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THE 3RD INDEPENDENT EXTERNAL EVALUATION OF EFSA 2011-2016 **FINAL REPORT**

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Date **June 2018**

Made by **Vanessa Ludden, Emma Godfrey, Andrea Kobilsky,
Fredrik Hahn and Lara Jansen**

**With contributions from experts Ron Dwinger
(Netherlands Food and Consumer Product Safety
Authority), Jeanne-Marie Membré (French National
Institute for Agricultural Research) and Michael
Wight (UK Food Standards Agency)**

Checked by **Jamie Fotheringham**

Disclaimer: This report has been prepared and produced by the consultancies identified on the first page of the document. It has been produced in accordance with Article 61 of EFSA's founding Regulation (Regulation (EC) N° 178/2002), which states that EFSA shall commission an independent external evaluation of its achievements every six years on the basis of the terms of reference issued by its Management Board in agreement with the Commission. The report assesses the working practices and impact of EFSA, taking into account the views of stakeholders at both EU and national levels.

ABSTRACT

The European Food Safety Authority (EFSA), established in 2002, is an EU agency tasked with risk assessment of issues related to food and feed safety, animal health and welfare, plant health and plant protection, and nutrition.

EFSA is required to carry out an independent external evaluation, every six years. In June 2017, Coffey International Development Ltd and Ramboll Management Consulting were contracted to conduct the third independent evaluation of EFSA covering the 2011-2016 period.

The scope of the third independent evaluation was to assess the Authority's achievements in its different areas of work, and the extent to which results were proportionate to costs incurred, its coherence with EU and Member States' political priorities, and its added value at EU level. The baseline for assessment is the previous external evaluation of EFSA, which was finalised in 2012.

Our findings show that EFSA has made significant progress in addressing weaknesses previously identified. Between 2011 and 2016, EFSA's mechanisms for cooperation and engagement with partners and stakeholders at national, EU and international level were strengthened, contributing to enhanced risk assessment capacity at the EU level. In response to demands for greater transparency and a need to maintain trust, EFSA has committed to reinforcing and refocusing efforts on transparency and independence. Crucially, EFSA has now strengthened its independence policy and rules and set out a plan to move towards an "Open Science organisation", through its "Transparency and Engagement in Risk Assessment" project. Linked to this, EFSA improved mechanisms for engagement with stakeholders and cross-cutting communication activities have contributed to improved clarity, accessibility and professionalism of its materials.

Nevertheless, challenges and areas for improvement were identified. EFSA's long-term ability to continue to produce scientific advice at the current level and to the same level of quality was found to be threatened by its ability to continue to engage the best possible external expertise. EFSA faces challenges in terms of resource allocation and competing demands for resources. There is limited flexibility in the internal allocation of work and human resources, creating a need to streamline processes and introduce better mechanisms for prioritisation.

This evaluation makes six recommendations for EFSA to consider:

1. Explore options to address the structural risks to the sustainability of the scientific production model
2. Ensure a wide pool of experts is maintained
3. Use a competency-based approach to internal resourcing
4. Continue efforts to develop more fit for purpose KPIs
5. Continue to maximise potential for collaboration with sister agencies and Member States' authorities
6. Identify strategic priorities for communication activities

EXECUTIVE SUMMARY

The European Food Safety Authority (EFSA) is the European agency for risk assessment pertaining to food and feed safety, animal health and welfare, nutrition, plant protection and plant health. EFSA was established in 2002 by Regulation (EC) N° 2002/178. Article 61(1) of this Regulation requires EFSA, in collaboration with the European Commission, to commission an independent external evaluation of its achievements every six years.

This evaluation covers the 2011-2016 period and evaluates EFSA's working practices and the impact of its activities in terms of relevance, effectiveness, efficiency, coherence, complementarity, EU added value and the extent to which the recommendations of the previous External Evaluation were put into practice. On this basis, the evaluation provides recommendations for areas of improvement for EFSA.

Approach

The evaluation assesses the relevance, effectiveness, efficiency, coherence and EU added value of EFSA. It contains responses to 18 evaluation questions in line with the Terms of Reference. Conclusions are drawn from a range of data collection and analytical tasks including an extensive documentary review (totalling nearly 300 separate documentary sources), five in-depth thematic case studies, 82 stakeholder interviews, and an online survey of EFSA stakeholders with more than 1,600 responses. The evaluation is underpinned by an evaluation question matrix (EQM), which links the evaluation questions to data sources, provides the indicators used to guide our analytical process and ultimately the conclusions reached.

The evaluation was carried out between June 2017 and June 2018 by Coffey International Development Ltd and Ramboll Management Consulting, reviewed by an expert group composed of a senior management and risk assessment expert, a risk assessment expert, and a food safety legislation expert.

Findings

EFSA has come a long way since its inception in 2002. The case for an independent authority able to provide high quality scientific advice at the EU level established in Regulation (EC) N° 178/2002 was confirmed in each independent evaluation to date, including this one.

The previous External Evaluation of EFSA, completed in 2012, identified key weaknesses and opportunities for improvement, such as the efficiency of the provision of scientific advice, cooperation, which could be improved through better sharing responsibilities and harmonising methodological approaches and data collection. It also identified a need to further strengthen EFSA's international engagement, and the risk communication mandate, which lacked clarity, with messages not being readily accessible to the public.

This evaluation found that, during the 2011-2016 period, EFSA made significant progress in addressing the weaknesses previously identified:

- EFSA strengthened its mechanisms for cooperation and engagement with partners and stakeholders at national, EU and international level, contributing to enhanced risk assessment capacity at the EU level.
- In response to demands (and a need to maintain trust), EFSA has committed to reinforcing and refocusing efforts on transparency and independence. EFSA strengthened its independence policy and rules and set out a plan to move towards an "Open Science organisation", through its "Transparency and Engagement in Risk Assessment" project. Linked to this, EFSA improved mechanisms for engagement with stakeholders.
- Cross-cutting communication activities have generated greater clarity, accessibility and professionalism of materials.

Notwithstanding these achievements, the present evaluation identified the following challenges and areas for improvement:

- EFSA's long-term ability to continue to produce scientific advice at the current level is at risk. The model for engaging experts has limitations, not least that it depends on the willingness of experts (and their home institutions) to support EFSA without remuneration for the time provided.
- Notwithstanding the importance of having established Key Performance Indicators (KPIs), during the period under review, EFSA's monitoring system had shortcomings, which meant it was not adequate to provide a realistic or meaningful assessment of performance over time, which also made it difficult to assess efficiency and cost-effectiveness. EFSA's management did not comment on the (in)adequacy of the monitoring system in their self-evaluation, but we understand these issues are already being addressed by EFSA, indicating the consistency of our findings with EFSA's own assessment.
- EFSA faces challenges in terms of resource allocation and competing demands; the most pressing issue being to ensure an appropriate balance of resources between its core scientific activities – the authorisation dossiers and the general scientific questions. In addition, significant resources are being allocated to openness, which could create imbalances in the long term. Further, during the period under review, limited flexibility in the internal allocation of work and human resources was identified and therefore a need to streamline processes where possible and better mechanisms for prioritisation. Given the fragmented legislative framework, further harmonisation or flexibility may not be fully within the control of EFSA as it may require legislative changes.
- Despite headway, tailored communication remains an area where continued efforts are needed to continue to foster trust and proactively explain EFSA's work and address misunderstandings.

EFSA's key strengths, weaknesses, opportunities and threats

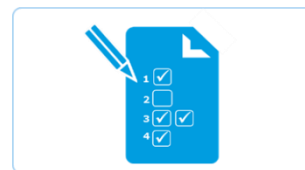
Strengths <ul style="list-style-type: none"> • Independent, neutral agency, free of political bias or commercial interests • High-quality, fit-for-purpose scientific advice • Collaboration and capacity building with Member States, EU agencies, international organisations • Horizontal expertise, European dimension • Contribution to food and feed safety standards at EU level • Strong relationship with stakeholders through transparency and openness 	Weaknesses <ul style="list-style-type: none"> • Limited flexibility in internal division of work and resources • Fixed budget and volatility of workload • Office location in Parma is inconvenient for external experts • Fragmented regulatory framework • Absence of a focused communication strategy
Opportunities <ul style="list-style-type: none"> • Continued access to a pool of experts • Potential to address new challenges as they emerge • Coordination role at EU level to harmonise standards and approaches • Strengthened international collaboration through facilitation, formalised relations and stronger cooperation with other EU agencies • Awareness raising about EFSA's work 	Threats <ul style="list-style-type: none"> • Talent gap and unsustainability of the scientific production system • Political sensitivity of the food safety sector

Conclusions and Recommendations

Our conclusions and recommendations are presented below.

Conclusion 1: There is a continued need for independent scientific advice at EU level

EFSA's original objectives as set out in Regulation (EC) N° 178/2002 are sufficiently broad to have allowed the Authority to identify and adapt to evolving needs and future challenges in line with its mandate. The evaluation confirms a continued need for an independent and EU level provider of scientific and technical advice on EU food and feed safety. It also highlighted the continued importance of EFSA's role in *preparing* for crises and *responding* to risk assessment demands in times of crisis.



Conclusion 2: EFSA is an increasingly outward looking organisation, engaging better with stakeholders and risk managers

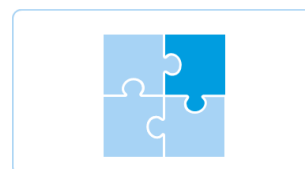


EFSA, as an organisation, has matured considerably since 2011. During the period under evaluation, EFSA adapted to better understand and respond to stakeholders' needs. Institutional mechanisms were strengthened and working practices and procedures streamlined and harmonised to engage more effectively with a broader base of stakeholders. The Authority initiated a formal feedback mechanism to

ensure its scientific advice meets risk managers' needs. The organisation has also committed to a transformation into an "Open Science organisation", which constitutes a significant undertaking. Despite EFSA's flexibility and proactivity, the Authority operates in an increasingly complex context and faces growing demands, which it must respond to within available resources. Closer cooperation with partners (i.e. Article 36 organisations) and a constant focus on working methods will continue to be critical to adequately address current and future needs and challenges.

Conclusion 3: High quality, fit for purpose scientific advice is being delivered, long-term risk to sustainability confirmed

The evaluation found EFSA's scientific system has successfully delivered high quality, fit for purpose scientific advice, that is responding to risk managers' needs. Specific concerns were raised regarding the adequacy of the peer review system for pesticides, which is the subject of ongoing assessment. However, there are long-term risks to the scientific production system, which may jeopardise EFSA's ability to effectively provide scientific advice in the future, most importantly the reliance on unpaid experts (and willing home institutions) to produce scientific advice.

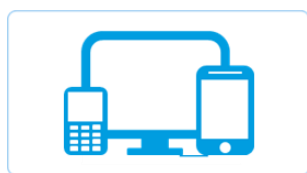


Conclusion 4: Effective cooperation at EU and progress at international level



EFSA has contributed to the harmonisation of methodologies and coherence of approaches on food safety at the EU level. EFSA has successfully enhanced its international engagement, and actively cooperates with third countries and international organisations in response to previous recommendations. Nevertheless, the evaluation found a misinterpretation among international organisations of EFSA's global engagement and ambition, of which the Authority ought to be aware going forward.

Conclusion 5: Commitment to core values and communication mandate



EFSA has reinforced its policy on independence. Despite being one of the most advanced bodies in the EU in this regard, EFSA continues to face criticism. This highlights the importance of strategic communication on this issue. Likewise, EFSA has committed to becoming an “Open Science organisation”. Although this journey is not complete, the progress made is significant. Complementing these changes are efforts to improve

communication activities (including an upgraded website and numerous communications channels). However, the absence of an up-to-date dedicated operational strategy for communications is considered a weakness, harming the full realisation of potential benefits in a targeted and efficient manner. Specifically, communication is not tailored enough to EFSA’s different audiences, particularly the public and media.

Conclusion 6: Scope to further improve monitoring systems for assessment of performance



To measure its performance, EFSA has internal mechanisms for programming, monitoring, reporting and evaluating. Notwithstanding the importance of having developed KPIs, this evaluation found that the monitoring mechanisms did not allow for a meaningful assessment of the Authority’s performance over the evaluation period. KPIs were largely output-based, have changed significantly over time and were not sufficiently qualified. KPIs were largely quantitative, lacking a corresponding story or qualitative explanation. EFSA itself recognises these shortcomings as, at the time of writing, EFSA was undertaking further work to set appropriate quantitative and qualitative indicators through its Process Architecture process variant mapping of input/output indicators, with the aim of improving the utility of its performance management.

Conclusion 7: Better mechanisms for prioritisation needed given limited resources



EFSA has made considerable investments to improve planning since 2011 but still lacks an adequate system for prioritisation of tasks based on available human and financial resources. Priorities are inherently difficult to set because of differences between sectors and areas, and because of the difficulty of estimating how much staff time or money a certain task will require. As part of EFSA Strategy 2020, the Authority began

developing a prioritisation scheme for its resources, which will anticipate risk assessment priorities and related methodology and evidence needs, as well as proactively identify priority areas of intervention, in collaboration with partners and stakeholders. In this context, it is important EFSA consider internal mechanisms to allow for more flexible allocation of resources to achieve efficiency gains.

Conclusion 8: EFSA’s complex legal basis and associated processes obstruct a meaningful evaluation of comparative cost per output



There are inherent differences in the costs of the different scientific production systems, resulting from their legal set-up. The differing levels of complexity associated with the work of the systems make a meaningful comparison between different outputs within the same system, let alone across systems, impossible. During the period under review (2011 – 2016), EFSA did not measure or report on such complexities and the workload associated with different outputs or production systems, which did not allow for a meaningful evaluation of their efficiency. From the data available, EFSA’s *total* spending on the four main

scientific production models remained stable between 2014-2016¹, though the costs associated with the different systems fluctuated. Crude measurement of cost/output fails to acknowledge the significant variances in the level of effort involved in producing outputs so cannot be taken as a reliable measure of cost-effectiveness.

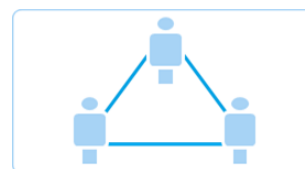
Conclusion 9: EFSA's work is complementary to that of national risk assessment organisations and mechanisms for cooperation can be enhanced



EFSA's mechanisms for engaging with national risk assessment organisations, like the Advisory Forum, CEN and the Focal Point Network allow for an early identification of potential divergence between scientific opinions and increase the degree of complementarity of work across the EU. Nevertheless, there are instances where there is a need for more regular and structured communication on specific programmes or topics

to avoid a loss of efficiency on either side. This suggests continued efforts to ensure cooperation and alignment are critical.

Conclusion 10: EFSA's work is coherent with and complementary to that of its sister agencies, and additional collaboration is required to maximise effectiveness and efficiency



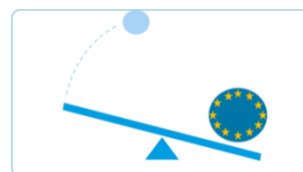
The mechanisms for collaboration and sharing of best practices have improved over time and the evaluation found little to no duplication of work. Memoranda of Understanding and related mechanisms for collaboration have greatly enhanced the effectiveness of cooperation between EFSA and its sister agencies, but there is scope to further capitalise on these to maximise impact and efficiency, notably in terms of harmonisation of methods and approaches.

Conclusion 11: EFSA's work has indirectly influenced standards and methods on food and feed safety beyond EU borders



EFSA is not mandated to promote EU standards at international level. Through its role as the Commission's main scientific adviser on food and feed safety, combined with its cooperation with international and third country organisations, it helps the EU promote regulatory standards and assessment methods in the international sphere. EU standards have been adopted by the WHO and FAO, and national risk assessment agencies in some non-EU countries have willingly adopted EFSA's risk assessment methods.

Conclusion 12: EFSA provides strong added value



EFSA's EU added value mainly lies in its core role in delivering fit for purpose pan European scientific advice to support risk management measures and policy-making. EFSA has a reputation for scientific excellence. In its absence, there would be negative impacts on food safety in the EU, as there would be less independent and coherent advice on the food chain, both at EU and national levels. The scientific basis for decision-making would be weaker and more fragmented, leading to greater risks of political interference and inconsistencies in risk assessment, and ultimately risk management, across the EU. EFSA's EU added value is also the result of its role as a facilitator of cooperation between and within Member States, including national authorities and a broad range of food safety organisations. EFSA's work increases the Member States' risk assessment capacity through harmonisation of methodologies. By undertaking this work at EU level, EFSA ensures a common approach to risk assessment across all Member States, filling a gap in capacity that exists at Member State level, especially in those that are less active in the field of food

¹ Data unavailable for 2011-2013

safety. The added value lies in providing a valuable service to Member States that would otherwise be unable to produce their own risk assessments to the same level of rigour, quality and consistency.

Recommendation 1: Explore options to address the structural risks to the sustainability of the scientific production model



It is recommended that EFSA further considers ways to organise its scientific work more sustainably. The most important aspect being to ensure the system continues to provide the necessary expertise and competence to support EFSA's work in the medium to long term. EFSA should consider:

- a model of distinct categories of experts for several types of work, appropriate to their expertise and availability. For example, preparatory work or more routine work (such as elements of literature reviews) could be outsourced to mid-career experts (through grants and/or procurement to Member State organisations), while higher level experts would be able to focus on work where more experience is needed.
- exploring new mechanisms of involving "home" organisations² in the scientific production process without adding additional burden, for instance, through a rotation of hosting working groups meeting in Member States instead of in Parma, with the logistics and organisation of meetings supported by EFSA. Member States should be consulted on this idea to gauge interest and to ensure it would not in fact impose additional burden upon them.
- new systems to support the institutions releasing experts to minimise inconvenience or provide benefits that counteract any inconvenience caused. For example, EFSA should consider if setting up staff exchange agreements for experts with national food safety bodies is feasible, and whether more training could be provided by EFSA based on a consultation of capacity gaps among staff performing risk assessments at national level.

Recommendation 2: Ensure a wide pool of experts is maintained

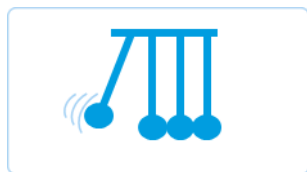


Closely linked to the above, it is recommended that EFSA undertake measures to ensure a wide pool of experts is maintained. EFSA should make the proposition of acting as an expert more appealing. At the same time, EFSA should be mindful to strike the right balance between the need to maintain an appropriate level of independence and the scientific expertise required, and ensure that the system is not made stricter than it already is. As a starting point EFSA should:

- offer the opportunity to publish more in-depth articles on research related to risk assessments carried out for EFSA in high-impact journals, in addition to, not instead of, the EFSA Journal;
- maximise the potential to streamline and shorten the application process for experts applying to EFSA's Scientific Panels, by introducing a staggered process with a short pre-application screening process for example to allow those unsure if they may have a conflict of interest to establish this before embarking on a full application (and thereby ensure this is not a deterrent).

Both recommendation 1 and 2 are in line with one of the main objectives of the Commission's proposal for a targeted revision of the General Food Law Regulation to "strengthen the ability of EFSA to maintain a high level of scientific expertise in the different areas of its work, especially its capacity to attract excellent scientists to be members of its Scientific Panels".

Recommendation 3: Use a competency-based approach to internal resourcing



There is a need for more flexibility to respond to peaks and troughs in workload and to priorities as they emerge. EFSA should ensure more flexibility in working procedures to allow staff to work across units where common skillsets and competencies can apply and where availability allows. To fulfil this recommendation, EFSA should first carry out a

² Meaning those organisations that release staff to support EFSA's scientific work.

comprehensive assessment of the distinct roles and competencies needed and the ones at its disposal in its different units, and on that basis, identify where there is scope for staff to be shared across units³. This also requires mechanisms for clear priority setting and resetting.

Recommendation 4: Continue efforts to develop more fit for purpose KPIs

There is a need for greater continuity in the gathering of monitoring data over time, as well as in how it is reported. Quantitative data should be complemented with sufficient qualitative narrative to understand and explain changes over time. This will serve to enable a more meaningful understanding of EFSA's activities. Where KPI targets are changed, the reasons should be fully explained, again to allow for meaningful interpretation over time. In addition, EFSA's efforts to better measure efficiency and cost effectiveness of its different scientific activities over time, which are on-going at the time of writing, should be prioritised.



Recommendation 5: Continue to maximise potential for collaboration with sister agencies and Member States' authorities



Building on the successful collaboration that exists between EFSA and sister agencies, as well as between EFSA and national authorities, EFSA should continue to look for opportunities to benefit from potential synergies. This is especially important considering the need to address shared challenges, such as the need for ever more openness, and harvesting and managing big data.

Recommendation 6: Identify strategic priorities for communication activities

EFSA needs to have and regularly update a communications workplan to make the relevant elements of its Strategy 2020 operational, and guide its work in this area, to effectively fulfil its second mandate. The workplan should be based on a cost-effectiveness analysis for these activities. It should provide a comprehensive roadmap linking audiences with materials tailored to their needs. It should include more proactive communication and engagement with the media. EFSA should build solid relationships with journalists such that they feel comfortable seeking clarification on issues to be covered, for example. The website should include a section dedicated to the rapid publication of press releases, directed to the media only, and aiming to help them write about news from EFSA.



³ We understand that a competency library has been developed and used to deploy staff, however this has been developed outside of the period of review and was not reviewed here.

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Evaluation questions matrix

Appendix 2

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Survey questionnaire

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Interview guides

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EFSA's cost-effectiveness

Appendix 6

EFSA Management self-evaluation

Due to their size, the appendices are presented in a separate document.

LIST OF ABBREVIATIONS

ADoI	Annual Declaration of Independence
AF	EFSA's Advisory Forum
AFCWG	The Advisory Forum Working Group on Communications
AHAW	Panel on Animal Health and Welfare
ANS	Panel on Food Additives and Nutrient Sources Added to Food
BIOHAZ	Panel on Biological Hazards
BMD	benchmark dose
BUS	The Business Services Department
CEF	Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids
CEP	Panel on Food Contact Materials, Enzymes and Processing Aids
CEN	Communications Expert Network
CFIA	Canadian Food Inspection Agency
CFSA	Chinese National Centre for Food Safety Assessment
COMCO	The Communication, Engagement and Cooperation Department
CONTAM	Panel on Contaminants in the Food Chain
DATA	Evidence Management Unit
DCF	Data Collection Framework
DEFRA	UK Department for Environment Food & Rural Affairs
DG RTD	Directorate-General for Research and Innovation
DG SANTE	Directorate-General for Health and Food Safety
DoI	Declaration of Interest
DWH	Data Warehouse
EC	European Commission
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EEA	European Economic Area / European Environmental Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EP	European Parliament
EPA	EFSA Process Architecture
EPPO	European and Mediterranean Plant Protection Organisation
EQM	Evaluation Questions Matrix
EU	European Union
EURLs	EU Reference Laboratories
FAF	Panel on Food Additives and Flavourings
FAO	Food and Agriculture Organisation
FCEC	Food Chain Evaluation Consortium
FEEDAP	Panel on Additives and Products or Substances used in Animal Feed
FPN	Focal Point Network
FSANZ	Food Standards Australia New Zealand

FSCJ	Food Safety Commission of Japan
FTE	Full Time Employees
GFL	General Food Law
GIFT	Global Individual Food consumption data Tool
GFL	General Food Law
GMO	Genetically Modified Organisms / Panel on Genetically Modified Organisms
HORECA	Hotel, Restaurants and Caterers
IAS	Internal Audit Service
ICS	Internal Control Standards
IFCSLG	International Food Chemical Safety Liaison Group
ILMERAC	International Liaison Group on Methods for Risk Assessment of Chemicals in Food
IMFSLG	International Microbial Food Safety Liaison Group
IPPC	Integrated Pollution Prevention and Control
JECFA	Joint FAO/WHO Expert Committee on Food Additives
JMPR	Joint FAO/WHO Meeting on Pesticides Residues
JRC	Joint Research Centre
KPIs	Key Performance Indicators
MRL	Maximum Residue Level
NCA	National Competent Authority
NDA	Panel on Dietetic Products, Nutrition and Allergies
NZMPI	Health Canada and New Zealand Ministry of Primary Industries
OIE	World Organisation for Animal Health
PaRMa	Project and Resource Management approach Project
PLH	Panel on Plant Health
PPR	Panel on Plant Protection Products and their residues
PRAS	EFSA's Pesticides Unit
PROMETHEUS	Promoting Methods for Evidence Use in Science project
RAR	Renewal Assessment Report
RASA	The Risk Assessment & Scientific Assistance Department
RMS	Rapporteur Member State
REFIT	Regulatory Fitness and performance programme
REPRO	The Scientific Evaluation of Regulated Products Department
SCER	Scientific Committee and Emerging Risks Unit
SCP	Stakeholder Consultative Platform
TERA	Transparency and Engagement in Risk Assessment project
ToR	Terms of Reference
TTC	Threshold of Toxicological Concern
USDA	United States Department of Agriculture
WHO	World Health Organisation

1. INTRODUCTION

1.1 Purpose

In accordance with Article 61 of Regulation (EC) N° 178/2002, the European Food Safety Authority (EFSA), in collaboration with the European Commission, has a legal obligation to contract an independent external evaluation of its achievements every six years. This evaluation assesses the working practices and the impact of the Authority over the period 2011-2016 and responds to the Terms of Reference (ToR) issued by EFSA's Management Board, in agreement with the European Commission.

The independent evaluation assesses the Authority itself, as well as its core activities in terms of relevance, effectiveness, efficiency, coherence, and EU added value, thereby answering the evaluation questions set out in the ToR (explained in chapter 3). Part of this study's objective is to look at the extent to which the recommendations issued by the Management Board, following the 2012 External Evaluation of EFSA, have been put into practice.

Ultimately, the study provides EFSA with recommendations to address identified weaknesses and enable the Authority to adapt to forthcoming challenges. EFSA's Management Board will examine the outcome of the evaluation and issue recommendations to the European Commission regarding any possible changes to the Authority and its working practices.

1.2 Scope

As per the ToR, the evaluation covers the six-year period from 2011 to 2016. Where appropriate, evidence and developments up to 2018 are considered as supporting evidence. The evaluation addresses and covers the whole scope of EFSA's mission and tasks, as set out in chapter 2, as well as its functioning as provided for in Regulation (EC) N° 178/2002. As per the ToR, the study addresses:

- EFSA's working practices to produce scientific advice, and scientific and technical support, and its communication thereof, also including its planning, priority setting and resource management;
- The impact of EFSA's work on all relevant partners and stakeholders at national, community and global level;
- EFSA's cooperation and reputation at EU and global level; and
- EFSA's governance structure.

The evaluation is based on EFSA's founding Regulation, (EC) N° 178/2002, and considers other secondary legislation creating additional mandatory procedures for EFSA (such as authorisation procedures). The starting point is the 2012 External Evaluation of EFSA and the related recommendations of the Authority's Management Board. The evaluation also considers the conclusions of the REFIT evaluation of the General Food Law Regulation to ensure the continuity and consistency of both exercises.

2. BACKGROUND TO THE EVALUATION

In this section, we present an overview of the context for the evaluation to summarise the rationale for EFSA and its role as a source of scientific advice and communication on risks associated with the food chain. It includes a description of how the Authority is organised and how it operates, to provide the necessary context for matters examined under the evaluation questions. The section also incorporates an intervention logic that provided a framework for the assessment of progress towards planned outputs, outcomes, and impacts, and how these are intended to be achieved, along with a summary of the baseline position for the evaluation.

2.1 EU food safety and EFSA

2.1.1 Food safety in the European Union

Within the EU, food safety has an inherent cross-border dimension. There could not be free trade in food within the common market if every product had to be controlled in each country based on different rules. Therefore, rules for food safety must be defined at EU level to guarantee that trade in foodstuffs does not threaten public health, and that the implementation of various food safety-related standards does not constitute a source of distortion of competition for industry. The EU considers food safety as both a key public health issue and an economic priority. Indeed, the EU aims to protect citizens', as well as animal and plant health, while the food industry, which as the largest manufacturing and employment sector in Europe, needs to work in the best possible conditions.⁴

There are continuous far-reaching challenges to food safety within the EU, including:

- Preventing animal and plant diseases from entering and circulating in the EU;
- Preventing the spread of disease from animals to humans;
- Ensuring common rules are maintained across the EU to protect consumers and prevent unfair competition;
- Protecting animal welfare;
- Ensuring consumers have clear, unambiguous information on the content and origin of food;
- Contributing to global food security and providing people with sufficient access to safe, quality food.⁵

A series of food incidents in the late 1990s, including the 1996 'mad cow' crisis, drew attention to the need for a European food policy centred on the requirement that only foodstuffs that are safe, wholesome and fit for consumption be placed on the market.⁶ Food crises and outbreaks of animal diseases inevitably occur from time to time, emphasising the relevance of streamlining health protection throughout the food production process and in emergency situations.

In addition, there are ongoing challenges that could put the European food system under stress. They include demographic imbalances, climate change, resource and energy scarcity, slowing agricultural productivity, increasing concentration of the supply chain, price volatility, changing dietary trends and the emergence of anti-microbial resistance.

Accordingly, the European Commission developed an integrated approach to food safety 'from farm to fork', primarily set out in its 2000 *White Paper on Food Safety*⁷. The provision of safe, nutritious, high quality and affordable food to European consumers is the central objective of EU policy, which covers all stages of the EU food supply chain, including feed production, primary production, food processing, storage, transport and retail sale.⁸ Its standards and requirements aim to ensure a

⁴ European Commission, 'From Farm to Fork: Safe and Healthy Food for Everyone', in *The European Union Explained: Food Safety*, ed. by European Union (Luxembourg, 2014), 1–16 <https://europa.eu/european-union/file/1280/download_en?token=AEeF-HZA> [accessed 25 May 2018]; Commission of the European Communities, *White Paper on Food Safety* (Brussels, Belgium, 2000).

⁵ European Commission, 'From Farm to Fork: Safe and Healthy Food for Everyone', in *The European Union Explained: Food Safety*, ed. by European Union (Luxembourg, 2014), 1–16.

⁶ Centre for Strategy & Evaluation Services (CSES), *The Cost of Non-Agencies with Relevance to the Internal Market*, ed. by Policy Department D: Budgetary Affairs (Brussels, Belgium, 2016).

⁷ Commission of the European Communities, *White Paper on Food Safety* (Brussels, Belgium, 2000).

⁸ See p.8, Commission of the European Communities, *White Paper on Food Safety* (Brussels, Belgium, 2000); European Union, *Future nutrition policy*, <https://ec.europa.eu/food/safety/future/future-nutrition-policy_en> [accessed 25 May 2018].

high level of food safety and nutrition in the EU within an efficient, competitive, sustainable and innovative global market.⁹

In 2002, the European Parliament (EP) and the Council adopted Regulation (EC) N° 178/2002 laying down the General Principles and Requirements of Food Law ("**General Food Law**" – GFL).¹⁰ It set out an overarching framework for the development of food and feed legislation, both at EU and national levels.¹¹ To this end, Regulation (EC) N° 178/2002 laid down procedures that underpin decision making in matters of food safety, covering all stages of food production and distribution. The three general **objectives of EU food safety policy** are:

1. To ensure that food and animal feed are safe and nutritious;
2. To ensure a high level of animal health, welfare and plant protection;
3. To ensure adequate and transparent information about the origin, content/labelling and use of food.¹²

2.1.2 EFSA: the European Food Safety Authority

The growing emphasis on evidence-based policy-making, and the critical importance of scientific evidence in food and feed safety legislation, coupled with the increasing complexity of scientific and technical issues in relation to the topic, called the EU to recognise the need to have "access to high-quality, independent and efficient scientific and technical support"¹³. In response, Regulation (EC) N° 178/2002 set up an independent agency, the European Food Safety Authority (EFSA).

EFSA was created as a specialised expert body or "decentralised agency"¹⁴. The rationale was that such an agency would be better placed to execute technical and scientific tasks (hitherto carried out at Union or national level) and to communicate independently on risks, to provide the Union with the necessary means to act effectively to enhance overall food and feed safety. This would, in turn, allow the Commission to refocus on its core policy-making activities based on scientific evidence and the precautionary principle¹⁵, while helping to enhance confidence in the food supply, within the internal market and through international trade.¹⁶

EFSA's mission is to "provide scientific advice and scientific and technical support for the Community's legislation and policies in all fields which have a direct or indirect impact on food and feed safety. It shall provide independent information on all matters within these fields and communicate on risks."¹⁷ The Authority is to carry out its tasks¹⁸ in an independent and transparent manner to enable it to serve as a point of reference and is to act in close cooperation with the competent bodies in Member States carrying out similar tasks to ensure coherence and consistency.

2.2 Baseline: Past evaluations and recommendations

2.2.1 Past external evaluations of EFSA

The first External Evaluation of EFSA¹⁹ was carried out in 2005, when the organisation had only been in operation for two years and was still very much in the process of establishing its working procedures. The review was expected to contribute to the adaptation of the newly created Authority. The overall conclusion of the Final Report was that EFSA had done well during these two

⁹ European Union, 'Future of EU food safety and nutrition policy', 2018 <https://ec.europa.eu/food/safety/future_en>.

¹⁰ European Parliament and Council, 'Regulation (EC) N° 178/2002 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', *Official Journal of the European Communities*, L31 (2002), 1–24 <<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:EN:PDF>>.

¹¹ For related resources, see European Commission, 'Food', 2018 <https://ec.europa.eu/food/safety/general_food_law_en> [accessed 15 March 2018].

¹² European Commission, 'From Farm to Fork: Safe and Healthy Food for Everyone', in *The European Union Explained: Food Safety*, ed. by European Union (Luxembourg, 2014), 1–16.

¹³ Regulation (EC) N° 178/2002.

¹⁴ European Union, 'Decentralised Agencies', 2018 <https://europa.eu/european-union/about-eu/agencies/decentralised-agencies_en> [accessed 15 March 2018].

