-2 virus low across
 Europe and globally
 Schools & childcare services
 are available

- Return to the office of all staff & contractors
 Entry of experts & visitors to EFSA's premises
 Review of rules on teleworking and flexible working measures

- Reinstatement of all standard building and corporate services and applicable rules Supply of hand sanitisers on all floors and in key communal

Readiness & implementation of all applicable digital, on-site & health-related services

Regular digital and on-site communication activities (signage, posters)

Figure 26. Transition steps from Tele to Office Working



Engagement and attractiveness

As 2021 was set to be a year of transition and change, EFSA decided not to launch the planned bi-annual Staff Engagement Survey but, in line with 2020, carry out more agile "pulse check" surveys to understand and respond faster to staff needs. Two pulse checks were run, one in June and one in November, to gather valuable insights from staff throughout the implementation of the Transparency Regulation and the adoption of the new Organisational Blueprint, while embracing the new ways of working brought by the SARS-CoV-2 crisis.

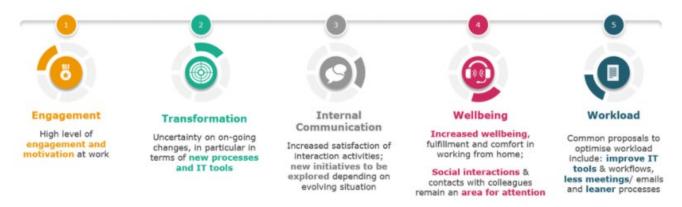


Figure 27. Areas and key messages of the June 2021 Pulse check survey

Results showed a high level of engagement and motivation at work (around 90%, June 2021), in line with past trends, and increased wellbeing in conditions of remote work, confirming great appreciation for the support initiatives and tools made available by the Organisation. However, some concerns on the long-term impact of the current working conditions emerged, as well as uncertainty related to the ongoing changes. 2022 will be a year of consolidation and EFSA will continue to listen to its people, to create a working environment based on trust and credibility, enabling people to deliver at their best.

Learning and development

As a follow-up on the findings emerged from the survey, EFSA set up a series of learning initiatives (the so-called "Managerial Onboarding Programme") to support EFSA staff during this period of change. The programme aims to provide all the necessary intelligence, tools and services focusing on the main corporate processes to facilitate a smooth transition for affected Units and a swift onboarding of the new managerial figures.

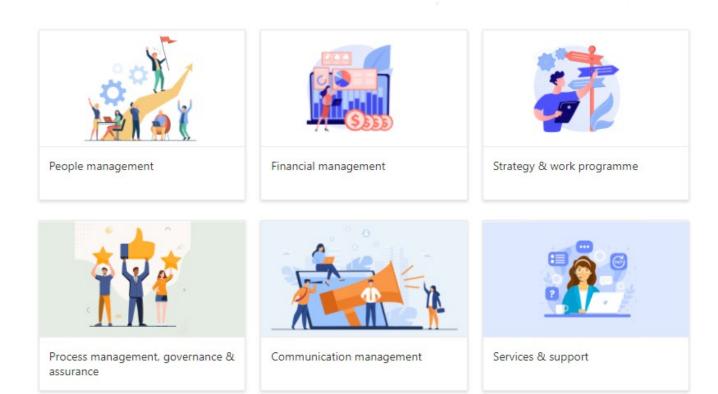


Figure 28. Areas of Managerial Onboarding Programme

Regarding the 2021 learning plan, EFSA continued delivering its learning plan via e-classroom to counter the limitations of the pandemic. Overall, the equivalent of 770 training days through 253 trainings (109 collective trainings and 144 individual trainings) were offered in 2021, involving a total of 1514 registered participants. Compared to the previous year, the figures increased for what concerns training days (+24%, from 621) and number of trainings offered (+12%, from 226), while remained stable in terms of registered participants (1514).

Furthermore, concerning learning, a key highlight has been the conclusion of EFSA's learning programme Personal Leadership, aimed at developing EFSA's future leaders. Based on the lessons learned derived from the first pilot, the programme will be fine-tuned and relaunched with a new cohort in 2022. Lastly, staff and managers were further supported in 2021 with individual coaching sessions and training in Mindfulness and Positive Psychology.



Table 46. Outcome indicators for SO5 – people and culture (1/2)

КРІ	Indicator	Baseline	Target 2020	Executed 2020	Status
Outcome: People and culture					
Staff engagement index	Total favourable	63% (2015)	N/A in 2021	66% (2019)	0
	on Total engagement	76% (2015)	N/A in 2021	79% (2019)	0
framework)	Organisational awareness/ commitment	93% (2017)	N/A in 2021	94% (2019)	0
	Management feedback survey: Line management	69% (2016)	N/A in 2021	74% (2019)	0
	Management feedback survey: leadership	46% (2016)	N/A in 2021	58% (2019)	0
Management and leaders index	Competence management maturity level: Feedback of participants in managers' development programme 2018	TBD	N/A	N/A	0
	Competence management maturity level: EFSA's compliance with ESCO	86% (2018)	86%	85%	0

In 2021 EFSA registered an overall³⁹ average occupancy rate of 93.5% in line with the target of 93.3% (see Table 47). Looking deeper to the sub-indicator on EFSA's 2021 baseline occupancy rate, the index is at 97.8%, a figure slightly above the yearly target of 97%. For the sub-indicator on the new Transparency Regulation hires, instead, EFSA is below the target of 73% set for 2021, reaching a yearly average occupancy rate of 67.6%. In the context of the 75 new posts allocated to EFSA in the context of the TR (and to be progressively filled in the period 2019-2022), 59 staff members were recruited as of 31/12/2021. Due to the limitation introduced to counter the pandemic outbreak, EFSA carried out the onboarding of new hires in 2021 completely in remote.

Table 47. Outcome indicators for SO5 – people and culture (2/2)

КРІ		Indicator	Baseline	Target 2021	Executed 2021	Status
Outcome: People and	l culture					
		Occupancy rate (%)	N/A	93.3%	93.5%	O
Management and leadership index	leadership	of which: EFSA baseline	95.0% (2016)	97%	97.8%	0
		of which: TR related (178 review) recruitments only	N/A	73%	67.6%	0

Finally, in terms of evolution, in the area of EFSA's employer branding strategy EFSA continued progressing on an activity to improve EFSA attractiveness, geographical staff balance and visibility in the job market. The first phase of this activity, a Market Research Study on EFSA's awareness as an employer, was finalised in 2021. This Study provided EFSA with insights about the barriers for applying to EFSA's opportunities and expectations of the candidates. The final delivery, which includes a targeted Employer Branding Strategy is scheduled for the beginning of 2022.

³⁹ EFSA baseline + 178 hires

Future of work

In preparation of EFSA's employees returning to the office environment at least partially and to further support in adjusting to a changing context, namely the changes brought by the SARS-CoV-2 crisis but also considering EFSA's commitment to the EU Green Agenda, the Transparency Regulation commitments and the ambitions of EFSA 2027 Strategy, EFSA embarked on a new project to assess its readiness to embrace the new ways of working. Specifically, this call for a reset in the way we use the office on the one hand and the ways we collaborate in teams, between teams, and with our external stakeholders on the other hand.

The core objective of the "Future of Work" assignment and survey was twofold:

- a. to conduct an **as-is assessment** of the Agency's **cultural organisational attributes**, to identify the most critical features (digital but not only) linked to EFSA's values and supporting a smooth implementation of the 2027 Strategy. The assessment aims at determining the current level of organisational maturity, as well as gaps in relation to desired attributes.
- b. to gather the insights of staff for a more attractive and productive office experience.



Part II(a). Management

1. Management Board

The EFSA Management Board acts in the public interest and ensures that the Authority delivers its mandate as defined in EFSA's founding Regulation and functions effectively and efficiently.

In the reporting period all Management Board meetings were held virtually due to the SARS-CoV-2 pandemic. Four meetings were held, in March, June, October and December, whilst in January an extraordinary Management Board workshop was organised to review the draft EFSA Strategy 2022-2027. On 14 October, the Management Board elected Prof. Aivars Bērziņš as its new Chair and Prof. András Székács as its new Vice-Chair. Mr Michael Winter retained his position of Vice-Chair. In December, the Management Board welcomed Prof. Marija Ceriak, who was appointed by the Council on 23 November.

In June, the Management Board approved the EFSA Strategy 2022-2027, which will guide the organisation in implementing its mandate in the coming years. In December, the Board endorsed EFSA's Performance Framework and the organisation's Strategic Key Performance Indicators and adopted the Programming Document 2022-2024, which inaugurates the implementation of the Strategy.

In line with the applicable rules and regulations, the Management Board adopted all statutorily required documents: the Consolidated Annual Activity Report 2020, opinion on EFSA accounts 2020, Programming Document 2022-2024 & draft Programming Document 2023-2025, appointment of new members of the Scientific Panels, list of competent organisations designated by the Members States that may assist the Authority and Implementing Rules of the Staff Regulations. In addition, the Management Board adopted EFSA's revised Anti-Fraud Strategy and revised its decisions on the Establishment and operation of the EFSA Scientific Networks and on the Establishment and operation of the Scientific Committee, Scientific Panels and of their Working Groups. Furthermore, the Board noted the report on the external review of the EFSA Competing Interest Management rules.

The Audit Committee of the Management Board continued to monitor the actions taken in response to audits and evaluations. EFSA provided the Management Board with regular reports on its performance and gave updates on progresses in key operational areas.

2. Major developments

As described in previous sections, 2021 has seen considerable developments in various fronts. Of particular mention are the entry into force of the Transparency Regulation and the finalisation of its Strategy 2027, both of which required dedicated resources for the development of new processes, the review of EFSA's organisation design, and the leveraging of EFSA's technology and information management capabilities. This has had implications on the availability of resources for EFSA's regular activities, and therefore resulted in some performance deviations, yet while safeguarding EFSA's core business and the overall organisational assurance. The implementation of some of these changes will continue in 2022, and therefore with possible concomitant performance implications expected, albeit to a lower extent.

EFSA Strategy 2027 adopted

In 2021 EFSA's new Strategy 2027 was adopted, following the thorough environment scan analysis performed in 2019 and 2020, providing the strategic focus and ambitions for the coming years in the context of EFSA's mandate including the Transparency Regulation provisions, and the evolving EU priorities—particularly the

European Green Deal and farm to fork strategy. The Strategy 2027 contains a high-level implementation plan with key action envisaged in each area of expected results that will drive EFSA's work in the strategy cycle 2022-2027. During the second half of the year EFSA embarked on the design of new Programmes to organise and manage the strategic development activities of EFSA's Strategy 2027 implementation plan. Three programmes are envisaged covering "Knowledge and Expertise", "Risk Assessment and Methods preparedness" and "Data and Evidence" planned to become fully operational in 2022.

TR implementation

Reaching the Strategy 2027 adoption milestone is concomitant, as planned, to a series of activities in the organisation aiming at preparing EFSA to address the requirements of the Transparency Regulation, into application since March 2021, i.e. EFSA reorganisation, EFSA process architecture review – EPA 3.0, operational as of 2022⁴⁰.

As already observed in year 2020, also in year 2021 the effort spent in the development and management of TR measures has demonstrated to be higher than the additional resources assigned to EFSA for those purposes in the same year. In particular the development projects (including FSCAP, IUCLID Appian, Process re-design, etc.) have absorbed around 55 FTEs in year 2021 and, in parallel to this, extra effort was needed in the areas of talent selection, procurement, engagement and communication. The extra effort suffered in these areas has been estimated for year 2021 at around 12 FTEs.

SARS-CoV-2 outbreak

On the contrary, in year 2021 no loss of capacity could be observed in relation to SARS-CoV-2, differently to what was observed in the previous year⁴¹.

3. Budget and financial management

3.1. Financial resources

The approved budget of EFSA for the year 2021 is EUR 129.2 million in commitment and EUR 120.2 million in payment appropriations following an increase of payment budget by EUR 1.5 million in differentiated credits approved by the Management Board in October. As of end of December, 100% of commitment appropriations and 89% of total payment appropriations were implemented. The payment execution corporate target was met for differentiated credits (100% execution) whereas slightly below the target for non-differentiated credits (87% executed vs. 90% target). All three Key Performance Indicators were in line with the 2020 budget execution; the cancellation of funds carried forward decreased from 5% to 4%.

 $^{^{\}mbox{\tiny 40}}\,$ See Programming document 2022-2024 adopted by the MB in December 2021

⁴¹ In year 2020 the SARS-CoV-19 crisis, has caused a 5% estimated reduction of the workforce and the sudden change in the ways of working (exclusively remotely), together with external causes (e.g. contractors delivery delays, applicants missing data provision delays, etc.) has also caused a global 6% internal inefficiency.



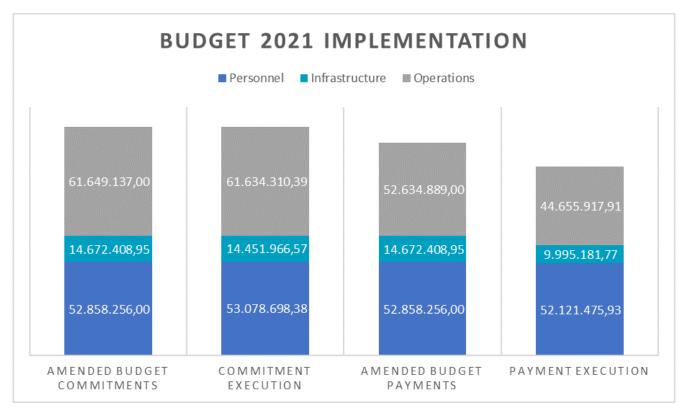


Figure 29. Budget implementation 2020 C1 credits

Title I: the commitment execution reached EUR 53.1 million – 100% of current budget appropriations, slightly above the initial budget of EUR 52.8 million. The increase vs. original budget was mainly the consequence of a higher increase in basic salary cost than originally estimated and of an increase of the budget allocated to interim services resulting from additional demand from units and projects. The major part of the amount com-mitted - EUR 45.8 million – was used for staff salaries and SNE allowances, followed by EUR 3.8 million for interim services and EUR 1.7 million to European School contribution and creches.

The payment execution reached 98% of available appropriations. Unpaid 2% corresponds to EUR 1.0 million that was carried forward to 2022. The carry forward stems from outstanding payment obligations for interim, medical and other external services and trainings.

Title II: the commitment execution of EUR 14.5 million is slightly lower than the initial budget planned to cover the additional needs in Title I. The main categories of expenditures covered were building and associated costs (EUR 6.7 million), IT expenditure (5.9 million) and investments have been made also for the movable property, mainly technical equipment for the meeting rooms and furniture.

Payment execution in the Title at 10.0 million reached 69% of available appropriations. EUR 4.5 million stemming mainly from building and IT related expenditures (pending invoices for supplies and services as well as ongoing works on building) were carried forward to 2022.

Title III: the commitment execution of EUR 61.6 million was in line with the initial budget although the changes in the workplan and travel restrictions related to SARS-CoV-2 outbreak required reallocation between the cost groups.

The budget execution of the scientific cooperation budget (scientific Grants & procurement) with EUR 24.5 committed was the highest category linked to the implementation of the provisions of Transparency

Regulation. Planning above the budget (safeguard planning) in this cost category permitted also absorption of surplus funds released from logistics and events which were the main categories affected by the pandemic.

Substantial investments have been done also in the area of operational IT systems (EUR 15.9 million) to support the implementation of Transparency Regulation, which required also increased investments for risk communication activities and operational development consulting which grew to EUR 4.9 million and EUR 2.1 million respectively.

EUR 12.1 million has been used for scientific meetings, out of which EUR 6.3 million for the risk assessment of regulated products and 5.8 million for generic risk assessment.

Payment execution reached 85% of available payment appropriations. Almost EUR 17.0 million has been carried over, stemming mainly from operational IT systems, communications and operational development.

3.1.1. Appropriations carried forward

Out of 11.5 million carried forward from 2020, 96% corresponding to EUR 11.0 million has been paid. 4% of appropriations carried forward were cancelled, mainly due to provisional nature of services purchased, quality issues and change in the project plans (impacted also by the SARS-CoV-2 related restrictions).

3.1.2. Debit notes

During 2021, 74 debit notes were issued and 72 debit notes effectively recovered for an amount of EUR 120.6 million. This amount includes the EU budget contribution (EUR 120.1 million). Four debit notes remained open at the end of year to the amount of EUR 0.07 million. One of these, issued in previous years, amounting to EUR 0.02 million, is in litigation before the courts.

3.1.3. Amending budgets

Two budget amendments have been approved by the EFSA Management Board: 1) In March 2021, integration of the bank account interest of EUR 44,943.95 into EFSA budget and 2) in October 2021, increase of differentiated payment appropriations of EUR 1.5 million to cover the shortfall identified.

3.1.4. Budget transfers

In the course of the year, seven budget transfers have been implemented to accommodate the updated budget needs. Three budget transfers were part of scheduled portfolio and budget review procedures, two ad hoc transfers were needed to cover immediate needs for home office support and salaries coverage and last two budget transfers done in December aimed to optimise the budget execution transferring uncommitted amount to building acquisition (Titles I and II) and scientific grants & procurement (Title III)

Title I has been globally increased via transfer from Title II by EUR 0.2 million to cover additional needs for the staff salaries due to higher than forecasted increase, interim services and home office support. Surplus funds have been released mainly from the lines covering Visiting experts due to lower than forecasted number of seconded national experts, staff missions, trainings and early childhood centres.

From Title II, EUR 0.2 million has been transferred to Title I to cover respective budget shortfalls. Within the Title, funds have been redirected mainly from building related expenditures and legal services to IT outsourced services and purchase of furniture for the meeting rooms. The main reason for these transfers have been the updates of the plan in the Enabling services project, low regime of building related services (due to low number of staff present) and lower than forecasted number of court cases.



In Title III, EUR 2.2 million have been transferred to scientific grants & procurements (differentiated credits), absorbing surplus funds caused by SARS-CoV-2 pandemic (full virtualisation of meetings and events impacting both meetings, events, and logistics budget) and limitation of staff missions to exceptional cases. Following the changes in project plans and limited possibilities to implement process improvement initiatives, budget has been released also from the lines covering operational IT systems and operational development and control. Additional funds have been transferred to scientific meetings covering risk assessment of regulated products in the areas of food ingredients and packaging and nutrition.

3.1.5. Procurement

The types of procurement procedures were carried out during the year are presented in table 48.

Table 48. Proportion of procurement procedure types used

Procurement types	Number	% of procurement procedure types used (e.g. open/negotiated etc.)
Open procedure (FR 164 (1)(a))	22	19%
Design contest (Annex 1 – 8)	1	1%
Negotiated procedure middle value contract (Annex 1 - 14.2)	9	8%
Negotiated procedure low value contract (Annex 1 - 14.3)	3	2%
Negotiated procedure very low value contract (Annex 1 - 14.4)	73	62%
Negotiated procedure without prior publication (Annex 1 - 11.1)	9	8%
Total	117	100%

3.1.6. Interest charged by suppliers through late payments.

In 2021, no invoice payment has generated late interests.

3.2. Grant, contribution and service level agreements.

EFSA started in June 2019 a new action: "Preparatory measures for the participation of IPA (In-strument for the Pre-Accession Assistance for EU candidate countries or potential EU candidate countries) beneficiaries in the European Food Safety Authority 2019-2021" with a budget of EUR 500 000. DG NEAR made available additional EUR 250 000 to extend this work up to 31 May 2022 in December 2019. With the additional funds EFSA intends to continue to involve IPA bene-ficiaries in its work and to provide opportunities to strengthen the capacities for risk assessment and communication through the promotion of networking and joint activities between EFSA IPA and Member States. One Seconded National Expert is financed under this contribution agree-ment.

3.3. Control results

The objective of the Public Procurement Committee (PPC) intervention is to verify the legality & regularity of major procurement procedures before the signature of the proposed contract. The PPC has been set up to examine, in an advisory capacity, contracts to be concluded on behalf of EFSA; and specifically the PPC will give its opinion on all procurement procedures carried out in function of the different thresholds in force, and, at the request of the Authorising Officer (AO) or the procurement team leader. In exercising its advisory capacity, the PPC will make sure that the resource investment envisaged is proportionate and cost effective. An opinion

is given on every file submitted and communicated to the AO or the unit/department concerned and includes whether the procedure has been properly followed. In 2021, EFSA managed 116 procurement procedures and the PPC reviewed 16 files. The main steps of verification of PPC activity consists of the scrutiny of the evaluation report, the consistency of evaluation of the offers, the consistency with the published criteria and minimum requirements, the verification of the application of principle of equal treatment, proportionality, transparency and competition, and if the proceedings and decisions of the evaluation committee are transparently and sufficiently documented. For the 16 reviewed procurement procedures, the PPC concluded with reasonable assurance that the procurement procedures and the resulting contracts are regular and legal (see Table 49).

Table 49. Control activity | Public Procurement Committee

	SCOPE	Plan	Monitoring Criteria	Owner	Monitoring	Reporting
FINANCE	All EFSA procurement procedures exceeding thresholds	Continuous	Legality & Regularity Procurement Procedures	FIN	Public Procurement Committee FIN/ GPS/LA	EFSA Integrated Management System

The mass payment procedure for scientific meetings and missions streamlines the financial payment procedure, having at the same time in one platform the monetary data and the financial information of the experts. The ex-post control provides assurance for the leaning verification on mass payments for scientific meetings and missions. The analysis in the area of experts' reimbursements is based on the tracking of complaints with a financial impact. The indicators taken into account to represent expert complaints are the following: additional payments inserted in ABAC in consequence of complaints introduced by experts or for corrections; recovery orders inserted in ABAC in consequence of complaints introduced by experts or for corrections; and deductions or integrations of amounts operated in the mass-payments in consequence of complaints introduced by experts or for corrections. Each mass payment processed for experts is subject to recording of corrections. During the year 2021 a total of 4 complaints were reported that represent 0.048% of the yearly volume of expert's reimbursements (approximately 8.248). In 2021, 68 mass-payments were launched for a total of 8.090 reimbursements and a global amount of €11.9 Million. Out of the 455 reimbursements via mass payment verified, 3 corrections were identified representing 0.70% of the total number of reimbursements verified and 0.04% on the total number of reimbursements processed. The net amount of €4,521 to be corrected after verification represents 0.04% of the global mass payment amount in the reporting year. The outcome of the ex-post financial verification on mass payments for scientific meetings and missions is within the monitoring criteria set for 2021 (Table 50).

Table 50. Control activity | Financial verification on mass payments

	SCOPE	Plan	Monitoring Criteria	Owner	Monitoring	Reporting
FINANCE	Additional payments, recovery orders and deductions mass payments experts	Yearly	< 1% (amounts paid)	FIN	Assurance Governance	EFSA Integrated Management System

In addition to the above ex-ante and ex-post financial controls, an ex-ante control activity is taking place within the remit of the Project Coordination Office (PCO). PCO is a coordination and support office assisting in the implementation of a portfolio, programme, project and process management approach within EFSA



at operational (i.e. work-programme/SPD) and strategic (i.e. strategy implementation plan) level, controlling compliance with the set methodological requirements/SOPs. More specifically the activities of PCO include:

- Play a general consultative role to projects, processes, programmes by supplying charter templates, best practices, training, access to information and lessons learnt from other projects;
- Support the control of the organisation's compliance with portfolio, programme, project and process management methodologies;
- Verify and monitor the impact of incoming mandates as well as of changes to ongoing projects and processes on the EFSA work-programme;
- Escalate appropriately with clear impact analysis and recommendations as necessary, e.g. if a prioritisation or resource issue arises, to support evidence-based decision making, integrating information related to planned activities, actual results and variance (actual vs. planned) analysis, performance/KPI implications;
- Maintain the register of requests for changes to the work-programme and relevant recommendations in preparation of the quarterly RFC information.
- Facilitate the identification of cross-cutting, overlapping and/or sensitive (impacting on communication strategy) mandates/applications.

3.4. Cost and benefits of controls

Overall, the cost of controls as % of total annual budget, procurement and grant spending is summarised in table 51^{42} .

Table 51. Cost and benefits of controls

v	Total b	oudget	G&P budget		
Year	Amount (M, €)	% Cost of control	Amount (M, €)	% Cost of control	
2021	129.1	0.41	24.5	2.14	
2020	103.0	0.34	11.9	2.93	
2019	78.7	0.48	7.9	4.81	

4. Delegation and sub-delegation of the powers of budget implementation to agency's staff

4.1. Time-limit of the delegation-sub-delegations

Unlimited (until further revision due to re-organisation or change of BL numbering).

4.2. List of the BLs covered by sub-delegations granted to another AOD;

The HoDs are delegated on the related BLs of competence with defined ceilings, lower than the ones of the ED. The Business Services HoD has received delegation with defined ceilings on all BLs in order to be the proper back-up in case of unforeseen absence/urgent need.

 $^{^{42}}$ Based on the actual FTEs involved in the control activities ex-ante and ex-post: 3.85 ftes with an average cost of 100,000/Fte

4.3. A summary of the conditions of these delegations and sub-delegations (i.e. the control and reporting requirements);

For the purposes of the budget implementation, and in line with Article 41(1) of EFSA's Financial Regulation, the Executive Director as the Authorising Officer of the Agency has delegated financial powers to the Heads of Departments for the budget lines, they are responsible for in line with their activities. In accordance with Article 41(2), the Head of Departments have further sub-delegated financial powers to the Heads of Unit of their Departments. For efficiency reasons, the Executive Director has also delegated financial powers to few staff members for lower amounts. Control done at department level, supervised by Finance unit and implemented in ABAC by IT unit based on the documents signed by the Executive Director. Reporting monitored by Finance as well as by ECA auditors + External auditors at least twice a year.

4.4. Information on the controls carried out, any weaknesses identified and the actions taken to remedy these;

As highlighted above, controls are done at department level, and thereafter by Finance unit. Im-plementation is done by IT based on the documents signed by the ED. The controls are done by ECA and External auditors at least twice a year, and no weaknesses were identified in 2021.

Validation User Access Rights granted in ABAC

ABAC is an integrated system allowing the execution and monitoring of all budgetary and accounting operations. The objective of the validation was to review the appropriate access rights management in ABAC by assessing the adequacy and effective application of the internal control system and governance processes implemented for the access rights management. In particular, the review assessed the compliance of ABAC access rights against responsibilities entrusted to the user in accordance with the standing procedures. The outcome of the assessment provided reasonable assurance that the access rights granted in ABAC are in line with delegations entrusted to staff for authorising officers and for financial actors other than authorising officers.

Table 52. Control Activity | Validation User Access Rights In ABAC

	Scope	Plan	Monitoring Criteria	Owner	Monitoring	Reporting
INFORMATION MANAGEMENT	ABAC Access Rights Management Compliance	Yearly	No invalid access rights AO's	FIN/LA	Assurance Council	EFSA Integrated Management System



5. Human resources management⁴³

5.1. Major HR Developments in 2021

In 2021, EFSA has been given 33 new staff posts for the implementation of the new Transparen-cy Regulation, reaching a total capacity of 526 statutory staff posts (Officials, TAs, CAs). EFSA has increased its efforts in branding and dissemination of calls, using a broader range of sourcing channels and promoting its job opportunities at various virtual career events. Overall EFSA count-ed:

- 131.000 LinkedIn followers (vs. 104.000 LinkedIn followers in 2020)
- 4.400 applicants to staff positions (vs. 3.000 applicants in 2020)

Throughout 2021, EFSA has extended more than 100 offers, onboarded around 65 statutory staff members and managed to continue its recruitment activities despite the pandemic. The Agency welcomed around 86 young professionals and 4 SNEs and managed an average of 75 interim staff. 11 new panel experts were appointed, in addition to around 200 experts to its working groups. By the end of the year, EFSA reached an average occupancy rate of 93.5% for statutory staff, in line with its target of 93.3%.

Since May 2020, EFSA has been using the EU Commission HR tool 'Sysper' for the management of staff time tracking & leaves, rights & obligations and for the issuing of certificates. Additionally, in 2021 e-payslips became available for staff in the tool.

For the second year in a row, EFSA had to propose its learning offer in remote modality and was able to deliver successfully not only the dense catalogue of internal and external classical courses (251 trainings - 1456 registered participants - 763 training days managed) but to continuously innovate with the Personal Leadership Programme, the mandatory catalogue now fully accessible on e-learning and the positive psychology to name a few. In parallel, a major effort was made to configure and deploy the Performance, Goals and Learning Management System which will pave the way towards becoming a learning organization as per EFSA strategy 2027.

The enhancement and coordination of the onboarding process for staff joining EFSA through ex-ternal recruitment, or changing roles as part of internal mobility, was one of the focus areas. To guide staff better through all aspects of the onboarding, a dedicated newcomer's space was cre-ated on EFSA's Intranet portal. It was complemented by a guide for managers, providing Report-ing Officers with all they need to create a positive onboarding experience for new staff members, and help them become effective contributors to EFSA's mission.

In addition to the above, EFSA went live on 17 April 2021 with an electronic onboarding module in the Taleo Recruitment Tool. This module manages and supports the onboarding of staff and trainees through an automated, customer-oriented solution. It offers EFSA and candidates a seamless experience and enhances the automatization and digitalisation of onboarding processes, reducing the time spent on administrative tasks.

The onboarding programme was fine-tuned and further adapted to the pandemic situation, the fully implemented relocation package was further consolidated standardising the range of ser-vices offered to newcomers (including house hunting, school search, public administration and bureaucracy, health matters). Despite the difficulties related to remote onboarding, all statutory deadlines of contract management were met. 30 staff successfully passed their probationary period, with 0 failures.

⁴³ Including, in accordance with the para. 28 Parliaments Discharge Report "2011 discharge: performance, financial man-agement and control of EU agencies" (P7_TA(2013)0134), the number of days of leave authorised to each grade under the flexitime and compensatory leave schemes. The reported nr of staff refers to the staff who have been authorized days of flexitime and/or compensatory leaves in 2021

The new organisational structure entered into force on 1 January 2022 was timely and fully im-plemented in Sysper by the end of 2021 and subsequent support and guidance was offered to staff and managers in relation to the tools.

Table 53. Number of days of leave authorised to each grade under flexitime

Grade (nr of staff)	Nr of staff	Total nr of Leave Days (Flexitime + Compensatory)	Of which Compensatory
AD5	6	18.0	
AD6	16	37.5	
AD7	10	23.0	
AD8	16	47.0	
AD9	8	23.5	
AD10	2	5.5	
AST3	6	11.0	5.0
AST4	5	23.0	2.5
AST5	11	54.5	3.5
AST6	4	22.0	
FGII4	1	0.5	-
FGII5	1	6.5	6.5
FGII6	1	1.0	1.0
FGII7	1	6.0	3.0
FGIII10	1	2.0	-
FGIV13	8	18.5	-
FGIV14	10	21.5	-
FGIV15	6	14.5	-
FGIV16	3	13.0	-
Total		348.5	21.5

On 31 December 2021, 516 of the available 542 posts were occupied (including officials, tempo-rary agents, contract agents and seconded national experts). With specific reference to statutory staff (officials, temporary agents and contract agents), 504 posts out of the 526 available were occupied on 31 December (95.8%). In terms of statutory staff average occupancy rate, 492 out of the available 526 posts (93.5%) were occupied throughout the year 2021 (vs the 2021 yearly target of 93.3%).



Table 54. Human resource overview (31/12/2021)

Home or a constant	2020	2021	2021
Human resources	budget request	budget request	(31/12/2020)
Temporary Agents and Officials Executives, Managers & Officers (AD)	255	284	266
Temporary Agents and Officials Assistant functions (AST)	99	96	98
Total TAs+Off	354	380	364
Contract Agents officer functions (CA FGIV) ⁴⁴	114	121	110
Contract Agents assistant functions (CA FG I, II, III)	25	25	30
Total CAs	139	146	140
Seconded National Experts	16	16	12
TOTAL STAFF ALL CATEGORIES	509	542	516

5.2. Implementing rules

In 2021, the EFSA Management Board adopted 1 implementing rule by analogy of a Decision of the European Commission on the transfer of pension rights. Details are available in the Annex IV.

5.3. Results from screening / benchmarking exercise

In 2021, the increase in the share of jobs allocated to 'operational' role (from 78.5% in 2020 to 79.0% in 2021) and corresponding decrease in the 'administration and coordination' role (from 17.5% to 17.1%) are in line with the trend of the past years.

Within the 'operational' role, the increase is particularly affecting the category of 'programme im-plementation', where most of the additional recruits of the 178 Transparency Regulation capacity have been allocated.

Within the 'administration and coordination' role, the decrease in the share is also due to the higher volume. This does not correspond to a decrease of the absolute number of FTEs allocated to this role. In particular, due to the allocation of additional staff on 178 Transparency Regulation related tasks an increase in the 'legal coordination' category can be observed.

6. Strategy for efficiency gains

In the context of its core business, EFSA had not planned for any downsizing or discontinuation of activities for which a mandate is ongoing.

The activities related to scientific evolution and preparedness have normally been identified as the lower priority in case of resource conflicts but also this area of investment is necessary to maintain EFSA relevant and effective in executing its core business. These re-prioritisations and resource deployments are dealt with on a rolling basis.

 $^{^{\}rm 44}\,$ Numbers include 4 CAs utilised by ECHA from 2020, as per EFSA-ECHA agreement

The increased capacity, apart from the 42 FTEs posts increase in the year 2020 and 32 posts in 2021 linked to TR, resulted from the implementation of actions aiming at efficiency gains by generating an extra 10-15 % capacity in the period 2016-2021 (5 years).

The efficiency gains together with an improved occupancy-rate (from 93.8 % in 2014 to 96.5 % in 2021 (not considering the new statutory staff posts of the year), obtained by improving the recruitment process and by optimising the use of interim resources for covering long-term absences more than compensated the 36 post reduction in the establishment plan that had occurred in the period 2013-2018 as per the MFF.

The efficiency initiatives generate capacity follow two streams:

a. Tools/resources/provisions and processes that facilitate efficiency and productivity/Increasing automation/streamlining of work processes, moving to e-administration and e-training

The ongoing investment on the re-design and the automation of the core business processes, made necessary for the efficient implementation of the TR requirements are oriented to facilitate higher productivity standards and implement efficiency gains.

In particular, the new IT solutions, once implemented, will support the dossier processes in the phase of acceptance, public consultation and confidentiality management as well as in the execu-tion of the risk assessment workflow and all the connected transparency measures.

b. Sharing services and IT development projects among agencies / Reviewing IT infrastructure

In the logic of maximising the synergies in the EC context, EFSA has adopted solutions that were already (partially) implemented in the EC parent DG (FSCAP solution for processing and validat-ing new regulated products dossiers) or in other agencies (ECHA IUCLID solution for handling all dossier information related to chemicals).

It has to be noted that considering the relevant transformation in terms of processes, IT tools and organisation that EFSA has embraced during years 2020 and 2021, no efficiency gains have been targeted for year 2021, 2022 and first half of 2023. Further details are provided in Table 55.



Table 55. Sources of human resource capacity increase (FTEs)⁴⁵ (numbers in each column represent the cumulative increase/decrease up to that year).

Source	Programme	Project	2015-2019	2020	2021
		EFSA Journal outsourcing	8.8	8.8	8.8
		EFSA website update (AGORA)	1.5	1.5	1.5
		Records and correspondence management	0.5	0.5	0.5
	IMP	Scientific data warehouse (SDWH)	2.1	2.1	2.1
		NWOW (ART) and digital collaboration ⁴⁷	1	2	2
		BIKE	0	1.3	1.3
Efficiency		Total IMP	13.9	16.2	16.2
gains 46	STEP 2018	STEP 2018 and paperless workflow	19	19	19
		Mission centralisation and travel outsourcing ⁴⁸	4	9	9
		Obligations and rights management (Sysper) ⁴⁹	2	2	2
	EMP	Talent management ⁵⁰	3	3	3
		Total EMP	9	14	14
	ADT	TBD ⁵¹	0	0	0
	ART programme	Total ART	0	0	0
Efficiency g	ains total		41.9	48.4	48.4

7. Assessment of audit and ex-post evaluation results during the reporting year

7.1. Internal Audit Service (IAS)

The work of the Internal Audit Service (IAS) in EFSA is based on a Strategic Internal Audit plan that originates from an in-depth risk assessment. The purpose of this exercise is to review all administrative, financial, operational and IT processes to constitute risk-based plans and deter-mine the priorities of the internal audit activity. This analysis serves as the basis for preparing the IAS Strategic Internal Audit Plan 2022-2024 for EFSA, whereby the IAS presents the key risks identified and proposes topics for future IAS audits. The shortlist of prospective audit topics to support the planning of the IAS audits during the following three years is the following:

⁴⁵ The list includes key efficiency initiatives targeted through specific projects and that aim at the generation of 'free capacity' that could be used elsewhere, therefore it is not fully comprehensive (e.g. it does not include incremental efficiencies via process streamlining or shared services and synergies with Member States and EU institutions expected to yield 'shared' benefits in the medium to long term). Figures indicating efficiency gains are to be considered as cumulative, for example. 'Mission centralisation and travel outsourcing' will produce efficiency gains of 4 FTEs in 2018, which will become 6.5 in 2019 and be carried over to 2020 and 2021. This is a 'living' table, to be updated as a result of the actual implementation of the projects over the years.

⁴⁶ Efficiency initiatives often have financial benefits in addition to or instead of FTE efficiencies. These financial savings are beneficial to EFSA human resource capacity by releasing the financial constraints that may limit the achievement of higher occupancy rates.

⁴⁷ New efficiency initiatives (e.g. NWOW, digital collaboration, BIKE) starting in 2019, and FTE savings are at the heart of the business case.

⁴⁸ Project closed and overachieved with redeployment of 2 additional FTE

 $^{^{\}rm 49}\,$ Delay of one year in the project with Go-live postponed by the EC

 $^{^{\}rm 50}\,$ Delay of one year with the late onboarding of a competency manager

⁵¹ Savings from the ART programme is an objective for the programme and have been calculated as an average year-on-year 3% efficiency improvement at EFSA level (all processes) starting from mid-year 2023.

- Enterprise data governance and management
- End to end risk management process
- Evaluation of regulated products in the areas of feed, nutrition and GMO for new approvals and renewals
- Strategic planning, programming, and performance management

During the reporting year, the audit report on the procurement and grant award processes was issued and the audit planning and fieldwork for the audit on information security and disaster re-covery was ongoing.

The fieldwork for the audit on the procurement and grant award processes was performed be-tween October 2020 and January 2021. The objective of the audit was to assess the adequacy of the design, the effectiveness and the efficiency of the processes established for the procurement and grant award processes within EFSA. The scope of the audit covered the procurement and grant award processes, from the identification of the needs until the contract/grant agreement signature, and its related governance, risk management and internal control framework. The au-dit covered the procurement and grant award procedures finalised in the years 2019 and 2020. The final report on the procurement and grant award processes in EFSA was issued on April 9, 2021.

Based on the results of its audit work, the IAS concluded that the governance, risk management and internal control framework set up by EFSA for its procurement and grant award processes is adequately designed, efficient and effective, therefore providing reasonable assurance that the key internal control objectives are achieved. The processes are adequately set up, resourced and coordinated, and related information is properly shared within EFSA.

Notwithstanding the overall positive conclusion, the IAS issued the following three important au-dit recommendations:

- Documentation of the monitoring of procurement and grant procedures
- Timing of the contract signature and the declarations in honour
- Procedure and documentation of the declaration of absence of conflict of interest and con-fidentiality in the procurement and grant award processes

EFSA replied to the audit report confirming the acceptance of the audit recommendations and EFSA prepared an action plan for all recommendations that was overall considered adequate by the auditors. EFSA is currently implementing this action plan.

The audit on information security and disaster recovery started in the last quarter of 2021. The objective of the audit is to assess the adequacy of the design and implementation of the govern-ance, management and control processes of EFSA's IT security and disaster recovery arrange-ments. The related audit report is planned for the first semester of 2022.

7.2. European Court of Auditors (ECA)

The ECA's responsibility is to provide the European Parliament with a statement of assurance as to the reliability of the annual accounts and the legality and regularity of the underlying transactions.

The European Court of Auditors conducted its annual financial and regulatory audit of the Au-thority's 2020 accounts and adopted its report on 29 October 2021. In the report, the ECA ex-pressed the following audit opinions:



- Opinion on the reliability of the accounts
 In the Court's opinion, the accounts of the Authority for the year ended 31 December 2020 pre-sent fairly, in all material respects, the financial position of the Authority at 31 December 2020, the results of its operations, its cash flows, and the changes in net assets for the year then end-ed, in accordance with its Financial Regulation and with accounting rules adopted by the Com-mission's accounting officer. These are based on internationally accepted standards for the public sector.
- Opinion on the legality and regularity of the transactions underlying the accounts
 In the Court's opinion, revenue and payments underlying the accounts for the year ended 31 December 2020 are legal and regular in all material respects.

The European Court of Auditors' audit report on the outcome of annual financial and regulatory audit of the Authority's 2020 accounts included one issue on the duration of the managerial tem-porary postings. EFSA's operations are heavily influenced by the Transparency Regulation, and the priorities of the European Commission, the most relevant in EFSA's field being the European Green Deal and Sustainable Development Goals. The overall aim is to further foster stakeholders' and citizens' trust in EFSA and to make our risk assessments more robust. The Transparency Regulation required shifting EFSA's operating model and in order to implement all new measures foreseen in the regulation, EFSA launched the ART programme including an Organisational De-sign project that was initiated at the end of 2018. Together with the drafting of EFSA's post 2020 Strategy, managerial calls were put on hold as the ambition was to have the new organizational structure in place together with the kick-off date of EFSA's new Strategy i.e. 1 January 2021. SARS-CoV-2 hit Italy as of February 2020 and as a consequence the EFSA's Strategy design and Organisational Design Project deliverables had to be postponed by one year. The full organisa-tional redesign has been performed throughout 2021 and will be rolled-out in 2022. The duration of the managerial temporary postings issue was generated by a combination of events that were not all under EFSA's control. EFSA accepted the ECA finding knowing that with the roll-out of EF-SA's Organisational Design project all concerns of the ECA are now fully addressed. At the time of preparing this report, EFSA had not received an opinion on the EFSA 2021 annual accounts.