¹⁵ Article 7, Regulation (EC) N° 178/2002; and Article 191, European Union, 'Consolidated Version of the Treaty on the Functioning of the European Union', *Official Journal of the European Union*, C/326 (2012), 47–390, defines the precautionary principle as aiming at ensuring a higher level of environmental protection through preventative decision-taking in the case of risk. In practice, the scope of this principle is far wider and covers consumer policy, EU legislation concerning food and human, animal and plant health.

¹⁶ EFSA Office of the Executive Director and the Management Board, *EFSA Strategic Plan 2009-2013* (Parma, Italy, 2008).

¹⁷ As per Article 22(2), Regulation (EC) N° 178/2002.

¹⁸ EFSA's tasks are listed in Article 23, Regulation (EC) N° 178/2002.

¹⁹ Bureau van Dijk Ingénieurs Conseils with Arcadia International EEIG, *Evaluation of EFSA - Final Report*, 2005.

years, but that it was still undergoing a learning and organisational process, having moved to Parma and facing a restrictive budgetary context. The 2005 External Evaluation concluded that:

- EFSA's structures, management, and organisation were functioning satisfactorily;
- EFSA's scientific work and added value were perceived positively by stakeholders;
- Risk communication had improved compared to the situation before EFSA;
- EFSA had established good relationships with stakeholders;
- EFSA had largely completed its basic regulatory provisions.

The report also identified a need for EFSA to ensure that its structures, organisation, procedures and systems were fit for the challenges ahead. Recommendations included:

- Strengthening EFSA's relations with its institutional partners and stakeholders;
- Developing active networking and stronger cooperation with Member States;
- Enhancing EFSA's organisation;
- Enhancing the impact and effectiveness of EFSA's communications;
- Developing EFSA's role in nutrition;
- Defining EFSA's medium and long-term vision.

The second External Evaluation of EFSA²⁰, completed in 2012, recognised the Authority's positive contribution to the EU's integrated food safety system, despite limitations in all dimensions of EFSA's activity. Operating in an increasingly complex regulatory environment, EFSA managed to adapt to meet the demand for scientific advice. Quality procedures and qualified experts were effective in providing quality advice, even if concerns remained as to the efficiency of the provision of scientific advice. The Evaluation also noted that EFSA's mandate regarding risk communication lacked clarity, and that the messages were not readily accessible to the public. Cooperation was considered adequate and allowed EFSA to have high quality expertise from different Member States, but remained an area for improvement to better share responsibilities and harmonise methodological approaches and data collection, while further strengthening EFSA's international role. The highest priority recommendations were:

- Increasing the awareness of mandates and self-tasking activities on emerging issues;
- Better communicating outputs and activities;
- Strengthening the role given to EFSA in supporting risk managers in ensuring coordinated and coherent communications when urgent scientific advice is required to address risks associated with the food chain;
- Further strengthening cooperation with Member States;
- Improving the monitoring system;
- Focusing the communication on independence, specific aspects of implemented rules, procedures and results that address still existing criticisms;
- Increasing the level of transparency on how external scientific studies, as well as suggestions and comments coming from stakeholders, are taken into account;
- Assessing the cost-benefit of the tools of stakeholder involvement, to prioritise them and focus efforts on the most efficient and effective ones.

2.2.2 Other assessments of EFSA's working practices

The Evaluation of the EU Decentralised Agencies²¹ in 2009 was designed to contribute to the debate on the future of the agency system by taking a horizontal look at all 26 EU agencies. The assignment evaluated aspects such as the relevance of the agencies' creation, and of their activities to the EU's work; principles of good governance in the supervision of the agencies; coherence between activities and objectives of the different agencies and with EU policy objectives; efficiency and cost-effectiveness in carrying out activities; and the adequacy of the monitoring mechanisms for assessing performance. The results of this Evaluation supported the formulation of a "common approach" to decentralised agencies.²²

²⁰ Ernst&Young, *External Evaluation of EFSA - Final Report*, 2012.

²¹ Ramboll-Euréval-Matrix, *Evaluation of the EU Decentralised Agencies in 2009*, 2009.

²² See for more information European Union, 'Decentralised agencies: 2012 Overhaul', <https://europa.eu/european-union/about-eu/agencies/overhaul_en> [accessed 19 April 2017].

In relation to EFSA, the Final Report presented the following key findings:

- EFSA's rationale was clearly established in Regulation (EC) N° 178/2002;
- EFSA was strongly relevant to the needs of its stakeholder groups;
- EFSA had developed close collaboration with other EU agencies;
- EFSA's work was of strong added value at international, EU and national levels;
- EFSA had succeeded in improving its effectiveness;
- EFSA's staff had been under increased pressure to deliver more scientific opinions resulting from increased demand;
- The number of applications for the release of authorisations from industry had also experienced an important leap;
- EFSA's location had resulted in budgetary constraints;
- EFSA's results-based approach allowed for the revision of resource commitments on a regular basis.

2.3 EFSA over the period under review

2.3.1 Strategic framework and goals

Compared to the founding regulations of other agencies undertaking safety assessments, Regulation (EC) N° 178/2002 does not provide an overall regulatory framework for the evaluation of regulated products. Rather, EFSA has a complex legal framework, encompassing 19 different pieces of legislation. There are 34 different legislative frameworks and almost 40 workflows for applications assessed by EFSA, which imply different procedures and working-practices. This has led to the introduction of significant changes to the regulatory framework for food safety since the Authority's creation in 2002.²³ As a result, the direction of travel for the Authority is set in a series of strategic, multiannual and annual, planning documents, aligned with policy priorities in EU food safety. Over the period of review the strategic direction of EFSA has been captured by a series of strategic documents developed, the key documents are summarised below. Frameworks for strategic cooperation at EU and international level are presented under section 2.3.3.4.

2.3.1.1 EFSA Strategic Plan 2009-2013

EFSA Strategic Plan 2009-2013²⁴ set the framework for annual work programmes by identifying six key strategic areas and outcome-oriented objectives in response to the identified challenges to food and feed safety and EFSA's operations (see Table 1).

Table 1: Key challenges and strategic areas as defined in EFSA Strategic Plan 2009-2013

Key challenges	Strategic areas
<ul style="list-style-type: none"> • Increased likelihood of new or re-emerging risks to the European food supply • Innovative technologies, evolving risk assessment practices and new science • Increasing importance of an integrated approach to risk assessment to meet sustainability and climate change goals • Societal changes associated with socio-demographic structure, diet and consumer behaviour • Changes in policies and the regulatory framework 	<ul style="list-style-type: none"> • Integrated approach to delivering scientific advice associated with the food chain from field to plate • Timely, high-quality evaluation of products, substances and claims subject to the regulatory authorisation process • Collation, dissemination and analysis of data in the fields within EFSA's remit • EFSA at the forefront of risk assessment methodologies and practices in Europe and internationally • Enhanced confidence and trust in EFSA and the EU food safety system through effective risk communication and dialogue with partners and stakeholders • Responsiveness, efficiency and effectiveness of EFSA

²³ See for more information European Union, 'Fitness check of General Food Law' <https://ec.europa.eu/food/safety/general_food_law/fitness_check_en> [accessed 19 April 2017].

²⁴ EFSA Office of the Executive Director and the Management Board, *EFSA Strategic Plan 2009-2013* (Parma, Italy, 2008).

This strategic framework was complemented by the Science Strategy 2012-2016²⁵, which emphasised the need to make the best possible use of the resources at EFSA's disposal to meet the strategic priorities while:

- further developing the excellence of EFSA's scientific advice;
- optimising the use of risk assessment capacity in the EU;
- developing and harmonising methodologies and approaches to assess risks associated with the food chain;
- and strengthening the scientific basis for risk assessment and risk monitoring.

2.3.1.2 Programming Document of the European Food Safety Authority 2014-2016

Transitioning from the previous strategy, the Programming Document of the European Food Safety Authority 2014-2016²⁶ incorporated the Management Board's recommendations (based on the second External Evaluation of EFSA) with the aim to:

- Ensure the long-term sustainability of the organisation;
- Increase the trust of stakeholders and citizens;
- Further enhance EU's risk assessment capacity;
- Improve the clarity and accessibility of EFSA's risk communication.

In turn, these recommendations defined three strategic objectives for EFSA:

- 1. Fit for purpose:** increased usefulness of EFSA's advice to risk managers in their quest for food safety, more efficient and predictable regulatory environment.
- 2. Sustainability:** strengthened cooperation with national food safety agencies, European bodies and international organisations to build an EU risk assessment community with a common agenda and streamline EFSA processes.
- 3. Trust:** openness incorporated into EFSA's scientific work to increase trust in the EU food safety system.

2.3.1.3 EFSA Strategy 2020 (2016–2020)

EFSA Strategy 2020 lays out the multiannual strategic framework for the Authority's work until 2020. The document considers the environment in which EFSA operates, the main drivers that are expected to influence the direction of its work, and the challenges and opportunities that it might encounter. It defines five strategic objectives, in line with its activities presented in our intervention logic below (section 2.4):

- Prioritise public and stakeholder engagement in the process of scientific assessment;
- Widen EFSA's evidence base and optimise access to its data;
- Build the EU's scientific assessment capacity and knowledge community;
- Prepare for future risk assessment challenges;
- Create an environment and culture that reflects EFSA's values of scientific excellence, independence and openness.²⁷

EFSA Strategy 2020 also presents the key values guiding the realisation of these objectives, which are accompanied by expected outcomes that lead the Authority's work up to 2020.²⁸

2.3.2 EFSA's key bodies and organisational structure

As a decentralised agency, EFSA has a legal personality and dedicated budget. Its internal organisation and working procedures are expected to enable the Authority to implement its mandate. Article 24 of Regulation (EC) N° 178/2002 established four of EFSA's bodies:²⁹

- A Management Board;
- An Executive Director and "his" staff;

²⁵ European Food Safety Authority, *Science Strategy 2012-2016* (Parma, Italy, 2012).

²⁶ European Food Safety Authority, *Programming Document of the European Food Safety Authority 2014-2016 Incorporating Annual Management Plan 2014 and Multiannual Plan 2014-2016* (Parma, Italy, 2013).

²⁷ European Food Safety Authority, *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016) <<https://www.efsa.europa.eu/sites/default/files/151008.pdf>>.

²⁸ European Union, 'EU Publications' <<https://publications.europa.eu/en/publication-detail/-/publication/b71f853f-18cc-11e6-ba9a-01aa75ed71a1>> [accessed 02 July 2018]

²⁹ Article 24, Regulation (EC) N° 178/2002.

- An Advisory Forum;
- A Scientific Committee and Scientific Panels.

In addition to the four bodies established by Regulation (EC) N° 178/2002, the Advisory Forum Communications Working Group (AFCWG), Focal Points, and Scientific Networks also support EFSA's work.³⁰

2.3.2.1 Management Board

The **Management Board** is EFSA's governance body. It is composed of 14 independent members, who do not represent any government, organisation or sector, and one representative of the European Commission. The Board establishes EFSA's budget and is responsible for ensuring that the Authority works effectively, and successfully cooperates with partner organisations across the EU and beyond. The Management Board also ensures that EFSA's activities are focused on the achievement of the expected results and monitors progress. The Management Board is hence required to adopt the Authority's annual work programme for the coming year, as well as to adopt a revisable multi-annual programme. In addition, it is to adopt the general report on the Authority's activities for the previous year, before 30 March each year.

2.3.2.2 Executive Director and staff

EFSA's **Executive Director** is the legal representative of the Authority. He is responsible for staffing issues and drawing up the annual work programmes in consultation with the European Commission, European Parliament and EU Member States. He is responsible for the operational management, with the support of Department and Unit managers.³¹

EFSA's Departments and Units have evolved since Regulation (EC) N° 178/2002 established the Authority, including over the period under review.

Over this period, the main change took place in 2011, when EFSA was reorganised into five Directorates³² and established an Applications Desk Unit to act as a first point of contact for industry applicants seeking assessment of regulated products. The reorganisation followed the strategic direction undertaken by the Authority with the definition of its Strategic Plan 2009-2013. Its aims were to make better use of resources to reflect a growing and diversifying workload, to increase efficiency and to provide an improved service to clients.³³

In 2013, EFSA stopped referring to 'Directorates'³⁴ and realigned its Risk Assessment and Scientific Assistance *Department*, to put data at the centre of the risk assessment process while achieving efficiencies through the pooling and sharing of tools and resources.³⁵

In 2015, the two Units that were part of the Science Strategy and Coordination Department (formerly directorate) were restructured into the Risk Assessment and Communication Departments and the number of Departments was reduced from five to four³⁶.

There were some further changes in subsequent years, including the creation of the Senior Science Coordinator, Chief Scientist and Senior Policy Adviser reporting to the Executive Director in 2016, and internal renaming and reorganisation within the Resources and Support (now Business Services) and Communications and External Relations (now Communication Engagement and Cooperation) Departments.

Although strictly outside of the period under review, since March 2018, the four following Departments report to the Executive Director:

³⁰ European Food Safety Authority, *Scientific Cooperation Annual Report 2015* (Parma, Italy, 2016).

³¹ European Food Safety Authority – EFSA, 'Operational management', 2018

<<https://www.efsa.europa.eu/en/people/operationalmanagement>> [accessed 4 April 2018].

³² Communications Directorate, Science Strategy & Coordination Directorate, Resources & Support Directorate, Risk Assessment Directorate and Scientific Cooperation & Assistance Directorate.

³³ EFSA Office of the Executive Director and the Management Board, *EFSA Strategic Plan 2009-2013* (Parma, Italy, 2008).

³⁴ The Communications Directorate, Science Strategy & Coordination Directorate, Resources & Support Directorate, Scientific Evaluation of Regulated Products Directorate, and Risk Assessment and Scientific Assistance Directorate were referred to in the organisational chart from March 2013. See European Food Safety Authority, *Work Plan 2013* (Parma, Italy, 2013).

³⁵ European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014).

³⁶ Communications Department, Scientific Evaluation of Regulated Products Department, Resources & Support Department, Risk Assessment and Scientific Assistance Department.

- The **Scientific Evaluation of Regulated Products** Department (REPRO), which supports EFSA's work in the evaluation of substances, products and claims intended to be used in the food chain to protect public, plant and animal health as well as the environment³⁷;
- The **Risk Assessment & Scientific Assistance** Department (RASA), which organises the work of the Scientific Committee on cross-cutting scientific issues, supports the Panels to carry out risk assessments on general health and safety priorities in areas such as biological hazards, chemical contaminants, plant health, and animal health and welfare, and provides specialised support on data collection, emerging risks, exposure assessment and risk assessment methodologies³⁸;
- The **Communication, Engagement and Cooperation** Department (COMCO), which manages EFSA's communication, engagement and cooperation activities³⁹;
- The **Business Services** Department (BUS), which provides solutions to produce trusted scientific advice through a strong partnering approach in six areas⁴⁰. It includes support structures, designed to ensure that the Authority's scientific and communication activities comply with its legal framework, core values and strategic objectives, as well as with principles of effectiveness and efficiency.⁴¹ Support structures are classified as transactional services, expert services, and strategic services.⁴² In addition, there is the legal support unit, which manages formal procedures of legal relevance on behalf of EFSA, including the handling of pre-litigation, administrative procedures and litigation.⁴³

2.3.2.3 Advisory Forum

Chaired by the Executive Director, the **Advisory Forum** is composed of representatives from the national food safety authorities, or those with a similar remit, of all 28 EU Member States, plus Iceland and Norway, and observers from Switzerland and (potential⁴⁴) candidate countries. The Forum advises EFSA's Executive Director "in drawing up a proposal for the Authority's work programme"⁴⁵ to prioritise EFSA's activities. It also provides a setting for EFSA and Member States to share data and opinions, notify novel issues, create liaison groups on emerging risks, coordinate risk communication and avoid duplication of work. Cooperation and appropriate exchange of information through the Advisory Forum aim to minimise the potential for diverging scientific opinions and to avoid the duplication of work, not only between EFSA and Member States but also between Member States. The Advisory Forum meets four times a year to discuss an operational and strategic agenda.

2.3.2.4 Scientific Committee and Panels

The **Scientific Committee and Panels** are responsible for EFSA's scientific work, with support from the Authority's scientific staff and the Working Groups. The Scientific Committee and Panels are composed of independent scientific experts, who carry out risk assessments, and develop related methodologies.⁴⁶ Their key role is to adopt scientific opinions. Experts are selected following a call for expressions of interest, based on their scientific expertise, and experience in risk assessment. The breadth of experience of all the experts taken together is an important consideration in the selection process (explained below). At the time of writing, ten Scientific Panels⁴⁷ are responsible for issuing opinions in their specific fields of expertise.⁴⁸

³⁷ Valdani Vicari & Associati, *EFSA APDESK Survey on Stakeholders' Satisfaction on Provided Services*, 2014.

³⁸ European Food Safety Authority - EFSA, 'Hans Verhagen' <https://www.efsa.europa.eu/en/staffdirectory/staff/hansverhagen_bio> [accessed 16 March 2018].

³⁹ No specific information was found on this department, apart from information of its recent restructuring (Communication Unit and Engagement and Cooperation Unit). See EFSA Scientific Committee and Emerging Risks Unit, *Scientific Committee Minutes of the 87th Plenary meeting Held on 14-15 February 2018*, 2018.

⁴⁰ Global Performance, Digital Transformation, Legal and Assurance, Human Capital, Financial, and Corporate Services. See p47, European Food Safety Authority, *EFSA Consolidated Annual Activity Report 2017 (DRAFT)* (Parma, Italy, 2018).

⁴¹ European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015).

⁴² European Food Safety Authority, *Programming Document 2016-2018* (Parma, Italy, 2015).

⁴³ European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015).

⁴⁴ At the time of the evaluation: Bosnia and Herzegovina; but not Kosovo.

⁴⁵ Article 27(3), Regulation (EC) N° 178/2002.

⁴⁶ European Food Safety Authority – EFSA, 'Scientific Committee and Panels' <<http://www.efsa.europa.eu/en/science/scientific-committee-and-panels>> [Accessed 23 January 2018].

⁴⁷ There are, in 2018, ten Panels; but their number and names may be adapted by the Commission at the Authority's request.

⁴⁸ Names and their area of responsibility have been amended in 2017 to reflect expected changes in technical and scientific development, as such the ANS, CEF and NDA Panels names and responsibilities have recently changed. See The European Commission, 'Commission Regulation (EU) 2017/228 of 9 February 2017 amending Regulation (EC) N° 178/2002 of the European Parliament and of the Council as regards the names and the areas of competence of the scientific panels of the European Food Safety Authority', 2017.

- Panel on Animal Health and Welfare (AHAW);
- Panel on Food Additives and Nutrient Sources Added to Food (ANS)⁴⁹;
- Panel on Biological Hazards (BIOHAZ);
- Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF)⁵⁰;
- Panel on Contaminants in the Food Chain (CONTAM);
- Panel on Additives and Products or Substances used in Animal Feed (FEEDAP);
- Panel on Genetically Modified Organisms (GMO);
- Panel on Dietetic Products, Nutrition and Allergies (NDA);
- Panel on Plant Health (PLH);
- Panel on Plant Protection Products and their Residues (PPR).

The Panels are of comparable size, with 15 to 21 members, and EFSA launches calls for expressions of interest for Scientific Committee and Panels every three years.⁵¹ Over the period under review, the call was aligned for the Scientific Committee and eight of the ten Panels, and there was a separate call for the remaining two.⁵² The call for all ten Panels and the Scientific Committee were synchronised for the 2018 renewal (from July 2018 onwards).⁵³ The Decision of the Executive Director⁵⁴ concerning the selection of experts establishes the rules of the process. The selection process consists of clearly defined steps and is designed to ensure that experts are sufficiently qualified to meet EFSA's standards and do not have conflicts of interests. The steps for this process during the evaluation period were as follows:⁵⁵

1. **Screening applicants for eligibility** based on the criteria set in the vacancy note, carried out by EFSA's Human Capital function;
2. **Evaluation of eligible applications**⁵⁶ carried out per the selection criteria listed in the call by appointed EFSA's evaluators⁵⁷;
3. **External review of EFSA's evaluation**, in which external evaluators are provided with a representative sample of at least 10% of the eligible applicants;
4. **Shortlist of candidates** including all eligible candidates scoring above the threshold defined in the call for expressions of interest⁵⁸;
5. **Selection of candidates** proposed for appointment for the Scientific Committee and Panels from the shortlist (expertise mapping)⁵⁹;

⁴⁹ The ANS Panel will be re-established as the Panel on Food Additives and Flavourings (FAF) following the renewal of EFSA's Scientific Panels in 2018. The new Panel will take over responsibility for the evaluation of flavourings from the current CEF Panel and will hand over responsibility for evaluation of nutrient sources to the NDA Panel. See European Food Safety Authority – EFSA, 'Panel on Food Additives and Nutrient Sources Added to Food', <<https://www.efsa.europa.eu/en/panels/ans>> [accessed 30 May 2018].

⁵⁰ The workload of the CEF Panel is likely to increase in the coming years due to the need for evaluation of pending applications for inclusion in the Union list of food enzymes, in accordance with Regulation (EC) N° 1332/2008 of the European Parliament and of the Council. Therefore, the evaluation of flavourings currently undertaken by the CEF Panel will be assigned to the ANS Panel. The CEF Panel will be re-established as the Panel on Food Contact Materials, Enzymes and Processing Aids (CEP) following the renewal of EFSA's Scientific Panels in 2018. The new Panel will hand over responsibility for evaluation of flavourings to the new FAF Panel, which replaces the current ANS Panel. See European Food Safety Authority – EFSA, 'Panel on Food Contact Materials, Enzymes, Flavourings and Processing Aids' <<https://www.efsa.europa.eu/en/panels/cef>> [accessed 30 May 2018].

⁵¹ European Food Safety Authority, *Corporate Governance Audit on the Role of the Expert in the EFSA Scientific Decision-Making Processes* (Parma, Italy, 2016).

⁵² The Panels on Food Contact Materials, Enzymes, Flavourings and Processing Aids (CEF) and on Food Additives and Nutrient Sources Added to Food (ANS) were created in 2008, and their mandates were not aligned. See EFSA Legal and Regulatory Affairs Unit, *Note to the Attention of the Management Board - Renewal of ANS and CEF Panels* (Parma, Italy, 2016). In addition, the NDA Panel will take over responsibility for the evaluation of nutrient sources added to food from the current ANS Panel following the renewal of EFSA's Scientific Panels in 2018. See European Food Safety Authority – EFSA, 'Panel on Dietetic Products, Nutrition and Allergies' <<https://www.efsa.europa.eu/en/panels/nda>> [accessed 8 March 2018].

⁵³ Per a forthcoming legislative amendment. See EFSA Human Capital Unit, *Update on the Procedure for the Renewal of the ANS and CEF Scientific Panels* (Parma, Italy, 2016).

⁵⁴ EFSA Executive Director, *Decision of the Executive Director Concerning the Selection of Members of the Scientific Committee the Scientific Panels, and the Selection of External Experts to Assist EFSA with Its Scientific Work* (Parma, 2017) <https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf> [accessed 23 January 2018].

⁵⁵ There have been some changes to the order of certain aspects for the 2018 Panel renewal; but given this is not pertinent or strictly in the period under review, they are not detailed here.

⁵⁶ The specific eligibility requirements are discussed for every renewal and listed in the call. *Specific areas* under the remit of the Scientific Panel, so called "Panel related criteria" have included: experience in carrying out scientific risk assessment; experience in providing other scientific advice; proven scientific excellence; experience in peer reviewing scientific work and publications. The others were *general selection criteria*, so called "non-Panel related" criteria: ability to analyse complex information and dossiers; professional experience in a multidisciplinary environment; experience in project management related to scientific matters; and proven communication skills.

⁵⁷ Before the evaluation of the eligible applications starts, the evaluators agree on the interpretation of the selection criteria to achieve a consistent and objective approach for the scoring.

⁵⁸ As per Article 7 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work, EFSA shall share, on a confidential basis, the shortlist of candidates with the Advisory Forum for information.

⁵⁹ As per Article 8 of the Decision of the Executive Director concerning the selection of members of the Scientific Committee the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work, shortlisted candidates not being proposed for appointment as members of the Scientific Committee and/or Panels are placed on a reserve list.

6. **Screening of Annual Declaration of Interests (ADoI)** submitted by all shortlisted candidates in accordance with EFSA's Independence policy and rules;
7. **Proposal on candidates** to be appointed as members of the Scientific Committee and Panels sent to the Management Board by the Executive Director.

The **Scientific Committee** consists of the chairs of all ten Panels and six additional experts who do not belong to any Panel. The Scientific Committee oversees the work of the Panels. It also addresses scientific matters of a horizontal nature and supports the work of Panels on cross-cutting issues, providing coordination and maintaining consistency in the scientific opinions produced by the Panels.

The Scientific Committee and Panels establish Working Groups to support them in carrying out their mandates.⁶⁰ They are tasked with preparing a draft scientific opinion on the mandate, which they submit to the Scientific Panel(s) or Committee in charge of approval. Working Group members are selected based on their scientific expertise and experience in risk assessment.

2.3.2.5 Advisory Forum Working Group on Communications

The **Advisory Forum Working Group on Communications (AFCWG)** was set up in 2003 to facilitate cooperation in communications among Member States. It was intended as a mechanism for exchange of information and experiences between the national authorities and EFSA, enabling tailoring of risk communication messages to the specific needs of European Member States and regions.⁶¹ Over the period under review, the AFCWG provided an important mechanism to exchange information and experiences, and was active in implementing activities and publishing guidelines and best practices. EFSA closely collaborated with Member States through the AFCWG to promote coherence in the risk communication process and to ensure appropriate cooperation regarding public information campaigns. The AFCWG changed its governance model from an institutional working group to a scientific network in 2016, to focus on the science of communication.⁶² In 2017, it became the **Communications Expert Network (CEN)**.⁶³

2.3.2.6 Focal Points

Focal Points were introduced in 2007-2008. The Focal Point Network (FPN) consists of members of all 28 EU Member States, plus Iceland and Norway, as well as observers from Switzerland and EU (potential) candidate countries. They act as an interface between EFSA and national food safety authorities, research institutes and other national stakeholders. They aim to improve scientific cooperation and networking activities between and among Member States, and EFSA, by:

- assisting in the exchange of scientific information and experts;
- advice on cooperation activities and scientific experts⁶⁴;
- promoting training in risk assessment; and
- raising EFSA's scientific visibility and outreach in Member States.

They play an essential role in sharing information between Member States and EFSA, raising EFSA's scientific visibility, and outreach at national level. Focal Points also support their Advisory Forum members in the practical implementation of activities related to networking and scientific cooperation, including ensuring the exchange of scientific information between national authorities and EFSA; supporting competent organisations under Article 36; and supporting training activities on risk assessment.⁶⁵

⁶⁰ European Food Safety Authority, *Corporate Governance Audit on the Role of the Expert in the EFSA Scientific Decision-Making Processes* (Parma, Italy, 2016).

⁶¹ European Food Safety Authority, *Advisory Forum Working Group on Communications (AFCWG) Terms of Reference (ToR)* (Parma, Italy, 2013) <<http://www.efsa.europa.eu/sites/default/files/assets/afcwgtor.pdf>>.

⁶² European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

⁶³ EFSA Advisory Forum and Scientific Cooperation Unit, *Terms of Reference of the EFSA Communications Experts Network (CEN)* (Parma, Italy, 2016).

⁶⁴ See p.4, EFSA Advisory Forum and Scientific Cooperation Unit, *Focal Points – Guidelines for new Focal Points*, no date <<https://www.efsa.europa.eu/sites/default/files/about/focal-point-new-members-guidelines.pdf>> [accessed 25 June 2018].

⁶⁵ European Food Safety Authority, *Focal Point Activities 2012* (Parma, Italy, 2013); European Food Safety Authority, *Focal Point Activities 2013, EFSA Supporting Publication* (Parma, Italy, 2014); European Food Safety Authority, *Scientific Cooperation Annual Report 2015* (Parma, Italy, 2016)

2.3.2.7 Scientific networks

EFSA's **scientific networks** facilitate the development of a scientific cooperation framework between EFSA and Member States, through the coordination of activities, exchange of information, development and implementation of joint projects, and exchange of expertise and best practices in the areas within the Authority's mission.⁶⁶ As at May 2018, EFSA had 15 scientific networks.⁶⁷

2.3.3 EU and international cooperation

2.3.3.1 Cooperation with EU institutions and sister agencies

EFSA works closely with relevant **EU institutions and sister agencies**⁶⁸ active in the field of health and safety issues relating to humans, animals and the environment:

- European Commission, especially the Directorates-General for Health and Food Safety (DG SANTE), for Research and Innovation (DG RDT), and the Joint Research Centre (JRC);
- European Parliament, especially the Committee for Environment, Public Health and Food Safety (ENVI Committee);
- European Centre for Disease prevention and Control (ECDC);
- European Chemicals Agency (ECHA);
- European Environmental Agency (EEA);
- European Medicines Agency (EMA).

2.3.3.2 EU cooperation

More generally, as per Regulation (EC) N° 178/2002, cooperation within the EU is necessary:

- To gain the confidence of other actors within the food safety system;
- To operate effectively and minimise the potential for diverging scientific opinions;
- To enable Member States to become more closely involved in scientific procedures;
- To ensure coherence of the global communication process.⁶⁹

As such, it is within EFSA's mission to **cooperate closely with Member States and the Commission**, to promote the effective coherence between risk assessment, risk management and risk communication functions, and ensure the accomplishment of its mission.⁷⁰ In addition, to facilitate scientific cooperation within the EU, EFSA must promote networking of relevant organisations, as per **Article 36** of Regulation (EC) N° 178/2002, which provides the legal basis for the cooperation between EFSA and designated competent organisations in Member States. It also provides for the establishment of the Article 36 list, which is the keystone for networking and promoting scientific cooperation in the areas within EFSA's remit. Organisations on the Article 36 list can work together on EFSA's scientific projects and participate in grants or procurement activities.⁷¹

EFSA also has mechanisms in place to directly engage with national risk assessment agencies, namely the Advisory Forum, the Advisory Forum Communications Working Group (now the Communications Expert Network (CEN)), the Focal Point Network, and Scientific Networks. The Advisory Forum is at the heart of EFSA's collaborative approach to working with Member States as it allows EFSA and Member States to join forces in addressing European risk assessment and risk communication needs.⁷²

2.3.3.3 International cooperation

Cooperation also takes place at international level as "the Authority shall work in close cooperation with all organisations operating in the field of data collection, including those from

⁶⁶ European Food Safety Authority, *Scientific Cooperation Annual Report 2015* (Parma, Italy, 2016).

⁶⁷ European Food Safety Authority – EFSA, 'Working groups & Networks' <<https://www.efsa.europa.eu/en/science/wgs-and-networks>> [accessed 31 May 2018].

⁶⁸ As per EFSA: "EFSA has a long record of cooperating with EU **sister agencies** such as the European Centre for Disease Prevention and Control (ECDC), the European Medicines Agency (EMA), the European Environmental Agency (EEA) and the European Chemicals Agency (ECHA)." See European Food Safety Authority – EFSA, 'Inter-agency scientific cooperation: EFSA's contribution in 2015', 2016 <<https://www.efsa.europa.eu/en/press/news/160302>> [accessed 29 June 2018].

⁶⁹ Recitals (40), (44), (51), (53), Regulation (EC) N° 178/2002.

⁷⁰ Article 22(8 & 9), Regulation (EC) N° 178/2002.

⁷¹ European Food Safety Authority, *Scientific Cooperation Annual Report 2015* (Parma, Italy, 2016).

⁷² Ibid.

applicant countries, third countries or international bodies.”⁷³ In addition, “[t]he Authority should contribute through the provision of support on scientific matters, to the Community’s and Member States’ role in the development and establishment of international food safety standards and trade agreements.”⁷⁴ Cooperation and networking are hence also required for EFSA to complete its task “to promote and coordinate the development of uniform risk assessment methodologies in the fields falling within its mission”⁷⁵, including at international level.

2.3.3.4 Strategic frameworks for cooperation at international and EU level

EFSA’s strategic framework increasingly emphasised the Authority’s **international activities**. Building on the 2009 Strategic Approach⁷⁶, and guided by recommendations of the Management Board following the 2012 External Evaluation of EFSA and the Science Strategy 2012-2016, the Multi-annual programme on International Scientific Cooperation 2014-2016⁷⁷ tackled key challenges by setting three distinct objectives for international scientific cooperation (Table 2).

Table 2: Challenges and objectives of the Multi-annual programme on International Scientific Cooperation

Key challenges for international scientific cooperation	Objectives for international scientific cooperation 2014-2016
<ul style="list-style-type: none"> • Development and implementation of harmonised risk assessment methodologies • Development of internationally harmonised frameworks for collection and appraisal of scientific evidence • Coherence with EU and international partners in risk communication • Enhance the EU’s visibility globally • Boost EFSA’s recognition and reputation globally 	<ul style="list-style-type: none"> • Support the EU in its international commitments • Support the strategic objectives of EFSA’s Science Strategy 2012-2016 • Promote coherence in risk communication and build awareness of EFSA’s activities at international level

The Scientific Cooperation Roadmap 2014-2016⁷⁸ places emphasis on building the EU’s risk assessment community, and on optimising the use of its resources, while strengthening the coherence of the EU’s international voice on these issues, by:

1. Promoting scientific cooperation initiatives aimed at using Member States’ scientific capabilities in the most efficient manner;
2. Building on Member States’ scientific expertise and ensuring that the scientific work carried out at national level is not duplicated at EU level;
3. Elaborating actions to stimulate Member States’ contribution to the consolidation of the EU’s risk assessment community.

Through scientific cooperation, EFSA also plays a role in supporting the EU’s international commitments. These are identified in several strategic documents, from EFSA’s Multi-Annual Programme on International Scientific Cooperation 2014-2016 to its International Scientific Cooperation Work Plan 2017-2020.⁷⁹ The latter sets out five objectives for EFSA’s international cooperation activities:

1. provide scientific and technical support to the European Commission to meet its international commitments and to promote a coherent European voice;
2. widen EFSA’s evidence base and optimise access to data;
3. increase international scientific assessment capacity and knowledge community;

⁷³ Article 33(2), Regulation (EC) N° 178/2002.

⁷⁴ Recital (39), Regulation (EC) N° 178/2002.

⁷⁵ Article 23(b), Regulation (EC) N° 178/2002.

⁷⁶ European Food Safety Authority, *International Activities – a Strategic Approach* (Rome, Italy, 2009).

⁷⁷ EFSA Advisory Forum and Scientific Cooperation Unit, *Multi-Annual Programme on International Scientific Cooperation 2014-2016* (Parma, Italy, 2014).

⁷⁸ European Food Safety Authority, *Scientific Cooperation Roadmap 2014-2016* (Parma, Italy, 2014).

⁷⁹ European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017); EFSA Advisory Forum and Scientific Cooperation Unit, *International Scientific Cooperation Work Plan 2017-2020 (Draft)*, 2017; European Food Safety Authority, *Management Plan of the European Food Safety Authority for 2013* (Parma, Italy, 2012); European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015); EFSA Advisory Forum and Scientific Cooperation Unit, *Multi-Annual Programme on International Scientific Cooperation 2014-2016* (Parma, Italy, 2014).

4. contribute to international efforts aimed at development, validation, implementation and harmonisation of methodologies, tools and approaches in risk assessment and risk communication; and
5. increase EFSA's visibility and reputation as a competent and innovative regulatory risk assessment agency operating at international level.

2.3.4 EFSA's scientific system

EFSA's scientific system predominantly relies on the Scientific Committee and Panels, and on EFSA's staff.⁸⁰ EFSA issues scientific opinions⁸¹ and provides scientific and technical assistance⁸² resulting from their work. The scientific system is divided between different procedures depending on the area or type of risk assessment.

2.3.4.1 Panel system addressing general scientific questions

Under the Panel system for addressing general scientific questions, EFSA receives a request for scientific advice, from the European Commission, European Parliament, Member State or EFSA's own initiative, outlining the issue, the Terms of Reference, and the timeframe to answer the question. If EFSA accepts the request, it becomes a mandate, and the mandate is assigned to a Working Group that carries out the risk assessment. This group drafts an opinion that is submitted to the relevant Scientific Panel for review. The output⁸³ is adopted by majority of the Panel members (minority opinions can be expressed). EFSA then sends the opinion to the original requester and publishes it in the EFSA Journal and on its website.

2.3.4.2 Panel system addressing authorisation dossiers

The Panel system for addressing authorisation dossiers covers the process for assessing applications for market authorisation of regulated products. Regulated products require scientific risk assessment by EFSA before they can be permitted by the risk managers for use on the EU market. They include substances used in feed and food, food contact materials and pesticides, GMOs, food processes and processing aids. The scientific substantiation of nutrition and health claims is also assessed by EFSA prior to their authorisation. EFSA provides independent scientific advice and a solid scientific foundation to underpin the market authorisation decisions taken by EU Member States and the European Commission. Under EU law, organisations or companies set to profit from regulated substances or products must provide the evidence to prove that these substances are safe or, in the case of health claims, that these are backed by sound science.

Applicants send a technical dossier to the European Commission/National Competent Authority (NCA), who forward the technical dossier and a mandate to EFSA. An application dossier is provided by the applicant, EFSA's staff validate the completeness of the application and may request missing information before validating the request. Relevant Community legislation makes provision for EFSA to be automatically in charge or whether to validate the application.⁸⁴ Additional data may be requested also during the risk assessment phase, in which case the clock may be stopped on the regulatory timetable until the necessary information is supplied. The relevant Scientific Panel carries out the risk assessment (this takes between three and nine months). Based on the outcome of this assessment, EFSA adopts a scientific opinion and publishes it. It is then up to the Commission/NCA to decide whether it will grant the authorisation of the substance, product, claim, process or organism for their placing or use on the EU market.

⁸⁰ In specific cases, EFSA's work is also supported by competent organisations designated by Member States in accordance with Article 36 of Regulation (EC) N° 178/2002 and Article 1 of Regulation (EC) N° 2230/2004. See EFSA's Management Board, 'List of competent organisations designated by the Member States which may assist EFSA with its mission', 2018 <<https://www.efsa.europa.eu/sites/default/files/assets/art36listg.pdf>> [accessed 4 May 2018].

⁸¹ Article 29, Regulation (EC) N° 178/2002.

⁸² Work that does not require evaluation by the Scientific Committee or Panels – Article 31, Regulation (EC) N° 178/2002.

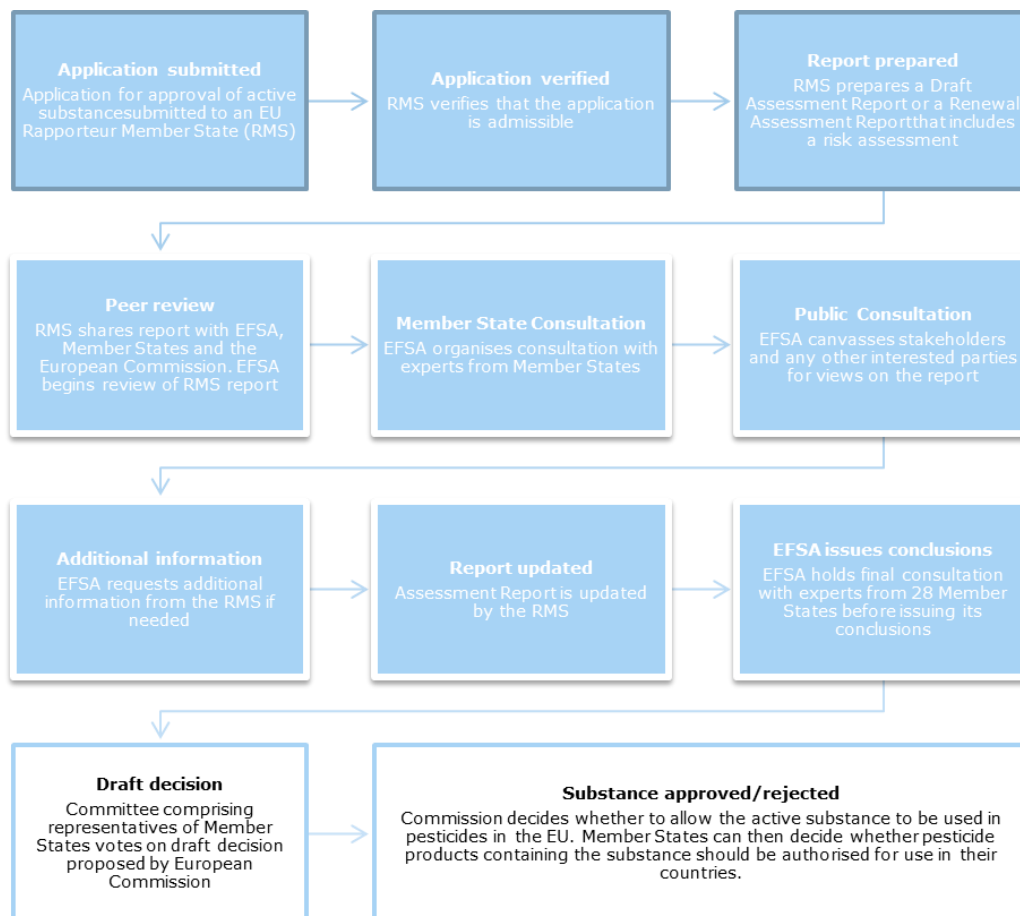
⁸³ It can be a scientific opinion, a statement, or a guidance document.

⁸⁴ In the case of Food Contact Materials for example, the application procedure is described in Regulation (EC) N° 1935/2004, and EFSA can validate the application, and start the risk assessment, or declare it to be not valid and send it back to the Member State. See European Food Safety Authority, 'Applications helpdesk – Food contact materials application procedure', <<https://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflowcm.pdf>> [accessed 4 May 2018]. In the case of Food additives, flavourings, food enzymes for example, the application procedure is described in Regulation (EC) N° 1331/2008, and EFSA can indicate the application to be suitable, in which case the Commission must validate it, or not suitable and send it back to the Commission. See European Food Safety Authority, 'Applications helpdesk – Food additives, flavourings, food enzymes application procedure' <<https://www.efsa.europa.eu/sites/default/files/applications/apdeskapplworkflowfoodadd.pdf>> [accessed 4 May 2018].

2.3.4.3 Peer review system on pesticides dossiers

In the case of pesticides dossiers, EFSA peer reviews Draft or Renewal Assessment Reports produced by a Rapporteur Member State (RMS). Key steps of the peer-review system on pesticides dossiers are presented below.

Figure 1: Key steps in the assessment process of a pesticide's active substance



Source: European Food Safety Authority (2016), Who assesses pesticides in the EU?

The role of the PPR Panel is to support the peer-review system through the development and update of risk assessment approaches, methodologies, guidance documents and models ensuring a constant alignment of the EFSA conclusions to the current state of scientific and technical knowledge. In addition, the PPR Panel may provide support to the evaluation of the properties and risks of specific active substances (Annex to Call for Expressions of Interest for Membership of the Scientific Panels and the Scientific Committee of EFSA 2017).⁸⁵

2.3.4.4 Technical advice provided by EFSA's scientific staff

Article 31 of Regulation (EC) N° 178/2002 details that the Authority may be requested by the Commission to provide scientific or technical assistance in any field within its mission.⁸⁶ The tasks of providing scientific and technical assistance consist of scientific or technical work involving the application of well-established scientific or technical principles, which does not require scientific evaluation by the Scientific Committee or a Scientific Panel. Such tasks may include in particular assistance to the Commission for the establishment or evaluation of technical criteria and in the development of technical guidelines. EFSA's scientific staff (or external experts) carry out this work, with the following outputs:⁸⁷

⁸⁵ European Food Safety Authority, Annex I EFSA's Scientific Panels and Scientific Committee, 2017 <<https://www.efsa.europa.eu/sites/default/files/documents/calls/ANNEX1CallExperts2017.pdf>> [accessed 25 June 2018].

⁸⁶ Article 31(1), Regulation (EC) N° 178/2002.

⁸⁷ European Food Safety Authority – EFSA, 'Definitions of EFSA Scientific Outputs and Supporting Publications' <<https://www.efsa.europa.eu/en/efsajournal/scdocdefinitions>> [accessed 4 May 2018].

- A **Statement of EFSA** is a document addressing an issue of concern and prepared as advice or factual statement for consideration by the European Commission, European Parliament, Council of the EU, Member States or stakeholders. A Statement of EFSA is prepared normally within a relatively short timeframe. EFSA may consult the Scientific Committee, a Panel, or an EFSA network during the process.
- A **Scientific Report** of EFSA describes original research results that pertain for example to a literature review, statistical data analysis, the compilation of scientific evidence – compilation/collation/assessment of survey or monitoring results, specifications for the design thereof – or a data collection report. In some cases, Scientific Reports of EFSA may be endorsed by the Scientific Committee or the respective Panel.
- **Technical Reports** are prepared by EFSA's scientific staff, and/or by an EFSA working group, and approved by the Executive Director. A Technical Report describes the nature, state of the art, progress, or results of a technical process.

2.3.5 EFSA's customers and framework for stakeholder engagement

Regulation (EC) N° 178/2002 defines **three main customers** of the scientific opinions produced by the Authority. These are the European Commission, the European Parliament, and Member States. Even though all three external entities are entitled to request opinions, EFSA's workload has mostly been generated by the Commission.⁸⁸

Stakeholders are defined as organisations with an interest in EFSA's work, or in the wider food sector. Based on this definition, EFSA divides its stakeholders into seven groups:

- Consumer organisations, defending and promoting consumers' interests;
- NGOs and advocacy groups (independent of industry, commerce and business) promoting environmental protection or consumers' health, or the place of science in policy-making and transparency in public administration;
- Business and food industry representing the interests of companies in any sector relevant to EFSA's work;
- Distributors and HORECA (Hotel, Restaurants and Caterers) representing the interests of stakeholders involved in preparing, distributing and serving food;
- Practitioners' associations, representing professionals (medical doctors, dieticians, nurses, pharmacists and veterinarians) in fields relevant to EFSA's remit;
- Academia representing scientific and technological communities;
- Farmers and primary producers representing the beginning of the food chain.⁸⁹

Over the period under review, EFSA mainly engaged with these groups through the **Stakeholder Consultative Platform (SCP)**. The SCP was made up of organisations representing consumers or involved in public health, plant health, animal health and welfare and environmental protection; farmers and primary processors; food industry; trade and catering. Its meetings were open to the public in accordance with the ToR.⁹⁰ The SCP met three times a year in plenary meetings and provided a forum for dialogue, exchange of views and information. In early 2016, following a review of the system, informed by a "target audience research", as well as different discussions on the matter, EFSA adopted a Stakeholder Engagement Approach and introduced the Stakeholder Bureau and Stakeholder Forum as permanent platforms.

- The **Stakeholder Bureau** is made of one representative from each of the seven stakeholder categories. The Bureau meets at least once a year and is chaired by EFSA's Executive Director. It advises EFSA on stakeholder engagement and provides input with regards to civil society's concerns on health, environment, food production and other issues in the Authority's remit. It also helps shape the agenda of the annual Stakeholder Forum.

⁸⁸ 2011-2016: 11,611 questions from the Commission, 1,858 from EFSA, 586 from Member States, 313 from Chair of Panel, 0 from the Parliament. Search conducted on EFSA's register of questions: European Food Safety Authority - EFSA, 'Register of Questions', 2018.

⁸⁹ European Food Safety Authority - EFSA, 'Stakeholder Engagement' <<https://www.efsa.europa.eu/en/partnersnetworks/stakeholder>> [accessed 27 March 2018].

⁹⁰ European Food Safety Authority - EFSA, '29th meeting of the EFSA Stakeholder Consultative Platform', <<https://www.efsa.europa.eu/en/events/event/151124>> [accessed 31 May 2018].

- The themes and topics of each annual **Stakeholder Forum** are determined by demands from registered stakeholders and by the priority areas identified in EFSA Strategy 2020. The Forum produces recommendations regarding strategic planning and activity implementation, the development of horizontal policies and processes, and the review of how the various engagement platforms function.

In addition, EFSA engages with stakeholders through targeted platforms, from Information Sessions to Mandate Working and Discussion Groups, through Scientific Colloquia, Roundtables, and Communicators Labs.⁹¹

2.3.6 Measuring performance

To measure its performance over time, EFSA uses Key Performance Indicators (KPIs).⁹² They are presented in EFSA's Annual Reports, supporting a broader discussion around EFSA's performance. In 2013, EFSA reviewed its KPIs to align them more closely with its strategic objectives and provide a multiannual assessment.⁹³ In 2016, the Authority adopted the EFSA Strategy 2020 and developed a performance framework including a new set of KPIs to monitor progress and performance at input, output, outcome and impact levels.⁹⁴

Over the period under review, EFSA categorised its work across several types of activities, and associated KPIs. The three first activities correspond to what EFSA named its "scientific activities".

- **Activity 1: Provision of Scientific Advice and Risk Assessment approaches**⁹⁵

This includes the provision of scientific advice and risk assessment approaches to risk managers in the areas of food and feed safety, animal health and welfare, and plant health. EFSA's work under this activity serves as the basis for risk managers to take measures in consumers' interest.

- **Activity 2: Evaluation of Regulated Products**

Regulated products include substances used in food and feed, food contact materials and pesticides, genetically modified organisms, food-related processes and processing aids, which EFSA evaluates before they can be authorised on the European market. EFSA's evaluation of regulated products refers to this scientific safety assessment.

- **Activity 3: Data Collection, Scientific Cooperation and Networking**

EFSA relies on data collection, scientific cooperation and networking to complete its risk assessment mission, based on sound independent science.

- **Activity 4: Communication and dialogue**

As part of its risk communication mandate, EFSA must provide appropriate, consistent, accurate, and timely communications on food safety issues to all interested parties. The Authority must also discuss potential divergences of opinions with interested parties.

- **Activities 5, 6 and 7: Governance, Support and Coordination**

Governance, Support and Coordination are covered by separate Activities 5, 6 and 7 since 2014. Before that, there was only one activity called Governance and Support.

2.4 EFSA's Intervention Logic

EFSA is a complex organisation. Figure 2 below presents an intervention logic depicting EFSA's role, from the input level, through to activities, outputs, and results, and indicates how they contribute to the food system's outcomes and impacts. It is based on a synthesis of information gathered by the evaluation team. The intervention logic demonstrates the duality of EFSA's mandate, as both risk assessor and communicator, and how it supports risk managers.

⁹¹ European Food Safety Authority, *EFSA Stakeholder Engagement Approach* (Parma, Italy, 2016) <[https://www.efsa.europa.eu/sites/default/files/EFSA Stakeholder engagement approach_FINAL.pdf](https://www.efsa.europa.eu/sites/default/files/EFSA%20Stakeholder%20engagement%20approach_FINAL.pdf)> [accessed 31 May 2018].

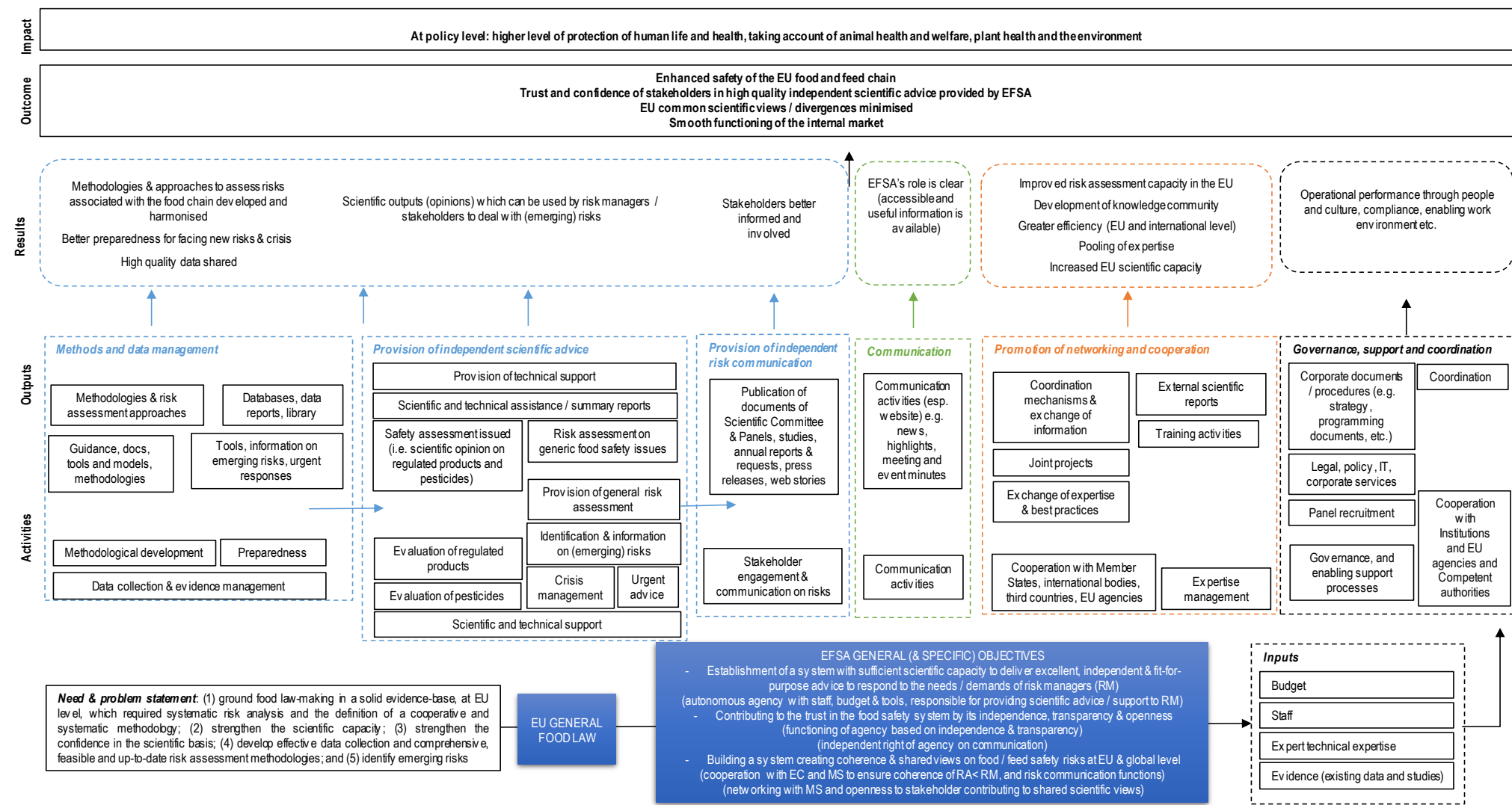
⁹² European Food Safety Authority, *EFSA Performance Indicators*, 2004.

⁹³ European Food Safety Authority, *Programming Document of the European Food Safety Authority 2014-2016 Incorporating Annual Management Plan 2014 and Multiannual Plan 2014-2016* (Parma, Italy, 2013).

⁹⁴ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017); *Programming document 2016-2019* (Parma, Italy, 2014).

⁹⁵ The name of Activity 1 was "Provision of Scientific Opinions and Advice and Risk Assessment approaches" until 2014.

Figure 2: Intervention Logic



Source: Developed by evaluation team

3. EVALUATION QUESTIONS

Below is the full list of evaluation questions required by the ToR⁹⁶, linked to the relevant section in the report where responses can be found. In some places the order of the questions has been changed to maintain a narrative in the report. To avoid duplication and improve flow, certain elements have been consolidated. Where relevant a brief explanation of any changes made in *italics* after a question has been provided.

Table 3: Evaluation questions by criterion

Relevance
<ul style="list-style-type: none"> How well do the original EFSA objectives of Reg. 178/2002 correspond to the current needs of and future challenges facing different target groups in the EU? [EQ 1], section 5.1.1 To what extent are EFSA's organisational structure and working practices/processes fit for purpose: to meet current needs and to adapt to future challenges? [EQ 2], section 5.1.2
Effectiveness
<ul style="list-style-type: none"> To what extent has EFSA contributed to creating and maintaining a sustainable scientific system, able to respond to needs from risk managers and to address emerging risks by delivery of state-of-the-art and fit-for-purpose scientific advice? [EQ 3a] section 5.2.1.2 <i>Note that the ToR included a reference to "unbiased" here but the issue of EFSA's independence is covered under 3b., section 5.2.3</i> To what extent are the current practices for collecting scientific data and evidence adequate for EFSA's risk assessment? [EQ 9], section 5.2.1.2 To what extent has EFSA contributed to an improved harmonisation of methodologies and coherence of approaches on food safety at EU and global levels through its networking and cooperation with EU and global risk assessment authorities? [EQ 3c], section 5.2.2 To what extent has EFSA contributed to creating a European food safety system that enhances citizens' trust, through its independence and transparency? [EQ 3b], section 5.2.3 <i>Note that the ToR included a reference to "scientific excellence" here but the issue of EFSA's state-of-the-art science is covered under 3a., section 5.2.1.1</i> To what extent is the Authority's governance model appropriate for ensuring the Authority's mission statement? [EQ 5], section 5.2.4 Are the internal mechanisms for programming, monitoring, reporting and evaluating EFSA adequate for ensuring accountability and appropriate assessment of the overall performance of the Authority? [EQ 6], section 5.2.5
Efficiency
<ul style="list-style-type: none"> Are resources used for EFSA proportionate to the results achieved? If not, why not? [EQ 10 and 11], section 5.3.1.1 To what extent is EFSA's scientific production system cost-effective? [EQ 18], section 5.3.1.2 Do established procedures minimise the administrative burden of the Authority and its stakeholders? [EQ 7], section 5.3.2.1 Does EFSA undertake prioritisation of certain topics or tasks and, if so, has this been appropriate? [EQ 8], section 5.3.2.2
Coherence
<ul style="list-style-type: none"> To what extent does EFSA's work contribute to the EU's political priorities? To what extent does EFSA's work contribute to the promotion of the EU food and feed safety regulatory standards on a global level? [EQ 12], section 5.4.1 To what extent is EFSA's work coherent with EU commitments at international level (e.g. CODEX, OIE, and IPPC)? Which aspects are not coherent, if any, and why? [EQ 14], section 5.4.2 To what extent is the involvement of Member State risk assessment organisations in the provision of EFSA's scientific advice adequate for ensuring Member States' ownership of a harmonised European assessment outcome and to which extent has the involvement been complementary to other public actors' activities? Which factors weighed on this adequacy and complementarity? [EQ 13], section 5.4.3 To which extent is there overlap/complementarity/coherence with the work of other EU Agencies, notably EMA, ECHA, ECDC? [EQ 15], section 5.4.4
EU added value
<ul style="list-style-type: none"> What is the additional value resulting from EFSA's existence, compared to what could be achieved by Member States at national level? [EQ 16], section 5.4 To what extent is EFSA recognised as a leading regulatory scientific authority at national, European and global level? Which factors have the most important influence on the scientific recognition and the reputation of EFSA? [EQ 17] <i>This question is covered as part of the previous question.</i>

⁹⁶ Note that EQ18 on the cost-effectiveness of EFSA was added and replaced one question (what would be the likely consequences at the EU level of stopping EFSA) which was subsumed in EQ16 (on EU added value).

- To what extent is there evidence that ceasing funding to EFSA would have (negative/positive) consequences for the provision of independent scientific advice on the food chain at EU level? *Note: This was formally EQ18 in the ToR but concerned EU Added value so has been into EQ16, section 5.4*

Conclusions

- What factors influenced what was achieved or not achieved? The assessment should include, among other aspects, observed unintended effects, an analysis of the strengths and weaknesses of EFSA and the tools for pooling expertise, in particular the collaboration arrangements between EFSA and external expertise (national experts, national scientific bodies including Article 36 organisations). [EQ 4], chapter 6

The table below provides an overview of where given topics are addressed in the report.

Table 4: Matrix of topics covered and location in report

Topics	Location in report				
	Relevance	Effectiveness	Efficiency	Coherence	EU added value
EFSA's organisational working practices	5.1.2				
EFSA's governance structure		5.2.4			
EFSA's scientific work: scientific advice		5.2.1.1			
EFSA's scientific work: data collection		5.2.1.2			
Independence, Transparency and Communication		5.2.3			
Cost effectiveness and operational efficiency			5.3		
EFSA's cooperation and reputation at EU and global levels			5.2.2	5.3	5.4

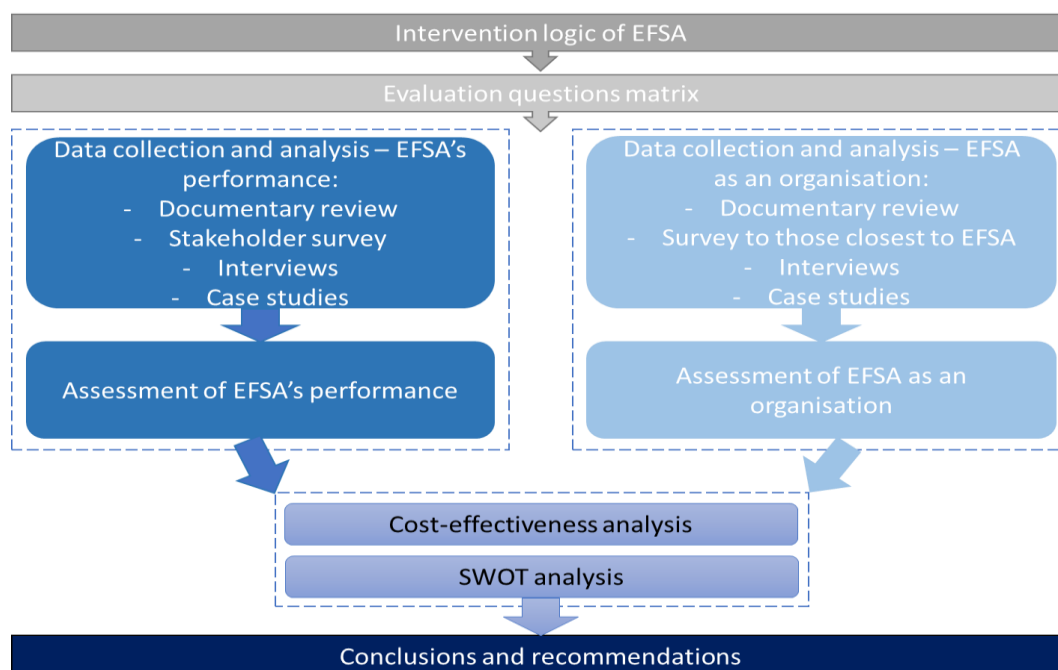
4. METHODOLOGY

This chapter provides an overview of the methodology employed for this evaluation, detailing the data collection activities and analytical tasks that have been undertaken. It also includes an analysis of strengths, weaknesses and limitations or possible bias related to these methods and activities, as well as ways in which such challenges were mitigated.

4.1 Evaluation Approach

A theory-based approach was taken to the evaluation, underpinned by a robust intervention logic and a defined set of evaluation questions covering the five mandatory evaluation criteria. The Evaluation Questions Matrix (EQM, Appendix 1) framed and guided the approach to the evaluation.

Figure 3: Approach to the evaluation of EFSA



4.2 Methods and process

4.2.1 Inception Phase

The inception phase consisted of familiarisation interviews and discussions with EFSA staff to develop a better understanding of the workings of EFSA, the changes the organisation had undergone since the previous evaluation, and expectations in relation to the evaluation. Preliminary desk research was undertaken to take stock of the documentary sources to be reviewed during the data collection phase.

4.2.2 Data collection phase and data analysis phase

The data collection methods employed are explained in turn below:

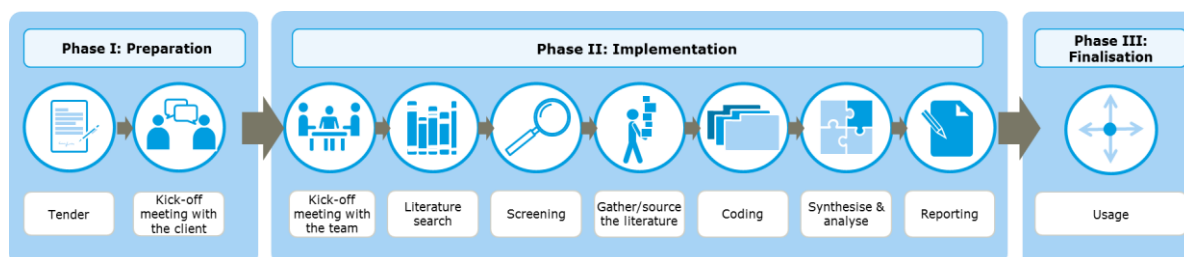
4.2.2.1 Documentary review

The documentary review was based on two elements: 1) a review of the internal documentation provided by EFSA and 2) the search for relevant and useful external documents to complement (and validate) findings from other data sources.

A full list of sources consulted is presented in Appendix 2, covering relevant EU legislation, EU strategies and policy documents, reports and data provided by EFSA, previous evaluations conducted for the Authority and external papers and reports related to EFSA’s work, including EFSA’s Management Self-Evaluation (which is provided in Appendix 6). **In total more than 270**

documents were reviewed in detail to inform the evaluation. The approach taken during the documentary review is summarised in Figure 4 below.

Figure 4: Process for the review of documentary sources



All relevant documentation identified by EFSA and the evaluation team during the inception phase, as well as any additional data or documentation provided by EFSA or identified by the evaluation team during the data collection phase was reviewed in detail and coded against relevant indicators (as per the EQM), using dedicated coding software (Atlas.ti). A qualitative review of the coded material was then carried out, producing summary reports for each indicator, which were used as the basis to answer the evaluation questions. Separately, an analysis of EFSA's performance against its KPIs was undertaken based on Annual Activity Reports. The KPIs are referenced throughout the report where relevant to the evaluation questions.

Given the importance accorded to external documentation by EFSA, the evaluation team worked with external experts (Ron Dwinger and Jeanne-Marie Membré) to identify relevant and useful documents for those indicators where external evidence was deemed necessary or relevant to ensure the robustness of findings. This included a search on Web of Science, EFSA's website, and other websites of relevance to the evaluation question being assessed (e.g. websites of Member States' national food safety agencies, other EU agencies and international organisations for questions regarding coherence). Extensive Google searches containing keywords relevant to specific evaluation questions were also undertaken. Experts were given three days each to provide relevant reference material for the relevant indicators to the extent possible (i.e. where evidence was readily available and accessible). This was in addition to documentary searches undertaken by the core evaluation team.

All sources used are referred to in the 'coverage of the question' section under each evaluation question and referenced throughout the report in footnotes.