8. Follow-up of recommendations

8.1. Follow-up of recommendations and action plans for audits and evaluations

After the follow-up audits performed during the reporting year concerning the IAS audits on Hu-man Resources Management and Ethics, and the Evaluation of Regulated Products Assessment Phase in Pesticides Authorisation, there were no critical or very important IAS recommendations outstanding. Both follow-up audits concluded that all audit recommendations had been adequate-ly and effectively implemented. There are two outstanding IAS important audit observations with a delay of more than six months in the implementation of the respective action plans, one con-cerns the weaknesses in the appraisal and promotion exercise and the other concerns the moni-toring of the remuneration cap for outside activities and the management of conflicts of interest for EFSA staff. The ECA followed up on the issue on the working language used in the procure-ment procedure for the EFSA Medical Adviser and considered the action taken by EFSA adequate to close this audit observation. Currently there is one outstanding very important audit recommendation concerning the duration of the temporarily occupation of the managerial postings.

One ECA audit finding from 2017 on the need to strengthen the accounting officer's independ-ence, where ECA and EFSA have a difference in opinion, is not included in the overview of out-standing audit recommendations. In EFSA's opinion, the formal requirements set by the financial regulation to ensure the independence of the accounting officer are already in place. The EFSA Management Board appointed the current accounting officer in 2008. The accounting officer re-ports to the Head of the Bus Department and to ensure the functional

independence of the ac-counting officer in the performance appraisal workflow, the Head of BuS Department is the re-porting officer and the Chair of the Audit Committee the Countersigning officer. The accounting officer may at any time be suspended temporarily or definitely from his duties by the Manage-ment Board. The Court did modify the outstanding observation on the independence of the ac-counting officer and the Court now agreed that the independence of the accounting officer to-wards the Management Board was in place in EFSA. There is still a difference in opinion between the Court and EFSA in making the accounting officer directly responsible to the Executive Director.

Table 56. Summary table on status outstanding audit recommendations

	Rating	Audit recommendation	Traget	Target revised	OWNER	STATUS
2021	nt	1. Duration temporarily occupation managerial postings (ECA)	Q2 2022	NA	HUCAP	Open
2020	Very Important	2. Accumulated batches of work of the re-evaluation of safety of food additives and enzymes (IAS)	Q4 2021	NA	FIP	Ready
2019	<u>=</u>	3. Weaknesses in the time management process (IAS)	Q4 2020	NA	HUCAP/LA/TS	Ready
2021		4. Documentation of the monitoring of grant and procurement procedures (IAS)	Q4 2021	Q2 2022	FIN	Open
	Important	5. Timing of contract signature and declaration of honour (IAS)	Q3 2021	NA	FIN	Ready
		6. Procedure and documentation declaration absence conflict of interest and confidentiality in the procurement and grant award process (IAS)	Q3 2021	NA	FIN	Ready
		7. Staff expertise, backup arrangements and training (IAS)	Q4 2021	NA	FIP/HUCAP	Ready
		8. Monitoring (IAS)	Q4 2021	NA	FIP/GPS	Ready
2020		9. Access rights and public information (IAS)	Q4 2021	NA	ISO/DMO/ART	Ready
		10. Follow up and approval of declarations of interest from EFSA staff (IAS)	Q4 2021	Q2 2022	LA	Open
2019		11. Weaknesses in appraisal and promotion exercise (IAS)	Q4 2020	Q4 2022	HUCAP/TS	Open
		12. Monitoring remuneration cap outside activities and management of conflicts of interest (IAS)	Q2 2020	Q2 2022	LA	Open

8.2. Follow-up of recommendations issued following investigations by the European Anti-Fraud Office⁵²

During the reporting year EFSA did not have to transmit or follow-up on any suspension of fraud cases to OLAF.

9. Follow up of observations from the Discharge Authority

On 28 April 2021, the European Parliament (EP) granted to EFSA the Discharge in respect of the implementation of the budget for the financial year 2019. This is the final approval of the budget implementation and the closure of the 2019 annual accounts. Regarding the observations made by the European Parliament in the Discharge 2019 with respect to some aspects of EFSA's opera-tions, EFSA has informed the European Parliament that the majority of the recommendations have been implemented, and the remaining are in the process of being completed.

⁵² Article 11 Regulation (EU/Euratom) 883/2013 of the European Parliament and of the Council concerning investigations conducted by the European Anti-Fraud Office (OLAF)



Table 57. Summary table on status observations from the Discharge Authority

	Discharge observation		
	Encourages the Authority to pursue the digitalisation of its services	Ongoing	
Performance	2. Encourages the Authority to actively seek further and broader cooperation with the Union agencies	Ongoing	
	3. Calls the Authority to address gaps in its risk assessments of GMOs	Implemented	
Stoff Dalies	4. Encourages the Authority to take further measures to ensure better geographical balance but acknowledge the efforts made	Ongoing	
Staff Policy	5. Calls the Authority to report if any further measures will be implemented to prevent future cases of harassment	Implemented	
	6. Calls the Authority to seek the confirmation of the Court of Auditors on EFSA internal auditor's independence	Implemented	
Prevention and management of conflicts of interest	7. Calls for the policy on independence to be updated without delay in order to ensure that experts' interests are viewed within the context of EFSA's overall remit	Implemented	
and transparency and democracy	8. Calls for the 25% research funding threshold to be removed from the Authority's independence policy	Implemented	
and democracy	9. Calls on the Authority to align its practices with the European Ombudsman recommendation to forbid moves of staff to the private sector after their term of office	Ongoing	
Internal Controls	10. Notes that the IAS made two very important observations and that it started an audit on the assessment and adoption of scientific outputs in the food ingredients and packaging domain		
Others	11. Calls on the Authority to aim at disseminating the results of its findings to the general public	Ongoing	

10. Environment management

EFSA maintained the Eco-Management and Audit Scheme (EMAS) and the Occupational health and safety management systems (ISO 45001) certifications, which were confirmed after the external audits that took place in May and in October. Significant progress was made in the context of the EMAS 2019/2021 objectives: 100% of the electric energy used by EFSA is produced by renewable sources; EFSA applied the identified green practices for events organisation in view of the One Conference (Brussels, June 2022); staff was informed about EMAS objectives and other green initiatives trough the EMAS dedicated microsite. Furthermore, significant reduction in CO2 emissions and savings in terms of travel costs were obtained due to missions and in-person meetings/events' suspension/virtualisation in response to the continuation of the SARS-CoV-2 pandemic.

Environmental sustainability was also further supported by green procurement criteria in call for tenders. Market analysis was conducted throughout the year to assess the green options to be included in selection and award criteria, in minimum requirements and certification requests. In addition, when preparing the call for tender for the shuttle services, EFSA relied on the Green Public Procurement helpdesk (GPP), an interinstitutional helpdesk which helps European Institutions and Bodies willing to strengthen sustainability in public procurement

In-line with EMAS procedures, every three years, EFSA defines an environmental programme setting out specific environmental objectives and an action plan to meet them, which is approved by external auditors. The progress made is illustrated in the following figure.

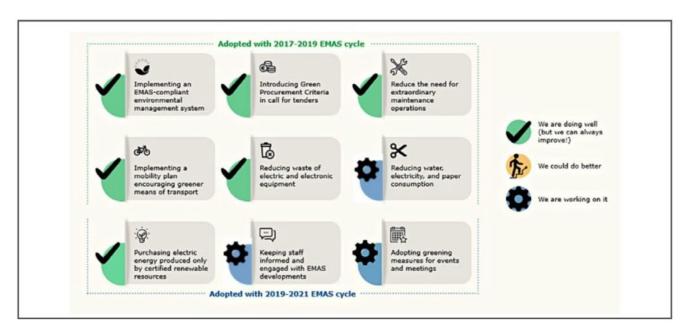


Figure 30. EFSA environmental programme: environmental objectives and action plan

11. Assessment by management

Conclusion on audit results and follow up

EFSA addresses all accepted audit recommendations by proportionate action plans and monitors their implementation regularly. The EFSA Assurance adviser reports on the progress made on the implementation of the outstanding audit recommendations twice per year to EFSA's Audit Com-mittee. None of the issues raised by the auditors were critical. The issue addressed by the Court of Auditors or the important weaknesses pointed out in the IAS audit report do not point to a sig-nificant repetitive error or deficiency in EFSA's internal control system. EFSA's implementation of audit recommendations is in general assessed as positive, auditors find EFSA's actions appropri-ate and risks are mitigated for both audit recommendations reported by the IAS as significantly delayed.



Part II(b). External Evaluations

The third external evaluation covered the EFSA's working practices and the impact of its activities in terms of effectiveness, efficiency, coherence, complementarity and EU added value for the period 2011-2017. The recommendations of the MB based on the result of this external evaluation are listed here below. EFSA identified actions to address the recommendations during the Strategy 2020 cycle, and already embedded relevant activities in the design of the strategy 2027 implementation plan. The table below provides a summary of these activities.

Table 58. Actions to address MB recommendations

#	MB recommendations consolidated	Actions 2021
1	Enhance the capacity for fit-for- purpose and responsive scientific advice, by improving the planning and responsiveness of the Agency, optimizing the use of resources, harmonizing EU assessments, and utilizing technological development in IT and data management	 In the context of ART programme leading the implementation of the Transparency regulation measures, the mandate negotiation process is built in collaboration with SANTE, and is embedded in the relevant tools. Regular update at the AF meeting on the EU RA Agenda. Tools to exchange information on risk assessment plans are in place (R4EU, AF surveys) and multiannual sourcing plan. Proactive publication of monitoring and survey data on EFSA's open access platform (Knowledge Junction) and open data portals such as Information Platform for Chemical Monitoring. Automation and artificial intelligence capacity building is developing.
2	Enhance communication activities to strengthen EFSA's reputation by increasing proactivity of communication, communicating more collaboratively, and contextualizing communication to address societal concerns while using communication science to improve communication about risk assessment	 Recommendations collected at the Stakeholder Forum in 2019 and through the review of the Stakeholder Engagement Approach (SEA) 2016-2019 are followed to gradually introduce the elements of a new engagement framework, to fulfil the requirements of the Transparency Regulation and meet the ambitions of the Strategy 2027 in the area of public engagement Broad programme of social advice and research activities, including commissioning of research (e.g. Eurobarometer).
3	Secure long-term efficiency and sustainability of operations by enhancing the efficiency of the advice production system, finding additional ways to utilize the expertise, and increasing EFSA financial resources	 Broader lean approach initiated across the entire organisation, with the first batch of training and improvement initiatives in 2020. The 'BAUHAUS' initiative started in 2019, evolved to the "Design, validate and integrate a framework that will allow the organisation to make strategic decisions with regards to outsourcing core business decisions" aiming at identifying activities like the preparatory work for the risk assessment and parts of the risk assessment that can be outsourced by using the most appropriate sourcing tool. In parallel, initiatives are ongoing with Sister Agencies⁵³ and the JRC to promote joint programming and the sharing and joint management of data and scientific expertise. Highlights are the EC HPAC (High Performance Analytics and Computing) initiative, joint projects with ECHA on shared data (e.g. IUCLID) and methodologies (e.g. endocrine disruptors), and other shared initiatives on HR (joint trainings, mobility and shared posts), and research (identification of joint projects under Horizon Europe). Strengthen resource outlook analysis in EFSA programming document and implementation of engagement plans with EC, EP and Council including advocacy messages and initiatives linked to resources/sustainability of the RA model. 'Fees discussion' kept on hold in an endeavour to avoid interferences with the implementation of the Transparency Regulation and accompanying resources.

 $^{^{\}rm 53}\,$ responding to the ENVI Committee of the EP

#	MB recommendations consolidated	Actions 2021
4	Continue the transformation to an Open Science Organisation, by making evidence transparent and re-usable, making the advice- development process accessible, enhancing the dialogue with stakeholders and safeguarding and explaining the organisation's independence	 Definition of the dossiers format and document format (IUCLID building blocks for managing PPP and MRL applications submission and validation in collaboration with SANTE and ECHA, FSCAP implementation for other regulated products areas in collaboration with DG SANTE, SIGMA Data formats in animal health area, in collaboration with MSs.) Definition of the Notification of Studies Register data format and its implementation. Proactive dissemination of non-confidential dossier content as per TR indications - before and after confidentiality assessment.
5	Invest in preparedness to cope with complex futures by scanning emerging risks while codeveloping adequate assessment methodologies, by co-developing European capacity for future risk governance and by co-influencing EU research funding priorities	 Membership of the EREN network expanding with additional observers. FAO and WHO now integrated and attending every meeting. Sister Agencies also integrated and participating to meetings. Reflection and plans linked to the 2027 Strategy, including a key-pillar on knowledge management and capacity building. The RAMPro programme prioritises the development of adequate new methodologies to address risk assessment needs of the future. A new instrument is being implemented (SPIDO), leveraging on the TR sustainability measures, to prioritise and invest in large-multistakeholder projects on developing the needed capabilities for the future (e.g. cumulative exposure assessment)." A new process "Strategic engagement is designed to strengthen role and advocacy in EU and MS research programmes, together with other regulatory science bodies, to ensure good coverage of research priorities and full and open access to research results. Particularly to support the set-up or linking-to ecosystem communities, platform(s), partnerships and engagement mechanisms for innovation covering i) the EFSA DEV topics/projects ii) the strategic F2F initiatives; iii) EU research projects; iv) horizon scanning and crises preparedness; including international and 3rd country organisations as relevant
6	Collaborate, cooperate and co- design to meet integrated "One health" protection targets by upgrading collaboration to a strategic level, by utilizing the opportunities of big data and by limitless sharing to tackle complexity and resources constraints.	 EFSA contribution to the Chemical substances strategy and one substance one assessment initiative with ECHA, as well as reflections and plans part of 2027 Strategy, following the "Changing context analysis" performed in EFSA during 2020. HPAC collaboration (Health EU Sister Agencies, JRC, DG SANTE< DIGIT) on shared solutions solving Artificial Intelligence, Data Management as well as Big Data solutions Joint One Health Project on WGS data analysis in collaboration with ECDC RUEDIS Project supporting the improvement of the RUEDIS database with BfR. As a continuation of the "Advisory Forum Task Force on Data Collection and Modelling" the implementation of a shared "data roadmap" with the MSs is aligned with EFSA 2027 Strategy.

EFSA also carried out a mid-term evaluation of the EFSA Strategy 2020 to take stock of progress made in EFSA's current strategy implementation and identify lessons learned for the next strategy cycle. The results and conclusions focused on improvement areas for EFSA's five strategic objectives and lessons learned considerations on (i) scientific risk assessment, (ii) risk communication and engagement and (iii) knowledge, resources and collaboration and fed the EFSA strategy 202754 and its implementation plan.

EFSA closed in 2021 the two pending recommendations from the third-party evaluation of the STEP 2018 project, namely on:

- 1. Centralisation harmonise and streamline the role of the DBC (Department business controls) vis-à-vis the coordinators across the departments
- 2. Enabling the Strategy to provide long-term benefits: Strategy (& work-programme) performance monitoring (streamlining the number of KPIs and linking benefits to strategic results)

Lastly, EFSA carried out a review of its rules on Independence, which is further described in the Annex IX herein.

https://www.efsa.europa.eu/en/corporate-pubs/efsa-strategy-2027-science-safe-food-sustainability



Part III. Assessment of the effectiveness of the internal control systems

1. Effectiveness of internal control systems

The EFSA Internal Control Framework, based on the equivalent standards laid down by the European Commission and international best practice, was adopted by EFSA's Management Board in December 2017. The Internal Control Framework consists of five internal control components and 17 principles based on the COSO Internal Control Framework. Internal control monitoring criteria for EFSA were defined to ensure an adequate assessment of the presence and functioning of all internal control principles. The assessment was based on the following elements: the internal control monitoring criteria, the results of the ex-post controls, the continuous monitoring and systematic registration of exceptions, non-conformities and internal control weaknesses, and the audit observations from the IAS and ECA.

2. Conclusions of assessment of internal control systems

EFSA conducts its operations in compliance with the applicable laws and regulations, working in an open and transparent manner and meeting the expected high level of professional and ethical standards. EFSA has adopted its Internal Control Framework aimed to ensure the achievement of policy and operational objectives. The financial regulation requires that the organisational structure and the internal control systems are set up in accordance with these principles. Compliance with the internal control framework is a compulsory requirement. EFSA uses the organisational structure and the internal control systems suited to achieving its policy and internal control objectives in accordance with the internal control principles and has due regard to the risks associated with the environment in which it operates. In its internal control system, EFSA embedded continuous monitoring measures to ensure that its internal control framework is effective.

EFSA assessed its internal control systems for the reporting year and concluded that overall, all internal control components and principles were present and functioning as intended. In addition, measures will be taken to further strengthen the management of grants & procurement, IT financial and vendor management.

In conclusion, management has reasonable assurance that, overall, suitable controls are in place and working as intended; risks are being appropriately monitored and mitigated; and necessary corrective action is being implemented.

3. Statement of the Manager in charge of risk management and internal control

I, the undersigned,

Manager in charge of risk management and internal control within EFSA,

In my capacity as Manager in charge of risk management and internal control, I declare that in accordance with EFSA's Internal Control Framework, I have reported my advice and recommendations on the overall state of internal control in the Agency to the Executive Director.

I hereby certify that the information provided in the present Consolidated Annual Activity Report and in its annexes is, to the best of my knowledge, accurate, reliable and complete.

Parma, 10 March 2022

Selomey Yamadjako SIGNED



Part IV. Management assurance

1. Review of the elements supporting assurance

In order to be able to sign his declaration of assurance, the Executive Director relies on various elements of the internal control system, referred to as building blocks of assurance:

- Audit Management, see Part II(a) 2.7 and 2.8
- Financial Reporting and Discharge, see Part II(a) 2.9
- Risk Management and Anti-Fraud Strategy, see below
- Internal Control, see Part III
- Legality and regularity monitoring, see below
- Evaluation, see Part II(b)
- Quality management, see below
- Performance Management, see below
- Continuous improvement, see below
- Information security, see below
- Security and Business Continuity, see below
- Health & Safety and Environment, see Part II(a) 2.10

1.1. Risk Management and Anti-Fraud Strategy

Risk management is about identifying and assessing potential issues that could affect the execution of the organisation's activities and the achievements of objectives. As part of EFSA's planning cycle, risks and mitigating actions are identified at process level and captured in EFSA's process documentation. A streamlined impact/likelihood approach is used to perform the risk assessment to select the appropriate risk response. The most relevant ones in the reporting period were the delivery of the Transparency Regulation and the SARS-CoV-2 uncertainties which are outlined together with the other critical and cross-cutting risks that could potentially impact the achievement of EFSA's objectives, and respective mitigating actions that reduce the risks to acceptable levels, in EFSA's 2021 Programming Document.

In light of the common approach on EU decentralized agencies developed by the European Commission that requires each agency to put in place a set of anti-fraud measures and in line with the guidance provided by the European Anti-Fraud Office (OLAF), EFSA has adopted a new Anti-Fraud Strategy in 2021. EFSA's Anti-Fraud Strategy encompasses all stages of the anti-fraud cycle, namely prevention, detection, investigation and recovery/sanction. The EFSA Anti-Fraud Strategy defines four main objectives focusing on enhancing an environment and culture that reflects EFSA's intolerance to fraud, strengthening fraud risk monitoring, maintaining a robust system for fraud detection and investigation, and readiness in recovering damages and sanctioning fraudulent activities. During the reporting year, EFSA did not have to transmit or follow-up on any suspicion of fraud cases to OLAF.

1.2. Legality and Regularity Monitoring

In accordance with the Internal Control Framework, EFSA has implemented a process for the management and control of ex ante exceptions and ex-post non-conformities, including the analysis of the root cause, the assessment of the risks and the identification of corrective and/or preventive actions. To ensure traceability, the deviations from all applicable rules and regulations are documented in an exception request or a non-conformity, which is recorded in an exception register. In 2021, EFSA recorded 81 deviations, 16 deviations concerned exception requests approved ex-ante, whereas 65 deviations concerned non-conformities noted ex-post. The deviations to rules and procedures mainly concerned the malfunctioning of the new Declaration of Interest tool and the unfeasibility of recording tollgates for the pre-Transparency mandates/dossiers on the Case Management tool. The financial value of the deviations amounted to EUR 1.547.961 with one single exception request representing a financial impact of EUR 1.388.534 due to a legal commitment that was made prior to the financial commitment for a service level agreement between EFSA and ECHA. Although the nature of the recorded deviations was impacted by the transition to new processes and tools and some issues were recurrent, the procedures in place function well and the existing controls are considered sufficient.