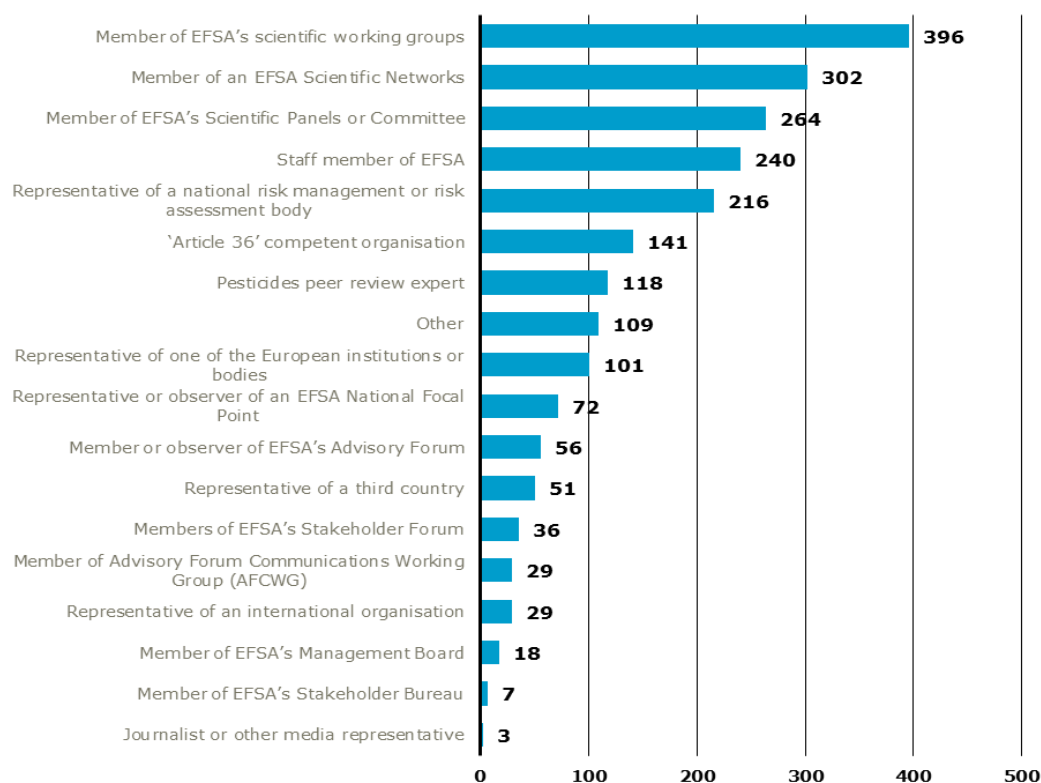
4.2.2.2 Stakeholder survey

An online survey of EFSA's stakeholders was launched on 29th September 2017, and closed on 27th October 2017, with the purpose of gathering views on EFSA's performance from a wide range of stakeholders and partners engaged in or with an interest in EFSA's work. It covered questions relating to the effectiveness, relevance, coherence and EU added value, governance structure, organisational set-up and working practices of the Authority. In total, the survey was distributed to 5,351 people⁹⁷. Of these, a total of 1,191 people (22%) completed the survey, and another 422 people (8%) partially completed it⁹⁸. This means that the survey reached an **overall response rate of 30%**. The number of responses by type of respondent is presented in the figure below. The full survey questionnaire is included in Appendix 3.

⁹⁷ This number excludes bounced emails. Hence, distributed to in this sense refers to the amount of people who received the invitation to participate in the survey.

⁹⁸ Partial completion indicates respondents who exited the survey before responding to all the questions relevant to them.

Figure 5: Response frequency by stakeholder group (n=2,188)



Note: Respondents were given the option to select multiple stakeholder categories, therefore the sum of responses to this background question (n= 2,188) is higher than the total number of unique respondents to the survey (n= 1,613). The 109 respondents that indicated "other" in response to this question comprised a mix of researchers, academics and individuals from the private sector.

The margin of error at a 95% confidence level for the entire sample was +/-3%. This is a low margin of error, an indication of accurate results⁹⁹. The overall sample response can therefore be considered as an accurate reflection of the overall opinion across EFSA's stakeholders.

The margins of error for sub-groups within the overall sample are lower, and in half of the cases incalculable due to an unknown population size. As can be seen

⁹⁹ See p.165, Rea, L. M., and Parker, R. A., *Designing and Conducting Survey Research: A Comprehensive Guide Fourth Edition*, 2014.

Table 5, the margin of error¹⁰⁰ per stakeholder group varied from 0% (members of EFSA's Stakeholder Bureau), and to 57% (media representatives). This variation is due to the number of respondents per stakeholder type, as well as whether the population was known or unknown for the stakeholder groups. With a median margin of error of 7.6% across the stakeholder groups, at least half of all stakeholder groups had an acceptable margin of error¹⁰¹. Where reference is made in the evaluation findings to responses from sub-groups, the limitations set out above are noted.

¹⁰⁰ For stakeholder groups whose population size was unknown, the margin of error was calculated assuming an infinite population size. For stakeholder groups with a known population size, the calculation of the margin of error was adjusted by the Finite Population Correction Factor.

¹⁰¹ See p.186, Rea, L. M., and Parker, R. A., *Designing and Conducting Survey Research: A Comprehensive Guide Fourth Edition*, 2014.

Table 5: Margin of Error across EFSA stakeholder groups (n=2,832)

Type of respondent	Population details	Population	Frequency	Margin of Error (+/-)
Staff member of EFSA	Known	492	240	5%
Member of EFSA's Management Board	Known	28	18	14%
Member or observer of EFSA's Advisory Forum	Known	79	56	7%
Member of Advisory Forum Communications Working Group (AFCWG)	Known	94	28	16%
Representative or observer of an EFSA National Focal Point	Known	69	67	2%
Member of EFSA's Scientific Panels or Committee	Combined ¹⁰²	1754	644	3%
Pesticides peer review expert	Known	405	114	8%
Member of EFSA's scientific working groups	Combined	1754	644	3%
Member of an EFSA Scientific Networks	Known	722	297	4%
Member of EFSA's Stakeholder Bureau	Known	7	7	0%
Members of EFSA's Stakeholder Forum	Known	95	36	13%
'Article 36' competent organisation (competent organisations designated by the Member States which may assist EFSA with its mission)	Known	813	141	8%
Representative of a national risk management or risk assessment body of an EU Member State, an EEA country or an accession or candidate country	Unknown	-	211	7%
Representative of a third country	Unknown	-	51	14%
Representative of one of the European institutions or bodies	Known	405	94	9%
Representative of an international organisation	Unknown	-	27	19%
Journalist or other media representative	Unknown	-	3	57%
Other	Unknown	-	154	8%

4.2.2.3 In-depth stakeholder interviews

A total of 82 in-depth interviews were conducted with diverse types of stakeholders, as summarised in the table below. The purpose of the interviews was to gather views on the performance of the Authority within the areas of expertise of the targeted respondents, while ensuring coverage of the full spectrum of stakeholders. The interview guide used for these interviews is included in Appendix 4.

¹⁰² The margin of error for Members of EFSA's Scientific Panels or Committee and Members of EFSA's scientific working groups was calculated for the sum of the two sample sizes, as only the sum of their populations was known.

Table 6: Interviews conducted per stakeholder group

Stakeholder group	Number of interviews conducted
EFSA Staff	14
Management Board	5
DG SANTE	8
DG TRADE	1
European Parliament	0 ¹⁰³
Stakeholder Bureau	6
Communications network expert	2
Advisory Forum	4
Focal Points	4
Scientific Committee	2
Scientific Panels	8
EU agencies (JRC, ECHA, ECDC, EEA)	4
International Organisations (WHO, OIE, FAO, JECFA/JMPR)	4
Third Countries (Health Canada, FSANZ, CFSA, FSCJ)	4
Article 36 Organisations	3
Stakeholder Forum	12
Media	1 ¹⁰⁴
Total	82

In reporting on interview findings, a differentiation is sometimes made between *internal and external stakeholders* whereby internal stakeholders are EFSA management and staff, and external stakeholders are other stakeholders that are involved in EFSA's work or have dealings with it.

4.2.2.4 Case study research

Five in-depth case studies were undertaken with the aim of delving deeper into matters of particular relevance to EFSA, in order to provide useful insights in the main areas of work. The case studies drew on findings from the documentary review, stakeholder interviews and online survey to compile findings on thematic areas of interest. The thematic areas of focus for the case studies were agreed with EFSA as follows:

1. Scientific work: The sustainability of the mechanism for engaging experts in EFSA's scientific work
2. EU-level cooperation & networking: Appropriate systems for scientific cooperation with Member State authorities
3. Cooperation & networking at international level: Framework to secure EFSA's role in promoting standards in the international community
4. Communication (of risks): Open EFSA (and EFSA's engagement with stakeholders)
5. Internal working practices: EFSA's internal practices/processes underpinning the different scientific production systems

Relevant findings from the case studies have been integrated in the answers to the evaluation questions in this report.

4.2.3 Synthesis and quality control phase

The synthesis and quality control stage focussed on the preparation of a SWOT analysis, cost-effectiveness analysis and the triangulation of evidence to inform conclusions and recommendations. Triangulation was undertaken to counteract various possible threats to the

¹⁰³ Despite numerous follow-ups through email and phone, the evaluation team did not manage to get in touch with the interviewee from the European Parliament. EFSA agreed on 22 November 2017 to help us get in touch with her.

¹⁰⁴ Next to foreseen interviewees for La Repubblica and Politico, the evaluation team emailed potential interviewees at the Guardian and Reuters, but never received a reply.

validity of the analysis and to produce a richer and more informed analysis. Three types of triangulation were applied:

- **Data triangulation** – when several types of data are used as information;
- **Source triangulation** – when the views of distinct types of stakeholder groups are compared;
- **Method triangulation** – when several types of quantitative (i.e. the survey in part) and qualitative (i.e. the in-depth interviews) methods are used to collect data.

In using data, source and method triangulation, the principle is that a **hypothesis can only be confirmed if statements collected from at least three sources from at least two types of collection sources/methods support it**. Where possible, three data collection methods were used (i.e. documentary review, in-depth interviews and survey) for each evaluation question, as set out in the evaluation question matrix. Where this was not possible, conclusions were based on at least two of the three data collection methods, of which maximum one includes stakeholder opinions. Preceding the answers to each evaluation question presented in chapter 5, the evidence on which a response is based is presented, and, where necessary, caveats as to the robustness or extent of data available to inform the evaluation are noted.

4.3 Limitations and Mitigation Strategies

4.3.1 Documentary review

Challenges in relation to the documentary review were the lack of/inability to identify readily available and accessible documentary evidence¹⁰⁵ from external sources, which led in some cases to a reliance on EFSA documentation. In some cases, further data was not readily available, which is a finding in itself (e.g. no external literature on EFSA's budget, no commentary on procedures in place to confirm the relevance of original needs, no academic literature on additional measures EFSA could take to build stakeholders' trust was available). Where relevant, additional documentary review was carried out to fill any gaps emerging through the process of triangulation. Where no additional information could be identified by the evaluation team nor by EFSA, a caveat in the findings chapter is included to make clear the evidence base and limitations.

Another challenge related to the nature and availability of the (KPI) data measured and provided by EFSA for the period under review, which in many cases was not appropriate for making meaningful comparisons over time or across systems. Most notably, a meaningful assessment of EFSA's cost-effectiveness could not be carried out due to the complex and unpredictable nature of EFSA's work, combined with a lack of outcome-level data (see section 5.3.1 and Appendix 5). Comparisons were made whenever possible, though in many cases consistent time series analysis has not been possible due to inconsistencies in the measurement of KPIs or reporting on KPIs during the period under review. Relevant sections in the report detail these shortcomings (see chapter 5). Moreover, EFSA's KPI data for the period under review was primarily output-based, meaning that data was not collected against outcome or result-level KPIs. EFSA sought to rectify this by introducing more outcome and result level KPIs from 2017, but these fall outside the direct scope of this study. For the purpose of this evaluation, where possible, output-focussed KPI data has been complemented by survey and interview results to provide insights into EFSA's achievements.

In instances where the indicators used to answer evaluation questions did not go as far back as 2011 (the baseline for this evaluation), the evaluation considers their evolution over the period for which they are available, considering the scope of the evaluation.

¹⁰⁵ Readily available and accessible documentary evidence is defined as evidence that the evaluation team and its external experts were able to gather through a variety of fee-free means including Web of Science, EFSA's website, google searches for key words, and other websites of relevance to the evaluation question being assessed (e.g. websites of Member States' national food safety agencies, other EU agencies and international organisations for questions regarding coherence).

4.3.2 Stakeholder survey

Overall, there was a satisfactory coverage of distinct types of stakeholders, from groups closely working with or for EFSA, and external stakeholders. However, limited evidence was collected from the media (three respondents). With such a small number of respondents, it was impossible to make generalisable conclusions on their views. Hence, this group was excluded from the results altogether. In line with this, although other stakeholder groups were satisfactorily represented, there was a limit to their representativeness in the statistical sense of the term. As the sample size was limited for most of the stakeholder groups, answers were not necessarily representative of the entire population. However, the online survey meets EFSA's definition of representativeness¹⁰⁶ in that it ensures wide representation of all stakeholder groups. The statistical representativeness of the survey is presented in Table 5.

4.3.3 Interviews

Five interviewees declined the interview request, and four contacts never responded, despite multiple follow-ups. The most notable problem encountered was with the European Parliament and media, where despite numerous attempts to reach out to alternate contacts, it did not prove possible to interview any or more than one representative respectively. Where possible, replacements for unavailable or uninterested interviewees were sought. Where minority views from given groups of stakeholders have been included, this has been clearly pointed out in the report.

Although interviews represent a very useful source of first-hand information and experiences, it is difficult to generalise based on the views of a small fraction of each stakeholder group or organisation. This issue is inherent to interview methods and could not be avoided within the scope of this evaluation¹⁰⁷. Interview notes were coded and analysed per evaluation question, with cross-fertilisation where relevant. In the presentation of the findings, the limitations related to the generalisability of findings is highlighted (e.g. minority views are reported on when deemed relevant or interesting, but they are specified as such).

¹⁰⁶ As per EFSA's clarification to minutes of Inception report meeting and accompanying email of 27 July 2017. "We are using the term [representativeness] to mean a selection that ensures wide representation of all stakeholder groups".

¹⁰⁷ Constructing a representative sample for all groups would have incurred disproportionate costs, which was not within the scope of this evaluation.

5. ANSWERS TO THE EVALUATION QUESTIONS

This chapter presents the findings of the evaluation, structured by evaluation criterion. At the start of each evaluation question, an introductory section sets out the coverage of the question, sources of evidence used to answer it, and the baseline, before moving on to present the analysis of evidence. A summary of the findings and of progress made relative to the baseline is presented at the end of each evaluation question.

5.1 RELEVANCE

This section assesses the extent to which EFSA's original objectives as per its Founding Regulation are still relevant vis-à-vis the needs of stakeholders, and the extent to which EFSA's organisational structure is fit for purpose (i.e. matches current needs and can address future challenges in relation to scientific and communication challenges in particular).

5.1.1 Objectives of Regulation (EC) N° 178/2002

How well do the original EFSA objectives of Reg. 178/2002 correspond to the current needs of and future challenges facing different target groups in the EU? (EQ 1)

Coverage of the question

This question is linked to EFSA's capacity to identify and adapt to evolving needs and challenges. It first examines the extent to which the original needs and corresponding objectives identified in EFSA's Founding Regulation (Regulation (EC) N° 178/2002) continue to be relevant. It then explores how the needs of the Authority's different target groups have evolved, and the extent to which EFSA's mandate can respond to new and emerging needs and challenges. The assessment is undertaken to reflect the changed context in which the Authority operates since its creation in 2002, determined by new drivers and challenges, including expectations of greater transparency and engagement, the emergence of new risks and hazards, technological breakthroughs and evolving scientific knowledge, and the impact of globalisation, among others.

Sources of evidence

Findings from the 2012 External Evaluation of EFSA and the ensuing recommendations from the Management Board were consulted to establish the baseline. To identify EFSA's original needs and objectives, Regulation (EC) N° 178/2002 was consulted. Internal EFSA documentation such as Programming Documents, Annual Activity Reports, strategic, communication and procedural documents were used to assess the continued relevance of original needs. External sources, such as the REFIT evaluation of the General Food Law and the Report on the identification of food safety priorities using the Delphi technique (conducted by Gene Rowe Evaluations), were also used to corroborate internal documentary evidence. Interviews with internal and external stakeholders, and findings from case study research on internal working practices related to scientific work provided additional evidence to assess the relevance of original needs. Online survey responses were a complementary source to assess the relevance of original objectives vis-à-vis the needs of target groups.

The analysis related to the emergence of new needs and future challenges draws on several internal and external sources. These include EFSA's strategic and governance documents covering the period under evaluation (EFSA's Strategic Plan 2009 – 2013, EFSA Science Strategy 2012-2016, EFSA Strategy 2020, EFSA Stakeholder Engagement Approach), and Programming Documents and Annual Activity Reports. External sources were also used to corroborate findings¹⁰⁸ and to identify

¹⁰⁸ Food Chain Evaluation Consortium (FCEC), *Scoping study: Delivering on EU food safety and nutrition in 2050 - Scenarios of future change and policy responses (Final Report)* (Berlin, Germany, 2013); European Commission, Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods] (Brussels, Belgium, 2018) <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A179%3AFIN>> [accessed 25 June 2018].

potential issues that EFSA has not considered. Interviews with internal and external stakeholders complemented the review of secondary sources in assessing needs and challenges.

Baseline

Section 2.1 provides details on the rationale and objectives of the Founding Regulation. The 2012 External Evaluation of EFSA acknowledged that the Authority's policies and procedures had evolved over the years – and in line with EFSA's mission – to respond to new challenges within the framework of the Founding Regulation. The report identified significant changes in EFSA's operating context resulting from phenomena such as the EU enlargement process, demographic trends and market globalisation. It also pointed to an adverse economic context, because of the financial and economic crisis in Europe, which had affected European institutions and national authorities operating in the food and feed safety area.

The evaluation encouraged EFSA to continue strengthening its 'intelligence capacity' to study the global context, be aware of and well-positioned to monitor international trends, and to make better use of stakeholder meetings to identify and respond to emerging challenges.

The ensuing recommendations from EFSA's Management Board stressed the importance of enhancing interaction and dialogue with the European Commission, risk managers in the Member States, EU Agencies and other stakeholders for the Authority to continue to address the specific needs of stakeholders, understand and consider the overall context, and anticipate how its work would evolve.

Analysis of evidence

Original needs identified in Regulation (EC) N° 178/2002 are still relevant

The original needs identified in Regulation (EC) N° 178/2002 remain relevant. The documentary review confirms the sustained need for an independent and centralised provider of scientific advice and technical support on EU food and feed safety which can address complex questions and provide a scientific view of the food chain in a progressively globalised food market.¹⁰⁹ As such, EFSA's role, in seeking to harmonise scientific risk assessment across the EU, remains relevant. Similarly, by pooling and aggregating information from 28 EU Member States, EFSA's work can facilitate increased synergies and greater impact across the EU.¹¹⁰ The evaluation identified specific examples which confirm EFSA's relevance in supporting the safety of the food chain in times of crisis or urgency (one of the needs identified in the Founding regulation), including EFSA's statements and involvement on the outbreaks of E. coli (STEC) and the Influenza A virus subtype H5N8; EFSA's reports on the risk of transmission of Ebola.¹¹¹

This is supported by the views of representatives of EFSA's main customers and stakeholder groups consulted for the evaluation. As shown below, the clear majority (at least 75%) of EFSA's stakeholders who responded to the online survey across stakeholder groups indicated that there

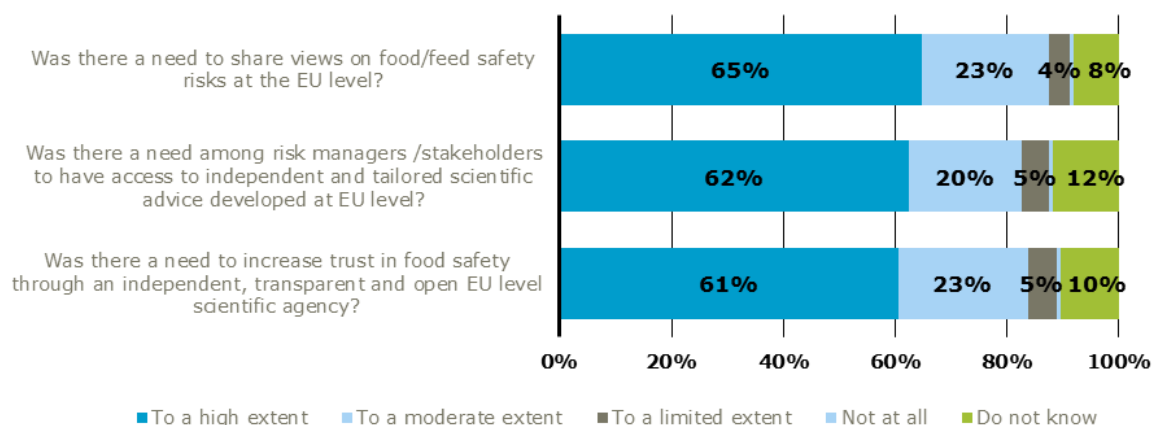
¹⁰⁹ European Commission, *The REFIT evaluation of the General Food Law (Regulation (EC) N° 178/2002)* (Brussels, Belgium, 2018). This independent assessment of the entire legislative framework for the food and feed sector introduced by Regulation (EC) N° 178/2002 was completed and published in January 2018. While the REFIT Evaluation of the General Food Law's conclusions concern the global system established by the General Food Law, it also applies to EFSA, since it was established to support the achievement of the core objectives set out in the Regulation.

¹¹⁰ European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002)* (Brussels, Belgium, 2018).

¹¹¹ European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015); European Food Safety Authority, *Scientific Cooperation Annual Report 2015* (Parma, Italy, 2016).; European Food Safety Authority, *Annual Report 2012* (Parma, Italy, 2013).

continued to be a need for EU-level sharing of views on food/feed safety, access to independent and tailored scientific advice, and a scientific agency at EU level.

Figure 6: Over the period 2011-2016, to what extent... (n = 1,613)



Source: Evaluation team based on survey results

Results from interviews with internal and external stakeholders further support the finding that original needs continue to be relevant. Interviewees who provided a view on this issue (38 out of 42) were of the view that the needs and problems that EFSA was set up to address still exist. As discussed below, many also considered that the challenges have become more pressing.

Certain challenges identified at the time of the adoption of the Regulation have evolved and intensified. Almost half of the interviewees providing a view on the continued relevance of EFSA's objectives (16, including members of EFSA staff, representatives from DG SANTE, EU Agencies and International Organisations, and members of the Scientific Panels, Stakeholder Forum and Communications Expert Group) were of the view that while the original needs remained relevant, these had evolved or become more urgent, which demanded more efforts from the Authority to keep pace with these changes. Examples given were: the globalisation of trade, an acceleration of trade in plant and animal products, the evolution of science, and the entry of new global players like China producing and exporting food. EFSA's strategic documents covering the period under assessment (EFSA's Strategic Plan 2009-2013; EFSA Science Strategy 2012 -2016; EFSA Strategy 2020) acknowledge changes in the Authority's operating context. Key drivers and challenges identified are summarised in Table 8.

Table 7: EFSA's key drivers and challenges during the period under assessment

EFSA's key strategic documents	Key drivers and challenges identified
EFSA's Strategic Plan 2009 - 2013	<ul style="list-style-type: none"> • Globalisation increases the likelihood of new or re-emerging risks to the European food supply • Innovative technologies, evolving risk assessment practices and new science • Sustainability and climate change will emphasise the importance of an integrated approach to risk assessment • Societal changes associated with socio-demographic structure, diet and consumer behaviour • Changes in policies and the regulatory framework will have implications for EFSA's workload and priorities
EFSA Science Strategy 2012 - 2016	<ul style="list-style-type: none"> • Innovative technologies to increase the competitiveness of Europe • Need to ensure food security, both within Europe and internationally • Need for environmental, social and economic sustainability • Societal changes, linked to the specific needs of an aging population

	<ul style="list-style-type: none"> • Increased nature and volume of scientific work • Limited resources to face increased workload
EFSA Strategy 2020	<ul style="list-style-type: none"> • Expectations of greater transparency and engagement • Emergence of new risks and hazards, requiring complex food safety questions • Evolving scientific knowledge, creating a need for innovative and collaborative approaches • Globalisation, characterised by increasingly globalised trade in food and feed products and a more complex food supply chain • Efficient operation of the Authority's activities • Availability of expertise for EFSA's multidisciplinary needs

Not all the challenges identified are areas directly under EFSA's remit (for example some issues would fall tangentially under EFSA's remit if there was a risk posed, such as food security). Similarly, not all can be adequately dealt with in the current legal framework (namely "expectations of greater transparency and engagement"; see below for discussion on this).

EFSA has strong procedures in place to confirm that original needs correspond to the needs of key target groups, and to identify new ones. EFSA's strategic and programming documents covering the evaluation period provide evidence of continuous processes in place to address long-term needs and priorities. In addition to those high-level strategies summarised above, one example was the development of a common EU Risk Assessment Agenda, proposed in the framework of EFSA's Scientific Cooperation Roadmap 2014-2016 to address common EU long-term needs and actions through collaborative projects between EFSA and Member States. A Delphi study was undertaken in 2015 involving over 200 experts from across Europe to identify the most important food safety risk assessment areas and priorities with a view to delineating the agenda.¹¹² The study identified 28 priority topics under four main categories, including chemical, microbiological, environmental risk assessment and nutrition, in addition to a further category of generic cross-cutting topics. These priority areas for collaboration were established as a basis to be further explored through joint projects and activities with Member States, and through engagement and consultation with EFSA's key stakeholder groups. In 2015, EFSA launched thematic grants that encourage networks to collaborate on large, long-term innovative projects.¹¹³

Internal procedures in place that EFSA utilises to identify current and emerging challenges include but are not limited to¹¹⁴:

- **Continuous dialogue with Member States, EU institutions, agencies and globally** – Cooperation and exchange of information with Member States takes place through EFSA's Advisory Forum, which provides mechanisms for sharing data and opinions between the Authority and national representatives, notify new issues, create liaison groups on emerging risks, coordinate risk communication and avoid duplication of work. A new Declaration of Commitment was signed in 2016.¹¹⁵ Cooperation with Member States is also supported by Scientific Networks (see 2.3.5). EFSA has processes in place to ensure continuous dialogue with EU institutions (such as the new "customer feedback mechanism" detailed under 5.2.1.1) and its cooperation with EU agencies and international bodies, as covered in detail under Coherence (section 5.4).
- **Structured dialogue with stakeholders:** EFSA's Stakeholder Engagement Approach includes provisions to increase capacity to identify priorities in which to invest, making the

¹¹² Gene Rowe and Fergus Bolger, *Final report on 'the identification of food safety priorities using the Delphi technique'*, 2016 <<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2016.EN-1007>>.

¹¹³ This was in response to an external evaluation looking at the delivery of EFSA's tasks through science grants and procurements, as per European Food Safety Authority, *Scientific Cooperation Annual Report 2015* (Parma, Italy, 2016).

¹¹⁴ Some of these procedures are pre-existing to the period under evaluation but continue to be relevant for the assessment of the validity of original needs.

¹¹⁵ European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017).

Authority more responsive to stakeholders' needs. EFSA proactively seeks stakeholders' input and exchanges different points of view, especially through the Stakeholder Forum and Bureau, as well as the Stakeholder Consultative Platform, which was active during the evaluation period (but is no longer in operation), and an annual Stakeholder Conference.¹¹⁶

- **Open dialogue with the scientific community and other stakeholders:** The use of public consultations to gather data and insights of EFSA's scientific assessments and institutional initiatives from the scientific community and other stakeholders is another way to ascertain the needs and concerns of different stakeholder groups and incorporate these in final outputs and initiatives. EFSA launched a total of 109 public consultations in the period under evaluation (2011–2016), with an average of 18 consultations per year over the six years under review.¹¹⁷

New challenges identified

Though the original objectives and EFSA's legal framework and mission are broad enough to cover wide-ranging new challenges relating to food and feed safety and other areas where relevant (like nutrition – where chapter three of Regulation (EC) N° 178/2002 explicitly covers nutrition, fraud and aspects of the environment where they specifically relate to food safety), there are some exceptions:

- The linkage with food safety and **food sustainability in general**, and more specifically, **food waste** could potentially be more comprehensively covered, as raised in the REFIT evaluation and corroborated by other external scientific sources¹¹⁸. Given that this challenge would go beyond EFSA's core competency, any judgement of the feasibility and desirability of this would need to be determined at the policy level.
- Linked to this issue of sustainability is **food security**; while certainly on EFSA's agenda¹¹⁹, it could be given more focus in light of the widespread understanding of factors which will put pressure on the entire food chain (demonstrated by an independent foresight study commissioned by DG SANTE in 2013) including: demographic imbalances, climate change, resource and energy scarcity, slowing agricultural productivity, increasing concentration of the supply chain, price volatility, changing diet trends and the emergence of anti-microbial resistant strands.¹²⁰
- EFSA will need to keep pace with **big data developments**. As noted by EFSA staff during interviews and in the documentation reviewed, EFSA would do well to improve its ability to deal with the substantial amounts of data available. Currently, most of the data collection and screening activities are conducted manually. Staff suggested the use of new IT tools and mechanisms to increase efficiency, while ensuring agility in a time of big data developments. EFSA has ongoing initiatives in machine learning and other applied artificial intelligence mechanisms for data analysis and insight and has ambitious plans for data as expressed in a "Concept paper on the future of scientific data in EFSA"¹²¹.

Although outside the temporal scope of the evaluation, the recent Commission proposal for a targeted revision of the General Food Law Regulation published in April 2018¹²² provides evidence

¹¹⁶ European Food Safety Authority – EFSA, 'Open EFSA', <<http://www.efsa.europa.eu/en/topics/topic/open-efsa>> [accessed 4 May 2018].

¹¹⁷ EFSA Register of questions, which includes encoding of public consultations related to EFSA outputs (information provided by EFSA).

¹¹⁸ European Union Committee, *Counting the Cost of Food Waste: EU Food Waste Prevention* (London, UK, 2014)

<<http://books.google.com/books?id=LGT2AwAAQBAJ&pgis=1%5Cnhttp://www.parliament.uk/documents/lords-committees/eu-sub-com-d/food-waste-prevention/154.pdf>>; Fusions, *Review of EU Member States Legislation and Policies with Implications on Food Waste* (Bologna, Italy, 2015); European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) No 178/2002)* (Brussels, Belgium, 2018).

¹¹⁹ EFSA Strategy 2020 highlights that "population growth, climate change and food waste all pose challenges to global food security and food safety", adding that "EFSA and its partners, at EU and international level, will have to address these new developments". European Food Safety Authority, *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

¹²⁰ Food Chain Evaluation Consortium (FCEC), *Scoping Study: Delivering on EU Food Safety and Nutrition in 2050 - Scenarios of Future Change and Policy Responses (Final Report)* (Berlin, Germany, 2013).

¹²¹ EFSA Evidence Management Unit, Digital Transformation Services Unit, Assessment and Methodological Support Unit, *Concept paper on the future of scientific data in EFSA* (Parma, Italy, 2017).

¹²² European Commission, Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) N° 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed],

of other areas where EFSA's legal basis would need to be altered to fully deal with intensified challenges and increasing societal demands in the context of limited resources. The proposal specifically addresses the issue of transparency and sustainability of the EU risk assessment in the food chain.

The proposal addresses the need to ensure more transparency by allowing citizens automatic and immediate access to safety related information in the risk assessment process; the creation of a common European Register of commissioned studies; the possibility for EFSA to request any additional studies deemed necessary; public consultations on studies submitted by industry to support product authorisation requests; and an increased involvement of Member States in EFSA's governance structure and scientific Panels. In doing so, the proposal also addresses another key challenge which EFSA faces in the context of increased demands, which relates to the limitations on resources (discussed in section 5.1.2).

The perceptions of internal and external interviewees consulted during the evaluation confirmed that there are some concerns regarding the ability of EFSA to meet all current and future challenges, some of which corroborate the above. According to 22 of 52 interviewees from various categories (including members of the Stakeholder Forum and DG SANTE staff, but also members of Scientific Panels, Management Board, Article 36 organisations and representatives of other groups), EFSA's mandate is sufficiently broad to cover most challenges identified. But more than half of interviewees (i.e. the remaining 30 out of 52) cited the emergence of "new" challenges. The areas highlighted included climate change, nutrition, sustainability, and food fraud. While some are not core competencies for EFSA's mission (climate change and sustainability), others are already covered (nutrition¹²³ and fraud¹²⁴).

An external challenge mentioned was the Brexit fallout. However, at the time of the evaluation, exit negotiations are still underway and the implications for UK-EU relations, including access to EU institutions and agencies, are unclear. The UK Food Standards Agency has indicated¹²⁵ that it intends to incorporate existing EU Food Safety Law into the UK's withdrawal bill to ensure that the body of law remains in place post-Brexit. However, it also acknowledges that the UK's exit will require the replacement or maintenance of regulatory functions, including the risk assessment function currently undertaken by EFSA. Exactly how this will unfold depends on the exit agreement reached and future decisions of the UK Government and the Food Standards Agency.

Most respondents (n=1,612) to the online survey (90%) were not aware of any needs in the food/feed safety area not listed in Regulation (EC) N° 178/2002 that should have been responded to by EFSA during the period under assessment. The small proportion of respondents (10%) who indicated that there were new needs not covered by EFSA's original objectives (most of them members of EFSA staff and Scientific Committee and Panels) mainly referred to specific food safety and security domains that in their view required further regulation, research, or inspection, such as surveillance in the pesticides area and a need for dedicated laboratory facilities to apply greater insight to pesticides. But there were also comments related to sustainability, such as the effect of diet choices on greenhouse gas emissions and the effect of farming practices on biodiversity and climate.

Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods] (Brussels, Belgium, 2018) <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A179%3AFIN>> [accessed 25 June 2018].

¹²³ Nutrition is covered by EFSA as specified by Article 22 (5a), while Article 5(1) does not mention nutrition. Regulation (EC) N° 178/2002.

¹²⁴ the protection of consumer's interests is covered in Article 8, Regulation (EC) N° 178/2002.

¹²⁵ Ainsworth, R., *The Food Standards Agency's Preparations for the UK's exit from the European Union*, 2017.