1.2.1. Information Management

Information security

EFSA is actively committed to safeguarding the confidentiality, integrity, and availability of all information that it manages, to ensure that regulatory, operational, and contractual requirements are fulfilled.

EFSA conducted an external maturity assessment with the objective of continuously improving our information security. The assessment identified improvements actions that shaped the new EFSA Information Security Strategy 2023 adopted by the EFSA Management Team. Planned actions included starting the ISO 27001 certification project and executing an Awareness Raising Plan.

EFSA adopted a detailed Information Security Handbook, which contains the required actions and procedures to ensure correct and secure operations of EFSA IT facilities.

The security of several EFSA IT systems was improved with the roll-out of Multi-Factor Authentication, which is also the standard for new IT systems.

EFSA organized web security tests for several EFSA IT systems.

Finally, EFSA conducted internal audits and security plan updates for key IT systems.

EFSA was not affected by any cyber-attacks during the reporting year. Some attack attempts have been stopped by our security tools.

1.2.2. Data protection

Following the General Data Protection Regulation (EU) 2016/679 (GDPR) which became applicable in the EU Member States on 25 May 2018, the 'GDPR for EU institutions, bodies, offices and agencies', Regulation (EU) 2018/1725 came into force on 11 December 2018. The GDPR legal framework puts increased emphasis on accountability of controllers and business owners for compliance on the personal data management within their remits following a risk-based approach. The European Data Protection Supervisor (EDPS) is the independent supervisory authority whose primary objective is to ensure that European institutions and bodies respect the right to privacy and data protection when they process personal data.

Throughout 2021, awareness-raising initiatives and data protection training took place and specific advice on calls for tender & grants launched and for the drafting of data protection notices (e.g. return to work decision,



green pass verification) was provided on top of the data protection compliance review of EFSA license subscriptions. No personnel data breach occurred during the reporting year.

During the reporting year, the European Data Protection Supervisor (EDPS) performed a query concerning the adoption of internal rules and implementation of restrictions to data subjects' rights and a questionnaire on COVID. In October 2020, the EDPS initiated a horizontal audit on personal data international transfers through outsourcing, services and operations of EUIs outside the EU for which EFSA provided a mapping of ongoing data processing operations and ongoing contracts involving transfers to third parties. The outcome of this horizontal audit is expected in 2022.

1.2.3. Quality management

EFSA's Quality Management System was awarded in 2016 the ISO 9001:2015 certification attesting EFSA's ability to consistently produce services that meet EFSA's customers' requirements and foster a culture of continuous improvement. In 2021, the focus continued to be ensuring that the requirements for the implementation of the Transparency Regulation were met. Work was carried out to improve the monitoring of process performance by revising and improving the existing process performance indicators. This work was carried out in conjunction of the update of the EFSA Process Architecture (EPA) which was modified and revised to align it with the changes brought on by the Transparency Regulation. The 2021 customer feedback interviews with DG SANTE resulted had a positive outcome and identified a number of improvement opportunities.

The 2021 surveillance audit by the certification body confirmed EFSA's ISO 9001:2015 Quality Management certification. The certification auditors reported zero non-conformities and did not identify any particular areas of weakness in our Quality Management System

1.2.4. Performance management

Performance management was ensured via regular measurement of the Key Performance Indicators that are part of the EFSA Strategy, as well as also via the measurement of additional elements such as project performance and specific metrics at process level.

In 2021 EFSA revised its Performance Framework to align it with the EFSA 2027 Strategy and the new EFSA process architecture (EPA 3.0), and it will be in use as of 2022. The new Performance Framework sees a reduced number of KPIs (around 60 unique indicators) to cover the 13 Expected Operational Results and the 4 Expected Outcomes of the EFSA 2027 Strategy. For what concerns the process metrics, instead, around 6 metrics/process were put forward, with stronger control in the area of scientific Risk Assessment. When applicable, synergies between KPIs and process metrics were created.

In the context of the new Performance Framework, EFSA worked on dedicated fiches per each KPI/process metric. These fiches capture elements like scope and measurement methodology, in order to systematize knowledge and increase the likelihood of a stable measurement over the years.

1.2.5. Continuous improvement

The continuous improvement process continued to support EFSA's LEAN initiatives in order to maximise resources and create more agile and efficient processes.

There was a total of 16 process improvement initiatives (PIIs) managed in 2021 under this process. These initiatives had various improvement aims such as: cycle time reduction, improvement of customer satisfaction and efficiency gains. An approach for the regular measurement of the benefits of these improvements was putting in place in 2021 and will be concluded during 2022.

In order to maximise the effectiveness of this process, the identification of improvements opportunities will be better linked to the various assurance triggers, and the Lean capability in the organisation will be strengthened with additional partnering and trainings

1.2.6. Security and Business Continuity

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

EFSA's Business Continuity is to maintain the continuity of its activity, systems, facilities and processes and where these are disrupted by an event to enable it to return to normal operations as soon as possible, taking fully into account the impact of any delay on the EFSA's quality of service, reputation and budget. EFSA's business continuity plan is based on a business impact analysis and used by trained staff to ensure that EFSA is able to continue working to the extent possible in case of a major disruption. EFSA's contingency plan was activated in due time when the information of SARS-CoV 2 spreading in the Lombardy region was released. EFSA activated its Business Continuity Plan and the Crisis Management Team (CMT) convened regularly since February 21, 2020 to deal the crisis situation throughout the 2021. In October 2021 a re-certification and transition audit by the certification body confirmed EFSA's ISO 22301 Business Continuity management certification.

1.2.7. Health & Safety and Environment

EFSA is committed to establish and continuously promote a sound management system that aims at ensuring a healthy and safe workplace and a sustainable business environment. In 2021 the external certification body has confirmed EFSA's ISO 14001:2015 environmental management standard and the Eco-Management and Audit Scheme (EMAS) registration. In 2021 the Occupational Health and Safety certification (ISO 45001:2018) was confirmed.

2. Reservations

Not applicable



Part V. Declaration of assurance

I, the undersigned, Director of EFSA,

In my capacity as authorising officer,

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

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

This reasonable assurance is based on my own judgement and on the information at my disposal, such as the activities and outcome of the 12 Assurance Pillars reported in EFSA's Assurance re-port, the work of the Internal Audit Service and the lessons learnt from the reports of the Court of Auditors for the years prior to the year of this declaration.

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

Parma, 10 March 2022

Bernhard Url SIGNED

Annexes

Annex I. Core business statistics

(a) Questions closed in 2021

Table 59. Questions closed in 2021

		REPRO						RASA					
Questions per strategic objective and type of output	APDESK	FEED	FIP	GMO	NUTRI	PRES	PREV	АГЬНА	AMU	BIOCONTAM	DATA	SCER	TOTAL
SO1 – Prioritise public and stakeholder engagement in t	he pro	cess of	scient	ific ass	essme	ent							
SO1 – EFSA scientific outputs – general risk assessment			3	4	3	54	2	77		28	1		172
Of which:													
- conclusion on pesticides peer review							1						1
opinion of the scientific committee / scientific panel			2	1	2			66		19			90
guidance of the scientific committee / scientific panel													
statement of the scientific commiittee / scientific panel				1	1					2			4
reasoned opinion						4							4
– scientific report of EFSA						49		11		7	1		68
– guidance of EFSA													
– statement of EFSA			1	2		1	1						5
SO1 – Technical reports – general risk assessment		1		1				41		5	8		56
SO1 – Other publications (external scientific reports/event reports) – general risk assessment			1		1			9		5			16
- Other publications - external scientific report			1					6		5			12
- Other publications - event report					1			3					4
SO1 – Sub total – general risk assessment		1	4	5	4	54	2	127	0	38	9		244
SO1 – EFSA scientific outputs – evaluation of regulated products		109	123	10	23	81	50			2			398
Of which:		116	80	5	38	80	22			1			342
- conclusion on pesticides peer review													
opinion of the scientific committee / scientific panel						1	20						21
guidance of the scientific committee / scientific panel		115	80	5	30					1			231
- statement of the scientific committee / scientific panel					8								8
- reasoned opinion		1					2						3
- scientific report of EFSA						79							79
– guidance of EFSA													
- statement of EFSA													



		REPRO						RASA					
Questions per strategic objective and type of output	APDESK	FEED	FIP	GMO	NUTRI	PRES	PREV	АГЬНА	AMU	BIOCONTAM	DATA	SCER	TOTAL
SO1 – Technical reports – evaluation of regulated products	12				5		22						39
SO1 – Other publications (external scientific reports/event reports) – evaluation of regulated products				2									2
– Other publications - external scientific report				2									2
– Other publications - event report													
SO1 – Sub total – evaluation of regulated products	12	116	80	7	43	80	44			1			383
SO1 – Total	12	117	84	12	47	134	46	127		39	9		627
SO2 – Widen EFSA's evidence base and optimise access to	o its da	ita											
SO2 – EFSA scientific outputs													
SO2 – Technical reports								2			3		5
SO2 – Other publications (external scientific reports/ event reports)											3	1	4
– Other publications - external scientific report											3	1	4
– Other publications - event report													
SO2 – Total								2			6	1	9
SO3 – Build the EU's scientific assessment capacity and k	nowle	dge co	mmun	ity									
SO3 – EFSA scientific outputs													
SO3 –Technical reports										2		1	3
SO3 – Other publications (external scientific reports/event reports)								4	1				5
– Other publications - external scientific report									1				
– Other publications - event report								4					
SO3 – Total								4	1	2		1	8
SO4 – Prepare for future risk assessment challenges													
SO4 – EFSA scientific outputs		1	2	1			4			1		8	17
Of which:													
– opinion of the scientific committee / scientific panel				1			2			1		3	7
– scientific report of EFSA													
– statement of the scientific committee / scientific panel							1					1	2
– guidance of the scientific committee / scientific panel		1											1
– guidance of EFSA (regulated products)			2									3	5
– statement of EFSA							1					1	2
SO4 – Technical reports			2	2			4					6	14
SO4 – Other publications (external scientific reports/event reports)							4	8	2	1	3	11	29
– Other publications - external scientific report							4	8	2	1	3	10	28
– Other publications - event report												1	1
SO4 – Total		1	4	3			12	8	2	2	3	25	60
Total questions	12	118	88	15	47	134	58	141	3	43	18	27	704

Table 60. Questions closed by food sector area for SO1 general risk assessment

SO1 General risk assessme	SO1 General risk assessment					
EFSA Unit	Total by Unit	Food/feed sector area	Questions closed			
Animal and plant health		Animal Health	40			
	127	Animal Welfare	6			
		Plant Health	81			
		Biological Hazards	7			
		Biological Hazards - Animal by-products	1			
Biological hazards and	38	Biological Hazards - EUSR TSE	2			
contaminants	36	Biological Hazards - EUSR zoonoses and AMR	19			
		Biological Hazards - Multinational foodborne outbreaks	3			
		Contaminants	6			
Evidence management	9	Data Collection and Analysis	9			
FEED	1	Feed Additives	1			
Food ingredients and packaging	4	Food Improvement Agents	4			
GMO	5	GMO	5			
Nutrition	4	Nutrition	4			
Pesticides residue	54	Pesticides MRL	54			
Pesticide peer review	2	Pesticides Peer Review (AIR)	2			
Total			244			



Table 61. Questions closed by food sector area for SO1 regulated products

SO1 Regulated products			
EFSA Unit	Total by Unit	Food/feed sector area	Questions closed
Applications desk	12	Administrative and Technical Support	12
Biological hazards and contaminants	1	Biological Hazards - Animal by-products	1
FEED	116	Feed Additives	116
Food ingredients and	00	Food Contact Materials	36
packaging	80	Food Improvement Agents	44
GMO	7	GMO	7
BL 4 *4*		Novel Foods	28
Nutrition	43	Nutrition	15
Pesticides residue	80	Pesticides MRL	80
		Pesticides Peer Review - Other Areas	15
Pesticide peer review	44	Pesticides Peer Review (AIR)	17
		Pesticides Peer Review (NAS)	12
Total			383

In some areas of the regulated products evaluation the delays registered concerning the initial deadline lead to the accumulation of backlog. These questions are part of the ongoing work programme and efforts are made to reduce their number during the actual year. To be noted that questions received in bulks and pending evaluation, are not part of this backlog. For these cases, called "bulk evaluations", a work plan is agreed or pends agreement with the risk managers.

Details on the actual backlog and its reduction per food sector area during 2020 are presented in table 62, while current status of bulk evaluations is included in table 63.

Table 62. Regulated products - Backlog reduction in 2020

Regulated products area	# at year start	# at year end
FEED	51	30
Feed additives - applications	51	30
GMO	2	1
GMO - miscellaneous	2	1
PRES	27	14
Pesticides MRL Application (Reg. 396/2005 - Art. 10)	27	14
PREV	5	2
Pesticides peer review - miscellaneous	5	2

Table 63. Regulated products - Bulk evaluation in 2021

Status	Regulated products area	Number of questions at year start	Number of questions at year end
	FIP	348	336
	Flavourings ⁵⁵	35	27
	Enzymes ⁵⁶	206	210
Deadlines agreed with Risk Manager	Food additives – re-evaluation	questions at year start 348 35 206 107 80	99
	PRES		52
	Pesticides MRL Review (Reg. 396/2005 - Art. 12) - ex backlog		52
Danding Disk Manager desision	NUTRI	1548	1548
Pending Risk Manager decision	Health Claims (Art.13.2) - botanicals	questions at year start 348 35 206 107 80 1548	1548

⁵⁵ Evaluation of flavouring substances included in the Union list with a footnote, according to Regulation (EC) 1565/2000 and Implementing Regulation (EU) 872/2012. The plan for addressing the remaining evaluations is influenced by the timing of submission of information from applicants. The number of on-going questions might be increased because of potential future FGEs (flavouring group evaluations) (confirmed only if no safety concerns are identified), or newly received requests.

⁵⁶ The number takes into account the questions closed for food enzymes applications until end 2020, and 4 additional question received during the year.



(b) Status of programme and projects

Table 64. Programmes – Status report

Strategic Objective	EFSA Programmes	Status
	Architecture Transformation Programme (ART)	
- Strategic Objective 1 - Strategic Objective 2 - Strategic Objective 3 - Strategic Objective 4 - Strategic Objective 5	To prepare EFSA for the requirements of the Transparency Regulation, which will come into force on 27 March 2021, has the double objective of driving the various changes related to processes, organisation, technology and information management needed within EFSA's new remit, and leaning EFSA's core and enabling processes	0
	Expertise Management Programme (EMP)	
- Strategic Objective 1 - Strategic Objective 2 - Strategic Objective 3 - Strategic Objective 4 - Strategic Objective 5	To build the EU scientific assessment capacity and knowledge community and creates an environment and culture that reflect EFSA's values	o
	Information Management Programme (IMP)	
- Strategic Objective 1 - Strategic Objective 2 - Strategic Objective 3 - Strategic Objective 4 - Strategic Objective 5	To coordinate all projects related to EFSA's information at 360 degrees: from information collection and (co)creation, to information classification and registration, from data analysis and data reporting to information sharing and re-use	•
	Risk Assessment Methodology Programme (RAMPro)	
- Strategic Objective 1 - Strategic Objective 2 - Strategic Objective 3 - Strategic Objective 4 - Strategic Objective 5	To ensure that EFSA is prepared for present and future challenges in a dynamic food safety system, by innovating and harmonising its risk assessment methodologies	o

Table 65. Projects and Process improvement initiatives under SO1 – Status report per expected result

Strategic Objective 1					
Expecte	d results	Projects	Status		
Foster engagement throughout the development of scientific assessments	Fit-for-purpose & timely advice to RM addressing stakeholders' expectations	Risk assessment project	<u></u>		
		Renewal assessment of glyphosate (PRAG)	O		
		Acceptable Daily Intake (ADI) for exposure to copper	o		
	Increased engagement of stakeholders in scientific activities	Relationship Management Project	O		
Ensure clarity and accessibility/ usability in the communication of findings	Strengthened communication effectiveness analysis	Joint research for evidence-based risk comms (microplastics)	o		

Table 66. Projects and Process improvement initiatives under SO2 – Status report per expected result

Strategic Objective 2				
Expecte	d results	Projects	Status	
Migrate towards structured scientific data	Increased standardisation of data	N/A		
		Data collection and analyses on animal disease outbreaks (SIGMA)	o	
Improve data interoperability to facilitate data exchange	Improve interoperability of data	Interoperating 'One Health' system	O	
	Increased standardisation of data Improve interoperability of data	Data Management and Data Analysis Virtualisation (DAMA) 2.0	O	

Table 67. Projects and Process improvement initiatives under SO3 – Status report per expected result

Strategic Objective 3					
Expecte	d results	Projects	Status		
		Talent Management Project	O		
Foster growth of the RA community with international	the RA community at individual	External Talent Pool & Attraction Package Project	Closed		
organisations	St Pr	Strategic Competencies Analysis - SCA Project	Closed		
		Joining forces at EU level - Artificial Intelligence	O		
Review and further develop EFSA's scientific assessment model	Strengthened capacity using innovative ways	CROWDSOURCING: Engaging communities in scientific assessment	O		
		Rened capacity using re ways Talent Management Project External Talent Pool & Attraction Package Project Strategic Competencies Analysis - SCA Project Joining forces at EU level - Artificial Intelligence CROWDSOURCING: Engaging communities in scientific assessment FEED production model EFSA conference 2022	Closed		
Strengthen capacity building and	Building & sharing capacity	EFSA conference 2022	O		
capacity sharing	organisational level	Pre-accession	O		
Increased RA efficiency at European and international level		,	0		



Table 68. Projects and Process improvement initiatives under SO4 – Status report per expected result

		Strategic Objective 4	
Expecte	ed results	Projects	Status
	Accessibility of EFSA	EFSA Toolkit for BMD analysis	0
	methods and tools	Pesticide Residue Assessment Tool (PRATo)	0
Become a hub in		PRIMo revision 4 (Pesticide Residue Intake model)	0
methodologies, tools and guidance		Update of the EFSA pesticides genotoxicity database	0
documents for RA		Critical appraisal tools - human observational epidemiological studies	0
		RUEDIS database	0
		R Services for EU projects (R4EU)	0
		EFSA Framework for problem formulation	0
		EFSA Template for protocol development	0
		Outsourcing of the application of NGS on noroviruses	0
		Harmonised exposure assessment methods for food of animal origin	0
		Updated guidance on the assessment of smoke flavourings	O
		OECD MetaPath: Incorporation of pesticide residues data	0
		Adverse outcome pathways of endocrine disruptors	0
Develop and	Harmonisation of	Critical appraisal forms for ecotoxicological studies	0
implement harmonised		Guidance on the impact of water treatment processes	0
methodologies and guidance documents for RA	RA methodologies	Guidance on how to characterise, document and explain uncertainties in RA	0
documents for KA		Develop cross-cutting guidances	0
		SC Guidance appraising, integrating evidence from epidemiological studies	0
		Non-monotonic dose-responses	0
		Update the Guidance on Food Enzymes for Safety Evaluation	0
		New approach method for RA of chemicals in food	0
		Update of the Guidance on the renewal of feed additives authorisations	Closed
		Animal dietary exposure assessment for GM Feed	0
		Guidance documents for the substantiation of health claims	N/A

		Strategic Objective 4	
Expecte	d results	Projects	Status
Expected r		Configuration IUCLID dossier for evaluation of active substances PPP by MS	
		Data Collection Tracing	o
		Food Classification For Tracing	O
Develop and implement		Read-across for Chemical RA in food safety	0
harmonised methodologies	Harmonisation of RA methodologies	Refinement of the RA method for Open Reading Frames	0
and guidance documents for RA		Food allergens (thematic) grant	0
		Updated Guidance exposure operators, workers, residents, bystanders	Closed
		In vitro comparative metabolism	Closed
		Risk-benefit assess of fish consumption in relation to dioxins	0
		Wildlife surveillance	0
		Plant Health preparedness to the risks of new plant pests	0
		Animal disease profiling: increased preparedness for risk assessments in the EU (Athropod vectors)	0
		Syndromic Surveillance	0
		Revision and update of AHAW Panel Guidance	0
		WGS Umbrella	0
	Foster use of	HLADQ Peptide Modelling	0
Strengthen EFSA's ability to anticipate	new approaches, enhanced ability	Guidance environmental concentrations active substances of PPP in soil	Closed
and respond to food safety risks	to anticipate & respond to risks	Integrated testing strategy - developmental neurotoxicity	0
	respond to risks	Revision of the EFSA Guidance on RA for Birds and Mammals	0
		Operations of the Scientific Panel on PPP and their Residues	0
		RA of metals used as active substances	Closed
		CRA of pesticides from 2020 onwards	0
		Revision of the EFSA Guidance on the RA of PPP BEES	0
		MUST-B project	0
		Guidance on the human, animal and environmental risk assessment	O



		Strategic Objective 4	
Expecte	d results	Projects	Status
		Scientific opinions SC overarching elements of ERA	Closed
		Update of the 2012 SC scientific opinion on the TTC	Closed
		Synthetic Biology	O
		Scientific Committee Guidance on aneugenicity assessment	Closed
		Identification of emerging chemical risks in food	0
		Capacity building for microbiome assessment	O
		MixTox:RA of combined exposure to multiple chemicals	O
		Non-monotonic dose-responses	Closed
		Tools for evidence management in global inf networks	0
	Foster use of	Derivation of HBGV for food additives and other RP	O
Strengthen EFSA's	new approaches, enhanced ability	PLH procurement on Xylella vectors	O
ability to anticipate and respond to food	to anticipate & respond to risks	Allergenicity of GM plants	O
safety risks		Exploring in silico/vitro tools & develop novel strategies	O
		Use and reporting of historical control data (HCD)	O
		Review of the IESTI equations in 2019/2020	Closed
		Finalization of the draft Guidance on photo transformation products of PPR	0
		EFSA's Activities on Emerging Risks	O
		RA Tools for the Safety of Global Food and Feed Supply Chains	Closed
		SPIDO	0
		AMR in environment	Closed
		Water in food processing	O
		Integrating new approaches in chemical risk assessment	0
		Emergency authorizations for use of neonics in sugarbeet crops	0

Table 69. Projects and Process improvement initiatives under SO5 – Status report per expected result

		Strategic Objective 5	
Expecte	d results	Projects	Status
	Assurance management and compliance with rules	Objectivity Policy Project 2016	0
		Confidentiality and Sanitisation project (CASA)	O
continuing	Quality and continuous improvement	Records and Correspondence Management	0
& processes: improving	Results-based management	BIKE	N/A
organisational per-formance/	Staying relevant in the organisational	Organisational Design	0
capabilities	and institutional evolving context	ICTAT Network 2020 Chairing	N/A
		Parma 2020	O
	World class	Digital collaboration	Closed
	environment to achieve	Travel Management Model	O
	EFSA's strategic capabilities	IUCLID project (MVP 2)	O
		Enabling services Project	O



(c) Impact - Outcome- Output indicators: Source of data

Table 70. Key performance indicators - Source of data and frequency of measurement

so	Туре	КРІ	Frequency	Tool /Source of data ⁵⁷
MULT	TANNUAL V	VORK PROGRAMME		
SO1	Impact	Impact of media coverage	Quarterly	Media Impact Analysis (MIA)
SO1	Impact	Satisfaction on EFSA journal	Quarterly	External provider - Wiley
SO1	Impact	Satisfaction on RA process (All stakeholders; Applicants; Risk managers)	Every two years	Customer/Stakeholder feedback survey
SO1	Impact	Satisfaction on other communication products	Every two years	Customer/Stakeholder feedback survey
SO2	Impact	Satisfaction on SO2: all Stakeholders	Every two years	Customer/Stakeholder feedback survey
SO3	Impact	Number of Member States active in sharing RA plan	Quarterly	Manual calculation
SO3	Impact	Potential divergence identified before the adoption of an opinion	Quarterly	Manual calculation
SO3	Impact	Potential duplication identified before an activity is started	Quarterly	Manual calculation
SO3	Impact	Follow-up actions within 10 days of identification of potential duplication	Quarterly	Manual calculation
SO3	Impact	Satisfaction on SO3: (EU, international, third countries; Individual experts)	Every two years	Customer/Stakeholder feedback survey
SO3	Impact	Outreach of supporting publications on grants and procurement (access, citations, downloads)	Quarterly	External provider - Wiley
SO4	Impact	% of questions delivered within the initially agreed timelines	Yearly	Appian/ Manual calculation
SO4	Impact	% of questions for which data, expertise, methods is readily available	Yearly	Manual calculation
SO4	Impact	Satisfaction on SO4: (Stakeholders; EU, international, third countries; Risk Managers)	Every two years	Customer/Stakeholder feedback survey
SO4	Impact	Use of EFSA's guidances (article access, citations, downloads)	Quarterly	Wiley
SO4	Impact	Use of EFSA's tools	Quarterly	R4EU
SO5	Impact	Accounts are closed	Yearly	Manual calculation
SO5	Impact	Discharge is granted	Yearly	Manual calculation
SO5	Impact	Observations are followed up within the prescribed deadlines	Yearly	Manual calculation
SO5	Impact	Proportion of Impact, Outcome, Output KPIs reaching target	Quarterly	Hyperion - Oracle Planning and Budgeting Cloud
SO5	Impact	Ratio of effort (FTE) spent in operational activities	Yearly	Sysper
SO5	Impact	Projects: improved index (delivery on budget, on time, in scope or better)	Quarterly	Manual calculation
SO1	Outcome	Impact, visibility and discoverability of EFSA's scientific outputs	Quarterly	External provider - Wiley
SO1	Outcome	Increase followers from social media platforms	Quarterly	Web-based application
SO1	Outcome	Number of subscribers to online subscription products (newsletter and alerts)	Quarterly	Web-based application
SO1	Outcome	Traffic to EFSA web content from social media	Quarterly	Web-based application
SO1	Outcome	Traffic to EFSA's web content (web metrics): number of sessions	Quarterly	Web-based application

⁵⁷ Tool / surce of data will in some cases change in 2021 due to technological updates linked to TR implementation.

so	Туре	КРІ	Frequency	Tool /Source of data ⁵⁷
SO1	Outcome	Proportion of EFSA' scientific outputs with direct access to datasets/metadata	Quarterly	Knowledge Junction
SO1	Outcome	Social interactions	Quarterly	Web-based application
SO1	Outcome	Number of public consultation comments received	Yearly	Manually
SO1	Outcome	Survey feedback from SEA members on EFSA's engagement activities	Every three years	Survey with SEA members
SO2	Outcome	Data quality index	Yearly	Data Warehouse
SO2	Outcome	Increased maturity in data interoperability : EIF/IMM index	Yearly	Manual calculation
SO2	Outcome	Number of data collection dashboards/aggregates published	Quarterly	EU Open Data Portal, EFSA website
SO2	Outcome	Number of publicly accessible data collections with no data aggreg. from EFSA	Quarterly	Data Warehouse
SO2	Outcome	User statistics from the data warehouse	Quarterly	Data Warehouse
SO2	Outcome	User statistics from the evidence hub	Quarterly	tracking of data re- use through DOIs/ Microstrategy
SO3	Outcome	Balance of applicants in terms of age, gender, and geography	Every three years	Taleo
SO3	Outcome	Elapsed time to hire (in months) working group experts	Yearly	Taleo
SO3	Outcome	Number of applicants (total and eligible), in total for the Panel renewals	Every three years	Taleo
SO3	Outcome	Application rate for EFSA's open calls	Yearly	e-Submission of procurement
SO3	Outcome	Number of Article 36 organisations applying to EFSA grants	Yearly	Manual calculation
SO3	Outcome	$Number of joint\ activities\ with\ international\ partners\ under\ coop.\ agreements$	Quarterly	Manual calculation
SO3	Outcome	Number of joint projects awarded in the reporting period	Quarterly	Manual calculation
SO3	Outcome	Number of Member States that have participated in joint projects	Quarterly	Manual calculation
SO3	Outcome	Number of partners that have participated in joint projects	Quarterly	Manual calculation
SO3	Outcome	Number of priority areas in the EU RAA covered	Quarterly	Manual calculation
SO3	Outcome	Number of projects not funded primarily by EFSA	Yearly	Manual calculation
SO3	Outcome	Number of research projects (EU/international) to which EFSA is participating	Yearly	Manual calculation
SO4	Outcome	Number of capabilities included in implementation plan further developed	Yearly	Manual calculation
SO5	Outcome	% of tele-meetings (experts & networks) over total meetings	Quarterly	MOS
SO5	Outcome	Social collaboration platforms (staff, experts, networks)	Quarterly	Web-based application
SO5	Outcome	Competence management maturity level via compliance with ESCO	Every three years	Sysper
SO5	Outcome	Management feedback survey (Leadership, Line Management)	Yearly	Management Feedback Survey
SO5	Outcome	Occupancy rate (%) Statutory staff (EFSA baseline only; TR new hires) year average	Quarterly	Sysper and manual calculation
SO5	Outcome	Staff Engagement Survey (Engagement, Favourable, Organisational awareness/commitment)	Every two years	Staff Engagement Survey
SO5	Outcome	Number of 'critical', 'significant' or 'very important' findings	Quarterly	Manual calculation
SO5	Outcome	Performance based management maturity level	Yearly	Manual calculation
SO5	Outcome	World class IT maturity level service compliance and satisfaction	Yearly	Manual calculation



so	Туре	КРІ	Frequency	Tool /Source of data ⁵⁷
ANNL	JAL WORK	PROGRAMME		
SO1	Output	Number of media enquiries addressed within agreed deadlines	Quarterly	Manual calculation
SO1	Output	Number of public consultations on EFSA outputs	Quarterly	RAW– Register of questions
SO1	Output	Number of service catalogue activities with applicants	Quarterly	RAW – Register of questions (APDESK meetings database)
SO1	Output	Number of stakeholders' enquiries addressed within agreed deadlines	Quarterly	Manual calculation
SO1	Output	Percentage of positive feedback on regulated product opinions from applicants	Quarterly	Survey
SO1	Output	Positive feedback from engagement activities with registered stakeholders	Quarterly	Survey
SO1	Output	Proportion of scientific outputs delivered within 28 working days of adoption	Quarterly	Manual calculation
SO1	Output	Reduction of bulk evaluation for MRL Art.12	Quarterly	RAW– Register of questions
SO1	Output	Total number of registered stakeholders	Quarterly	Manual calculation
SO1- SO4	Output	Number of questions delivered for "other publication" (external reports, event reports)	Quarterly	Appian/Manual calculation
SO1- SO4	Output	Number of questions delivered for scientific output/technical report	Quarterly	Appian/Manual calculation
SO1- SO4	Output	Proportion of scientific/technical questions adopted within deadline	Quarterly	Appian/Manual calculation
SO2	Output	Number of new tools	Quarterly	Manual calculation
SO3	Output	Number of cooperation agreements with international/non-EU country organisations	Quarterly	Manual calculation
SO3	Output	Number of international cooperation activities (meetings, events, missions)	Quarterly	Manual calculation
SO3	Output	Number of MS cooperation activities	Quarterly	Manual calculation
SO5	Output	Commitment execution; Payment execution (differentiated and non-differentiated credits)	Quarterly	ABAC
SO5	Output	Service Delivery Index	Quarterly	Survey



Annex II. Statistics on financial management

(a) Budget execution

Table 71. Expenditures

Title Chapter Article Item	Heading 2021	Initial commitment appropriations	Amended budget	Current commitment appropriations	Commitment execution	% committed	Initial payment appropriations	Amended budget	Current payment appropriations	Payment execution	% paid
1	STAFF										
11	STAFF EXPENDITURE										
110	Salaries and allowances										
1100	Salaries and allowances of staff provided for in establishment plan	35,727,000.00	35,727,000.00	35,841,749.25	35,841,749.25	100%	35,727,000.00	35,727,000.00	35,841,749.25	35,841,749.25	100%
1104	Entitlements on Entering and Leaving the Service	200,000.00	200,000.00	294,796.10	294,796.10	100%	200,000.00	200,000.00	294,796.10	294,796.10	100%
	Article 110 - Total	35,927,000.00	35,927,000.00				35,927,000.00	35,927,000.00			
111	Other staff										
1113	Stagiaires	1,018,000.00	1,018,000.00	1,021,520.14	1,021,520.14	100%	1,018,000.00	1,018,000.00	1,021,520.14	1,021,520.14	100%
1115	Contract staff	7,851,256.00	7,851,256.00	8,041,210.49	8,041,210.49	100%	7,851,256.00	7,851,256.00	8,041,210.49	8,041,210.49	100%
1116	Visiting experts, National Experts on Detachment	780,000.00	780,000.00	623,143.46	623,143.46	100%	780,000.00	780,000.00	623,143.46	618,643.46	99%
1117	Authority officials temporarily assigned to national civil services, to international organisations or to public or private institutions	0.00	0.00	0.00	0.00	#DIV/0!	0.00	0.00	0.00	0.00	#DIV/0!
	Article 111 - Total	9,649,256.00		9,685,874.09	9,685,874.09				9,685,874.09	9,681,374.09	
112	Interim staff										
1120	Interim services	3,500,000.00	3,500,000.00	3,750,000.00	3,750,000.00	100%	3,500,000.00	3,500,000.00	3,750,000.00	3,144,215.25	84%
	Article 112 - Total										



Title Chapter Article Item	Heading 2021	Initial commitment appropriations	Amended budget	Current commitment appropriations	Commitment execution	% committed	Initial payment appropriations	Amended budget	Current payment appropriations	Payment execution	% paid
113	Establishment or maintenance of pension righ	ts for temporary s	taff								
1133	Establishment or maintenance of pension rights for temporary staff	0.00	0.00	0.00	0.00	0%	0.00	0.00	0.00	0.00	0%
	Article 113 - Total			0.00							
	CHAPTER 11 - TOTAL	49,076,256.00		49,572,419.44	49,572,419.44					48,962,134.69	
CHAPTER 12	EXPENDITURE RELATING TO STAFF RECRUITMENT										
120	Expenditure relating to Staff recruitment										
1200	Miscellaneous expenditure on recruitment	175,000.00	175,000.00	207,520.66	207,520.66	100%	175,000.00	175,000.00	207,520.66	198,521.11	96%
	Article 120 - Total	175,000.00	175,000.00	207,520.66	207,520.66				207,520.66	198,521.11	
	CHAPTER 12 - TOTAL			207,520.66	207,520.66				207,520.66	198,521.11	
CHAPTER 13	MISSIONS AND DUTY TRAVEL										
130	Missions and travel expenses										
1300	Missions and travel expenses	125,000.00	125,000.00	4,279.91	4,279.91	100%	125,000.00	125,000.00	4,279.91	4,279.91	100%
1301	Shuttles for missions and duty	30,000.00	30,000.00	0.00	0.00	#DIV/0!	30,000.00	30,000.00	0.00	0.00	#DIV/0!
	Article 130 - Total			4,279.91							
	CHAPTER 13 - TOTAL	155,000.00		4,279.91							
CHAPTER 14	SOCIOMEDICAL INFRASTRUCTURE										
141	Medical service										
1410	Medical service	238,000.00	238,000.00	232,072.05	232,072.05	100%	238,000.00	238,000.00	232,072.05	207,943.05	90%
	Article 141 - Total	238,000.00	238,000.00	232,072.05	232,072.05		238,000.00	238,000.00	232,072.05		
	CHAPTER 14 - TOTAL	238,000.00	238,000.00	232,072.05	232,072.05		238,000.00	238,000.00	232,072.05		
CHAPTER 15	TRAINING										
150	Training, language courses and retraining for staff										
1500	Further training, language courses and retraining for staff	500,000.00	500,000.00	419,071.12	419,071.12	100%	500,000.00	500,000.00	419,071.12	277,024.07	66%
	Article 150 - Total			419,071.12	419,071.12					277,024.07	



Title Chapter Article Item	Heading 2021	Initial commitment appropriations	Amended budget	Current commitment appropriations	Commitment execution	% committed	Initial payment appropriations	Amended budget	Current payment appropriations	Payment execution	% paid
	CHAPTER 15 - TOTAL		500,000.00					500,000.00		277,024.07	66%
CHAPTER 16	SOCIAL WELFARE										
160	Special assistance grants, other interventions	and complementar	y aid for disabled								
1600	Special assistance grants, other interventions and complementary aid for disabled	10,000.00	10,000.00	172,992.57	172,992.57	100%	10,000.00	10,000.00	172,992.57	171,938.41	99%
	Article 160 - Total		10,000.00	172,992.57	172,992.57			10,000.00	172,992.57		99%
161	Social contacts between staff										
1610	Social contacts between staff	10,000.00	10,000.00	150.00	150.00	100%	10,000.00	10,000.00	150.00	0.00	0%
	Article 161 - Total										0%
161	Early childhood centres and other creches										
1630	Early childhood centres, creches and EU school contribution	1,780,000.00	1,780,000.00	1,673,226.97	1,673,226.97	100%	1,780,000.00	1,780,000.00	1,673,226.97	1,663,767.15	99%
	Article 161 - Total			1,673,226.97	1,673,226.97				1,673,226.97		99%
	CHAPTER 16 - TOTAL	1,800,000.00	1,800,000.00	1,846,369.54				1,800,000.00			99%
18	EXTERNAL SERVICES										
180	External services										
1800	Translation and interpretation	100,000.00	100,000.00	14,112.75	14,112.75	100%	100,000.00	100,000.00	14,112.75	14,112.75	100%
1801	Payment for administrative assistance from the Community institutions	290,000.00	290,000.00	275,000.00	275,000.00	100%	290,000.00	290,000.00	275,000.00	249,491.72	91%
1802	Consultancy and HR services	250,000.00	250,000.00	361,642.00	361,642.00	100%	250,000.00	250,000.00	361,642.00	229,605.00	63%
1803	Other services	274,000.00	274,000.00	146,210.91	146,210.91	100%	274,000.00	274,000.00	146,210.91	142,658.07	98%
	Article 180 - Total	914,000.00	914,000.00	796,965.66	796,965.66	100%	914,000.00	914,000.00	796,965.66	635,867.54	80%
	CHAPTER 18 - TOTAL	914,000.00	914,000.00	796,965.66			914,000.00	914,000.00		635,867.54	80%
	TITLE 1 - TOTAL	52,858,256.00	52,858,256.00	53,078,698.38	53,078,698.38	100%	52,858,256.00	52,858,256.00	53,078,698.38	52,121,475.93	98%



Title Chapter Article Item	Heading 2021	Initial commitment appropriations	Amended budget	Current commitment appropriations	Commitment execution	% committed	Initial payment appropriations	Amended budget	Current payment appropriations	Payment execution	% paid
2	BUILDINGS, EQUIPMENT AND MISCELANEOU	S OPERATING EXP	ENDITURE LINKED	TO AUTHORITY							
20	INVESTMENTS IN IMMOVABLE PROPERTY, RENTA	L OF BUILDING AN	D ASSOCIATED COST	ΓS							
200	Building										
2000	Rent	42,855.00	42,855.00	33,542.97	33,542.97	100%	42,855.00	42,855.00	33,542.97	33,542.97	100%
2001	Acquisition	1,650,000.00	1,694,943.95	2,152,605.85	2,152,605.85	100%	1,650,000.00	1,694,943.95	2,152,605.85	2,152,605.85	100%
2002	Studies and technical assistance in connection with building projects	734,960.00	734,960.00	490,014.00	490,014.00	100%	734,960.00	734,960.00	490,014.00	296,188.50	60%
2003	Refurbishment of premises/fitting out	1,713,900.00	1,713,900.00	1,634,808.81	1,634,808.81	100%	1,713,900.00	1,713,900.00	1,634,808.81	847,002.10	52%
	Article 200 - Total	4,141,715.00	4,186,658.95	4,310,971.63				4,186,658.95		3,329,339.42	
202	Expenditure on buildings										
2020	Water, gas, electricity and heating	535,000.00	535,000.00	540,000.00	540,000.00	100%	535,000.00	535,000.00	540,000.00	400,328.07	74%
2021	Cleaning and maintenance	673,000.00	673,000.00	647,927.09	647,927.09	100%	673,000.00	673,000.00	647,927.09	581,730.73	90%
2023	Security and surveillance of buildings	736,000.00	736,000.00	687,814.24	687,814.24	100%	736,000.00	736,000.00	687,814.24	596,674.74	87%
2024	Insurance	38,000.00	38,000.00	24,450.41	24,450.41	100%	38,000.00	38,000.00	24,450.41	24,450.41	100%
2025	Other expenditure on buildings	840,000.00	840,000.00	476,395.77	476,395.77	100%	840,000.00	840,000.00	476,395.77	409,229.66	86%
	Article 202 - Total	2,822,000.00	2,822,000.00	2,376,587.51	2,376,587.51		2,822,000.00	2,822,000.00	2,376,587.51		
	CHAPTER 20 - TOTAL	6,963,715.00	7,008,658.95	6,687,559.14	6,687,559.14			7,008,658.95	6,687,559.14		
21	INFORMATION TECHNOLOGY AND EXPENDITUR	E ON DATA PROCES	SING								
210	Purchase and maintenance of IT for administra	ation and non-ope	rational								
2100	Purchase and maintenance of IT equipment and standard software	2,730,805.00	2,730,805.00	2,726,404.20	2,726,404.20	100%	2,730,805.00	2,730,805.00	2,726,404.20	1,691,969.82	62%
2103	External services for the operation, implementation and maintenance of software and user support	2,796,195.00	2,796,195.00	3,156,825.14	3,156,825.14	100%	2,796,195.00	2,796,195.00	3,156,825.14	2,169,446.30	69%
	Article 210 - Total	5,527,000.00	5,527,000.00	5,883,229.34	5,883,229.34		5,527,000.00	5,527,000.00	5,883,229.34	3,861,416.12	
	CHAPTER 21 - TOTAL	5,527,000.00	5,527,000.00	5,883,229.34	5,883,229.34		5,527,000.00	5,527,000.00	5,883,229.34	3,861,416.12	