Summary of findings and progress relative to baseline

EQ 1 (Relevance): How well do the original EFSA objectives of Reg. 178/2002 correspond to the current needs of and future challenges facing different target groups in the EU?

Evaluation findings from all sources consulted **confirm the continued relevance of the original objectives** identified in Regulation (EC) N° 178/2002. Primary evidence collected also indicates that the original objectives of the Authority's Founding Regulation are perceived to continue to remain relevant vis-à-vis the needs of key target groups. There was consensus among interviewees that EFSA's mandate is sufficiently broad and that it has a degree of **flexibility to respond to new needs and future challenges**.

Evidence confirms that **EFSA has procedures in place to verify the relevance of original needs and to identify and address new and increased challenges**, and action has been taken since the previous External Evaluation to ensure that EFSA better understands and responds to stakeholder needs.

Though EFSA has developed flexible and proactive processes to address new needs and increased challenges in an ever more complex operating context, EFSA's strategic, programming and activity documents highlight the inherent difficulties of responding to increasing demands with the resources available to the Authority. **The new Proposal for a targeted revision of the General Food Law addresses the issue of increasing societal demands, most importantly regarding transparency.** In line with this legislative proposal, cooperation with partners will continue to be an important means for EFSA to be able adequately address current and future needs and challenges.

5.1.2 EFSA's organisational structure and working practices

To what extent are EFSA's organisational structure and working practices/processes fit for purpose: to meet current needs and to adapt to future challenges? (EQ 2)

Coverage of the question

To remain relevant and be fit for purpose, the organisational structure and working practices and procedures which govern EFSA must facilitate its mission. At the same time, they must be responsive to meet current needs and adapt to future challenges (as identified in the previous question).

This evaluation question investigates how EFSA's organisational structure and working practices allow the Authority to adequately respond to current needs and future challenges. In addition, it explores the extent to which EFSA's organisational structure and working practices are aligned with recognised good practices for EU executive decentralised agencies.

Sources of evidence

Findings from the 2012 External Evaluation of EFSA and the ensuing recommendations from the Management Board were consulted to establish the baseline. To assess the adequacy of EFSA's organisational structure and working practices and procedures to meet identified needs and respond to unforeseen challenges, the evaluation consulted the Authority's Founding Regulation (EC) N° 178/2002 and internal EFSA documentation such as Programming Documents and Annual Activity Reports. External sources relevant to the evaluation period, such as staff engagement surveys carried out in 2011, 2012 and 2015, were reviewed to gain the views of EFSA members of staff on the extent to which the organisational structure and management practices are consistent with EFSA's overall goal and the attainment of its objectives. Online survey responses and interviews with internal and external stakeholders provided primary evidence on perceptions on these issues. Findings from case study research on internal working practices and working practices for EU-level cooperation provided additional evidence for assessing the adequacy of working practices and procedures.

The analysis of the alignment of EFSA's organisational structure and working practices with recognised good practices for executive decentralised agencies featured the review of internal EFSA documentation such as Programming Documents and Annual Activity Reports, as well as results from EFSA engagement surveys. External sources were also reviewed to identify comparative information from other EU agencies. These included the Final Summary Report of Deloitte's Ex post evaluation of EFSA's independence policy, and a special report of the European Court of Auditors on Agencies' use of grants.

Baseline

The 2012 External Evaluation of EFSA acknowledged that EFSA's organisational structure had been designed and restructured over the years to reflect the Authority's main priorities, mission and tasks established in Regulation (EC) N° 178/2002. Although the working practices and procedures were found to be generally appropriate to the tasks entrusted to EFSA, concerns were raised about the heterogeneity of processes and systems in place, which impacted negatively on the Authority's efficiency.

The subsequent recommendations from EFSA's Management Board acknowledged that EFSA had matured as an organisation, but also recognised that the requests for advice had become more complex, often requiring multi-disciplinary work across several scientific areas. In the context of resource constraints and increasing complexity, the Management Board recommendations stressed the need for the Authority to place greater emphasis on its working practices and procedures with a view to achieving efficiency, prioritisation and forward planning with partners to better meet current needs and adapt to future challenges.

Analysis of evidence

EFSA's organisational structure has proved adequate to meet identified needs and respond to unforeseen challenges

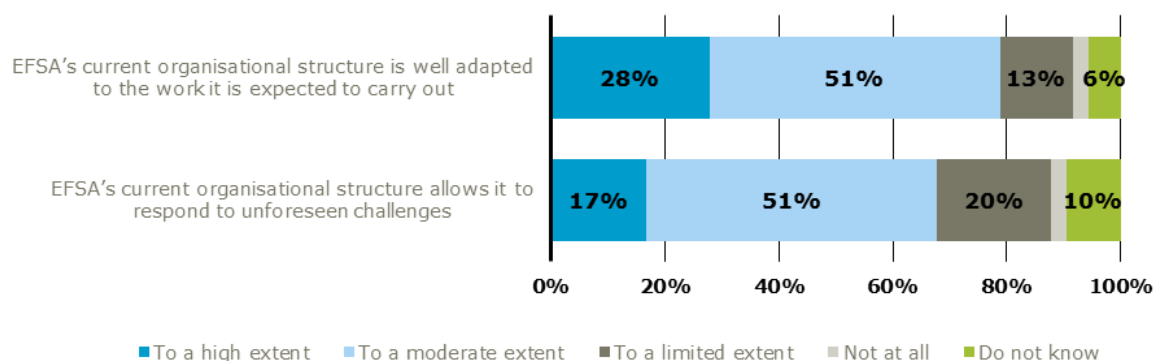
The composition and responsibilities of each of the four 'Bodies of the Authority' (the Management Board, Executive Director, Advisory Forum and Scientific Committee and Panels), described in detail under Articles 25 to 28 of Regulation (EC) N° 178/2002 (see also section 2.3.2), have remained relatively unaltered since EFSA's inception in 2002. However, in practice, the Authority's organisational structure that supports its governance and operational management has been flexible during the evaluation period to enable it to respond to identified needs (as described in Chapter 2).

EFSA staff and Management Board members, EFSA Advisory Forum members or observers, and AFCWG members were asked to provide their views on the extent to which EFSA's organisational structure was well adapted to the work it was expected to carry out and allowed it to respond to unforeseen challenges. Out of a total of 335 responses¹²⁶, 79% indicated that they believed, to a "high" or "moderate" extent, that EFSA's organisational structure was well adapted to the work it was expected to carry out. Fewer respondents in these four groups – 68% in total – indicated that they believed, to a "high" or "moderate" extent, that EFSA's current organisational structure allowed it to respond to unforeseen challenges. No statistically significant differences in opinions were registered across different sub-groups, including EFSA's staff.¹²⁷

¹²⁶ The question was displayed to (a) members of EFSA's staff, (b) members of EFSA's Management Board, (c) members or observers of EFSA's Advisory Forum, or (d) members of the Advisory Forum Communications Working Group (AFCWG).

¹²⁷ A survey result is here considered to differ largely from the sample average if it differs from the sample average by 2 or more standard deviations in absolute terms. The basis for this is the assumption that the responses are normally distributed, which implies that 95% of the responses should lie within 2 standard deviations of the mean."

Figure 7: To what extent do you agree with the statements below regarding EFSA's organisational structure (e.g. organisation in departments and units, reporting lines)? (n=335)



Source: Evaluation team based on survey results

Trends in EFSA's staff engagement and satisfaction regarding the Authority's organisational structure provide complementary evidence of staff perceptions on the issue. Staff perceptions have been assessed through consecutive external employee engagement surveys, three of which were completed during the period under review: 2011¹²⁸, 2012¹²⁹ and 2015¹³⁰. Staff satisfaction survey results assessed during the period under evaluation confirm that the areas that have scored comparatively lower are those more closely related to the Authority's organisational structure and management practices, namely:

- **Communication, trust and leadership** – top-down communication, particularly in relation to decisions affecting members of staff (reorganisations, contract renewals, promotions, allocation of training, etc.) was perceived to be lacking a coherent strategy. Levels of support on EFSA's senior management have been an area of improvement across the staff surveys. To give some examples from each year: in 2011 just 25% of respondents had favourable responses in relation to how well recent reorganisations had been communicated; in 2013, 52% of employees were "challenged in understanding the reasons behind decisions taken by the Managerial Community"; in 2015 "leadership" received just under half - 46% - favourable assessments.
- **Workload across units** – low levels of agreement were registered in relation to the availability of sufficient staff to handle workload across the different units (the levels of favourable assessment fluctuated between 30 and 50% over the period: 30% in 2011, 54% in 2013, and 31% in 2015).

Building on these findings, though much lower in number than survey respondents, interviewees were divided on the adequacy of EFSA's organisational structure to carry out its work and respond to identified needs. In the view of 11 out of 25 interviewees who answered this question, including mainly members of EFSA staff, the Management Board and representatives of the Advisory Forum, EFSA's organisational structure was fit for purpose and provided a solid basis for its working practices. However, more than half of interviewees (13 out of 25) observed that some of the structures were not fully fit for purpose. A recurring theme raised by interviewees was insufficient organisational flexibility. EFSA members of staff highlighted that the fragmented structure limited mobility across departments, which was problematic given the imbalance in workloads across different scientific departments and the volatility in workloads. Stronger coordination of the work undertaken by Experts in the Panels/Scientific Committee and EFSA staff, was perceived as a positive move that would bring about improvements in the quality and timeliness of scientific outputs, in line with the Authority's mandate.

¹²⁸ Towers Watson, *European Food Safety Authority – Staff Feedback 2011 Results: All Staff Presentation*, 2012.

¹²⁹ ORC International, *European Food Safety Authority – Employee Engagement Survey 2012* (London, UK, 2013).

¹³⁰ EFSA Human Capital & Knowledge Management Unit, *2015 Engagement Surveys results* (Parma, Italy); *2015 Staff Engagement Survey Results*.

The online survey also found evidence of this issue among the minority of respondents who were more critical about EFSA's current organisational structure (77 in total)¹³¹, including EFSA members of staff, and to a lesser extent, members of the AFCWG, Management Board, members of Scientific Working Groups, national risk assessment bodies and other groups. The shared concern voiced by respondents in this group pointed to a hierarchical organisational structure and budgetary constraints, which were considered to erode EFSA's capacity to respond to unforeseen challenges. The impact of this external constraint features in EFSA's own reporting documents. For instance, the Programming Document (2017-2019) outlines the risks of a predicted shortfall in resources due to an increase in demand compared to capacity over the coming years and highlights a corresponding need to apply "negative priorities" to non-core activity.¹³² Budget availability is an external constraint impacting on EFSA's ability to meet current needs and future challenges and EFSA's approach has been to maintain focus on the delivery of core work.

EFSA's working practices/procedures have proved adequate to its work and to meet identified needs and respond to unforeseen challenges

EFSA's working practices and procedures respond to a **complex set of sector-specific regulations, internal policies and rules**. Previous evaluations pointed to the heterogeneity of EFSA's processes and their difficult coexistence. The Authority has invested heavily in streamlining and harmonising its working practices and procedures during the period covered by the evaluation to better align them to its growing and diversifying workload. In addition, annual programming documents and reports have reflected a continuous realignment of practices and procedures in recent years to remain relevant and respond to identified needs of target groups.

Since the 2012 External Evaluation, **EFSA has undergone a significant re-structuring and rationalisation of its processes**¹³³ with the aim of improving the efficiency and transparency of its work. This has included centralisation of tasks related to finance, procurement, planning and monitoring¹³⁴, and the centralisation of the Declaration of Interest assessment¹³⁵, the introduction and roll-out of a Quality Management System covering the Authority's scientific activities¹³⁶, the launch of a project management approach to the Authority's scientific work ("PaRMa" Project)¹³⁷, and the adoption of EFSA's first IT Operational Roadmap¹³⁸, among others. EFSA also introduced changes to ensure an effective use of legal resources and adequate management of its staff.¹³⁹ Following the publication of EFSA's 2020 Strategy, the Authority launched its first draft corporate performance dashboard to guide the implementation of the strategy through the monitoring and reporting of data in line with strategic KPIs.¹⁴⁰ EFSA tracks its budget execution (proportion of original budget committed/paid) as one of its KPIs. A description of how EFSA measures performance is provided under section 2.3.6. A review of EFSA's performance over the period shows

¹³¹ 15% indicated that they believed, to a "limited extent" or "not at all", that EFSA's organisational structure was well adapted to the work it was expected to carry out, and 22% indicated that they believed, to a "limited extent" or "not at all", that EFSA's current organisational structure allowed it to respond to unforeseen challenges. No significant differences in opinions were registered across different sub-groups.

¹³² Details of the expected shortfall and the areas which would be prioritised are included in the Programming Document 2017-2019, which specifies that core activities are prioritised at the potential expense of the pace of transformation, outlined in EFSA's five-year strategy. EFSA's Management Board, *Programming document 2017-2019* (Parma, Italy, 2016).

¹³³ As detailed in EFSA RASA, REPRO, COMMS, BUS Departments, *Internal document follow-up on implementation of EFSA's Management Board recommendations*, (Draft), 2017.

¹³⁴ European Food Safety Authority, *Annual Activity Report of the European Food Safety Authority for 2011* (Parma, Italy, 2012).

¹³⁵ Positively assessed by the European Parliament in 2016 and 2017. "13. Notes with satisfaction that the function ensuring the centralised handling of competing interest management within Authority's legal and regulatory affairs unit became fully operational in 2016", European Parliament Committee on Budgetary Control, *Draft Report on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2016 (2017/2159(DEC))*, 2018. "8. Notes that the Authority completed the centralisation of the validation process of all the annual declarations of interest submitted by its experts and staff to its legal and regulatory affairs function", The European Parliament, 'Resolution (EU) 2017/1670 of the European Parliament of 27 April 2017 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2015', *Official Journal of the European Union*, 226-230, 2017.

¹³⁶ The development and roll-out of a quality management system led to a better coordination between resource allocation and delivery and to the more effective identification of bottlenecks and priorities in programming documents. European Food Safety Authority, *Annual Activity Report of the European Food Safety Authority for 2011* (Parma, Italy, 2012).

¹³⁷ The launch of the Project and Resource Management Approach (PaRMa) Project in 2012 aimed at harmonising working practices and improving efficiency and transparency of the Authority's scientific work. European Food Safety Authority, *Annual Activity Report of the European Food Safety Authority for 2012*, 2013.

¹³⁸ European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014).

¹³⁹ European Food Safety Authority, *Consolidated Annual Activity Report 2015* (Parma, Italy, 2016).

¹⁴⁰ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

a positive picture of overall improvement for four of the five categories of activities (i.e. 1, 2, 3 and 5 but not 4) when comparing the situation in 2011 with the situation in 2016. The introduction of multiannual work plans from 2014 onwards, and the adoption of strategic documents have also been instrumental in providing a medium to long-term horizon for activities and projects implemented.

Governance, strategy and programming documents during the period under assessment have highlighted the **importance of cooperating with partners in the EU** to ensure that EFSA's work remains relevant in a scenario of limited resources. The development of harmonised methodologies and the sharing of data and risk assessment expertise with EU Member States were identified as key objectives of EFSA 2020 Strategy. Findings from case study research on EU level cooperation evidence found a deliberate focus of EFSA to improve its systems and processes regarding the involvement of Member States in its activities. This deliberate approach has been shaped through coordination at various levels, including at the national level through the work of the Advisory Forum, the Focal Points and scientific networks. Specific mechanisms include the exchange of information and experiences between national authorities and EFSA, through the AFCWG and the Focal Points, and support to cooperation and mentoring directly among Member State organisations, through sharing of work programmes, training and thematic grants.

Similarly, EFSA's alignment with other EU agencies has been significantly strengthened during the period under evaluation as a result of a strategic and practical measures to prioritise and better plan future work with partners. Interagency cooperation is an element within EFSA's Scientific Cooperation Roadmap 2014-2016, it is part of ensuring complementarity, and a consistent risk assessment approach at EU level.¹⁴¹ In addition, the set up and implementation of a common risk assessment and research agendas with Member States and EU agencies is outlined as an operational objective in EFSA's 2020 Strategy. EFSA staff interviewed highlighted that EFSA works closely with sister agencies (EMA and ECDC), to ensure alignment in the areas of antimicrobial resistance, foodborne outbreaks and zoonosis. Relations with ECHA have been substantially reinforced and there is now a better integration of work on chemicals. Another recent joint endeavour illustrating successful alignment and collaboration between these two agencies is a jointly developed guidance for identifying endocrine disruptors.¹⁴² EFSA is also an active member, and has been the Chair in 2017, of the EU Agencies Network, a collective initiative set up by the Heads of the 45 EU agencies to coordinate common actions, exchange information and agree positions of shared interest which ensures that EFSA is aligned with other EU agencies and following best practices.¹⁴³

The online survey asked representatives of staff, members, observers, or experts in EFSA activities¹⁴⁴ to provide their views on the extent to which **EFSA's working practices and procedures were well adapted to the work the Authority was expected to carry out and allowed it to respond to unforeseen challenges**. Out of a total of 1,197 responses, 89% indicated that they believed, to a "high" or "moderate" extent, that EFSA's working practices and procedures were well adapted to the work it was expected to carry out. EFSA staff members were less positive than respondents in other groups – with 78% in total – indicating that they believed, to a "high" or "moderate" extent, that EFSA's working practices and procedures allowed it to respond to unforeseen challenges. Looking at the qualitative feedback from EFSA staff provides anecdotal insight into some of the reasons for a slightly lower assessment. Issues relating to a "top down culture", a lack of dialogue between management and staff, frequent change, siloed working

¹⁴¹ European Food Safety Authority, *Scientific Cooperation Roadmap 2014-2016* (Parma, Italy, 2014).

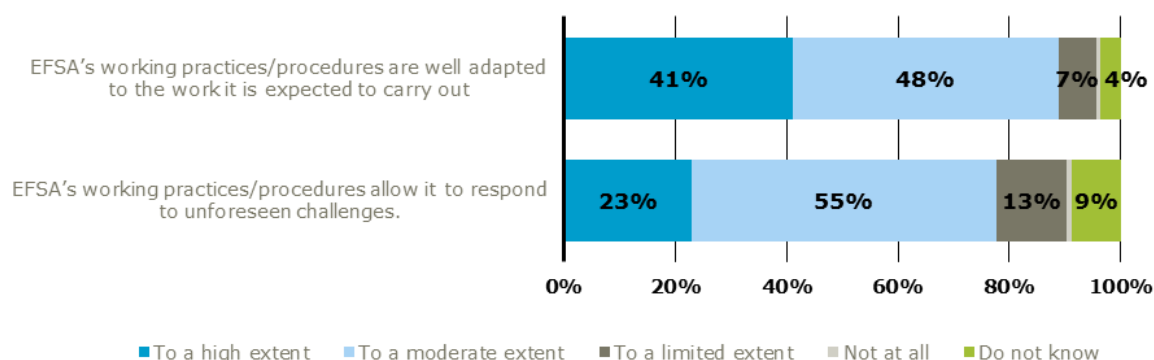
¹⁴² The document was made available between the 7th of December 2017 and 31st of January 2018 for comments. See European Chemicals Agency, 'Give comments on the draft guidance for identifying endocrine disruptors', 2017 <<https://echa.europa.eu/-/give-comments-on-the-draft-guidance-for-identifying-endocrine-disruptors>> [accessed 4 May 2018].

¹⁴³ EU Agencies Network, 'EU Agencies Network', 2016 <<https://euagencies.eu/>> [accessed 4 May 2018].

¹⁴⁴ Respondents in the following nine groups were asked to respond to this question: (a) members of EFSA's staff, (b) members of EFSA's Management Board, (c) members or observers of EFSA's Advisory Forum, (d) members of the AFCWG, (e) representatives or observers of an EFSA National Focal Point, (f) members of EFSA's Scientific Panels or Committee, (g) Pesticides peer review experts, (h) members of EFSA's Scientific Working Groups, and (i) members of one of EFSA's Scientific Networks.

and a reliance on external staff featured in multiple responses. However, they remain the minority overall, given 80% of EFSA staff have a positive assessment of EFSA's systems.

Figure 8: To what extent do you agree with the statements below regarding EFSA's working practices/procedures (e.g. cooperation with external experts, coordination with national authorities)? (n=1,197)



Source: Evaluation team based on survey results

EFSA's structure and working practices are mostly aligned with good practices of EU agencies

The documentary review found evidence of alignment and good practices through the comparison of the organisational structure and working practices of EFSA with those of other executive decentralised agencies. The focus of the analysis below is on a selection of working practices for which comparative information was found, including independence policy, the use of grants and staff engagement.

- **Independence policy:** EFSA's policies, structures and practices on independence have been compared with those of other EU agencies and scientific organisations and found to be comprehensive, sophisticated and robust.¹⁴⁵ The most recent evaluation of EFSA's independence policy, published in 2017¹⁴⁶, pointed to good practices of EMA and ECHA that EFSA could consider transposing into its specific operational and legal framework, including for example, the differentiation between risk profiles of experts, the use of a risk analysis approach for the screening of Declarations of Interest and the publishing of special annual reports on the implementation of its independence policy. The report also encouraged EFSA to intensify its cooperation with similar EU agencies to combine resources and to set-up shared support functions for the management of its independence policy system.
- **Use of grants:** A special report of the European Court of Auditors on the use of grants of five EU agencies during the period 2013-2015¹⁴⁷ praised EFSA's flexibility and the adequate use of ex ante evaluation, reviews and consultations to assess the impact of its existing grants with a view to introducing new and more effective grant concepts in its Scientific Cooperation Roadmap for 2014-2016.
- **Staff engagement:** Results of a survey on engagement of EFSA's staff carried out in 2015 showed that EFSA staff reported above average scores in 88% of questions when compared with six other EU agencies in the same cluster (i.e. with more than five years of history and more than 150 members of staff). The areas scoring well which relate most closely with working practices and organisational structure were under the themes of "resilience and adaptability", and work with "line managers" and "work within unit". To be clear, other aspects which gave EFSA an above average score did not necessarily relate to organisational structure (for instance "accountability", "customer service" and "integrity"),

¹⁴⁵ Milieu, Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organisations similar to EFSA, Revised Final Report, 2011.

¹⁴⁶ Deloitte, *Ex Post Evaluation of the Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority (EFSA) and of Its Implementing Rules on Declaration of Interest - Final Summary Report*, 2017.

¹⁴⁷ European Court of Auditors, *Special Report N° 12 – Agencies' use of grants: not always appropriate or demonstrably effective* (Luxembourg, 2016).

while a smaller number of questions (12%) where EFSA scored less well than the average included “work-life balance” which arguably links to working practices.¹⁴⁸

Summary of findings and progress relative to baseline

EQ 2 (Relevance): To what extent are EFSA's organisational structure and working practices/processes fit for purpose: to meet current needs and to adapt to future challenges?

EFSA's **organisational structure**, outlined in Article 24 of Regulation (EC) N° 178/2002, provides the foundation through which the Authority operates. The documentary review undertaken by the evaluation evidences that the structure has been adapted ever since EFSA's inception to enable it to respond to identified needs and future challenges. Following an important reorganisation that took place in 2011, the Authority implemented some further adjustments to its structure during the period covered by the evaluation with the aim of continuing to reflect EFSA's priorities, mission and tasks.

The documentary review and views of stakeholders collected during the evaluation confirm that **EFSA's working practices and support structures have also been instrumental to achieving the Authority's mission**. The centralisation of support structures and the customisation of planning and monitoring resources have strengthened the capacity of the scientific and communication departments to achieve their operational and strategic objectives, in line with EFSA's mission and allowed for a more streamlined and harmonised approach.

Despite the positive evidence, the main challenges for EFSA's organisational structure to adequately address its mission statement relate to the **need for more flexibility in the distribution and assignment of EFSA staff** across departments and Scientific Panels to manage volatility in workloads. This is linked to the issue around silo working and a top-down approach which featured in qualitative feedback from EFSA staff in employee engagement surveys.

The documentary review found evidence of alignment and good practices through the comparison of (elements of) the organisational structure and working practices of EFSA with those of other executive decentralised agencies. In particular, comparative evidence was found of EFSA's positive performance vis-à-vis other EU agencies in relation to the Authority's independence policy and the use of grants.

¹⁴⁸ EFSA Human Capital & Knowledge Management Unit, *2015 Engagement Surveys results* (Parma, Italy); *2015 Staff Engagement Survey Results*.

5.2 EFFECTIVENESS

This section assesses EFSA's effectiveness in two respects. The first tackles the effectiveness of EFSA's core activities namely the authority's scientific activities and the role of cooperation (and networking) to facilitate these and communication. The second covers EFSA's governance, processes and implementation and the ways in which these affect the achievement of EFSA's objectives.

5.2.1 Scientific work

5.2.1.1 Provision of scientific advice and sustainability

To what extent has EFSA contributed to creating and maintaining a sustainable scientific system, able to respond to needs from risk managers and to address emerging risks by delivery of fit-for-purpose and state-of-the-art scientific advice? (EQ 3a)

Coverage of the question

To assess the effectiveness of EFSA's system for providing scientific advice, the question asks for a judgement of two elements:

1. The ability of EFSA's scientific system, and its different components to respond to risk managers' needs, but also address emerging risks, through fit-for-purpose and state-of-the-art **scientific advice**.
 - **Fit-for-purpose** is taken to mean that the advice effectively fulfils its purpose, i.e. to support risk managers' decision making. More specifically, EFSA uses the criteria below to assess fitness for purpose¹⁴⁹:
 - Extent to which the opinion adheres to and provides a clear answer to the ToR;
 - Extent to which the opinion allows for a full understanding of the uncertainties, variability, assumptions and weight of evidence;
 - Extent of the transparency regarding the data sources and methods used to identify relevant data together with the inclusion/exclusion criteria used and strengths/limitations of the data used;
 - Extent to which the opinion provides a clear basis for regulatory action.
 - **State-of-the art** is taken to refer to the need for advice to be based on the most recent data, scientific developments and methods.
2. The **sustainability** of EFSA's scientific system is taken to mean the ability to maintain capacity to respond to needs from risk managers at the current rate or level in the long-term (particularly the willingness, independence and availability of experts to contribute to EFSA).

Sources of evidence

EFSA has self-set KPIs covering its scientific work which are included in the analysis to present an overview of EFSA's publications and timeliness of outputs over the period under review.

To assess the fitness for purpose of scientific advice, self-reported feedback gathered from EFSA's qualitative customer feedback mechanism provided direct insights into DG SANTE's satisfaction (EFSA's main customer), making it a strong source of evidence.¹⁵⁰ To complement this, reference is made to the evidence collected through the online survey, which includes the views of national risk management or assessment authorities on the various parts of the system. To judge whether EFSA's scientific system responds to needs, by delivery of state-of-the-art scientific advice:

- **For the Panel system** – EFSA's selection criteria and the composition of the Panels was assessed. Interviewees provided valuable qualitative insights supporting the documentary evidence. Analysis of h-index scores of a sample of experts was undertaken but ultimately

¹⁴⁹ European Food Safety Authority, *Customer feedback Presentation for ERWG*, 2013.

¹⁵⁰ The results of the feedback mechanism for years 2014, 2015 and 2016 were shared with the evaluation team and are summarised in EFSA's Quality Manager Reports available online; although the areas for improvement are not systematically included and the focus is on general (positive) assessment in the summary reports. See European Food Safety Authority – EFSA, 'Corporate documents and publications', 2018 <<https://www.efsa.europa.eu/en/about/corporatedocs>> [accessed 4 May 2018].

deemed to be an inadequate measure to objectively and meaningfully assess quality since not all EFSA experts are expected to have a strong track record of publication, and wide variations in what constitutes a 'good' h-index score across scientific disciplines.

- **For the peer review system on pesticide dossiers** – the Final Audit Report on Evaluation of Regulated Products: "Assessment" Phase in Pesticides Authorisation in the European Food Safety Authority¹⁵¹ was assessed, but it was not possible to corroborate this information with other data due to a lack of knowledge or threshold of responses from the parties consulted. Only nine interviewees provided their views on this system. The fact that interviewees expressed mixed views on its quality meant this was not deemed sufficiently robust to report on.
- **For technical advice provided by EFSA's scientific staff** – the Authority's own explanation (and compliance with international standards) was relied on and this was combined with views gathered from interviewees (particularly the Scientific Committee) to provide qualitative insights confirming the documentary evidence.

To assess the sustainability of the scientific system, different documentary sources were used, both internal and external to EFSA. The Survey of Institutions Employing EFSA Panel Members, as well as the different reports on the Evaluation of Applicants for Membership in the Scientific Panels and Committee, together with documents on the Renewal of the ANS and CEF Panels were relevant internal sources to assess the availability of high level independent experts and their willingness to contribute to EFSA. The Ex post evaluation of EFSA's Policy on Independence and Scientific Decision-Making Processes and of its Implementing Rules on Declaration of Interest constituted a relevant external source of evidence to evaluate its impact on experts' availability. Member States authorities' procedures for selecting their experts were also looked at to compare their system with EFSA. The conclusions were corroborated by the REFIT evaluation of the General Food Law. Interviews with EFSA's staff (3), two members of the Scientific Committee and seven members of the Panels provided valuable qualitative insights supporting the documentary evidence. In addition, the online survey provided the opinions of 1,137 respondents on EFSA's scientific system.

Baseline

The 2012 External Evaluation of EFSA found that the provision of outputs from external requests was effective – meeting stakeholders' needs, in terms of high quality, accessibility and reliability of outputs.¹⁵² It found that EFSA was less effective when it came to self-tasking.

Regarding the sustainability of the system, the distribution of work among staff and experts was found to be "unbalanced to adequately face future challenges". There was no separate analysis of the sustainability of different elements of the scientific production system. Ensuring the long-term sustainability of EFSA's operations was the first recommendation adopted by the Management Board following the 2012 Evaluation. There was a recognition of the need to optimise the respective roles of experts, staff and others in the risk assessment process, for EFSA to proactively identify scientific fields for self-tasking.

Analysis of evidence

Scientific advice

EFSA's self-set KPIs show a downward trend of the Authority's publications between 2011 and 2016
Over the period under review, EFSA had 18 KPIs relating to its three scientific "activities" (these activities are described in 2.3.6). Only the proportion of scientific outputs adopted within deadline was reported on consistently between 2011 and 2016. The results of a selection of EFSA's KPIs covering most of the period and considered most pertinent are presented below. An overview of

¹⁵¹ European Commission Internal Audit Service, *Final Audit Report on Evaluation of Regulated Products: "Assessment" Phase in Pesticides Authorisation in the European Food Safety Authority (EFSA)*, 2017.

¹⁵² Ernst&Young, *External Evaluation of EFSA - Final Report*, 2012.

KPIs relating to EFSA's publications is presented first, followed by the KPIs on timeliness of its scientific outputs.¹⁵³

The three KPIs presented below provide an overview of EFSA's achievements regarding self-set targets for three types of publications over the period under review (this are also combined graphically in Figure 9 below):

- ✓ **Number of scientific outputs adopted:** Notwithstanding issues with how comparable one output is to another, EFSA's self-set KPIs show that the Authority has produced fewer scientific outputs than targeted over most years to varying degrees (except for 2013). The reasons vary. Some are within EFSA's control, such as carrying over production of outputs from one year to another for example, or inadequate planning. Others lie outside of EFSA's control, such as occasions when an envisioned mandate does not materialise. The significant difference in 2011 is mainly due to non-receipt of mandates, delays in the enactment of legislation, requests for additional data and changes in priorities agreed with the Commission, according to the Annual Report 2011.¹⁵⁴ The discrepancy between targeted and achieved has decreased over time.
- ✓ **Number of technical reports¹⁵⁵:** Over the period under review, EFSA finalised more technical reports than targeted. EFSA's 2016 KPI¹⁵⁶, shows that for both Activities 2 and 3, EFSA finalised more technical reports than targeted, mainly in the peer review system on pesticides dossiers, where 40 technical reports were produced instead of the 24 initially planned (Activity 2).¹⁵⁷
- ✓ **Number of other publications (external scientific reports¹⁵⁸ and event reports¹⁵⁹):** EFSA did not always meet the targets for this self-set KPI but its performance improved from 2014¹⁶⁰, though in part due to it setting lower targets.

Table 8: Number of other publications (Activity 3)

	2011		2012		2013		2014		2015		2016	
	Target	Achieved	Target	Achieved	Target	Achieved	Target	Achieved	Target	Achieved	Target	Achieved
External scientific reports	42	37	45	73	86	74	n/a	79	54	120	n/a	n/a
Event reports	9	8	15	11	14	11	n/a	10	93* ¹⁶¹	9	n/a	n/a
Total	51	45	60	84	100	85	n/a	89	147*	129	45	72

Source: Evaluation team, based on data from EFSA's Annual (Activity) Reports and Management Plans (2011-2016)

Taking all the distinct types of publications together, Figure 9 shows an overall downward trend in the number of publications over the period under review, both in terms of targets and achieved. This is mostly due to the production of fewer scientific outputs, and the fact that the backlog of scientific outputs linked to authorisation dossiers (which peaked following the adoption of the new Regulation on health and nutrition claims in 2008) was gradually addressed.¹⁶²

¹⁵³ A full assessment of the utility of the KPIs deployed by EFSA is included in sub-section "measuring performance", where some of the issues with KPIs – including lack of comparability over years are described.

¹⁵⁴ European Food Safety Authority, *Annual Report 2011* (Parma, Italy, 2012).

¹⁵⁵ Technical reports directly support the Authority's scientific work. Note that technical reports were only reported as a KPI from 2016, the figures were combined and reported elsewhere.

¹⁵⁶ which presents technical reports separately for all three activities.

¹⁵⁷ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

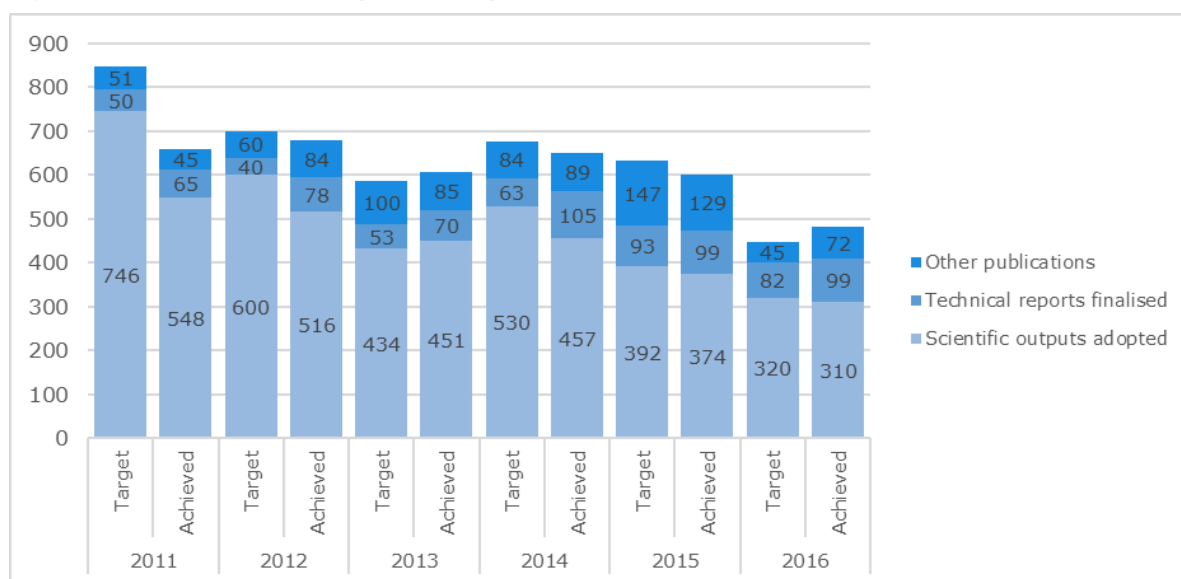
¹⁵⁸ External Scientific Reports describe, for example, data collection, literature reviews, or the development of models used in risk assessment. EFSA can request a beneficiary of a grant, a contractor, or a joint working group consisting of experts proposed by EFSA's Advisory Forum and Scientific Committee and Panels together with staff members, to prepare External Scientific Reports, with the aim to enhance its collaboration with Member States.

¹⁵⁹ Event Reports can be prepared by EFSA's staff or by a contractor upon request of the Executive Director and can contain the presentations given at the event as well as summaries of the discussions, outcomes and conclusions. They constitute EFSA's supporting publications, with Technical Reports. See European Food Safety Authority – EFSA, 'Definitions of EFSA Scientific Outputs and Supporting Publications' <<https://www.efsa.europa.eu/en/efsajournal/scdocdefinitions>> [accessed 4 May 2018].

¹⁶⁰ The number of other publications appeared as one of EFSA's KPIs in 2016. To find previous figures and compare them over the period under review, we combined the two elements that made up the indicator in 2016. Given that technical reports were analysed separately, we did not include them again here (except in 2015 where the data was not disaggregated). This explains why figures below might vary from EFSA's own Annual Activity Reports.

¹⁶¹ The target for 2015 (93) includes technical reports as no detailed figure was available.

¹⁶² Indeed, we found evidence that since 2011 the number of outputs linked to authorisation dossiers has followed a downward trend over the period of review. See Appendix 7, European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002) - Appendices* (Brussels, Belgium, 2018).

Figure 9: Publications of EFSA (2011-2016)¹⁶³

Source: Evaluation team, based on data from EFSA's Annual (Activity) Reports and Management Plans (2011-2016)

To evaluate whether these publications responded to risk managers' needs, EFSA's KPI linked to timeliness was also assessed.

- ✓ **Proportion of scientific outputs adopted within deadline:** this KPI allowed to judge whether EFSA responded to needs from risk managers in a timely manner. Between 2011 and 2013, this indicator was measured in the group of Activities 1, 2 and 3 and the targets of this KPI increased, whereas the numbers achieved reduced.¹⁶⁴ From 2014, timeliness was measured per Activity.¹⁶⁵ While timeliness in Activity 1 (general risk assessment area) significantly improved, reaching the 100% target in 2016, the timeliness of EFSA's scientific outputs on the regulated products area (Activity 2) where legal deadlines apply, improved but did not reach the 90% target.

Table 9 (a): Proportion of scientific outputs adopted within deadlines (target/achieved)¹⁶⁶

2011	2012	2013
85/81	90/81	95/75

Source: Evaluation team, based on data from EFSA's Annual (Activity) Reports and Management Plans (2011-2013)

¹⁶³ The number of scientific outputs adopted was originally the "number of scientific opinions", but definitions changed over time. The definition of "scientific outputs" used here was adopted in 2010. See European Food Safety Authority – EFSA, 'Definitions of EFSA Scientific Outputs and Supporting Publications' <<http://www.efsa.europa.eu/en/efsajournal/scdocdefinitions>>. Though it has been reported to EFSA's Management Board since the beginning, it appeared as a KPI in the Annual Reports only in 2014, for activities 1, 2 and 3 separately. Before 2014, the Annual Reports included an annex presenting the number of scientific outputs and supporting publications, allowing us to compare the data over the period of review. The number of scientific outputs is presented below for Activities 1, 2 and 3 combined.

¹⁶⁴ Note that in 2013, EFSA experienced delays in pesticide Maximum Residue Levels (MRL) conclusions. This was due to several factors including delays in Rapporteur Member States, difficulties in identifying suitable contractors, changes in risk manager priorities, and poor alignment of the ambitious targets laid down in Regulation (EC) N° 396/2005 with EFSA's resources. Overall timeliness for EFSA's scientific outputs in 2013 was heavily impacted by the delays in the MRL conclusions, which are very numerous (18% proportion of total outputs) and are generally non-sensitive. If MRL work were excluded, EFSA's timeliness would be 87% in 2013. See European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014).

¹⁶⁵ European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014).

¹⁶⁶ For 2011-2013, EFSA presented this KPI jointly for the three scientific activities (1, 2 and 3), whereas in 2014, EFSA started monitoring timeliness by activity (1, 2 and 3). Therefore, the data are presented only for 2011-2013. See European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015).

Table 9 (b): Proportion of scientific outputs adopted within deadlines (target/achieved)¹⁶⁷

	2014	2015	2016
Activity 1	90/98	100/92	100/100
Activity 2	90/58	90/84	90/75
Activity 3	90/85	100/100	100/89

Source: Evaluation team, based on data from EFSA's Annual (Activity) Reports and Management Plans (2014-2016)

EFSA's scientific system responds to needs but can still be improved

EFSA is proactively engaging with risk managers through a formal feedback process to better understand and respond to their needs and refine the scope of work and its fitness for purpose.¹⁶⁸ This active engagement is gradually reaping results and showed that overall the Commission was satisfied, but that it is still possible to improve and better serve customers' needs.¹⁶⁹

In conjunction with its main customer, DG SANTE, EFSA developed the feedback mechanism in 2013, as part of a continuous improvement programme and as a requirement of the Quality Management System¹⁷⁰ that is now ISO 9001:2015 certified. The feedback was positive overall, for instance regarding the scientific detail and justification for conclusions reached. Specific areas for improvement were identified in the years falling within the scope of this study:

- 2014 was the pilot year and covered six (out of ten) Panels¹⁷¹. The areas for improvement relating to fitness for purpose included more clarity regarding whether risk is more likely to be over or underestimated in cases of extreme uncertainty and to minimise repetition and avoid re-interpretation of the legislation.¹⁷²
- In 2015, the mechanism was extended to all ten Panels and there were more areas for improvement in line with the increased coverage. They related mainly to the need for greater clarity or issues with timeliness.¹⁷³
- In 2016, the areas for improvement identified were that EFSA could sometimes be more assertive with its conclusions to avoid ambiguity; inconsistencies between scientific and legal definitions and consistency of wording between different opinions needs to be ensured, particularly on related topics. The issue of timeliness was also raised again.

Based on this feedback, EFSA developed actions to better respond to risk managers' needs showing a willingness to continually improve and recognise areas of weaknesses.¹⁷⁴ The evaluation found that the process for follow-up is tailored to the issue at hand. As a continuous process, still in relatively initial stages, it was not possible at the time of writing to definitively assess whether sufficient or insufficient measures have been introduced. The evidence shows commitment in ensuring effective communication with DG SANTE staff to address their needs.

In 2016, the mechanism was piloted in a Member State.¹⁷⁵ Whilst not representative of other Member States, feedback was positive in terms of collaboration, communication during ToR development, and the quality of scientific outputs. Areas for improvement included closer cooperation on use of resources, deeper discussion and communication on divergent views, and

¹⁶⁷ In 2014, for Activity 2, if the reasoned opinions under MRLs were excluded, the figures (achieved) would stand at 77% instead of 58%.

¹⁶⁸ European Food Safety Authority, *Scientific Cooperation Roadmap 2014-2016* (Parma, Italy, 2014).

¹⁶⁹ L. Miko (Deputy Director-General for the food chain), 'Commission Feedback Mechanism on EFSA's Scientific Opinions', 2014; EFSA, '2015 Management Feedback - April 2015', April, 2015, 1-52; European Food Safety Authority, '2015 Management Feedback: 1st Survey Jan-Feb 2015', 2015.

¹⁷⁰ EFSA, *Annual Quality Manager's Report 2013*, 2013.

¹⁷¹ Panels Covered: GMO, PPR, ANS, FEEDAP, PLH, CONTAM. Not covered in 2014: AHAW, BIOHAZ, CEF, NDA. See European Food Safety Authority, *Customer Feedback Mechanism 2014 – 55th AF meeting 4-5 March 2015*, 2015.

¹⁷² EFSA's Executive Director, *Commission feedback mechanism on EFSA's scientific opinion* (Letter Ref SANCO.DDG02.03/MW/am(2014)87892), 2014.

¹⁷³ The letter from EFSA's Executive Director highlighted the following areas for improvement: Consistency of wording between different opinions particularly on related topics needs to be ensured; in some cases, it is felt that essential information in the opinion could be made more prominent. In the case of work considered urgent, intermediate steps such as Statements are appreciated to facilitate the Risk Managers' work. See also European Food Safety Authority, *Customer feedback exercise – 2015 Outcome*.

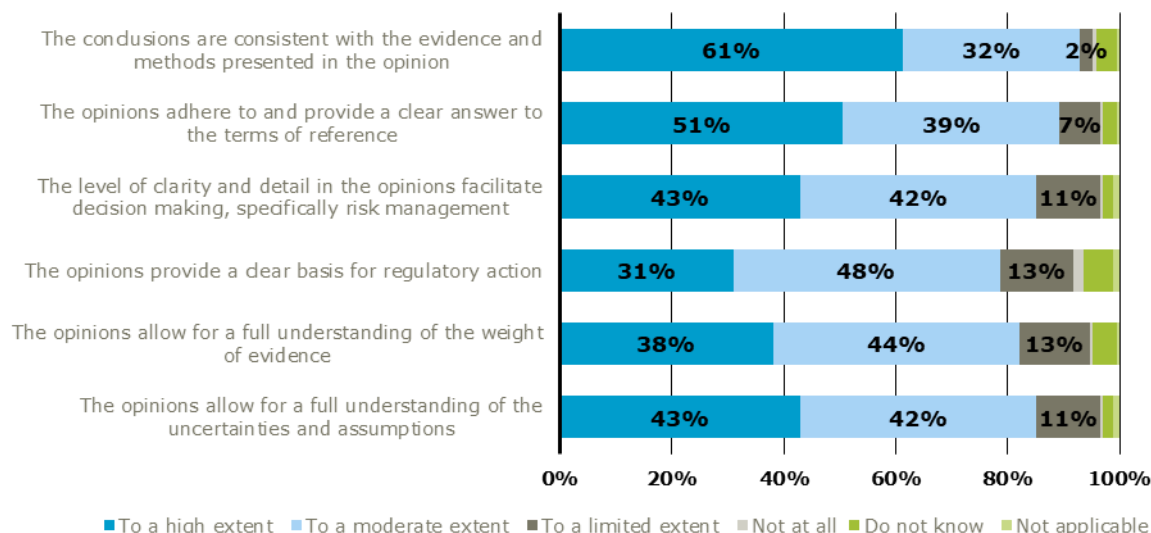
¹⁷⁴ European Food Safety Authority, *Customer Feedback – Progress report on actions from 2014*, 2014.

¹⁷⁵ through one interview with the risk assessment authority in Germany (BfR) for one opinion (Risk assessment for peri- and post-menopausal women taking food supplements containing isolated isoflavones), conducted by ANS.

the need to better highlight key messages and findings in abstracts, summaries and conclusions for communication with the public.¹⁷⁶

Online survey results corroborate the overall picture of satisfaction with EFSA's scientific opinions; and this is accentuated when only the views of national risk assessment organisations are considered. Indeed, for each of the points presented in Figure 10, between 79% and 93% of representatives of national risk management or assessment bodies of an EU Member States, an EEA country or an accession or candidate country, agreed either to a high or moderate extent.

Figure 10: To what extent do you agree with the following statements regarding EFSA's scientific opinions? (n=168)



Source: Evaluation team based on survey results

The Panel system (addressing general scientific questions and authorisation dossiers) responds to needs by delivery of state of the art scientific advice

By design, EFSA's Panel system allows the Authority to source multidisciplinary scientific expertise necessary for state-of-the-art risk assessment. The Panel system, which between 2011 and 2016 delivered 48.8%¹⁷⁷ of EFSA's scientific outputs (responding to general scientific questions and dealing with authorisation dossiers, except pesticides)¹⁷⁸, relies on the engagement of independent experts recruited based on their expertise (both in terms of general as well as topic specific expertise¹⁷⁹).

The model allows for the cumulative breadth of experience of all experts taken together to be considered when they are selected¹⁸⁰. Given the applied nature of its work, EFSA engages experts with multidisciplinary expertise: academics, and those with experience in risk assessment authorities in different topic areas, and from several types of institutions, mainly universities, public research institutions and government bodies.¹⁸¹

There is no definitive method for assessing the quality of experts engaged, rather there are different measures that can be used. EFSA defines quality through the selection criteria, and the

¹⁷⁶ Member States customer feedback exercise, 62nd Advisory Forum Meeting, Parma, EFSA, 8-9 December 2016 (Parma, Italy, 2016).

¹⁷⁷ Figures supplied by GPS unit based on EFSA Register of Questions (excludes assistance and G&P).

¹⁷⁸ "EFSA's Scientific Panels of experts are responsible for the bulk of EFSA's scientific assessment work." European Food Safety Authority – EFSA, 'Scientific experts' <<https://www.efsa.europa.eu/en/howwework/scientificexperts>> [accessed 4 May 2018].

¹⁷⁹ Panel related experience includes: experience in carrying out scientific risk assessment; experience in providing other scientific advice; proven scientific excellence and experience in peer reviewing scientific work and publications. Non-panel related criteria include: ability to analyse complex information and dossiers; professional experience in a multidisciplinary environment; experience in project management related to scientific matters; and proven communication skills.

¹⁸⁰ the "overall mix of knowledge areas available to the Scientific Panel/Committee to cover its foreseen needs", Article 8, p6, EFSA Executive Director, *Decision of the Executive Director Concerning the Selection of Members of the Scientific Committee the Scientific Panels, and the Selection of External Experts to Assist EFSA with Its Scientific Work* (Parma, Italy, 207).

¹⁸¹ European Food Safety Authority – EFSA, 'New Experts Join EFSA's Scientific Committee and Panels', 2015 <<https://www.efsa.europa.eu/en/press/news/150608>> [accessed 12 March 2018].

weight given to each criterion – the most important one being the experience in scientific assessment and/or provision of scientific advice to risk managers (weighting coefficient: 6, maximum 30 points out of 100) and “proven scientific excellence” (weighting coefficient: 5, maximum 25 points out of 100).¹⁸² The majority (17 out of 22) of interviewees from within and external to EFSA believed that the Authority attracts the best scientists in their field. In addition, 83% of survey respondents who provided an answer¹⁸³ indicated that general scientific questions addressed by EFSA’s Panel system responded to their organisation’s expectations in terms of usefulness over the period 2011-2016 to a high or moderate extent. This confirms that EFSA’s scientific system responds to risk managers’ needs by delivery of fit-for-purpose and state-of-the-art advice. By contrast, while only 60% of survey respondents¹⁸⁴ indicated that authorisation dossiers addressed by EFSA’s Panel system responded to their organisation’s expectations in terms of usefulness over the period 2011-2016 to a high or moderate extent, it is worth highlighting that a sizeable proportion of the remaining 40% responded that they did not know (30% of respondents selected “do not know”¹⁸⁵).

EFSA’s peer-review on pesticides dossiers is being improved to better respond to needs

Multiple sources suggest the peer review system on pesticides dossiers requires improvements and is overly complex. EFSA understands that the peer-review system on pesticides dossiers does not adequately respond to needs. The Authority is hence trying to address this issue. Indeed, EFSA started working on an Action plan for improving the peer review process. The Action plan aims to enhance the overall quality of the process, optimise different steps, improve the efficiency, and facilitate the cooperation between EFSA and Member States. It addresses concerns about the overall quality of the peer review system on pesticides dossiers and the fact that Member States’ views are inadequately presented in EFSA’s conclusions. The document specifies that these are short-term solutions and that legislative changes are required.¹⁸⁶

In tandem, there is an ongoing REFIT evaluation of the EU legislation on plant protection products and pesticides residues (Regulation (EC) N° 1107/2009 and Regulation (EC) N° 396/2005) due for completion in November 2018.¹⁸⁷ In addition, the IAS Audit on Evaluation of Regulated Products confirmed that the peer review system on pesticides dossiers is too complex. It involves different actors: applicant, Rapporteur Member States (RMS), EFSA, Member States, the European Commission, and other stakeholders (public consultations). Among the challenges that the implication of many actors imply are differences in the quality of the Draft/Renewal Assessment Reports.¹⁸⁸ The online survey confirmed this: only 53% of survey respondents who provided an answer¹⁸⁹ indicated that pesticide dossiers covered through the peer review system responded to their organisation’s expectations in terms of usefulness over the period 2011-2016 to a high or moderate extent, and a high proportion (39%) did not know¹⁹⁰. An example illustrates the many actors involved in the system, which contributes to the complexity described:

- Menno Chemie-Vertrieb GmbH applied for the renewal of approval of the active substance benzoic acid to the RMS, Hungary, and co-RMS, the Netherlands, as required by Commission Implementing Regulation (EU) N° 844/2012.

¹⁸² See p.25, EFSA Executive Director, *Decision of the Executive Director Concerning the Selection of Members of the Scientific Committee the Scientific Panels, and the Selection of External Experts to Assist EFSA with Its Scientific Work* (Parma, Italy, 2014).

¹⁸³ The question required respondents to select “not applicable” if their organisation never used this type of advice. Those who selected this option were hence not included here. This results in 1012 responses.

¹⁸⁴ The question required respondents to select “not applicable” if their organisation never used this type of advice. Those who selected this option were hence not included here. These remaining responses total 811.

¹⁸⁵ The reason for these “do not know” responses cannot be determined with the information available and is not speculated on here.

¹⁸⁶ European Food Safety Authority, *Action plan for improving the peer review process*, 2017.

¹⁸⁷ European Commission, ‘Evaluation and Fitness Check (FC) Roadmap’, 2016 <http://ec.europa.eu/smart-regulation/roadmaps/docs/2016_sante_197_evaluation_plant_protection_products_en.pdf>.

¹⁸⁸ European Commission Internal Audit Service, ‘Final Audit Report on Evaluation of Regulated Products: “Assessment” Phase in Pesticides Authorisation in the European Food Safety Authority (EFSA)’, 2017.

¹⁸⁹ The question required respondents to select “not applicable” if their organisation never used this type of advice. Those who selected this option were hence not included here. These remaining responses total 734.

¹⁹⁰ As with previously, the reason for these “do not know” responses cannot be determined with the information available and is not speculated on here.

- Complying with Article 8 of the Regulation, Hungary checked the application was admissible and informed the applicant, the co-RMS, the European Commission, and EFSA.
- Hungary prepared a Renewal Assessment Report (RAR) and sent this to EFSA.
- In accordance with Article 12 of the Regulation, EFSA provided comments and distributed the RAR to the Member States and the applicant for their comments.
- EFSA conducted a public consultation on the RAR, collated and forwarded all comments received to the European Commission.
- Following consideration of the comments received on the RAR, EFSA requested additional information from the applicant and concluded that there was no need to conduct an expert consultation.
- EFSA issued conclusions on peer review of the pesticide risk assessment of the active substance benzoic acid, based on the evaluation of the representative use of benzoic acid as a disinfectant in rooms, buildings and equipment used in floriculture, horticulture and agriculture, and in small tools in preventive treatment, listing missing information identified as being required by the regulatory framework.
- Data were submitted to conclude that the uses of benzoic acid as a disinfectant, according to the representative uses proposed at EU level, result in a “sufficient efficacy” against the target organisms.
- Data gaps were identified for the determination of the boiling point of the representative formulation, for validation data of the monitoring method in water and for a method for body fluids and tissues.
- In other areas, EFSA did not identified any other data gaps, or issues that could not be finalised or critical area of concern.¹⁹¹

Technical advice provided by EFSA’s scientific staff responds well to needs

EFSA’s scientific staff supported the Authority’s scientific advice being state-of-the-art, including ensuring up-to-date methods and use of evidence for scientific assessment.

70% of EFSA’s staff are involved in the Authority’s scientific production system.¹⁹² It includes contributing to outputs, termed “other Scientific Outputs of EFSA” in EFSA’s lexicon (including Statement of EFSA and Guidance of EFSA among others¹⁹³), which represent 20% of the total output production in EFSA. EFSA’s scientific staff carry also out preparatory tasks for the Panels.

To ensure excellence, external sources of guidance such as those developed by FAO and WHO on food safety risk assessment or OECD test guidelines¹⁹⁴, are followed in line with the principle of “methodological rigour”¹⁹⁵. During the period under review, a specific development was the mapping of the process for ensuring quality through the “PROmoting METHods for Evidence Use in Science” (PROMETHEUS) project. As presented in EFSA’s Annual Report 2016, the result of this investment was a defined set of principles for evidence use, and an analysis of “methodological needs for evidence use”¹⁹⁶. This exemplifies how the technical support provided by EFSA contributes to best practice in the scientific assessment process.

Half of the 40 representatives of European institutions or bodies who responded to the online survey indicated that technical advice provided by EFSA’s scientific staff to the Commission responds to their needs to a high extent; 86% of those who provided an answer¹⁹⁷ indicated either to a high or moderate extent. This was corroborated by the widespread agreement among the interviewed

¹⁹¹ European Food Safety Authority, ‘Conclusion on the peer review of the pesticide risk assessment of the active substance benzoic acid’, *EFSA Journal*, 14(12), 14pp., 2016.

¹⁹² European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002)* (Brussels, Belgium, 2018).

¹⁹³ European Food Safety Authority – EFSA, Definitions of EFSA Scientific Outputs and Supporting Publications, <<https://www.efsa.europa.eu/en/efsajournal/scdocdefinitions>> [accessed 4 May 2018].

¹⁹⁴ As described in EU-ANSA, sub-network of the Network of Heads of Agencies, *Overview of the Scientific Processes of the EU agencies Network for Scientific Advice (EU-ANSA)* (Luxembourg, 2015) <<https://publications.europa.eu/en/publication-detail/-/publication/6656c7c5-46df-468b-b375-b999d4d335be>>.

¹⁹⁵ European Food Safety Authority, *Quality Policy (DRAFT)*.

¹⁹⁶ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

¹⁹⁷ Excluding 4 respondents who selected “Not applicable” (none selected “Do not know”).

Scientific Panel chairs that EFSA's staff are highly qualified, motivated and dedicated to supporting the production of high quality outputs.

EFSA's scientific system is able to address emerging risks¹⁹⁸

The 2012 External Evaluation of EFSA highlighted the need to self-task and tackle emerging risks. The present evaluation found that over the period under review, EFSA¹⁹⁹ addressed emerging risks effectively. Several issues were successfully identified, and the Authority self-tasked different follow-up actions.²⁰⁰ In addition, EFSA addressed emerging risks identified by Member States.²⁰¹

Sustainability

EFSA's workload has grown to include new competencies

EFSA's workload has expanded since the creation of the Authority. Indeed, a series of legislative changes introduced new or changed competencies, but also the requirement to re-evaluate existing substances within a time frame. These are described below. While some of the changes occurred prior to the period of review, their consequences continued into the period. This presented a fundamental challenge for how EFSA organises its work.

1. Regulation (EC) N° 1924/2006 on health and nutrition claims, although prior to the period of review, increased the scope of EFSA's work significantly and EFSA was still dealing with the consequences during the evaluation period.²⁰²
2. Regulation (EC) N° 1333/2008 mandated EFSA to re-assess *all* food additives permitted before 20 January 2009.²⁰³ EFSA's Panel on Food Additives and Nutrient Sources Added to Food (ANS) must complete this re-evaluation of authorised food additives by 2020.²⁰⁴
3. At the beginning of the period under review, there was growing importance given to the safety evaluation of other regulated products such as genetically modified organisms, pesticides, food flavourings, colours and contact materials.²⁰⁵ By 2012 these represented more than two-thirds of EFSA's outputs.
4. Regulation (EC) N° 2015/2283 on novel foods, which came into effect in January 2018 (not part of the period under review), increased pressure on EFSA as it introduced a centralised authorisation and assessment procedure by the European Authority, previously done by Member States.²⁰⁶

The model for engaging independent experts is strained

The current system relies on pooling individual expertise from relevant institutions (academia, research organisations and national Food Safety authorities). Home institutions must be prepared to support their staff in devoting part of their professional time to EFSA.²⁰⁷ Yet, experts are a crucial resource and in high demand within their home institutions. As explained below, the evaluation revealed some resistance from these institutions to releasing them from their day to day roles to undertake work for EFSA.

¹⁹⁸ EFSA defines an emerging risk as: "A risk resulting from a newly identified hazard to which a significant exposure may occur, or from an unexpected new or increased significant exposure and/or susceptibility to a known hazard." See European Food Safety Authority – EFSA, 'Emerging Risks' <<https://www.efsa.europa.eu/en/topics/topic/emerging-risks>> [accessed 4 May 2018].

¹⁹⁹ One team within the Scientific Committee and Emerging Risks Unit (SCER), is dedicated to coordinating activities related to emerging risks.

²⁰⁰ See the activity reports, European Food Safety Authority – EFSA, 'Emerging risks' <<https://www.efsa.europa.eu/en/topics/topic/emerging-risks>>.

²⁰¹ Such as Fluorinated alternatives to perfluoroalkyl sulfonate (PFAS) for example. As a follow-up, EFSA self-tasked a mandate for an extensive literature search and provision of summaries of studies related to the oral toxicity of perfluoroalkylated substances (PFASs), their precursors and potential replacements in experimental animals and humans. See Ana Afonso and others, *EFSA's Activities on Emerging Risks in 2016*, EFSA Supporting Publications, 2017 <<http://doi.wiley.com/10.2903/sp.efsa.2017.EN-1336>>.

²⁰² The Regulation, which started to apply on 1 July 2007, is the legal framework used by food business operators who want to highlight the beneficial effects of their products, in relation to health and nutrition, on its label or in its advertising. It required EFSA to assess more than 4,000 claims already used on the market creating a significant backlog. See European Union, 'Nutrition and Health Claims', 2018 <https://ec.europa.eu/food/safety/labelling_nutrition/claims_en> [accessed 4 May 2018].

²⁰³ The European Parliament and the Council of the European Union, 'Regulation (EC) N° 1333/2008 of the European Parliament and of the Council of 16 December 2008 on food additives', *Official Journal of the European Union*, 16-33, 2008.

²⁰⁴ European Food Safety Authority – EFSA, 'Food additive re-evaluations' <<https://www.efsa.europa.eu/en/topics/topic/food-additive-re-evaluations>> [accessed 4 May 2018].

²⁰⁵ European Food Safety Authority, *Science Strategy 2012-2016* (Parma, Italy, 2012).

²⁰⁶ European Food Safety Authority – EFSA, 'Novel Food' <<http://www.efsa.europa.eu/en/topics/topic/novel-food>> [accessed 4 May 2018].

²⁰⁷ Hubert Deluyker and others, *Survey of Institutions Employing EFSA Panel Members*, 2017.

Experts receive only nominal compensation from EFSA when participating in meetings, which includes the reimbursement of travel expenses and a daily and accommodation allowance.²⁰⁸ The implication is that home institutions need to 'subsidise' experts by reducing their core workload and must deal with the opportunity costs that imposes on their own work. Indeed, results from EFSA's expert employer survey, conducted across 40 institutions in 25 countries, found that the time spent working for EFSA was largely paid by the home organisations – rather than by EFSA.²⁰⁹ Moreover, this same survey showed that home organisations think that sending experts to EFSA may impact on their capacity to deliver other work these experts have in their organisations. Interviews conducted for this evaluation revealed that this is particularly the case for national food safety authorities, many of which face serious budget constraints and were aware of the opportunity cost of releasing their experts for EFSA work. Members of the Advisory Forum said that the time required from experts can represent up to one-third of their working time, therefore not all organisations can afford to release their scientists to spend such a significant amount of time supporting EFSA's work.²¹⁰ Experts sometimes had to use annual leave to participate in EFSA's activities.²¹¹

It is noted that the introduction of fees for EFSA was previously explored in an Impact Assessment²¹². This was deemed unworkable for several reasons:

- Complexity of the legal framework, embracing 19 different pieces of legislation;
- Heterogeneity of the authorisation procedures with different sharing of work between EFSA's staff, EFSA's Panels, Member States and EU Reference Laboratories (EURL);
- Limited number of dossiers, variable from one sector to another, received by EFSA for the scientific assessment of regulated products and an even smaller number of eligible dossiers for fees;
- Member States and EURL already charge fees in the framework of the same authorisation process in certain sectors;
- Several types of authorisation granted (generic and individual);
- EFSA was created as a provider of services mainly to the public authorities.

The strict rules for independence also have the potential to limit the pool of experts.²¹³ The data on the number of applicants passing or failing the independence check under the period of review indicate this could affect between 8-15% of eligible candidates in the period of review (384 out of 447 candidates remained (85%) after checks in 2012 and 380 out of 414 in 2015 (92%)²¹⁴). These figures do not account for the possibility that qualified scientists may already self-select out if they expect to "fail" the checks. EFSA must balance concerns for scientific excellence with concerns for independence, especially given the scrutiny over competing interests (discussed below in section 5.2.1.2). However, as mentioned in the REFIT evaluation of the General Food Law, there might be a risk that strict rules become more problematic with the trend for mandatory public-private partnerships in scientific research (implying even public-sector experts will have connections with industry).²¹⁵

In addition, there are challenges to the attractiveness of working as an expert. The number of experts applying to Panels (and the number of eligible applicants) for the period of review was

²⁰⁸ European Food Safety Authority, *EFSA explains Scientific Panel renewal* (Parma, Italy, 2013).

²⁰⁹ Hubert Deluyker and others, *Survey of Institutions Employing EFSA Panel Members*, 2017.

²¹⁰ An internal assessment conducted by EFSA in 2016 estimated that EFSA's work can require more than 50 days a year for experts.

²¹¹ European Food Safety Authority – EFSA, 'Scientific independence and integrity', 2011

<<https://www.efsa.europa.eu/en/press/news/110111>> [accessed 4 May 2018].

²¹² European Commission, 'Impact Assessment on the Revision of Regulation (EC) No 178/2002 Laying down the General Principles and Requirements of Food Law, Establishing EFSA and Laying down Procedures in Matters of Food Safety on the Establishment of Fees for EFSA', *European Commission*, 57/April (2016).

²¹³ Deloitte, *Ex Post Evaluation of the Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority (EFSA) and of Its Implementing Rules on Declaration of Interest - Final Summary Report*, 2017.

²¹⁴ EFSA Executive Office, *Appointment of the members of the Scientific Committee and eight Scientific Panels and placement of suitable candidates in the reserve list* (Parma, Italy, 2012); EFSA Executive Directorate, *Report on the evaluation of applicants for membership in the 8 Scientific Panels and the Scientific Committee of EFSA and placement of suitable candidates on the reserve list*, 2015.

²¹⁵ European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) No 178/2002) – Appendices* (Brussels, Belgium, 2018).

relatively stable. During the period under review, the number of eligible applicants slightly increased, from 848 in 2009 (the last renewal before the period under review), to 871 in 2012, and to 935 in 2015.²¹⁶ This could be taken as a positive indicator of the continued attractiveness of the system. However, in 2017, EFSA reported that it did not reach its target for the “total number of applicants for Panel renewal”, despite considerable efforts, showing its difficulties in attracting new Panel members.²¹⁷ For example, in 2012, 59% of the candidates served a first term on a Panel.²¹⁸ They were only 24% in 2014 for the ANS Panel and 37% for the CEF Panel. This number dropped to 19% in 2017 for both Panels.²¹⁹ These figures, when taken with the feedback and threats shared over the course of the evaluation, show that there are fewer new candidates proposed for nomination over the years.

The lack of recognition and visibility of experts outside of the risk assessment sphere further reduces the attractiveness of expert positions, especially for (young) scientists (as explained below). Between the 2012 and 2015 renewals, the average age of Panel experts increased, from 53.6 years to 55.3 years²²⁰, while for the 2018 Panel renewal, which is not strictly in the period of review, the average age of experts appointed was 54 years.²²¹

Multiple experts from the Scientific Committee and Panels (four) provided insight into some of their concerns relating to balancing their contributions to EFSA with progressing their career, which apply more strongly to young and mid-career researchers. They explained that their EFSA work is not necessarily visible outside of the risk assessment sphere, what matters more for career advancement is being published in high impact publications and progressing within their home organisations. As per its Annual Activity Report 2016, EFSA began assigning authorship to its scientific outputs in that year, to improve its ability to attract and retain experts.²²² EFSA was not cited by Web of Science during the period under review and the move of the EFSA Journal to Wiley, which improved the accessibility of the Authority’s publications, was very recent at the time of writing. Data provided by EFSA on 24 May 2018 show a continuous increase in the number of times it is cited per year over the period under review, from about 300 times in 2011, to slightly less than 2,000 in 2016.