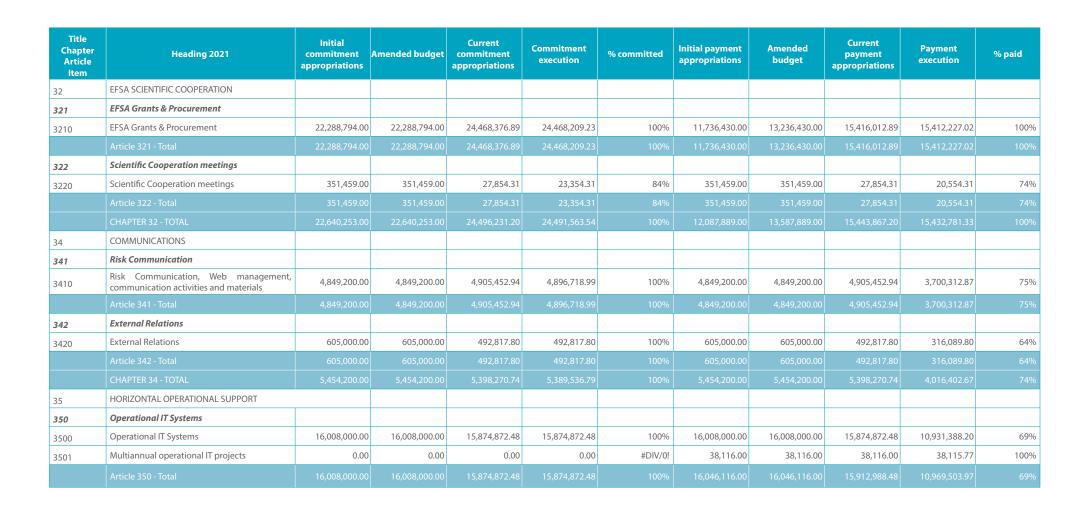


Title Chapter Article Item	Heading 2021	Initial commitment appropriations	Amended budget	Current commitment appropriations	Commitment execution	% committed	Initial payment appropriations	Amended budget	Current payment appropriations	Payment execution	% paid
22	MOVABLE PROPERTY AND ASSOCIATED COSTS										
220	Technical equipment and instalations										
2200	Technical equipment and installations	1,065,000.00	1,065,000.00	1,041,284.39	1,041,284.39	100%	1,065,000.00	1,065,000.00	1,041,284.39	357,405.55	34%
	Article 220 - Total		1,065,000.00				1,065,000.00				34%
221	Furniture										
2210	Furniture	429,000.00	429,000.00	525,859.44	525,859.44	100%	429,000.00	429,000.00	525,859.44	245,616.80	47%
	Article 221 - Total	429,000.00	429,000.00	525,859.44	525,859.44		429,000.00	429,000.00	525,859.44	245,616.80	47%
	CHAPTER 22 - TOTAL	1,494,000.00	1,494,000.00	1,567,143.83	1,567,143.83		1,494,000.00	1,494,000.00	1,567,143.83	603,022.35	38%
23	CURRENT ADMINISTRATIVE EXPENDITURE										
230	Stationery and office supplies										
2300	Stationery and office supplies	56,500.00	56,500.00	21,475.28	21,475.28	100%	56,500.00	56,500.00	21,475.28	5,163.18	24%
	Article 230 - Total			21,475.28	21,475.28				21,475.28		24%
232	Financial charges										
2320	Bank and other financial charges	1,000.00	1,000.00	200.00	200.00	100%	1,000.00	1,000.00	200.00	40.00	20%
	Article 232 - Total										20%
233	Legal expenses										
2330	Legal expenses and damages	238,250.00	238,250.00	31,016.00	31,016.00	100%	238,250.00	238,250.00	31,016.00	13,916.00	45%
	Article 233 - Total	238,250.00	238,250.00				238,250.00	238,250.00		13,916.00	45%
235	Other operating expenditure										
2350	Miscellaneous insurance	5,000.00	5,000.00	3,300.00	3,300.00	100%	5,000.00	5,000.00	3,300.00	2,640.00	80%
	Article 235 - Total										80%
239	Publications										
2390	Publications	17,000.00	17,000.00	7,500.00	7,500.00	100%	17,000.00	17,000.00	7,500.00	7,500.00	100%
	Article 239 - Total	17,000.00	17,000.00	7,500.00	7,500.00	100%	17,000.00	17,000.00	7,500.00	7,500.00	100%
	CHAPTER 23 - TOTAL	317,750.00	317,750.00	63,491.28	63,491.28	100%	317,750.00	317,750.00	63,491.28	29,259.18	46%



Title Chapter Article Item	Heading 2021	Initial commitment appropriations	Amended budget	Current commitment appropriations	Commitment execution	% committed	Initial payment appropriations	Amended budget	Current payment appropriations	Payment execution	% paid
24	POSTAL CHARGES AND TELECOMMUNICATIONS										
240	Postal charges and telecommunications										
2400	Postal charges and telecommunications	245,000.00	245,000.00	186,825.64	186,825.64	100%	245,000.00	245,000.00	186,825.64	108,813.75	58%
	Article 240 - Total		245,000.00	186,825.64	186,825.64		245,000.00		186,825.64	108,813.75	
	CHAPTER 24 - TOTAL		245,000.00	186,825.64	186,825.64		245,000.00		186,825.64	108,813.75	
25	GOVERNANCE EXPENDITURES										
250	Governance expenditures										
2500	Management Board meetings	80,000.00	80,000.00	63,717.34	63,717.34	100%	80,000.00	80,000.00	63,717.34	50,917.34	80%
	Article 250 - Total			63,717.34							
	CHAPTER 25 - TOTAL	80,000.00		63,717.34					63,717.34		
	TITLE 2 - TOTAL	14,627,465.00	14,672,408.95	14,451,966.57	14,451,966.57	100%	14,627,465.00	14,672,408.95	14,451,966.57	9,995,181.77	69%
	OPERATING EXPENDITURE LINKED TO AUTHO	DRITY									
30	SCIENTIFIC EVALUATION OF REGULATED PRODU	ICTS									
302	REPRO Experts Meetings										
3020	REPRO Experts Meetings	5,764,100.00	5,764,100.00	6,313,882.17	6,313,882.17	100%	5,764,100.00	5,764,100.00	6,313,882.17	6,179,868.92	98%
	Article 302 - Total			6,313,882.17	6,313,882.17				6,313,882.17	6,179,868.92	
	CHAPTER 30 - TOTAL	5,764,100.00		6,313,882.17	6,313,882.17				6,313,882.17	6,179,868.92	
31	RISK ASSESSMENT AND SCIENTIFIC ASSISTANCE										
312	RASA Experts Meetings										
3120	RASA Experts Meetings	6,072,399.00	6,072,399.00	5,803,024.50	5,801,599.50	100%	6,072,399.00	6,072,399.00	5,803,024.50	5,638,807.55	97%
	Article 312 - Total	6,072,399.00	6,072,399.00	5,803,024.50	5,801,599.50		6,072,399.00		5,803,024.50	5,638,807.55	
313	Crisis support										
3130	Crisis support	0.00	0.00	0.00	0.00	0%	0.00	0.00	0.00	0.00	0%
	Article 313 - Total	0.00	0.00	0.00	0.00	0%	0.00	0.00	0.00	0.00	0%
	CHAPTER 31 - TOTAL	6,072,399.00	6,072,399.00	5,803,024.50	5,801,599.50	100%	6,072,399.00	6,072,399.00	5,803,024.50	5,638,807.55	97%







Title Chapter Article Item	Heading 2021	Initial commitment appropriations	Amended budget	Current commitment appropriations	Commitment execution	% committed	Initial payment appropriations	Amended budget	Current payment appropriations	Payment execution	% paid
351	Operational support										
3511	Translation, Interpretation, Linguistic Proofreading and Editing	200,000.00	200,000.00	338,000.00	338,000.00	100%	200,000.00	200,000.00	338,000.00	257,039.48	76%
3512	Library	750,000.00	750,000.00	696,549.23	696,549.23	100%	750,000.00	750,000.00	696,549.23	592,874.00	85%
3513	Mission of staff related to operational duties	355,000.00	355,000.00	0.00	0.00	#DIV/0!	355,000.00	355,000.00	0.00	0.00	#DIV/0!
3514	Shuttles and prepaid travels for experts and shuttle for staff related to operational duties	792,000.00	792,000.00	0.00	0.00	#DIV/0!	792,000.00	792,000.00	0.00	0.00	#DIV/0!
3515	Catering	15,685.00	15,685.00	793.15	793.15	100%	15,685.00	15,685.00	793.15	528.77	67%
	Article 351 - Total	2,112,685.00		1,035,342.38	1,035,342.38			2,112,685.00	1,035,342.38	850,442.25	82%
352	Conference & outreach										
3520	Conferences, outreach and representation cost	1,292,500.00	1,292,500.00	647,289.04	647,289.04	100%	1,292,500.00	1,292,500.00	647,289.04	525,762.31	81%
	Article 352 - Total	1,292,500.00	1,292,500.00	647,289.04	647,289.04		1,292,500.00	1,292,500.00	647,289.04	525,762.31	81%
353	Operational development, control and quality										
3530	Operational Development, Control and Quality	2,305,000.00	2,305,000.00	2,080,224.49	2,080,224.49	100%	2,305,000.00	2,305,000.00	2,080,224.49	1,042,348.91	50%
	Article 353 - Total	2,305,000.00		2,080,224.49	2,080,224.49			2,305,000.00	2,080,224.49	1,042,348.91	50%
	CHAPTER 35 - TOTAL	21,718,185.00		19,637,728.39	19,637,728.39			21,756,301.00	19,675,844.39	13,388,057.44	68%
	TITLE 3 - TOTAL	61,649,137.00	61,649,137.00	61,649,137.00	61,634,310.39	100%	51,134,889.00	52,634,889.00	52,634,889.00	44,655,917.91	85%
GRAND TOTAL		129,134,858.00	129,179,801.95	129,179,801.95	129,164,975.34	100%	118,620,610.00	120,165,553.95	120,165,553.95	106,772,575.61	89%

(b). number and value of Budget transfers

Table 72. Budget Transfers January – December 2020

Title Chapter Article Item	Budget Headings	Commitment and payment appropriations 2021				
		Initial	Amended budget	Transfers	Current	
	STAFF					
11	STAFF EXPENDITURE					
110	Salaries and allowances					
1100	Salaries and allowances of staff provided for in establishment plan	35,727,000.00	35,727,000.00	114,749.25	35,841,749.25	
1104	Entitlements on Entering and Leaving the Service	200,000.00	200,000.00	94,796.10	294,796.10	
	tot. of 110	35,927,000.00	35,927,000.00	209,545.35	36,136,545.35	
111	Other staff					
1113	Stagiaires	1,018,000.00	1,018,000.00	3,520.14	1,021,520.14	
1115	Contract staff	7,851,256.00	7,851,256.00	189,954.49	8,041,210.49	
1116	Visiting experts, National Experts on Detachment	780,000.00	780,000.00	-156,856.54	623,143.46	
1117	Authority officials temporarily assigned to national civil services, to international organisations or to public or private institutions	0.00	0.00	0.00	0.00	
	tot. of 111	9,649,256.00	9,649,256.00	36,618.09	9,685,874.09	
112	Interim staff					
1120	Interim services	3,500,000.00	3,500,000.00	250,000.00	3,750,000.00	
	tot. of 112	3,500,000.00	3,500,000.00	250,000.00	3,750,000.00	
113	Establishment or maintenance of pension rights for temporary staff					
1133	Establishment or maintenance of pension rights for temporary staff	0.00	0.00	0.00	0.00	
	tot. of 113	0.00	0.00	0.00	0.00	
	tot. of 11	49,076,256.00	49,076,256.00	496,163.44	49,572,419.44	
12	EXPENDITURE RELATING TO STAFF RECRUITMENT					
120	Expenditure relating to Staff recruitment					
1200	Miscellaneous expenditure on recruitment	175,000.00	175,000.00	32,520.66	207,520.66	
	tot. of 120	175,000.00	175,000.00	32,520.66	207,520.66	
	tot. of 12	175,000.00	175,000.00	32,520.66	207,520.66	
13	MISSIONS AND DUTY TRAVEL					
130	Missions and travel expenses					
1300	Missions and travel expenses	125,000.00	125,000.00	-120,720.09	4,279.91	
1301	Shuttles for missions and duty	30,000.00	30,000.00	-30,000.00	0.00	
	tot. of 130	155,000.00	155,000.00	-150,720.09	4,279.91	
	tot. of 13	155,000.00	155,000.00	-150,720.09	4,279.91	
14	SOCIOMEDICAL INFRASTRUCTURE					
141	Medical service					
1410	Medical service	238,000.00	238,000.00	-5,927.95	232,072.05	
	tot. of 141	238,000.00	238,000.00	-5,927.95	232,072.05	
	tot. of 14	238,000.00	238,000.00	-5,927.95	232,072.05	



Title Chapter Article Item	Budget Headings	Comm	2021		
		Initial	Amended budget	Transfers	Current
15	TRAINING				
150	Training, language courses and retraining for staff				
1500	Further training, language courses and retraining for staff	500,000.00	500,000.00	-80,928.88	419,071.12
	tot. of 150	500,000.00	500,000.00	-80,928.88	419,071.12
	tot. of 15	500,000.00	500,000.00	-80,928.88	419,071.12
16	SOCIAL WELFARE				
160	Special assistance grants, other interventions and complementary aid for d	lisabled			
1600	Special assistance grants, other interventions and complementary aid for disabled	10,000.00	10,000.00	162,992.57	172,992.57
	tot. of 160	10,000.00	10,000.00	162,992.57	172,992.57
161	Social contacts between staff				
1610	Social contacts between staff	10,000.00	10,000.00	-9,850.00	150.00
	tot. of 161	10,000.00	10,000.00	-9,850.00	150.00
163	Early childhood centres and other creches				
1630	Early childhood centres, creches and EU school contribution	1,780,000.00	1,780,000.00	-106,773.03	1,673,226.97
	tot. of 163	1,780,000.00	1,780,000.00	-106,773.03	1,673,226.97
	tot. of 16	1,800,000.00	1,800,000.00	46,369.54	1,846,369.54
18	EXTERNAL SERVICES				
180	External services				
1800	Translation and interpretation	100,000.00	100,000.00	-85,887.25	14,112.75
1801	Payment for administrative assistance from the Community institutions	290,000.00	290,000.00	-15,000.00	275,000.00
1802	Consultancy and HR services	250,000.00	250,000.00	111,642.00	361,642.00
1803	Other services	274,000.00	274,000.00	-127,789.09	146,210.91
	tot. of 180	914,000.00	914,000.00	-117,034.34	796,965.66
	tot. of 18	914,000.00	914,000.00	-117,034.34	796,965.66
	tot. of 1	52,858,256.00	52,858,256.00	220,442.38	53,078,698.38

Title Chapter Article Item	Budget Headings	Comm	nt appropriations	s 2021	
		Initial	Amended budget	Transfers	Current
2	BUILDINGS, EQUIPMENT AND MISCELLANEOUS OPERATING EXPENDITURE	LINKED TO THE AU	THORITY		
20	INVESTMENTS IN IMMOVABLE PROPERTY, RENTAL OF BUILDING AND ASSOCIATED COSTS				
200	Building				
2000	Rent	42,855.00	42,855.00	-9,312.03	33,542.97
2001	Acquisition	1,650,000.00	1,694,943.95	457,661.90	2,152,605.85
2002	Studies and technical assistance in connection with building projects	734,960.00	734,960.00	-244,946.00	490,014.00
2003	Refurbishment of premises/fitting out	1,713,900.00	1,713,900.00	-79,091.19	1,634,808.81
	tot. of 200	4,141,715.00	4,186,658.95	124,312.68	4,310,971.63
202	Expenditure on buildings				
2020	Water, gas, electricity and heating	535,000.00	535,000.00	5,000.00	540,000.00
2021	Cleaning and maintenance	673,000.00	673,000.00	-25,072.91	647,927.09
2023	Security and surveillance of buildings	736,000.00	736,000.00	-48,185.76	687,814.24
2024	Insurance	38,000.00	38,000.00	-13,549.59	24,450.41
2025	Other expenditure on buildings	840,000.00	840,000.00	-363,604.23	476,395.77
	tot. of 202	2,822,000.00	2,822,000.00	-445,412.49	2,376,587.51
	tot. of 20	6,963,715.00	7,008,658.95	-321,099.81	6,687,559.14
21	INFORMATION TECHNOLOGY AND EXPENDITURE ON DATA PROCESSING				
210	Purchase and maintenance of IT for administration and non operational				
2100	Purchase and maintenance of IT equipment and standard software	2,730,805.00	2,730,805.00	-4,400.80	2,726,404.20
2103	External services for the operation, implementation and maintenance of software and user support	2,796,195.00	2,796,195.00	360,630.14	3,156,825.14
	tot. of 210	5,527,000.00	5,527,000.00	356,229.34	5,883,229.34
	tot. of 21	5,527,000.00	5,527,000.00	356,229.34	5,883,229.34
22	MOVABLE PROPERTY AND ASSOCIATED COSTS				
220	Technical equipment and installations				
2200	Technical equipment and installations	1,065,000.00	1,065,000.00	-23,715.61	1,041,284.39
	tot. of 220	1,065,000.00	1,065,000.00	-23,715.61	1,041,284.39
221	Furniture				
2210	Furniture	429,000.00	429,000.00	96,859.44	525,859.44
	tot. of 221	429,000.00	429,000.00	96,859.44	525,859.44
	tot. of 22	1,494,000.00	1,494,000.00	73,143.83	1,567,143.83
23	CURRENT ADMINISTRATIVE EXPENDITURE				
230	Stationery and office supplies				
2300	Stationery and office supplies	56,500.00	56,500.00	-35,024.72	21,475.28
	tot. of 230	56,500.00	56,500.00	-35,024.72	21,475.28
232	Financial charges				
2320	Bank and other financial charges	1,000.00	1,000.00	-800.00	200.00
	tot. of 232	1,000.00	1,000.00	-800.00	200.00



Title Chapter Article Item	Budget Headings	Commitment and payment appropriations 2021			
		Initial	Amended budget	Transfers	Current
233	Legal expenses and damages				
2330	Legal expenses and damages	238,250.00	238,250.00	-207,234.00	31,016.00
	tot. of 233	238,250.00	238,250.00	-207,234.00	31,016.00
235	Other operating expenditure				
2350	Miscellaneous insurance	5,000.00	5,000.00	-1,700.00	3,300.00
	tot. of 235	5,000.00	5,000.00	-1,700.00	3,300.00
239	Publications				
2390	Publications	17,000.00	17,000.00	-9,500.00	7,500.00
	tot. of 239	17,000.00	17,000.00	-9,500.00	7,500.00
	tot. of 23	317,750.00	317,750.00	-254,258.72	63,491.28
24	POSTAL CHARGES AND TELECOMMUNICATIONS				
240	Postal charges and telecommunications				
2400	Postal charges and telecommunications	245,000.00	245,000.00	-58,174.36	186,825.64
	tot. of 240	245,000.00	245,000.00	-58,174.36	186,825.64
	tot. of 24	245,000.00	245,000.00	-58,174.36	186,825.64
25	GOVERNANCE EXPENDITURE				
250	Governance expenditure				
2500	Management Board meetings	80,000.00	80,000.00	-16,282.66	63,717.34
	tot. of 250	80,000.00	80,000.00	-16,282.66	63,717.34
	tot. of 25	80,000.00	80,000.00	-16,282.66	63,717.34
	tot. of 2	14,627,465.00	14,672,408.95	-220,442.38	14,451,966.57