Evidence suggests that there may be an issue that experts are not attracted by **the type of work**. Interviews conducted for this evaluation revealed that EFSA’s strict and standardised production processes, and the amount of routine authorisation work can make EFSA’s work less attractive to experts. As demonstrated by Lloyd’s 2015 Quality Management Systems implementation assessment (which only looks at a sample of activity), 30% of the AHAW and PLH Panels’ time was spent on providing preparatory work.²²³

Linked to the above-mentioned problems is the fact that scientists also see limited links between the top-quality knowledge they generate and policy, making the work less attractive to them (as a report from the European Policy Centre²²⁴ showed).

In addition, despite EFSA’s achievements in facilitating 20% of all meetings virtually and the existence of an airport shuttle service²²⁵, EFSA’s **location in Parma** remains a discouraging factor

²¹⁶ European Food Safety Authority, *Report on the evaluation of scientific experts to be considered for the membership of eight Scientific Panels and the Scientific Committee (2009)*, 2009; EFSA Executive Office, *Appointment of the members of the Scientific Committee and eight Scientific Panels and placement of suitable candidates in the reserve list* (Parma, Italy, 2012); EFSA Executive Directorate, *Report on the evaluation of applicants for membership in the 8 Scientific Panels and the Scientific Committee of EFSA and placement of suitable candidates on the reserve list*, 2015.

²¹⁷ European Food Safety Authority, *EFSA Consolidated Annual Activity Report 2017 (DRAFT)* (Parma, Italy, 2018).

²¹⁸ EFSA Executive Office, *Appointment of the Members of the Scientific Committee and Eight Scientific Panels and Placement of Suitable Candidates in the Reserve List* (Parma, Italy, 2012).

²¹⁹ European Food Safety Authority, *Renewal of the Panel on food additives and nutrient sources added to food (ANS) and the Panel on food contact materials, enzymes, flavourings and processing aids (CEF)*, 2017.

²²⁰ Ernst&Young, *External Evaluation of EFSA - Final Report*, 2012; EFSA Executive Directorate, *Report on the Evaluation of Applicants for Membership in the 8 Scientific Panels and the Scientific Committee of EFSA and Placement of Suitable Candidates on the Reserve List* (Parma, Italy, 2015).

²²¹ European Food Safety Authority, *Panel Renewal 2018 – Management Board Meeting 21 March 2018*, 2018.

²²² European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

²²³ Lloyd’s Register LRQA, *QMS Implementation Assessment for EFSA – European Food Safety Authority*, 2015.

²²⁴ EPC, ‘Science and decision-making – A relationship under strain’, 2013
<http://www.epc.eu/events_rep_details.php?pub_id=3467&cat_id=6>.

²²⁵ EFSA Executive Director Office, *Management Self-Evaluation* (Parma, Italy, 2017).

to attracting experts. This is not only linked to the inconvenience in travelling for meetings (in a location poorly served by air links), but also to the fact that the location requires experts to be away from their home institutions longer than if the Authority was in a more accessible location.²²⁶ While EFSA is already combining face to face meetings in Parma with more teleconferences and online meetings, as well as increasing the use of tools such as online shared-folders, webinars, shared-screens, etc. the feedback received as part of this evaluation shows that this remains an issue.

The 2012 External Evaluation of EFSA raised concerns about the sustainability of the scientific system. Six years later, the findings from across the data sources reviewed for the period 2011-2016, again found the sustainability of the scientific system – particularly the model for engaging independent experts – to be a long-term risk. This was also the conclusion reached by the REFIT evaluation of the General Food Law, which found “negative signals” relating to the capacity of EFSA to maintain a high level of scientific expertise and to fully engage all Member States in scientific cooperation.²²⁷ A follow up consultation for a proposed targeted revision to the General Food Law Regulation includes measures to increase Member State involvement by reinforcing the resources of the Authority and giving it access to a large pool of scientific experts nominated by Member States.²²⁸

Summary of findings and progress relative to baseline

EQ 3a (Effectiveness): To what extent has EFSA contributed to creating and maintaining a sustainable scientific system, able to respond to needs from risk managers and to address emerging risks by delivery of fit-for-purpose and state-of-the-art scientific advice?

The use of external experts is positively associated with the delivery of state-of-the art scientific advice, as is the technical support provided by EFSA staff, whereas there are some questions about the adequacy of the peer review system on pesticides dossiers (and this is therefore the subject of a more detailed review under the remit of DG SANTE). EFSA can respond to risk managers’ needs and the introduction of a feedback mechanism in 2013 has allowed for areas for improvement to be identified and greater engagement with its customers to adequately respond to their needs. Relatively minor issues (for instance regarding clarity and timing concerns) have been raised and action is being taken but it is too early for a definitive assessment of this action.

While EFSA has contributed to creating, and maintaining a scientific system that responds to risk managers’ needs, there are issues around its sustainability, a concern which was also raised during the 2012 External Evaluation of EFSA. A weakness which is repeated in many sources of evidence is that the reliance on unpaid external experts represents a long-term risk to sustainability. While evidence was found regarding efforts being made to make internal adjustments (for example to adjust the proportion of preparatory work done in house and by experts), the relationship with external experts represents a real long-term risk to sustainability.

5.2.1.2 Scientific data and evidence

To what extent are the current practices for collecting scientific data and evidence adequate for EFSA’s risk assessment? (EQ 9)

²²⁶ In relation to this, one Panel member explained that he has seven Panel meetings of two days per year, and at least the same amount of Working Group meetings per year. This means that he is currently spending two days every two weeks in Parma.

²²⁷ European Commission, *Executive Summary of the Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002)* (Brussels, Belgium, 2018).

²²⁸ For more information: European Union, ‘Transparency and sustainability of the EU risk assessment in the food chain’, 2018 <https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en> [accessed 4 May 2018].

Coverage of the question

The objective of the question is to evaluate the EFSA's practices for collecting scientific data and evidence. Collection of data is the subject of Article 33 of Regulation (EC) N° 178/2002: "The Authority shall search for, collect, collate, analyse and summarise relevant scientific and technical data in the fields within its mission"²²⁹. Collection of data is a fundamental component of EFSA's risk assessment activities. As outlined on its website, EFSA carries out two types of data collection:

- Ongoing collection of harmonised EU-wide data to assess and monitor trends over time and support risk management measures;
- Specific collections to support risk assessments and other tasks – the question focuses on this second kind of activity (with a focus on risk assessment rather than risk management).

EFSA receives data from different parties, such as Member States, the European Commission, research institutions, and industry.²³⁰ Data collection is hence closely related to scientific cooperation and networking, as EFSA relies on other organisations operating in the same fields, including those from third countries and international bodies. This constitutes the third of EFSA's three scientific activities – "Activity 3: Data Collection, Scientific Cooperation and Networking". Indeed, EFSA depends on this activity to complete its risk assessment mission, based on sound evidence.

Sources of evidence

In addition to EFSA's Annual Activity Reports, the Authority's recent Management Self-Evaluation from late 2017 (annexed to this report as EFSA's request) and information regarding the data collection system provided online were reviewed. Given the potential bias in self-reporting, this was corroborated with an assessment from the European Commission Internal Audit Service, on Scientific Support to Risk Assessment and Evaluation of Regulated Products with Focus on Data Collection and Analysis.

The results from our online survey were limited to two questions, both of which received over 1,000 responses. The evidence gathered from interviews on this topic was not considered strong because of the small number of responses. Findings are presented where they add useful corroborating insights, or from particularly credible informants.

Baseline

The 2012 External Evaluation of EFSA found that data collection was compliant with Regulation (EC) N° 178/2002 and adequately supported the Authority's risk assessment activities. Data were of quality, accessible and available. Nonetheless, the evaluation also recommended EFSA:²³¹

- improve the compatibility of the Data Collection Framework with national IT systems, making the formats for data submission more flexible and usable for all Member States;
- identify strategies to harmonise EFSA's collection requirements with non-European ones.

EFSA's Management Board acknowledged that the Authority should improve its IT systems to enhance data sharing with Member States, provide training on data collection where needed and contribute to harmonisation of data collection systems (among others).

Analysis of evidence

Systems have been upgraded to ensure better data collection and evidence management to support risk assessment

EFSA's own documents demonstrate the steps the Authority has taken to address shortcomings in data collection and evidence management to better support risk assessment activities, as does its Management Self-Evaluation (see Appendix 6). This is corroborated by the Internal Audit Service

²²⁹ Article 33, Regulation (EC) N° 178/2002.

²³⁰ European Food Safety Authority – EFSA, 'Calls for data' <<https://www.efsa.europa.eu/en/calls/data>> [accessed 4 May 2018].

²³¹ Ernst&Young, *External Evaluation of EFSA – Final Report*, 2012.

(IAS) of the European Commission. In its 2015 Final Audit Report, the IAS identified the following strengths of EFSA's current practices for collecting data and evidence management:²³²

- The **Data Collection Framework** (DCF)²³³ web-based system allows providers to submit their files for different collections, and ensures that the dataset is compliant with EFSA IT standards. It also enables sharing with EU Member States, international bodies and third countries.²³⁴
- The **Evidence Management Unit** (DATA) carries out data collection activities to assess and monitor trends over time and centralises data collection/management and dietary exposure assessment since 2014.²³⁵
- The **Data Warehouse** (DWH), developed in 2015, allows the publication, analysis and distribution of data EFSA collected, in different formats and at various levels of granularity.²³⁶ The data are accessible through tables, reports, graphs, maps and dashboards, which are updated regularly.²³⁷ With this, EFSA aims to make available as much as possible of the data it holds.²³⁸
- The **Information Management Programme**, set up in 2015, coordinates and monitors IT projects handling EFSA's information.²³⁹ It includes projects such as "Open SCAIE", which aims to provide access to scientific information needed for evidence-based risk assessment, such as peer and non-peer reviewed documents, mathematical models and data not in the scientific data warehouse; and the information governance launched in 2016 aiming to set up organisation-wide information governance.²⁴⁰
- An ongoing data standardisation process to achieve standardisation of data-exchange formats with ECHA and EMA.²⁴¹
- Various tools that EFSA developed to assist data collection and evidence management, such as detailed guidance and support to the external data providers, or a standard format for data transmission. For example, EFSA has improved its food classification and description system "FoodEx2", which was first released in 2011 and went through a testing and feedback phase. It was updated and re-released in 2015.²⁴² The system is now being adapted to the international level, in cooperation with WHO and FAO, as the Global Individual Food consumption data Tool (GIFT).²⁴³

In addition, following up on its Management Board's recommendations, EFSA introduced a 'Data and methodologies' section in the template for its scientific outputs.²⁴⁴

In 2015, an IAS audit concluded that EFSA lacked a comprehensive framework for data governance, which would clearly define responsibilities and accountability for all scientific data domains.²⁴⁵ Consequently, EFSA included the setting up of an "Information Governance Framework" within the Information Management Programme launched in 2015.²⁴⁶

²³² European Commission - Internal Audit Service, *Final Audit Report on Scientific Support to Risk Assessment and Evaluation of Regulated Products with Focus on Data Collection and Analysis in the European Food Safety Authority (EFSA)*, 2015.

²³³ The DCF already existed at the time of the 2012 External Evaluation of EFSA, but has been improved since then.

²³⁴ EFSA RASA, REPRO, COMMS, BUS Departments, *Internal document follow-up on implementation of EFSA's Management Board recommendations, (Draft)*, 2017.

²³⁵ European Food Safety Authority – EFSA, 'Data collection' <<http://www.efsa.europa.eu/en/topics/topic/data-collection>>; European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

²³⁶ European Food Safety Authority, *The EFSA Data Warehouse access rules*, 2015.

²³⁷ European Food Safety Authority – EFSA, 'Data collection, standardisation and analysis' <<https://www.efsa.europa.eu/en/science/data>> [accessed 4 May 2018].

²³⁸ European Food Safety Authority – EFSA, 'Opening EFSA's "treasure trove" of food safety data', 2015 <<https://www.efsa.europa.eu/en/press/news/150302>> [accessed 4 May 2018].

²³⁹ European Food Safety Authority, *Information Governance Framework at EFSA*, 2017.

²⁴⁰ European Commission - Internal Audit Service, *Final Audit Report on Scientific Support to Risk Assessment and Evaluation of Regulated Products with Focus on Data Collection and Analysis in the European Food Safety Authority (EFSA)*, 2015.

²⁴¹ EFSA's Management Board, *Programming Document 2018-2020 (Draft)* (Parma, Italy, 2017).

²⁴² European Food Safety Authority, *The food classification and description system FoodEx2 (revision 2)*, 2015 <<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2015.EN-804>>; European Food Safety Authority – EFSA, 'Data standardisation' <<https://www.efsa.europa.eu/en/data/data-standardisation>> [accessed 4 May 2018].

²⁴³ The food categorisation and description system called FoodEx2 was originally developed by EFSA to serve as a catalogue for food items consumed in the EU member countries and as a harmonising tool for the Member Countries' food consumption surveys. EFSA expanded it further through collaboration with FAO and WHO, to cover foods consumed globally and serve as a harmonisation tool for data to be inserted in FAO/WHO GIFT. The system is being updated by EFSA once a year. See FAO/WHO, *FAO/WHO Global Individual Food Consumption Data Tool - GIFT*, 2017.

²⁴⁴ European Food Safety Authority, *Information Governance Framework at EFSA*, 2017.

²⁴⁵ European Commission - Internal Audit Service, *Final Audit Report on Scientific Support to Risk Assessment and Evaluation of Regulated Products with Focus on Data Collection and Analysis in the European Food Safety Authority (EFSA)*, 2015.

²⁴⁶ A summary file with an overview of progress at 14 June 17 showed that EFSA is part way through its "Information Governance Roadmap". See European Food Safety Authority, *Information Governance Framework at EFSA*, 2017, <https://joinup.ec.europa.eu/sites/default/files/inline-files/9_Session%20I_PRESA%20ZUNINO.pdf>.

A positive perception of EFSA's data collection system is supported by the survey results. Over 75% of more than 1,000 respondents believed EFSA had access to the data and evidence needed to provide useful risk assessments to policy makers at national and EU level. More specifically 35% of respondents agreed to a high extent and 42% to a moderate extent. This was consistent across all groups (which included internal and external views). Similarly, the utility of "structured and unstructured data (e.g. data warehouse and EU summary reports)" was either to a large or moderate extent useful for 81% of the 877 respondents who expressed an opinion (385 respondents did not know or selected not applicable).

Challenges for effective data collection are largely outside of EFSA's control

Challenges relating to effective data collection were identified, but they are not considered to be within EFSA's direct control. The strong dependency on external providers²⁴⁷ was identified in 2015 as part of an IAS audit as one of the main challenges EFSA faces for data collection to adequately support its risk assessment activities.²⁴⁸ The same audit stated that the other main challenges EFSA faced in fulfilling its mandate for data collection and analysis were the increasing number of data management related service requests, and the changing priorities to fulfil urgent or unforeseen requests by the Authority's stakeholders.²⁴⁹

Summary of findings and progress relative to baseline

EQ 9 (Effectiveness): To what extent are the current practices for collecting scientific data and evidence adequate for EFSA's risk assessment?

Evidence from the documentary review and in-depth interviews shows the practices for collecting scientific data and evidence have improved significantly since the previous evaluation, and evidence was found to confirm that weaknesses have been systematically addressed (including specifically improving the compatibility of data of the Data Collection Framework and improvements to the accessibility of the data and information).

The remaining challenges which emerged from the documentary review are largely outside of EFSA's control, namely the reliance on external providers (i.e. the issue about sustainability of the model) and increasing volume of requests (i.e. the issue about managing competing demands with limited resources, as discussed under the previous question).

5.2.2 Scientific cooperation and reputation at EU and global levels

To what extent has EFSA contributed to an improved harmonisation of methodologies and coherence of approaches on food safety at EU and global levels through its networking and cooperation with EU and global risk assessment authorities? (EQ 3c)

Coverage of the question

The objective of the question is to evaluate the systems EFSA has put in place for EU level cooperation; and the initiatives it has implemented to achieve its objectives with respect to international cooperation, as means to improve harmonisation of methodologies and coherence of approaches on food safety.²⁵⁰ Harmonisation of methodologies refers to the need for the use of common risk assessment methodologies. It is a means to enhance confidence and robustness in risk assessment and avoid duplication of work and diverging opinions, especially at EU level.²⁵¹ This, in turn, supports coherence of approaches on food safety.

²⁴⁷ National Food, Feed and Veterinary Institutes, local and regional competent authorities, competent laboratories and universities, research institutions, academia, trade associations, and food business operators.

²⁴⁸ It specified that this could undermine collaborative decision-making and fostering of shared responsibility for EFSA's data assets.

²⁴⁹ European Commission - Internal Audit Service, *Final Audit Report on Scientific Support to Risk Assessment and Evaluation of Regulated Products with Focus on Data Collection and Analysis in the European Food Safety Authority (EFSA)*, 2015.

²⁵⁰ European Food Safety Authority, *Scientific Cooperation Roadmap 2014-2016* (Parma, Italy, 2014).

²⁵¹ European Food Safety Authority, *EFSA Scientific Network for Harmonisation of Risk Assessment methodologies*, 2013.

In its Science Strategy 2012-2016, EFSA set the development and harmonisation of methodologies to assess risks associated with the food chain and to strengthen the scientific basis for risk monitoring, as one of its main objectives at *global level*.²⁵² This was reiterated in its Multi-Annual Programme on International Scientific Cooperation 2014-2016.²⁵³ Yet, international organisations consider a level of health protection that is fit for most countries, while EFSA's work is the scientific basis for EU law, which usually sets higher levels of health protection. Coherence of approaches on food safety at global level is hence covered more extensively under section 5.4.2, including through the work of CODEX. At EU level, coherence refers to the goal of having a common approach to food safety among Member States and talk with one voice to ensure that the public receives consistent food safety advice and increase trust in the food safety system.²⁵⁴ The question assesses the extent to which EFSA's cooperation and networking activities have *contributed* to an improved harmonisation of methodologies and coherence of approaches on food safety at EU and global levels.

Sources of evidence

The 2012 External Evaluation of EFSA and corresponding Management Board recommendations provide the baseline for this evaluation. For the period of review, EFSA's Scientific Cooperation Roadmap 2014-2016 constituted the starting point for identifying priorities and strategic direction. Progress on its implementation was captured in EFSA's Scientific Cooperation Annual Reports 2014-2016, in addition to the 2015 Mid-Term Report to EFSA's Management Board. These were used as sources of evidence for both EU and international levels.

Focal Point Activities and Article 36 Reports were used to evaluate the impact of cooperation and networking at EU level on harmonisation of methodologies and coherence of approaches prior to the Roadmap. To assess the extent to which EFSA's cooperation and networking activities contributed to an improved harmonisation of methodologies and coherence of approaches on food safety at EU level, external sources were examined, including the European Court of Auditors' 2016 Special Report on Agencies' Use of Grants²⁵⁵, and ICF's Reputation barometer²⁵⁶, as well as national and international agencies' websites and publications. Interviews with members of the Advisory Forum and Focal Points provided valuable qualitative insights supporting the documentary evidence.

In terms of cooperation and networking at international level, the challenges and achievements of EFSA's Multi-Annual Programme on International Scientific Cooperation 2014-2016 were reviewed. Additional external sources were required to assess EFSA's contribution to harmonised and coherent approaches to food safety at global level. Joint publications, as well as international organisations' and third countries' own publications provided robust evidence, with corroborating academic papers. Interviews with representatives of four international organisations (WHO, OIE, FAO and JECFA/JMPR) and third countries, DG TRADE and DG SANTE also provided qualitative insights.

In addition, the online survey was a reliable source of evidence, providing the opinions of 1,210 respondents on the state-of-play of harmonisation of methodologies and coherence of approaches on food safety across the EU and at global level, and on EFSA's contribution to it. In the analysis of the survey, attention was specifically paid to the 185 responses from representatives of Member States' risk management or assessment bodies, and EEA and candidate countries, and the 44 responses from third country representatives.

²⁵² European Food Safety Authority, *Science Strategy 2012-2016* (Parma, Italy, 2012).

²⁵³ EFSA Advisory Forum and Scientific Cooperation Unit, *Multi-Annual Programme on International Scientific Cooperation 2014-2016* (Parma, Italy, 2014).

²⁵⁴ European Food Safety Authority, *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

²⁵⁵ European Court of Auditors, *Special Report No 12 - Agencies' Use of Grants: Not Always Appropriate or Demonstrably Effective* (Luxembourg, 2016).

²⁵⁶ ICF, *Reputation Barometer* (London, UK, 2017) – which strictly falls outside of the period of review but provides a snapshot for the end of the period.

Baseline

The 2012 External Evaluation of EFSA concluded that there was scope to enhance cooperation at EU level, by better sharing responsibilities, priorities and future workloads, to improve harmonisation and coherence of approaches to food safety and consequently avoid duplication of work and divergent opinions with Member States and EU institutions. EFSA's Management Board recommended that the Authority should define a common EU risk assessment agenda, reinforce cooperation, coordination (especially through the Advisory Forum), and networking on a multiannual basis. Their recommendations also focused on increasing EU risk assessment capacity.

The 2012 External Evaluation of EFSA recommended that the Authority enhance its international role and recognition, and improve links with third countries and international organisations, through formal agreements and collaboration frameworks. The ensuing recommendations from the Management Board brought in specific goals at international level, including the development of a framework for cooperation with international partners such as the WHO, OIE, FAO and CODEX Alimentarius.

Analysis of evidence

EU level

EFSA contributes to harmonisation of methodologies and coherence of approaches at EU level

Over the period under review, EFSA carried out many activities, including trainings for Member States on its risk assessment methodologies and on approaches to risk assessment, the preparation of guidelines on methodologies, the organisation of meetings and targeted consultation with Member States on draft guidance documents at network meetings. At EU level, the Authority also worked toward harmonisation, including within Member States, through the work of the Advisory Forum, Focal Points²⁵⁷ and scientific networks. EFSA's unique position as a facilitator for coordinating exchanges with Member States paved the way for improved coordination and networking *between* and *within* Member States.²⁵⁸ These have been instrumental in improving harmonisation of methodologies at EU level, but also coherence of approaches. By providing a forum where Member States can exchange knowledge, methods and ideas, EFSA is contributing to a less fragmented approach to risk assessment at EU level. This is evidenced by the small number of identified divergences between EFSA and Member States (7 from a total of 1,117 scientific opinions over the period 2011-2014²⁵⁹) and the even lower number of unsolved divergences (see Table 10 below).

Table 10: List of scientific divergences subject to Article 30 procedure (2011-2014)

Year	Topic of the controversial issue	Unit responsible	Result of divergence
2011	Sweeteners	ANS	Solved
	Coumarin	NDA	Solved
	Bisphenol A	CEF	Confirmed
2012-2014	Bisphenol A	FIP	Confirmed
	Caffeine	Nutrition	Solved
	Perchlorate	BIOCONTAM	Solved
	Mycotoxins T2/HT2	BIOCONTAM	Confirmed

Source: European Commission, The REFIT evaluation of the General Food Law (Regulation (EC) N° 178/2002) – Appendices, 2018 (pp.81-82)

²⁵⁷ See European Food Safety Authority, *Focal Point Activities 2011* (Parma, Italy, 2012); *Focal Point Activities 2012* (Parma, Italy, 2013); *Focal Point Activities 2013* (Parma, Italy, 2014).

²⁵⁸ European Food Safety Authority, *Annual Report on Article 36 Activities 2011* (Parma, Italy, 2012); European Food Safety Authority, *Article 36 Report 2012 - Activities on the Article 36 List and Networking with Article 36 Organisations* (Parma, Italy, 2013); European Food Safety Authority, *Article 36 Report 2013 - Activities on the Article 36 List and Participation of Article 36 Organisations in EFSA's Grant and Procurement Schemes, EFSA Supporting Publications* (Parma, Italy, 2014) <<http://doi.wiley.com/10.2903/sp.efsa.2014.EN-612>>; European Court of Auditors, *Special Report No 12 - Agencies' Use of Grants: Not Always Appropriate or Demonstrably Effective* (Luxembourg, 2016).

²⁵⁹ 1,117 scientific opinions found on EFSA's website over the period 2011-2014, European Food Safety Authority – EFSA, 'Scientific Outputs at a glance' (filters: type = scientific opinion; date = from 01/01/2011 to 31/12/2014) <https://www.efsa.europa.eu/en/publications/?start_date=1293836400&end_date=1419980400&f%5B0%5D=sm_field_so_type%3Aopinion> [accessed 27 June 2018].

The Authority has also supported the improvement of Member States' risk assessment capacity. Specific mechanisms included the exchange of information and experiences between national authorities and EFSA, for example, through the Advisory Forum Working Group on Communications (AFCWG), and support to cooperation and mentoring directly among Member States organisations, through training and thematic grants for instance. By building risk assessment capacity in the Member States based on common ground, EFSA contributes to the harmonisation of methodologies and coherence of approaches across the EU. EFSA also developed a common risk assessment agenda.²⁶⁰

The outcome of these networking and cooperation activities has contributed to harmonisation of approaches. The survey found that 78% of respondents²⁶¹ believed that methodologies and approaches were harmonised and coherent at EU level, either to a high or moderate extent. More specifically, 76% of representatives of national risk management or assessment bodies of EU Member States, EEA or accession or candidate countries agreed either to a high or moderate extent. In addition, AFCWG members positively stood out, with 83% of them (23 responses) agreeing to a high or moderate extent. Specific views the degree to which EFSA's tools increase risk assessment capacity at MS level (and build capacity in third countries) were not in scope for the evaluation²⁶². However, EFSA's own analysis of survey responses found that there were some nuances in the views expressed: that the staff exchange tool was less positively assessed compared to training, workshops and joint events.

Limitations to harmonisation beyond EFSA's control

Despite the improvements highlighted above, remaining imbalances in Member States' risk assessment capacity and political factors that come into play across EU countries were identified as challenges to further harmonisation. Four of 19 interviewees stressed that some Member States are inclined to see EFSA's opinions as secondary to their own, and hence prefer to continue carrying out their own assessments, leading to duplication of work and potentially diverging opinions. While this is a minority view, it nonetheless highlights the challenges in seeking harmonisation.

International level

EFSA made efforts to contribute to harmonised methodologies and approaches to food safety internationally over the period of review

Over the period under review, EFSA strengthened bilateral relations with third countries' competent authorities, including through four Exchanges of Letters²⁶³ and four Memoranda of Cooperation²⁶⁴ (2011-2016), which set a formal basis to stimulate harmonisation in food safety risk assessment methods and approaches. We recognise that these are outputs, but we have not found evidence of tangible results, given that it was outside the scope of this evaluation to approach these organisations extensively to gather data. The content of these formal agreements is nonetheless paving the way for improved harmonisation of methodologies at international level in the future.

The documentary review also revealed evidence of cooperation between EFSA and international organisations²⁶⁵, towards the harmonisation of methodologies, and resulting in the publication of joint guidance for harmonising risk assessment.²⁶⁶ EFSA noted good progress in the cooperation

²⁶⁰ European Food Safety Authority, *Scientific Cooperation Annual Report 2014* (Parma, Italy, 2015) <<https://efsa.onlinelibrary.wiley.com/doi/epdf/10.2903/sp.efsa.2015.EN-788>>; European Food Safety Authority, *Scientific Cooperation Annual Report 2015* (Parma, Italy, 2016); European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017).

²⁶¹ EFSA's staff and Management Board members were excluded from this question, n=1,210.

²⁶² As agreed in the Inception Report, certain questions were added to the Evaluation Survey for EFSA's own analysis (as per Appendix 4 of the inception report). The information referred to here pertains to question 64 of the survey, not assessed by the evaluators.

²⁶³ With New Zealand's Ministry for Primary Industries (MPI), the United States Department of Agriculture (USDA)'s Animal and Plant Health Inspection Service (APHIS) and Epidemiology & Animal Health (CEAH), the USDA's Agricultural Research Service (ARS), and the USDA's Food Safety and Inspection Service (FSIS).

²⁶⁴ With the Canadian Food Inspection Agency (CFIA), the Chinese national Centre for Food Safety risk Assessment (CFSA), the Agencia Chilena para la Inocuidad y Calidad Alimentaria (ACHIPIA), and the Food Safety Commission of Japan (FSCJ).

²⁶⁵ Including the World Health Organisation (WHO), the Food and Agriculture Organisation (FAO), the World Organisation for Animal Health (OIE) and the European and Mediterranean Plant Protection Organisation (EPPO).

²⁶⁶ Examples include collaboration with WHO and FAO Joint Expert Committees on developing internationally harmonised methodologies and approaches for risk assessment, data collection and risk communication. See European Food Safety Authority,

with WHO and FAO, on harmonised approaches for the collection of food consumption and composition data at international level.²⁶⁷ This was corroborated by FAO/WHO's briefing document on the Global Individual Food consumption data Tool, which indicates that the collection process will be similar to the EU comprehensive database within EFSA²⁶⁸. The document refers to EFSA as a key partner in the development of the GIFT, specifying that the FAO/WHO team worked with the Evidence Management Unit to scale up EFSA's food categorisation and description system²⁶⁹ at the global level.²⁷⁰

EFSA also contributed to an improved harmonisation of methodologies at global level through multilateral activities, including active participation in workshops, seminars, meetings and International Liaison Groups²⁷¹ on harmonisation of methodologies, both with partner countries and international organisations.²⁷² Resulting changes in risk assessment methodologies include EFSA's guidance on the benchmark dose (BMD) approach²⁷³; and the Threshold of Toxicological Concern (TTC) approach²⁷⁴. In addition, EFSA provides scientific and technical support to the EU delegation to the CODEX Alimentarius, which is developing international food safety standards, on request of the Commission.²⁷⁵

Harmonised methodologies and coherent approaches remain limited at international level

The documentary review did not produce further evidence of harmonised methodologies or coherent approaches at global level. This is aligned with the survey findings, with 50% of the 1,210 respondents (excluding EFSA staff) indicating that methodologies were harmonised and approaches coherent at a global level only to a limited extent, or not at all. It is important to understand the reasons for this: the interviews with representatives of international and third countries' organisations, highlighted the inherent difference of approach linked to EFSA's risk assessment mandate, as opposed to other organisations operating internationally that often hold a combined mandate for risk assessment and risk management. No evidence of scientific divergence between EFSA and international bodies was identified, apart from one instance relating to Glyphosate, where EFSA was not in agreement with the International Agency for Research on Cancer. In this case EFSA was aligned with other national and international bodies²⁷⁶.

In addition, seven out of 16 interviewees who provided an opinion highlighted that external factors beyond EFSA's control limit its capacity to contribute to coherence of approaches at global level. Inherent differences between countries, including their size, various levels of health protection, and differing levels of resources dedicated to regulatory research and science, sometimes necessitate different approaches.²⁷⁷ Despite these challenges and the continued need for a coherent approach, EFSA has achieved its objective of *contributing* to a more coherent approach to food and feed safety.

Annual Report 2011 (Parma, Italy, 2012); *Annual Report 2014* (Parma, Italy, 2015); *Annual Report 2015* (Parma, Italy, 2016); *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

²⁶⁷ European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017).

²⁶⁸ At that time, the database contained 51 surveys from 23 EU countries, covering all age classes from infants to elderly.

²⁶⁹ The food categorisation and description system called FoodEx2 was originally developed by EFSA to serve as a catalogue for food items consumed in the EU member countries and as a harmonising tool for the Member Countries' food consumption surveys. EFSA expanded it further through collaboration with FAO and WHO, to cover foods consumed globally and serve as a harmonisation tool for data to be inserted in FAO/WHO GIFT. The system is being updated by EFSA once a year.

²⁷⁰ FAO/WHO, *FAO/WHO Global Individual Food Consumption Data Tool - GIFT*, 2017.

²⁷¹ Such as the International Liaison Group on Methods for Risk Assessment of Chemicals in Food (ILMERAC).

²⁷² EFSA Advisory Forum and Scientific Cooperation Unit, *International Scientific Cooperation Work Plan 2017-2020 (Draft)*, 2017.

²⁷³ The associated workshop that took place in March 2017 allowed the 60 representatives of partner organisations to reach a consensus on the principles behind the dose-response modelling and benchmark dose analysis European Food Safety Authority – EFSA, 'Workshop confirms BMD approach as the best method for dose-response modelling in risk assessment', 2017 <<https://www.efsa.europa.eu/en/events/event/170301-0>> [accessed 4 May 2018].

²⁷⁴ EFSA reviewed it together with WHO, implementing an expert workshop, informed through a public call for data and an open stakeholder meeting EFSA (European Food Safety Authority) and WHO (World Health Organization), *Review of the Threshold of Toxicological Concern (TTC) Approach and Development of New TTC Decision Tree*, EFSA Supporting Publication, 2016 <http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/1006e.pdf> [accessed 4 May 2018].

²⁷⁵ The Codex Alimentarius coordinates the harmonisation of food standards and requirements. See European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002) - Appendices* (Brussels, Belgium, 2018).

²⁷⁶ From Canada, Japan, Australia and New Zealand, and the Joint UN Food and Agriculture Organisation/World Health Organisation Meeting on Pesticide Residues (JMPR). See European Commission, *Communication from the Commission on the European Citizens' Initiative 'Ban Glyphosate and Protect People and the Environment from Toxic Pesticides'* (Strasbourg, France, 2017).