Title Chapter		Commitment appropriations 2021				Payment appropriations 2021			
Article Item	Budget Headings	Initial	Amended budget	Transfers	Current	Initial	Amended budget	Transfers	Current
3	OPERATING EXPENDITURE LINKED TO THE AUTHORITY								
30	SCIENTIFIC EVALUATION OF REGULATED PRODUCTS								
302	REPRO Experts meetings								
3020	REPRO Experts Meetings	5,764,100.00	5,764,100.00	549,782.17	6,313,882.17	5,764,100.00	5,764,100.00	549,782.17	6,313,882.17
	tot. of 302	5,764,100.00	5,764,100.00	549,782.17	6,313,882.17	5,764,100.00	5,764,100.00	549,782.17	6,313,882.17
	tot. of 30	5,764,100.00	5,764,100.00	549,782.17	6,313,882.17	5,764,100.00	5,764,100.00	549,782.17	6,313,882.17
31	RISK ASSESSMENT & SCIENTIFIC ASSISTANCE								
312	RASA Experts meetings								
3120	RASA Experts Meetings	6,072,399.00	6,072,399.00	-269,374.50	5,803,024.50	6,072,399.00	6,072,399.00	-269,374.50	5,803,024.50
	tot. of 312	6,072,399.00	6,072,399.00	-269,374.50	5,803,024.50	6,072,399.00	6,072,399.00	-269,374.50	5,803,024.50
313	Crisis support								
3130	Crisis support	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	tot. of 313	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	tot. of 31	6,072,399.00	6,072,399.00	-269,374.50	5,803,024.50	6,072,399.00	6,072,399.00	-269,374.50	5,803,024.50
32	EFSA SCIENTIFIC COOPERATION								
321	EFSA Grants & Procurement								
3210	EFSA Grants & Procurement	22,288,794.00	22,288,794.00	2,179,582.89	24,468,376.89	11,736,430.00	13,236,430.00	2,179,582.89	15,416,012.89
	tot. of 321	22,288,794.00	22,288,794.00	2,179,582.89	24,468,376.89	11,736,430.00	13,236,430.00	2,179,582.89	15,416,012.89
322	Scientific Cooperation meetings								
3220	Scientific Cooperation meetings	351,459.00	351,459.00	-323,604.69	27,854.31	351,459.00	351,459.00	-323,604.69	27,854.31
	tot. of 343	351,459.00	351,459.00	-323,604.69	27,854.31	351,459.00	351,459.00	-323,604.69	27,854.31



Title Chapter	Budget Headings	Commitment appropriations 2021				Payment appropriations 2021			
Article Item		Initial	Amended budget	Transfers	Current	Initial	Amended budget	Transfers	Current
323	Pre-accession and ENP Programmes								
3230	Pre-accession programme	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
3231	ENPI (European Neighbourhood programme)	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	tot. of 323	0.00	0.00	0.00	0.00	0.00	0.00	0.00	0.00
	tot. of 32	22,640,253.00	22,640,253.00	1,855,978.20	24,496,231.20	12,087,889.00	13,587,889.00	1,855,978.20	15,443,867.20
34	COMMUNICATIONS								
341	Risk Communication								
3410	Risk Communication, Web management, communication activities and materials	4,849,200.00	4,849,200.00	56,252.94	4,905,452.94	4,849,200.00	4,849,200.00	56,252.94	4,905,452.94
	tot. of 341	4,849,200.00	4,849,200.00	56,252.94	4,905,452.94	4,849,200.00	4,849,200.00	56,252.94	4,905,452.94
342	External Relations								
3420	External Relations	605,000.00	605,000.00	-112,182.20	492,817.80	605,000.00	605,000.00	-112,182.20	492,817.80
	tot. of 342	605,000.00	605,000.00	-112,182.20	492,817.80	605,000.00	605,000.00	-112,182.20	492,817.80
	tot. of 34	5,454,200.00	5,454,200.00	-55,929.26	5,398,270.74	5,454,200.00	5,454,200.00	-55,929.26	5,398,270.74
35	HORIZONTAL OPERATIONS								
350	Operational IT Systems								
3500	Operational IT Systems	16,008,000.00	16,008,000.00	-133,127.52	15,874,872.48	16,008,000.00	16,008,000.00	-133,127.52	15,874,872.48
3501	Multiannual operational IT projects	0.00	0.00	0.00	0.00	38,116.00	38,116.00	0.00	38,116.00
	tot. of 350	16,008,000.00	16,008,000.00	-133,127.52	15,874,872.48	16,046,116.00	16,046,116.00	-133,127.52	15,912,988.48
351	Operational support								
3511	Translation, Interpretation, Linguistic Proofreading and Editing	200,000.00	200,000.00	138,000.00	338,000.00	200,000.00	200,000.00	138,000.00	338,000.00
3512	Library	750,000.00	750,000.00	-53,450.77	696,549.23	750,000.00	750,000.00	-53,450.77	696,549.23
3513	Mission of staff related to operational duties	355,000.00	355,000.00	-355,000.00	0.00	355,000.00	355,000.00	-355,000.00	0.00
3514	Shuttles and prepaid travels for experts and shuttle for staff related to operational duties	792,000.00	792,000.00	-792,000.00	0.00	792,000.00	792,000.00	-792,000.00	0.00
3515	Catering	15,685.00	15,685.00	-14,891.85	793.15	15,685.00	15,685.00	-14,891.85	793.15
	tot. of 351	2,112,685.00	2,112,685.00	-1,077,342.62	1,035,342.38	2,112,685.00	2,112,685.00	-1,077,342.62	1,035,342.38







(c) Budget outturn and cancellation of appropriations

Table 73. Calculation budget outturn

Budget out-turn	2019	2020	2021
Reserve from the previous years' surplus (+)			
Revenue actually received (+)	80,496,256.65	99,371,850.48	120,634,993.95
Payments made (–)	-72,966,330.23	-88,130,988.95	-107,488,851.15
Carry-over of appropriations (–)	-7,854,893.86	-12,297,809.31	-13,971,330.00
Cancellation of appropriations carried over (+)	424,520.61	324,289.38	450,050.09
Exchange-rate differences (+/-)	-1,475.69	-745.54	-1,607.40
Adjustment for carry-over from previous years of assigned revenue	335,797.06	1,084,754.98	844,122.88
Out-turn pre-accession programme DG Neighbourhood and Enlargement Negotiations	-4,499.95	na	na
Total	429,374.59	351,351.04	467,378.37

Out of the EUR 120.17 million of C1 payment appropriations available, EUR 106.77 million or 88% (88 % in 2020) was paid while EUR 13.37 million corresponding to 13% of non-differentiated C1 was carried forward. Cancelled C1 payment appropriations amount to a total of € 0.02, out of which major part are non-differentiated payment appropriations linked to commitment appropri-ations not implemented. Out of the EUR 11.5 million in payment appropriations carried over, EUR 11.0 million or 96% was paid, leaving EUR 0.5 million unutilised. The cancellation stems mainly from unused C8 funds, mainly due to provisional nature of ser-vices purchased, quality issues and change in the project plans (in part impacted by the COVID related restrictions).

The budget out-turn 2021 is in line with previous years and stands at million EUR 0.47 million (EUR 0.35 million in 2020 or 0.4% of total revenue, stemming mainly from adjustment for carry-over of assigned revenue from previous years. Tight treasury manage-ment and payment forecast system allow optimisation of treasury utilisation thereby keeping the out-turn low.



Annex III. Organisational chart

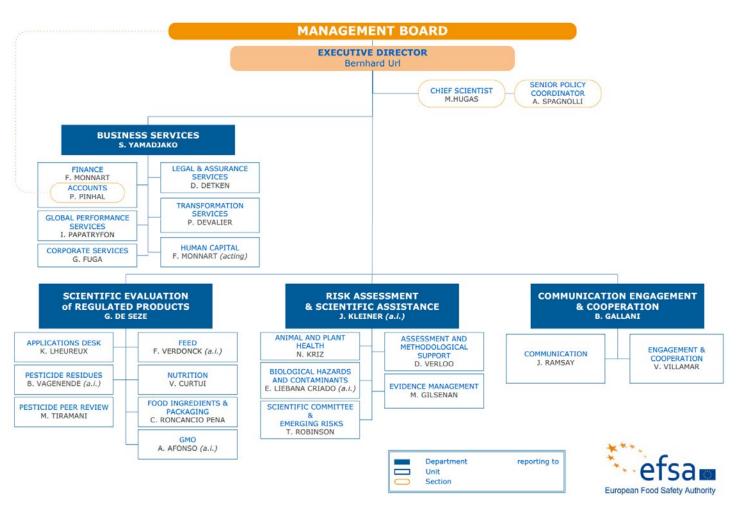


Figure 31. Organisational chart (31/12/2021)



Annex IV. Establishment plan and additional information on Human Resources management

Table 74. Establishment plan 2021

	2021			
	Authorised und	er the EU Budget	Filled as of	31.12.2021
Function Group and Grade	Permanent	Temporary	Permanent	Temporary
	posts	posts	posts	posts
AD16				
AD15		1		1
AD14				
AD13		4		3
AD12		4		5
AD11		10		4
AD10		20		18
AD9	1	43		38
AD8	4	68	4	67
AD7		68	1	54
AD6		52		56
AD5		9		15
Total AD	5	279		261
AST11				
AST10				
AST9				
AST8		2		
AST7		4		3
AST6		9		9
AST5		21		22
AST4		32		31
AST3		17		23
AST2		11		9
AST1				1
Total AST	0	96	0	98
Total	5	375	5	359
Grand total		380		364

Table 75. Information on recruitment grade/function group for each type of post

Key functions (examples – terminology should be adjusted to each agency's job titles)	Type of contract (official, TA or CA)	Function group, grade of recruitment*58	Indication whether the function is dedicated to administrative support or operations [subject to definitions used in screening methodology]
CORE FUNCTIONS			
Executive Director (Senior Manager)	TA	AD 14	Coordination
Adviser/Senior Expert	TA	AD 13	Operational
Head of Department (Manager)	TA	AD 12	Coordination/Operational
Head of Unit (Manager)	Official/TA	AD 9	Coordination/Operational/Administration
Senior Scientific Officer	Official/TA	AD 8	Operational/Administration
Scientific Officer	Official/TA/CA	AD 5 / FGIV 14	Operational/Administration
Junior Scientific Officer	CA	FGIV 13	Operational/administration
Technical Assistant	TA/CA	AST4 / FGIII	Operational/Administration
Assistant	TA/CA	AST 1 / FGI	Operational/Administration
SUPPORT FUNCTIONS			
Head of Business Services (Head of Administration)	TA	AD 12	Administration
Head of Unit (Manager)	Official/TA	AD 9	Coordination/Operational
Senior Officer	Official/TA	AD 8	Administration
Officer	Official/TA/CA	AD 5 / FGIV 14	Administration
Junior Officer	CA	FGIV 13	Administration
Technical Assistant	TA/CA	AST4 / FGIII	Administration
Assistant	TA/CA	AST 1 / FGI	Administration
SPECIAL FUNCTIONS			
Data Protection Officer	TA	AD 6	Administration
Accounting Officer	TA	AD 6	Administration
Assurance Advisory Officer (Internal Audit)	TA	AD 6	Administration

Table 76. Implementing rules

Decisions adopted by the MB in analogy of EC decisions on 25/03/2021 (Decision no.mb210325-a4)

Commission Decision C(2020)4818 of 20 July 2020 amending the Commission Decision C(2011)1278 of 3 March 2011 on the general implementing provisions for Articles 11 and 12 of Annex VIII to the Staff Regulations on the transfer of pension rights

⁵⁸ For TA, please specify if the recruitment was internal, inter-agency or external as well as the specific grade of recruitment (No brackets)



Table 77. Results of the benchmarking exercise in accordance with provision of Art. 29 (3) Framework Financial Regulation and Methodology for Agencies Job Screening (a)

Job Type (sub) category	2020	2021
Administrative support and Coordination	17.5%	17.1%
Administrative Support	13.4%	13.3%
Coordination	4.1%	3.8%
Operational	78.5%	79.0%
Top level Operational Coordination	1.4%	1.5%
Programme management and Implementation	64.7%	66.3%
Evaluation & Impact assessment	0.6%	0.5%
General operational	11.8%	10.7%
Neutral	4.0%	3.9%
Finance/ Control	3.7%	3.6%
Linguistics	0.3%	0.3%
Total	100.0%	100.0%

Annex V. Human and financial resources by activity

1. Financial resources per strategic objective

Table 78. Budget allocations per strategic objective (% of the total EFSA budget)

EFSA'S strategic objective		Budget 2021		Executed 2021		
	M€	M€	%	M€	%	
SO1 Prioritise public and stakeholder engagement in the process of scientific assessment	43.68	55.69	43 %	52.25	40%	
SO2 Widen EFSA's evidence base and optimise access to its data	4.68	6.52	5 %	6.66	5%	
SO3 Build the EU's risk assessment capacity and knowledge community	8.91	10.66	8 %	11.87	9%	
SO4 Prepare for future risk assessment challenges	10.44	17.67	14 %	15.18	12%	
SO5 Create an environment and culture that reflects EFSA's values	35.26	38.60	30 %	43.20	33%	
Of which operations	17.75	19.85	15 %	23.54	18%	
Of which support	17.51	18.75	15 %	19.66	15%	
Total EFSA	103.00	129.14	100 %	129.16	100%	

"of which TR" - financial resources per strategic objective allocated	Financial Resources					
to Transarency regulation implementation	Initial plan	%	Actual	%		
SO1. Prioritise public and stakeholder engagement in the process of scientific assessment	27.92	52%	23.58	44%		
SO2. Widen EFSA's evidence base and optimise access to its data	1.68	3%	0.36	1%		
SO3. Build the EU's risk assessment capacity and knowledge community	3.24	6%	5.28	10%		
SO4. Prepare for future risk assessment challenges	7.40	14%	5.53	10%		
SO5. Create an environment and culture that reflects EFSA's values	13.33	25%	18.89	35%		
— of which operations	5.54	10%	10.25	19%		
— of which support	7.79	15%	8.65	16%		
Total EFSA	55.58	100 %	53.63	100 %		



of which TD by TD abit arise		Resources dedicated to TR by objective			
of which TR by TR objective		Initial Plan	%	Actyal	%
TRA: Improve and clarify the rules on transparency,		2.01	04%	1.00	2%
especially with regards to the scientific studies supporting the risk assessment	FTEs	15	511%	7	8%
QUA: Increase the guarantees of reliability, objectivity		11.40	1221%	8.99	17%
and independence of studies used by EFSA in its risk assessment for authorisation purposes	FTEs	31	1323%	17	20%
CAP: Improve the governance, strengthen the involvement of Member States and address the limitations affecting the long term scientific capacity of EFSA		5.5010.85	2120%	11.38	21%
		412	99%	1	1%
COM: Develop a more effective and transparent risk communication with the public in collaboration with Member States		2.454.24	108%	5.53	10%
	FTEs	213	510%	6	7%
CROSS CUTTING - DEVELOPMENT	EUR million	11.6321.06	4539%	20.98	39%
	FTEs	2247	35%	43	50%
CROSS CUTTING - SUPPORTING PROCESSES	EUR million	2.794.00	7%	5.75	11%
	FTEs	615	11%	11	13%
Total EFSA	EUR million	25.6153.58		53.63	
TotalElisk	FTEs	42133		86	

2. FTEs and budget indicators per strategic objective

Table 79. Input indicators for SO1 (FTEs and Budget as full cost of all Titles)

Input Indicators						
Total SO1	Resources invested per year	Target 2021	Executed 2021			
	FTEs	255	237			
	Budget (M, €)	55.69	52.25			
Scientific – general risk assessment						
Input sub-indicator	FTEs	69	67			
	Budget (M, €)	21.40	17.99			
Scientific – regulated products evaluation						
Input sub-indicator	FTEs	161	139			
	Budget (M, €)	26.71	26.50			
Communication & engagement						
Input sub-indicator	FTEs	25	22			
	Budget (M, €)	7.58	7.76			



Table 80. Input indicators for SO2 (FTEs and Budget as full cost of all Titles)

Input Indicators						
	Resources invested per year	Target 2021	Executed 2021			
Total SO2	FTEs	21	20			
	Budget (K, €)	36.52	6.66			

Table 81. Input indicators for SO3 (FTEs and Budget as full cost of all Titles)

Input Indicators						
	Resources invested per year	Target 2021	Executed 2021			
Total SO3	FTEs	34	34			
	Budget (K, €)	10.66	11.87			

Table 82. Input indicators for SO4 (FTEs and Budget as full cost of all Titles)

Input Indicators						
	Resources invested per year	Target 2021	Executed 2021			
Total SO4	FTEs	41	43			
	Budget (K, €)	17.67	15.18			

Table 83. Input indicators for SO5 (FTEs and Budget as full cost of all Titles)

Input Indicator						
	Resources invested per year	Target 2020	Executed 2021			
Total SO5	FTEs	187	204			
	Budget (K, €)	38.60	43.20			



3. Human resources per strategic objective

 Table 84. FTE allocations per strategic objective

EFSA'S strategic objective	Executed 2020	Plan 2021			Executed 2021 ⁵⁹		
	FTE ⁶⁰ / posts	FTE/posts	%	FTE	%		
SO1 Prioritise public and stakeholder engagement in the process of scientific assessment	216	254	47%	237	44%		
SO2 Widen EFSA's evidence base and optimise access to its data	24	21	4%	20	4%		
SO3 Build the EU's risk assessment capacity and knowledge community	31	36	7%	34	6%		
SO4 Prepare for future risk assessment challenges	43	41	8%	43	8%		
SO5 Create an environment and culture that reflects EFSA's values	192	186	35%	204	38%		
Of which operations	71	86	16%	94	17%		
Of which support	121	100	19%	110	20%		
Total EFSA	506	538	100%	538	100%		

"of which TR" - human resources per strategic objective allocated	Human Resources						
to Transarency regulation implementation	Initial plan	%	Actual	%			
SO1. Prioritise public and stakeholder engagement in the process of scientific assessment	89	67%	42	49%			
SO2. Widen EFSA's evidence base and optimise access to its data	43	2%	2	2%			
SO3. Build the EU's risk assessment capacity and knowledge community	20	0%	4	5%			
SO4. Prepare for future risk assessment challenges	6	5%	6	7%			
SO5. Create an environment and culture that reflects EFSA's values	35	26%	32	37%			
— of which operations	13	10%	13	15%			
— of which support	22	17%	19	22%			
Total EFSA	133	100 %	86				

⁵⁹ Due to the transition to Sysper2 during year 2020 and the different ways actual time spent from staff is collected, the information of actual allocation of time spent by activity is not available for year 2020. For this the actual distribution has been assumed equal to the initial plan.

⁶⁰ Actual available FTEs.



Annex VI. Contribution, grant and service level agreements. Financial Framework Partnership Agreements

Table 85. Contribution, grant and service level agreements

				Gener	al information	Financ	ial and	HR impa	cts	
	Date of signature	Total amount	Duration	Counterpart	Short description		N-1			N
Grant agreements										
						Amount	CA	PA	CA	PA
Total grant agreeme	nts: 0					Number of CAs				
						Number of SNEs				
Contribution agreen	nents									
J							CA	PA	CA	PA
1 2010/405 020	Support to the implementation of Preparatory measures for participation of IPA beneficiaries in the European Food Safety Authority 2019-2022, contract 2019/405-828	Amount		54000	G/ t	54000				
1. 2019/405-828		Drago Marojević		Number of CAs						
					7.44.10.1.6, 20.12 20.24, 20.114.05.20.12, 100.020			1		1
						Amount	CA	PA	CA	PA
Total contribution a	greements: 0					Number of CAs				
						Number of SNEs		1		1
Service level agreem	nents									
						Amount	CA	PA	CA	PA
Total service-level a	areements: 0									
Total service lever a	greements. o					Number of CAs				
						Number of SNEs				
						Amount	CA	PA	CA	PA
TOTAL	14,156,	998.42				Number of CAs				
						Number of SNEs		1		1

⁶¹ In March 2019, EFSA's Management Board approved the signature of a grant agreement with DG NEAR of € 0.5 million (R0 budget) to allow EFSA to support food safety risk assessment training activities to neighbour countries; the grant amount was increased to € 0.75 million in December of the same year, prolonging its duration until 2022



Annex VII. Environment management

EFSA's commitment to environmental sustainability was high on the 2021 agenda. Here are the main actions implemented to reduce EFSA's impact on the environment by CORSER and FIN.

Important achievements in this area included maintaining the Occupational health and safety management systems (ISO 45001) and the Eco-Management and Audit Scheme (EMAS) registra-tion. Specifically, regarding the EMAS registration, all the findings from the previous audit were considered closed, and no non-conformities were highlighted, with the process considered effective and running in compliance with the standard.

Significant progress was made in the context of the EMAS 2019/2021 objectives:

- 100% of the energy used by EFSA is produced by renewable sources;
- due to missions and in-person meetings/events suspension/virtualisation in response to the continuation
 of the COVID-19 pandemic, CO2 emissions and travel costs were reduced by +99% compared to 2019
 (2019 data are taken as reference as in 2020 in-person meetings and missions were suspended/virtualised);
- building up on the <u>internal communication campaign</u> of 2021, the EMAS dedicated micro-site continued to inform staff on all green initiatives at EFSA and at global level;
- EFSA applied the <u>identified green practices</u> for events organisation in view of the One Conference (Brussels, June 2022)
- environmental sustainability was also further supported by green procurement criteria in call for tenders.
 Market analysis was conducted where appropriate to assess the green op-tions to be included in selection
 and award criteria, in minimum requirements and certifi-cation requests. For example, the procedure
 for the award of the new contract for Shut-tles services will include criteria that consider the carpooling
 option and the use of low emission hybrid vehicles.

Annex VIII. (draft/final) Annual Accounts

The Final Annual Accounts will be published <u>here</u>, once adopted in June 2021.



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

1. Executive Summary

Independence is one of EFSA's key values, and the Authority attaches great importance to ensuring an impartial scientific process devoid of conflicts of interest. This annual report provides a clear and complete picture of the investments and efforts made by EFSA during the reporting period for the implementation of its Policy on Independence, of the Decision of the Executive Director on competing interests management and the management of conflicts of interest.

The reference year, 2021, has been a peculiar year for the implementation of the competing interest management function. At the beginning of May 2021, EFSA launched the so-called "complete Dol IT solution", aimed at replacing the legacy part of the former IT tool in line with the criteria set out in the EFSA IT strategy.

The new IT solution experienced technical issues that negatively affected the implementation of the independence related activities including the screening of declarations of interests (DoIs) subject to the EFSA independence rules.

Considerable efforts were required to allow for business continuity and performing all independence related activities without the IT support.

Despite the technical constraints, EFSA succeeded in:

- Screening a total of 2183 annual Dols submitted by its scientific experts and nine conflicts of interest were identified and prevented.
- Processing 17 Dols submitted by its Management Board members, 67 Dols of staff members, 138 Dols of members of the Selection Boards in the context of selection procedures for vacant positions as statutory staff members and 101 Dols of candidates pre¬selected in the context of recruitment procedures. With regard to the latter, one conflict of interest was identified, which resulted in the non-recruitment of the candidate for that particular position. In other occasions, ordinary risk mitigation measures were adopted before the recruitment of new staff members.
- Screening 179 "Institutional Dols" and 566 "individual Dols" submitted by participants in procurement and grant awarding procedures, identifying and preventing three conflicts of interests.
- Evaluating the applications of 13 former staff members wishing to engage in occupational activities, eight of which were considered overlapping with EFSA's tasks, and applied five restrictions.
- Classifying 171 organisations necessary for the screening of Dols and for the updating of the list of "public institutions" published on the EFSA website.
- Carrying out in the context of ex-post controls two breach of the rules and one compliance and veracity check, which led to the identification of five minor non-conformities, none of which required the adoption of remedial measures.
- Delivering one training session to staff members assessing Experts' Dols submitted for their participation in EFSA scientific groups and two ad hoc training sessions on the development of the new IT tool and on the workflows supporting the Dol manual processing were provided, respectively.

2. Background

Regulation (EC) No 178/2002⁶² laying down the general principles and requirements of food law and establishing the European Food Safety Authority, prescribes that EFSA shall be a point of reference for risk assessment in the food chain by virtue of the quality of its scientific outputs and of its independence. Independence and high standards of professional conduct are crucial to EFSA's work, for it is essential that interested parties and the public at large trust the process leading to the adoption of its scientific outputs.

Against this background, as acknowledged in the EFSA Strategy 2027, EFSA's vision of delivering "Safe food and sustainable food systems through transparent, independent and trustworthy scientific advice" requires adherence to robust ethics and integrity standards⁶³. An impartial scientific process populated with datasets gathered or developed in an objective manner and processed by scientists devoid of conflicts of interest is of fundamental importance to achieve EFSA's objective of being truly accountable to EU citizens and its institutional partners. Adequate management of conflicts of interest is of key importance for EFSA.

In its Policy on Independence⁶⁴, EFSA committed to making publicly available an annual report on independence related activities, thereby increasing the transparency of related processes. This is further implemented by the Decision on Competing Interest Management, on the management of competing interests applicable to all members of EFSA's Scientific Committee, Scientific Panels, Working Groups, participants in peer-review meetings, network members, members of EFSA's governance bodies, hearing experts, observers, participants in procurement and grant awarding procedures as well as staff of EU institutions, bodies or other agencies taking an active role in EFSA's meetings⁶⁵.

This annual report aims at providing a clear picture on the status of the processing of independence related activities and efforts made by the Authority to meet the expectations of EU citizens and its institutional partners. The numbers reported in this document show the strong commitment of EFSA to ensuring the adherence with EFSA's independence rules. ent of measures aimed at ensuring business continuity and the performance of EFSA's activities remotely.

3. Regulatory developments

In accordance with Article 26(3) of the Decision of the Executive Director on Competing Interest Management, in Q4 2020, EFSA launched the review of its rules on Competing Interest Management. The exercise, completed in April 2021, was aimed at evaluating the effectiveness, sustainability, efficiency, relevance, proportionality and coherence of those rules and the way these are implemented. The summary and main steps of the report were presented at the EFSA Management Board in the June 2021 public session66.

The main findings of the external review can be summarised as follows:

• Relevance and coherence – The Decision on Competing Interest Management complies with the principles outlined in the Independence Policy in all areas.

⁶² Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 031, 01/02/2002, 2-24 as last amended.

⁶³ EFSA, EFSA Strategy 2027. Science Safe food Sustainability, available at https://www.efsa.europa.eu/sites/default/files/2021-07/efsa-strategy-2027. ndf.

⁶⁴ EFSA's Policy on Independence. How the European Food Safety Authority assures the impartiality of professionals contributing to its operations, mb170621-a2, available at http://www.efsa.europa.eu/en/corporate/pub/policyonindependence.

⁶⁵ EFSA, Decision of the Executive Director of EFSA on Competing Interest Management, EFSA/LA/DEC/19568050/2018, available at http://www.efsa.europa.eu/en/corporate/pub/independencepolicy17.

⁶⁶ Available at https://www.efsa.europa.eu/sites/default/files/event/management-board-210624/16-review-competing-interest-rules-10.
mb210624-i5.pdf



- Effectiveness and impact on reputation Accuracy of assessment of Dols and EFSA capacity of detecting conflict of interest increased. EFSA's reputation in preventing conflict of interest also improved.
- Efficiency and room for simplification Positive assessment of the semi-centralised screening process by means of an efficient IT tool some room for improvement as compared to the previous situation.
- Proportionality and sustainability in light of the Transparency Regulation A wider use of sourcing models might suggest to perform a holistic review of the screening criteria.
- Policy changes A considerable degree of harmonisation reached on the main principles underlying conflict of interest prevention among "life sciences" European Union agencies.

In accordance with Article 6 of the Independence Policy, the review of the policy itself is planned to be carried out in 2023.

EFSA continued developing a regulatory framework for the implementation of articles 11 and 11a of the EU Staff Regulations on the prevention of conflicts of interest of EFSA employees and candidates to EFSA vacant positions⁶⁷. Consultation with the Commission on the drat decision is being carried out with a view to have it adopted by the EFSA Management Board in 2022.

4. Ex-ante controls - figures on Dol processing operations

FSA screened a total of 2183Annual Dolssubmitted by its scientific experts. Nine conflicts of interest were identified and prevented (details are provided below).

As well, EFSA screened 17Dols submitted by Management Board members in charge and made publicly available⁶⁸2 Dols as part of the registry of activities of former Management Board members. Dols have to be submitted also by all tenderers and participants in grant awarding procedures regarding the outsourcing of scientific tasks or projects. This resulted in the screening of 179 "Institutional Dols" and of 566 "Individual Dols". In the context of these screening processes, three conflicts of interests were identified and prevented.

Moreover, EFSA screened 138 Dols of Selection Boards members engaged in selection procedures for vacant positions as EFSA statutory staff members and 101 Dols of candidates being pre-selected for engagement as contract agents, temporary agents, seconded national experts, or participants in the guest programme. For staff candidates, one conflict of interest preventing the recruitment of the candidate was identified, whilst ordinary mitigating measures were adopted in a number of cases to prevent conflict of interests.

These ordinary mitigating measures⁶⁹ include the exclusion of the concerned individual from processes and projects regarding their previous employer in the private sector, such as those regarding the evaluation of application dossiers submitted to EFSA by applicants, participation in the evaluation of tender proposals submitted by previous employers, or the review of the candidate's own work.

As far as the screening of staff members' interests is concerned, including seconded national experts and participants in the guest programme, EFSA processed 67 Dols. This process experienced significant disruption due to the already mentioned IT deficiencies, which prevented the staff to comply with the obligation to submit their Dol annually as set out in Article 20(3) of the Decision of the Executive Director on Declarations

⁶⁷ Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community, OJ P 045 14.6.1962, p. 1385

⁶⁸The registry of post mandate activities in which former MB members engage is available at https://www.efsa.europa.eu/en/people/mbmembers
69Definition of "Ordinary mitigating measure" is retrievable on SOP 039 on management of competing interests available at https://www.efsa.europa.eu/en/people/mbmembers
69Definition of "Ordinary mitigating measure" is retrievable on SOP 039 on management of competing interests available at https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/SOP-039
A.pdf.

of Interest⁷⁰. Pending the deployment of an alternative workflow for the manual processing of Dols, a non-conformity report was filed to record the deviation from the independence rules applied to staff members.

4.1. Competing Interests prevented by sector

In the context of *ex ante controls* performed on the DoIs submitted by its experts, EFSA identified and prevented 9 conflicts of interest. This resulted in the exclusion of the concerned experts from membership to the relevant scientific group.

The breakdown by sector of the conflicts prevented is provided in Table 86.

Table 86. Competing interests prevented by sector

Sector	Number of conflicts of interest prevented
Animal Health and Welfare	6
Feed	1
Genetically Modified Organisms	1
Pesticides	1
Total	9

5. Ex post controls

5.1. Background and aggregated results

Pursuant to the Decision of the Executive Director on Competing Interest Management, twice a year EFSA should perform a check of the compliance and veracity of a sample of screening processes of Dols submitted by experts who participated in meetings of the Scientific Committee, Scientific Panels, Working Groups, Peer Review meetings as well as of Dols submitted in the context of outsourcing procedures.

For each reporting period, relevant documents related to 15 experts and 15 tenderers and grant beneficiaries are randomly selected and are checked for compliance with the regulatory framework in force at the time the Dol was screened and for the veracity of the information contained. Tenderers and grant beneficiaries who are part of the teams being awarded contracts and grants in the scientific domain as well as experts participating as Chairs or members in scientific meetings are included in the list for random selection. Experts participating as hearing experts or observers, as well as experts participating in meetings of the Management Board, (scientific) Networks, Advisory Forum or Focal Points, those participating in scientific preparatory or follow-up meeting and in scientific conferences and/or workshops on EFSA's behalf are not part of the exercise as they are not implicated in developing or adopting EFSA's scientific outputs.

It was decided to perform only one compliance and veracity check in Q2 of the reporting period due to the strong IT deficiencies jeopardising the extraction of relevant data.

Overall, the check performed in Q2 2021 identified five findings, none of which consisted in a non-conformity requiring the adoption of remedial measures.

In the reference year, this was complemented by two actions taken in response to a breach of the applicable rules.

To EFSA, Decision of the Executive Director of EFSA on Declarations of Interest, EFSA/LRA/DEC/02/2014, available at https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independencerules2014.pdf.



5.2. Findings of compliance and veracity checks and breach of the rules

The compliance check demonstrated that, for 15 out of 15 experts checked, the Decision on Competing Interest Management had been applied correctly.

12 out of 15 Individual Dols checked in the context of procurement and grant awarding procedures were found to be fully compliant. In three cases a non-compliance with the applicable rules was identified that upon declaration or clarification by the concerned individual and EFSA evaluation, did not result into a conflict of interest:

- A team member of a grant awarding procedure failed to declare the current employment. Following up the outcome of the check, the team member submitted the updated Individual Dol including the missing interest. The updated Individual Dol was evaluated and no conflict of interest was identified.
- In another grant awarding procedure, a team member declared to serve as member of a regulatory committee advising on risk management matters, but the subject matter and topic were missing. Following up the outcome of the check, the team member submitted an updated Individual Dol clarifying that, although the employment organisation performs risk management activities, the team member in question is not empowered to take any management decisions. The updated Individual Dol was evaluated and no conflict of interest was identified.
- For a procurement awarding procedure, the description of a team member role in relation to an interest declared under "VIII Other Membership or Affiliation" was missing. The team member submitted the updated Individual Dol including the missing information, which was evaluated and no conflict of interest was identified.

The veracity check revealed that the Annual Dols of 14 experts out of 15 were complete, while for one expert the Annual Dol revealed the following two omissions:

• Two research activities falling within EFSA's remit. The expert clarified that these ended more than 10 years ago. In light of the clarifications provided by the expert, EFSA agreed that those activities were not supposed to be declared.

The veracity check run in the framework of the scientific grants and procurement schemes showed that, 14 out of 15 Individual Dols were complete while for one Dol the following omission was identified:

• A team member failed to declare the current employment. Following up the outcome of the check, the team member submitted the updated Individual DoI including the missing employment. The updated Individual DoI was evaluated and no conflict of interest was identified.

Finally, in 2021 EFSA also took action in response to a breach of the applicable rules by issuing two reprimand letters to the concerned experts.

6. Assurance Working Group on Independence

Pursuant to Article 22 of the Decision on Competing Interest Management, EFSA's Legal and Assurance Services are advised by the Assurance Working Group on Independence (AWGI). The AWGI reports to the EFSA Assurance Council, which in turn informs the Audit Committee of the EFSA Management Board.

One AWGI meeting took place in 2021, which focused the discussion on interpretive issues linked to the implementation of the rules concerning Competing Interest Management.

Due to the IT deficiencies affecting the competing interests function, in July 2021 EFSA set up a Task Force to analyse and implement the actions needed to overcome the crisis. The Task Force reported monthly to the

EFSA Management Team and concluded its mandate in Q4 2021. A new project team will take over the task to rebuild and restore the IT capacity support for the processing of the independence related activities.

7. Activities undertaken by former EFSA staff members

7.1. Background

In accordance with Article 16 of the EU Staff Regulations, an official, temporary agent or contract agent intending to engage in an occupational activity, whether gainful or not, shall inform EFSA within two years of leaving the service. If the activity is related to the work carried out by the official, temporary agent or contract agent during the last three years of service and could lead to a conflict with the legitimate interests of EFSA, the Appointing Authority/Authority empowered to conclude contracts may, having regard to the interests of the service, either forbid him/her from undertaking it or give its approval subject to any conditions it thinks fit.

In the case of former senior officials⁷¹ as defined in implementing measures of the EU Staff Regulations, the Appointing Authority/Authority empowered to conclude contracts shall, in principle, prohibit them, during the 12 months after leaving the service, from engaging in lobbying or advocacy *vis-à-vis* staff of their former institution for their business, clients or employers on matters for which they were responsible during the last three years in the service. Each institution shall publish annually information on its implementation, including a list of the cases assessed, in compliance with Regulation (EC) 2018/1725 of the European Parliament and of the Council⁷².

7.2. Overview

No former staff member occupying a position corresponding to senior official left EFSA or informed the Authority of the intention to engage in an occupational activity pursuant to Article 16 of EU Staff Regulations. Furthermore, in the reference year, EFSA processed the applications of 13 staff members having left the Authority. Of these, seven opted for the public sector, and six for the private sector (see Table 2). Eight of these activities were deemed to be overlapping with EFSA's tasks and five restrictions were applied. These restrictions involved forbidding the activity, temporary bans from engaging in the concerned activities for a certain period of time (cooling off period) and the reminder to take into account possible conflicts of interest before accepting tasks involving EFSA.

Table 87. Overview of dossiers submitted under Article 16 of the Staff Regulations.

Reference year	Total number of cases	Total number of cases Of which to the private sector		Restrictions applied	
2021	13	6*	8	5	

*companies providing consultancies services; industry founded non-profit organisation active in food safety; agrochemical and industrial chemical company; clinical-stage biotechnology company; foundation whose mission is to prevent the youth from smoking

⁷¹ The term 'senior officials' refers to officials occupying functions corresponding to the basic post of Director-General in grades AD16 or AD15 as well as those occupying functions corresponding to the basic post of Director in grades AD15 or AD14. Basic post in this context, and in accordance with Annex 1 of the Staff Regulations, means all positions falling within the function group of Director-General or Director, as the case may be. At EFSA, the only position relevant in this context is the one of Executive Director.

⁷² Regulation (EU) 2018/1725 of the European Parliament and of the Council of 23 October 2018 on the protection of natural persons with regard to the processing of personal data by the Union institutions, bodies, offices and agencies and on the free movement of such data, and repealing Regulation (EC) No 45/2001 and Decision No 1247/2002/EC, OJ L 295, 21.11.2018, p. 39–98.



8. Awareness-raising and training

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

In the reference period a training session was delivered to EFSA staff in order to keep raising awareness about the key features of the Decision on Competing Interest Management. Furthermore, ad hoc training sessions on the development of the new IT tool and on the workflows supporting the Dol manual processing were provided.

Table 88. Training activities

Training activities	
Sessions for Scientific Panels	0
Sessions for Dol assessors	3
Sessions for EFSA procurement team in the Finance unit	0

9. IT developments

On 3 May 2021, the so called "complete Dol IT solution" aimed at replacing with a technical commercial offthe-shelf solution the legacy part of the previous IT solution went live whilst the previous IT system was switched off.

Despite the efforts the technical issues linked to the new IT tool could not be solved and it was decided to set aside the complete Dol IT solution and prioritise business and technical support for the manual processing of Annual Dols without the support of the integrated IT tool. To respond to the IT crisis, EFSA established a Task Force focusing on setting up the basis to restore a reliable Dol IT tool supporting the independence related activities. The Task Force will be followed up by a project focusing to build a comprehensive Dol automated solution.

10. Transparency

EFSA is highly committed to respond to the highest transparency requirements making available independence-related processes accessible to citizens and interested parties.

In accordance with EFSA's Independence Policy adopted by its Management Board in June 2017, EFSA updated and made publicly available on its website the list of "public institutions"⁷³. This list is instrumental to the screening of the Dols submitted by the concerned individuals in accordance with EFSA's Independence Policy and its Decision on Competing Interest Management. In general terms, the inclusion of an entity in this list certifies that the institutional activities performed by its employees in the public interest do not create a risk of conflict with EFSA's interest. The inclusion of an entity presupposes compliance with the criteria set out in Article 2(1), point m, of the Decision of the Executive Director on Competing Interest Management. In 2021, 171 organisations have been classified by EFSA.

Due to the technical issues encountered in the reporting period, the adherence and implementation of the transparency requirements was heavily compromised as it was communicated to the public by means of a notice published on the EFSA website indicating that 'We are having a technical issue with the publication

⁷³ The list is publicly available at https://www.efsa.europa.eu/en/howwework/independentscience

of DoIs and are working to resolve it. If you are looking for a specific DoI and cannot find it on the system please contact interestmanagement@efsa.europa.eu'.

This mainly applied to the publication on the EFSA website of the Dols of EFSA's experts, as well as to the updated version of the Dols of the members of its operational management team, comprising EFSA's Heads of Departments and Heads of Unit.

11. Engagement

In the spirit of interagency cooperation, EFSA's Head of Legal and Assurance Services served as alternate Chair of the European Chemical's Agency Independence Advisory Committee.

In 2021, EFSA engaged 34 times with members of the European Parliament, citizens, media professionals and external parties inquiring about EFSA's policy on independence and competing interest management practices by providing the requested clarifications or support.

12. Conclusions

Although technical issues were encountered that affected the independence function, in the reference period EFSA has devoted its investments and all possible efforts in this sector to provide business continuity and ensure compliance with the fundamentals of EFSA independence system.

Out of 3,242 Dols screened by EFSA in the context of the *ex-ante* controls, 13 cases of conflicts of interest were identified and prevented.

Pending the deployment of the comprehensive Dol automated solution, the outcome of the review of the rules on Competing Interest Management finalised in April 2021 evidenced that the regulatory framework currently in place is robust and in line with what is needed to ensure the EFSA independence.





Ex Ante Control							Ex post controls		Awareness- raising									
No of ADols screened	No of conflicts of interest prevented	No of waivers granted	No of Hearing experts	Dols screeed for tenderers and partici-pants in grant- awarding procedures	No of Staff ADols screened	No of staff members leaving EFSA	No of organisations classified	Breach of the rules	Non- compliance findings and actions	No of training activities								
Experts:				179: Institutional Dols		Total: 13												
2,183				566: Individual Dols	67: statutory staff	Private sector: 6*												
Management Board members: 17			-			C	3: conflict of interest prevented	t t	Restrictions:5			5 non- compliances	3: sessions for					
Former Management Board members: 0	9: ADols	9	9	9	9	9	9	9	9	9	312		101: candidate staff		171	2	none leading to a conflict of interest	Dol as-sessors
Total: 2,200 ADols					1: conflict of interest													
					prevented 138: SB members													

^{*}Companies providing consultancies services; industry founded non-profit organisation active in food safety; agrochemical and industrial chemical company; clinical-stage biotechnology company; foundation whose mission is to prevent the youth from smoking.

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