²⁷⁷ Keiji Fukuda, 'Food Safety in a Globalised World', *Bulletin of the World Health Organization*, 2015, 209–84 <<http://www.who.int/bulletin/volumes/93/4/15-154831/en/>> [accessed 24 April 2018].

EFSA's international engagement can be misinterpreted

Representatives of international organisations consulted for this evaluation identified concerns and revealed some misinterpretation of EFSA's engagement beyond the EU. These were primarily concerns over potential overlap with their own international mandate, and the prospect of EFSA trying to lead and set global standards. EFSA does not have the mandate to lead and set global standards for the international community, and representatives of international organisation saw this as their role – and their committees', such as the Joint FAO/WHO Expert Committee on Food Additives (JECFA). They were not suggesting that EFSA should withdraw from its international activities, but the shared request was to further formalise working arrangements with a view to establishing clear procedures and responsibilities. This points to a misunderstanding regarding EFSA's risk assessment mandate and the need for clearer communication of EFSA's specific role.

EFSA's overall contribution to harmonisation of methodologies and coherence of approaches (EU and global levels)

EFSA's activities have contributed to harmonisation of methodologies and increase in coherence of approaches

Survey respondents were asked to consider EFSA's contribution to harmonisation and increase in coherence at EU and global levels (without distinguishing between the two) and there was a consensus that EFSA had made a positive contribution. Note that respondents were not commenting on whether there is complete harmonisation (or not), but on EFSA's contribution to harmonisation at both EU and international level.

76% of survey respondents believed EFSA's activities contributed to increasing the *harmonisation of methodologies*, at both EU and international levels, either to a high or moderate extent. 86% of representatives of third countries who provided an opinion, agreed either to a high or moderate extent. Similarly, 84% of those who provided an answer also agreed that EFSA participated in the *increased coherence of approaches* over the period 2011-2016, at both levels. 81% of third country representatives who provided an answer agreed either to a high or moderate extent.

This was confirmed by interviewees, who overall believed EFSA's activities had contributed to a more coherent food safety system. They specified that EFSA uses its scientific networks to ensure coherence of approaches. The Authority also assists (potential) candidate countries with risk assessment methods. Indeed, an Advisory Forum member mentioned that EFSA supported Croatia in adapting their methodologies upon accession. Interviewees pointed out that, in addition to Member States, several non-EU countries, including Turkey and Switzerland, have adapted their own risk assessment agencies to fit EFSA's approaches. This is corroborated by a European Parliament Report²⁷⁸.

Beyond the border of Europe, the US mentions EFSA on a regular basis, for example.²⁷⁹ Countries like Japan and China also refer to EFSA's opinions, as highlighted by interviewees from third countries, international organisations and the Stakeholder Bureau. 24 out of 36 interviewees agreed that EFSA set good standards in terms of methodologies and is adequately engaging with Member States and third countries to ensure their application.

²⁷⁸ European Parliament, DG Internal Policies of the Union, *Food Safety situation in Turkey*, 2008.

²⁷⁹ A search for 'EFSA' on FDA's website gives about 57 results, mostly after 2011. See U.S. Food and Drug Administration, 'Search Results', 2018

<https://google2.fda.gov/search?q=EFSA&client=FDAGov&output=xml_no_dtd&proxystylesheet=FDAGov&site=FDAGov&getfields=*&requiredfields=-archive:Yes&partialfields=&filter=1&sort=date:D:S:d1&ie=UTF-8&ulang=en&access=p&entqr=1&entqrm=0&wc=200&wc_mc=1&oe=UTF-8&ud=1&start=0>.

Summary of findings and progress relative to the baseline

EQ 3c (Effectiveness): To what extent has EFSA contributed to an improved harmonisation of methodologies and coherence of approaches on food safety at EU and global levels through its networking and cooperation with EU and global risk assessment authorities?

EFSA's cooperation and networking at EU level are well-established, including through the work of the Advisory Forum and Focal Point Network, and contribute to harmonisation of methodologies and coherence of approaches on food safety. Over the period under review, EFSA has gradually built a more integrated system for embedding EU level cooperation in its work, leading to improvements in harmonisation of methodologies and coherence of approaches at EU level. There are still limitations, but these are largely outside of EFSA's control as they relate to national legislative and contextual differences.

The Authority has actively *contributed* to the harmonisation of methodologies and coherence of approaches at global level to the extent possible. Given substantial differences between EU law and legislations in the rest of the world, there is an inherent limit to the contribution of EFSA's international engagement to harmonisation of methodologies and coherence of approaches at global level. Further, EFSA's risk assessment mandate differentiates it from other bodies operating globally (FAO and WHO, but also US agencies), as they often also manage (rather than solely assess) risks. International organisations sometimes misinterpret EFSA's international engagement, and clearer communication on this is required.

5.2.3 Independence, transparency, and risk communication

To what extent has EFSA contributed to creating a European food safety system that enhances citizens' trust through its independence and transparency? (EQ 3b)

Coverage of the question

EFSA operates in a complex and challenging environment, with various sensitivities around its remit. Trust is influenced by several factors, which may not always be based on facts, but on values. Within the Authority's control is the scientific excellence of its work (covered under 5.2.1.1), as well as its independence, to some extent²⁸⁰ transparency, and – crucially – how it communicates the results and processes of its work to interested parties. Independence, transparency and communication are intrinsic to EFSA's work:

- **Independence** and **transparency** are the subject of two distinct articles of Regulation (EC) N° 178/2002²⁸¹. Both are among the core values to which the Authority committed in its Programming Documents over the period and EFSA Strategy 2020.²⁸²
- Article 40 of Regulation (EC) N° 178/2002 outlines **communication** (of risks) as the Authority's second mandate, indicating that EFSA must provide reliable and easily accessible information to the general public²⁸³ and other interested parties regarding the results of its work.²⁸⁴ The Regulation also enshrines the Authority's responsibility for collaboration with Member States in promoting coherence in risk communication, and a

²⁸⁰ Notwithstanding the importance of confidentiality requirements as per Article 39 Regulation (EC) N° 178/2002 and data and copyright protection requirements (which vary depending on the sub-area of regulation concerned).

²⁸¹ Articles 37 and 38 of Regulation (EC) N° 178/2002.

²⁸² European Food Safety Authority, *Work Plan 2011* (Parma, Italy, 2011); *Work Plan 2012* (Parma, Italy, 2012); *Work Plan 2013* (Parma, Italy, 2013); *Programming Document of the European Food Safety Authority 2014-2016 Incorporating Annual Management Plan 2014 and Multiannual Plan 2014-2016* (Parma, Italy, 2013); *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

²⁸³ Article 40 specifically states that "In order to achieve these objectives, the Authority shall develop and disseminate information material for the **general public**" (emphasis added). Regulation (EC) N° 178/2002.

²⁸⁴ The General Food Law also defines 'risk communication' in Article 3, Other definitions (13), as: "the interactive exchange of information and opinions throughout the risk analysis process about hazards and risks, risk-related factors and risk perceptions, among risk assessors, risk managers, consumers, feed and food businesses, the academic community and other interested parties, including the explanation of risk assessment findings and the basis of risk management decisions". See Regulation (EC) N° 178/2002.

requirement for cooperation with interested parties regarding public information campaigns.

In addition, EU agencies are expected to use the “highest procedural standards and operate with the utmost independence”²⁸⁵.

Given the above, to assess the effectiveness of EFSA’s system for contributing to trust, the question asks for a judgement of:

1. EFSA’s activities to ensure **independence**...
2. ...and **transparency**
3. EFSA’s systems in place to **communicate** with its stakeholders, partners and citizens
4. Measures to improve **trust**

Sources of Evidence

Findings from the 2012 External Evaluation of EFSA and the ensuing recommendations from the Management Board were consulted to establish the baseline. EFSA’s relevant policies, strategies and initiatives relating to independence, transparency and communication over the period under review were consulted (for example successive Independence Policies, Open EFSA and Transparency and Engagement in Risk Assessment – TERA initiatives)²⁸⁶.

Issues relating to upholding the independence policy, trust in EFSA’s work or EFSA’s engagement with stakeholders were the subject of external research papers and evaluations. These are cited directly in the analysis where relevant.²⁸⁷ In addition, findings of the REFIT evaluation of the General Food Law and the subsequent Commission proposal for a targeted revision to tackle criticisms regarding transparency provide important external insight into EFSA’s performance.

Given the focus of this question on EFSA’s contribution to building trust, perceptions are an important indicator. Where relevant a distinction between distinct groups of survey respondents has been made. However, it was not within the scope of the evaluation to collect citizens’ views. The last Eurobarometer survey covering perceptions of food related risks was conducted in 2010²⁸⁸, meaning it related to a period outside the period under review here.

EFSA has self-set KPIs covering its independence and communication activities. These are presented where relevant though their usefulness is sometimes limited due to inconsistencies in measurement over time and lack of explanation regarding changes in targets set. For example, despite the existence of a KPI on “number of web visits”, this was not deemed robust enough to report on given that the data were not comparable over the period of review.²⁸⁹

Baseline

The 2012 External Evaluation of EFSA found that the Authority’s procedures maintained independence in line with Regulation (EC) N° 178/2002; but that EFSA could increase its capacity to deal with criticism through communication on independence and the monitoring of scientific and political criticism. With regards to transparency, there was an overall positive assessment, but the risk assessment process was found to be too closed, with the functioning of the Panels and its decision-making not being open to public scrutiny.

A recommendation from the 2012 External Evaluation was that the Authority should consider different parties’ needs (e.g. different Member States, industry, and the public) and better customise its services. The Evaluation recommended that EFSA evaluate whether the public

²⁸⁵ European Ombudsman, ‘Event summary – EU agencies – How to manage the risk of reputational damage’, 2017 <<https://www.ombudsman.europa.eu/en/activities/eventdocument.faces/en/84866/html.bookmark>> [accessed 26 June 2018].

²⁸⁶ These are cited directly in the analysis.

²⁸⁷ For instance, ECA reports were relevant in relation to independence, and EFSA has commissioned studies to look at stakeholder engagement as well as an external Evaluation of EFSA’s Policy on Independence and Scientific Decision-Making Process conducted in 2017.

²⁸⁸ European Food Safety Authority – EFSA, ‘New research results on EU consumers’ perceptions of food-related risks’, 2010 <<https://www.efsa.europa.eu/en/press/news/101117>> [accessed 4 May 2018].

²⁸⁹ Concerns were raised by EFSA regarding the comparability of the KPI data following a break in reporting in 2014. As such these data are not included here.

represents a priority target for communication and thus, design adequate information tools. Specific recommendations to improve risk communication were also made: to improve clarity in EFSA's communication; to increase the effectiveness of the website and to strengthen EFSA's role in crisis situations.

The resulting recommendations from EFSA's Management Board contained two strategic priorities: to increase trust "by continuing to ensure independence and enhancing transparency and openness" as well as "strengthen clarity and accessibility of EFSA Communication".

Analysis of evidence

Independence: EFSA has robust measures in place to ensure independence

EFSA has further strengthened measures to manage competing interests. In its mission to provide unbiased scientific advice, EFSA is committed to ensuring the independence of its experts from any undue external influence.²⁹⁰ To ensure this, there are strict policies and procedures in place for the selection of experts. Over the period under review, EFSA further revised its screening policy for candidates, making it stronger and clearer. Developments were:

- In 2011, a new policy and implementing rules strengthened procedures for screening and managing interests declared by those involved in EFSA's activities by providing a clearer and more transparent set of general principles applicable to those engaged in the Authority's work. EFSA's policy on independence and scientific decision-making process of December 2011²⁹¹ and the corresponding implementing rules of February 2012²⁹² superseded the previous policy of October 2007²⁹³ and corresponding implementing rules of September 2009²⁹⁴.
- In July 2014, the implementing rules were again updated to improve readability and present a clearer expression of principles.²⁹⁵ Criteria for the screening of Declarations of Interest (DoI) in tenders and grant awarding procedures were introduced, and requirements for outsourcing processes were simplified. This followed an independent assessment conducted in 2012 by the European Court of Auditors, which found that EFSA had (already) developed some of the most advanced policies and procedures for declaring, assessing and managing conflict of interest, but the assessment criteria for screening candidates' declarations of interest (still) lacked clarity.²⁹⁶
- Although not strictly within the period under review, a significant and relevant development is EFSA's new 2017 policy on independence and corresponding implementing decision by the Executive Director.²⁹⁷ This has further reinforced EFSA's impartiality and protection against undue external influence, responding to repeated requests from the European Parliament to introduce a "cooling-off" period²⁹⁸.

EFSA's reporting of compliance with the independence policy and rules confirms the effectiveness of EFSA's systems over the period under review:

²⁹⁰ European Food Safety Authority, 'Values' <<https://www.efsa.europa.eu/en/about/values>> [accessed 4 May 2018].

²⁹¹ European Food Safety Authority, *Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority* (Warsaw, Poland, 2011).

²⁹² EFSA – European Food Safety Authority, *Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests*, 2012.

²⁹³ European Food Safety Authority, *EFSA policy on Declarations of Interests* (Parma, Italy, 2007).

²⁹⁴ Executive Director of the European Food Safety Authority, *Implementing act to the Policy on Declaration of Interests – Guidance document on Declarations of Interest* (Parma, Italy, 2009).

²⁹⁵ EFSA Executive Director, *Decision of the Executive Director on Declarations of Interest* (Parma, Italy, 2014).

²⁹⁶ European Court of Auditors, *Special Report No 15 - Management of Conflict of Interest in Selected EU Agencies* (Luxembourg, 2012).

²⁹⁷ EFSA revised its policy on independence in June 2017 and implementing rules in October 2017 (as per the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management, which is applicable for Panel renewal 2018 and as of July 2018, for all experts). See European Food Safety Authority, *EFSA explains Independence* (Parma, Italy, 2017); *Decision of the Executive Director of the European Food Safety Authority on Competing Interests Management* (Parma, Italy, 2017); EFSA's Management Board, *EFSA's policy on independence* (Parma, Italy, 2017).

²⁹⁸ The new process includes a 'cooling off' period that bars experts from participation in Panels if they have participated in potentially conflicting activities EFSA deems relevant during the preceding two years. See EFSA Resources & Support Department, *Concept paper on the review of EFSA's Policy on independence and scientific decision-making process*, 2016. See also repeated requests from the European Parliament in their Discharge Reports.

- EFSA met its self-set KPIs in this area over the period under review²⁹⁹;
- Compliance and veracity checks on a random sample of DoIs for (up to) 30 experts from 2013 onwards did not uncover any major conflicts of interest, just minor omissions highlighting a continued need to increase understanding of reporting requirements but no cause for concern regarding the effectiveness of the system.³⁰⁰

In addition to the above, as of 2014 EFSA introduced an annual compulsory training on independence policy and rules for all staff and experts. EFSA also organised information sessions, and public consultations, to broaden accessibility and knowledge of how independence works.

Despite this, views on independence are divided demonstrating how contentious the issue is. This has been reported in studies commissioned by EFSA, the REFIT evaluation of the General Food Law³⁰¹, and was observed directly during in-depth interviews conducted for this evaluation.

On the one hand, EFSA has been praised on how it applies the principle of independence within its daily business, as well as manages potential conflicts of interest. Indeed, in 2017, more than 60% of EFSA's 298 scientific experts who responded to Deloitte's web-based survey stated that EFSA's 2011 Independence Policy and the 2014 DoI rules had positively contributed to its reputation.³⁰² This was confirmed by interviewees from a range of categories³⁰³, who were positive in their overall assessments of EFSA's independence (30 out of 44).

On the other hand, almost all interviewees highlighted that there are people who question EFSA's independence from industry. This was confirmed by open responses to the survey as 11% of the comments³⁰⁴ pointed to the need to strengthen the rules against conflicts of interest to ensure the independence of experts, and heightened transparency on the expert selection process in general. Research commissioned by EFSA in 2015³⁰⁵ and 2017³⁰⁶ drew a similar conclusion. The REFIT evaluation of the General Food Law also detailed the contrasting views on EFSA's rules on independence, which were deemed too permissive (NGOs, supported by some MEPs and Member States) or prohibitive (stakeholders and other Member States).³⁰⁷

Evidence from the survey showed 86% of 1,309 respondents considered the scientific advice provided by EFSA over the period 2011-2016 to be an unbiased, independent source of information to a high or moderate extent. Notwithstanding the strength and robustness of EFSA's policy on independence, which is considered robust, EFSA still needs to proactively manage its image. Indeed, in March 2017, Deloitte recommended that EFSA strengthen responsiveness to outspoken criticisms regarding independence policy issues for example, by more pro-active communication on conflict-sensitive topics, and by a more proactive approach in replying to complaints.³⁰⁸

²⁹⁹ Compliance is measured by two KPIs throughout the period: the proportion of experts with approved annual Declarations of Interests (DoIs) before their first meeting invitation (target met since 2013), and the proportion of experts with approved specific DoIs before participation in an EFSA meeting (target met if figures are rounded to whole numbers).

³⁰⁰ Positively, the number of experts with omissions has fallen since 2013. For 2013, 10 experts needed to update their DoI, see European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014); while in 2014, 8 experts had omissions, see European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015); and in 2015 this was the case for just 4 experts, see European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

³⁰¹ European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) No 178/2002)* (Brussels, Belgium, 2018).

³⁰² Deloitte, *Ex Post Evaluation of the Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority (EFSA) and of Its Implementing Rules on Declaration of Interest - Final Summary Report*, 2017.

³⁰³ including the Management Board, EFSA staff, and DG SANTE, but also the Stakeholder Forum, Stakeholder Bureau, as well as individuals from other groups

³⁰⁴ Survey respondents from across stakeholder groups who indicated that EFSA's activities contributed to a limited extent or not at all to building trust in food safety over the period 2011-2016 were asked how trust in the information produced by EFSA could be increased. This yielded a total of 288 responses.

³⁰⁵ In 2015, EFSA commissioned Ipsos MORI a report on stakeholders' views which showed how contentious the issue of independence is for certain groups. Representatives of NGOs consulted (nine) were concerned that some academics in the Panels have links with business, and EFSA staff can come from or move to industry. Ipsos Mori, *EFSA stakeholder research - Final report*, 2015.

³⁰⁶ Although strictly outside the scope of the present evaluation, further insight into the challenges EFSA faces is illustrated by the results of the 2017 pilot Reputation barometer commissioned by EFSA, which revealed that views and expectations vary among different stakeholder groups who have fundamentally different points of view on the subject.

³⁰⁷ European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) No 178/2002)* (Brussels, Belgium, 2018).

³⁰⁸ Deloitte, *Ex Post Evaluation of the Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority (EFSA) and of Its Implementing Rules on Declaration of Interest - Final Summary Report*, 2017.

EFSA has undertaken to implement a wide-ranging vision to continue improving transparency

During the period under review, **EFSA's senior management put in place measures and a vision that commits EFSA to being an open organisation**, including through more transparency throughout the risk assessment process.

The Open EFSA initiative started as a 2014 Discussion Paper, which set out a conceptual framework, methodology and plan for the transformation of EFSA's identity to an "Open Science organisation" over the period 2015-2020.³⁰⁹ The ultimate ambition of this "overarching organisational transformation"³¹⁰ is to make the Authority's outputs reproducible, thanks to transparency, from open data to availability of processes. The initiative evolved into the EFSA 2020 Strategy, and specifically Strategic Objective 1 (SO1), which aims to "prioritise public and stakeholder engagement in the process of scientific assessment", and its four operational objectives:³¹¹

1. Promote enhanced dialogue with stakeholders on mandates in collaboration with risk managers
2. Make documentation on information gathering and the evaluation process available
3. Foster engagement throughout the development of scientific assessments
4. Ensure clarity and accessibility/usability in the communication of findings

The Open EFSA initiative explores how EFSA can better meet society's expectations as the scientific risk assessor of the EU's food safety system, to understand the implications that increased transparency have for the Authority's organisational structure.³¹²

EFSA's vision on the path to an Open EFSA is that "Society engages in EFSA's scientific work and gains trust in the EU food safety system"³¹³. The TERA project is a key instrument for implementing this vision. At its June 2015 Management Board meeting, EFSA clarified the evolution from Open EFSA to the TERA project, coordinating the gradual implementation of 35 measures for enhancing transparency and engagement in EFSA's risk assessment workflow. The workplan for the full rollout sees its completion in 2020.³¹⁴ For example, one element is to (ultimately) publish all raw monitoring data so that information is immediately accessible to interested parties, but at present these data are only available on request. A review of EFSA's annual reports shows that EFSA's self-reporting against its implementation plan is on track during the period under review.³¹⁵

Although the commitment and measures are in place for notable change in the way EFSA's work is perceived, they are not complete, and their impacts can only be partially assessed at this stage. Notwithstanding this limitation, 86% of 1,309 survey respondents already considered the scientific advice provided by EFSA over the period 2011-2016 *to be* transparent regarding the evidence, methods and expertise used to a high or moderate extent³¹⁶. In addition, views on the extent to which different activities to increase access to, and the transparency of, scientific methods, data, the output production process and the actors involved through this process, contributed to *building trust* in the food safety over the period 2011-2016 overall already show a positive picture (see Figure 11). This should be further improved by EFSA's proactive activities under TERA.

³⁰⁹ European Food Safety Authority, *Discussion Paper - Transformation to an 'Open EFSA'* (Parma, Italy, 2014).

³¹⁰ See p.2, EFSA Management Board, 'Transparency and Engagement in Risk Assessment' (Parma, Italy, 2015), 1-7.

³¹¹ European Food Safety Authority, *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

³¹² European Food Safety Authority, *Discussion Paper - Transformation to an 'Open EFSA'* (Parma, Italy, 2014).

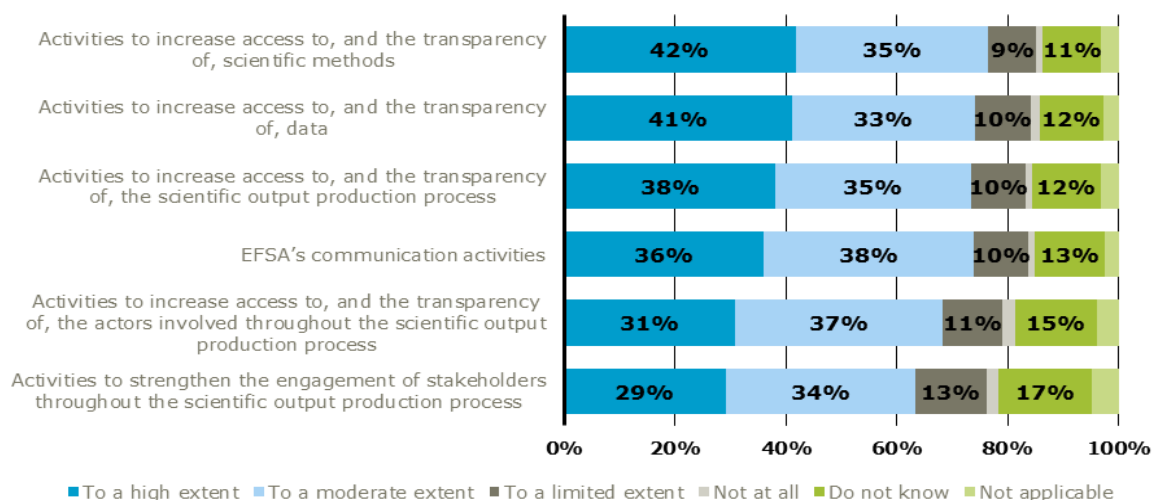
³¹³ See p.8, European Food Safety Authority, *Discussion Paper - Transformation to an 'Open EFSA'* (Parma, Italy, 2014).

³¹⁴ See European Food Safety Authority, *Transparency and Engagement in Risk Assessment (TERA): implementation plan to "Open EFSA" - 62nd Advisory Forum Meeting, Parma, EFSA, 8-9 December 2016*, 2016.

³¹⁵ Up to and including European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

³¹⁶ This was one of the propositions for the following question: "To what extent do you consider the scientific advice provided by EFSA over the period 2011-2016"

Figure 11: To what extent have the following activities contributed to building trust in food safety over the period 2011-2016? (n=1,454 and includes EFSA staff)



Source: Evaluation team based on survey results

Direct feedback from three interviews with the Stakeholder Bureau and Forum conducted for the evaluation was that the range of enhanced transparency mechanisms support better communication and greater engagement. Examples cited included the holding of open plenaries and Panel meetings, web-streaming and webinars, which offer greater opportunities for dialogue and feedback.

Evidence of greater clarity and accessibility of EFSA's communication

EFSA's KPIs show EFSA's self-reporting and monitoring of communication has evolved over the period of review.

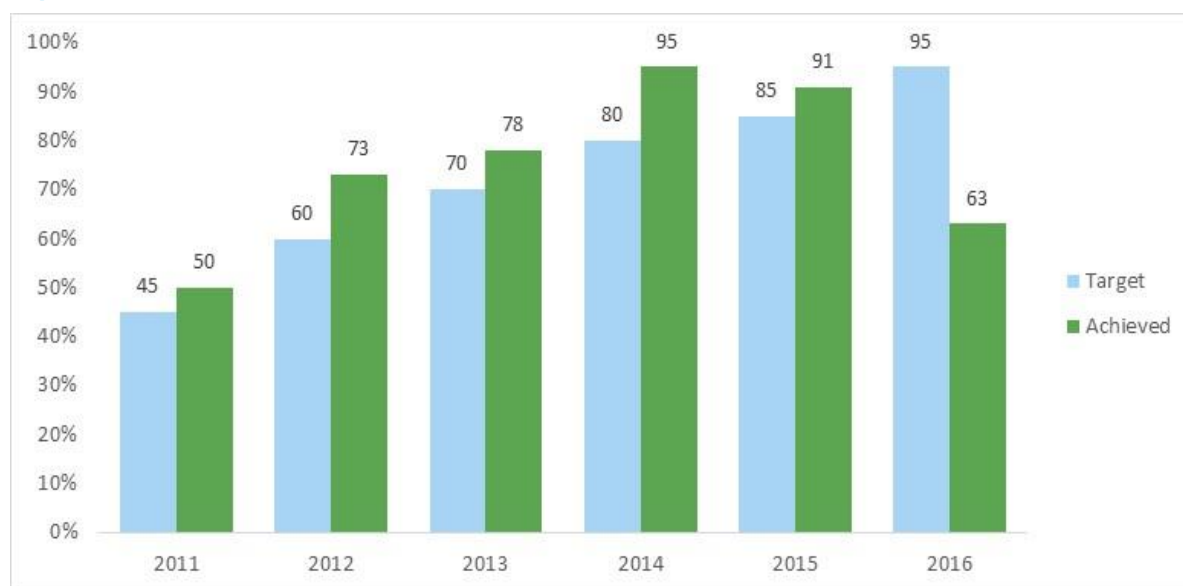
EFSA had 17 KPIs relating to "communication and dialogue" activities over the period of review but these changed to incorporate new activities and approaches. There is just one KPI ("number of web visits") which was reported on consistently over the period under review (albeit with a break in 2014 and issues relating to comparability over time meaning it is not included here). The results of a selection of EFSA's KPIs covering most of the period (i.e. at least three years) and considered most pertinent, are presented below³¹⁷:

- ✓ **Traffic from social media:** EFSA also began to report traffic to its web content from social media in 2015, including data from the previous year. EFSA planned to double the 2014 proportion (from 1.5% to 3%) but did not reach this target in 2015 (managing 2.1%). For 2016 it set a lower target of 2.0%, and consequently surpassed it (2.6%).
- ✓ **Number of press releases and web news items:** EFSA publishes press releases and web news items on its website, addressed to the media, but also to the public. The target for the number of press releases and web news items was 80 over the period 2012-2014, based on 80 press releases and news achieved in 2011. This KPI scored particularly well in 2014, reaching 118 press releases and web news items, significantly over the target. Except for 2013 where the target was just missed (78 instead of 80), EFSA met the targets for this self-set KPI. Data for 2015 and 2016 were not reported.

³¹⁷ A full assessment of the utility of the KPIs deployed by EFSA is included in sub-section "measuring performance", where some of the issues with KPIs – including lack of comparability over years are described. An example here, under communication, is the KPI for social media followers: While EFSA launched its official Twitter account in 2012, as part of its Social Media Strategy. By the end of that year, the Authority had more than 2,000 followers. Yet, EFSA introduced this KPI only in 2015. In 2015, EFSA monitored the "increase in the number of Twitter followers (%)", which can be converted into gross numbers, based on the 7,500 followers EFSA had in October 2014. In 2016, EFSA reported the "increase followers from social media platforms where EFSA is active (Twitter, Linked In, YouTube)" with both percentage and numbers. In 2015, the Authority met the target for this self-set KPI. However, for 2016, the figures included LinkedIn and YouTube and no specific breakdown for Twitter. Also, EFSA's *Consolidated Annual Activity Report 2016* specified that LinkedIn contributed the most to the increase, and that the Authority exceeded 16 500 and 20 500 followers on Twitter and LinkedIn. Even though there was no specific target for Twitter, the increase overall between 2015 and 2016 is like the one between 2014 and 2015.

- ✓ **Proportion of press releases/web news accompanying scientific output within 20 working days of adoption:** Press releases and web news are supposed to accompany the publication of scientific outputs within a specified timescale. Before 2016, the goal was set for 20 working days, but extended to 28 with the introduction of the new Wiley publication process.³¹⁸ Figure 12 presents the evolution of this KPI over the period 2011-2016. The proportion of press releases/web news accompanying scientific outputs within 20 working days followed an upward trend over the years 2011-2015, with continuously better results than planned. However, despite an extended period of adoption to 28 days, EFSA did not meet its target in 2016.

Figure 12: Proportion of press releases/web news accompanying scientific outputs within 20*³¹⁹ working days



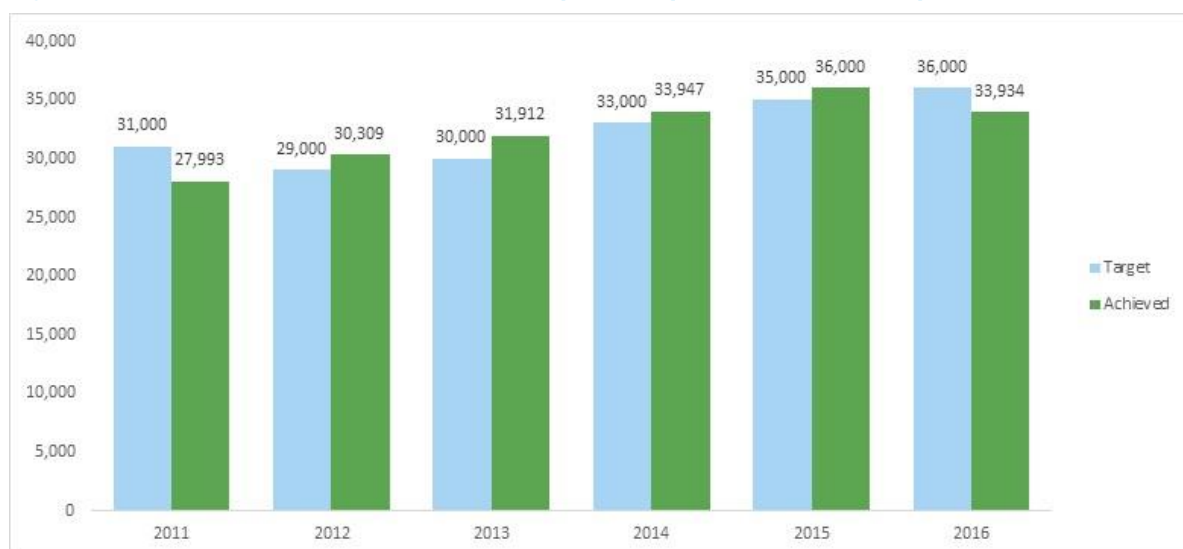
Source: Evaluation team, based on data from EFSA's Annual (Activity) Reports and Management Plans (2011-2016)

- ✓ **Total number of subscribers to online subscription products (newsletter and alerts):** While the number of subscribers to online products continuously increased, from 27,993 in 2011, to 36,000 in 2015, it decreased to 33,934 in 2016, representing fewer subscribers than in 2014 (see Figure 13). Our analysis does not uncover any efforts to understand why the number of subscribers decreased – this would be relevant for EFSA to understand how to improve communication material.

³¹⁸ 2016 is when the *EFSA Journal* moved to a professional publisher, Wiley, which required the transfer of more than 6,000 scientific outputs to the Wiley Online Library, including a significant clean-up of data and metadata.

³¹⁹ In 2016, the 20 working days of adoption were extended to 28, as it was impossible for EFSA to respect the previous deadlines with the introduction of the new Wiley process.

Figure 13: Total number of subscribers to online products (newsletter and alerts)



Source: Evaluation team, based on data from EFSA's Annual (Activity) Reports and Management Plans (2011-2016)

It is particularly important for EFSA to understand why some people unsubscribed to EFSA's online products given that newsletters and email alerts are the most used of EFSA's communication channels. Responses to the online survey provide some insights (although we recognise the limitations in these data, which do not include responses from the public, among others). Indeed, to the question "Do you follow EFSA on any of these services and social networks?"³²⁰ 27% of the responses selected were "email alerts" and 27% "newsletter". Despite the Authority's attention to social media, only 7% of the 3,330 responses selected were Twitter and 6% YouTube. The results of the survey hence show that direct channels are more used by respondents than social media.

Nevertheless, the above illustrates how **EFSA significantly changed its approach to communication and its internal organisation over the period under review** to ensure it had adequate systems in place to communicate with all interested parties.

EFSA has undertaken work to improve the clarity of its communication and directly address recommendations of the 2012 External Evaluation. During the period under review, EFSA completed an overhaul of its website and relaunched it in 2016 to make it more accessible to external users.³²¹ As noted in the KPIs, the rationalisation of the website resulted in a reduction in visits to the site of almost 40% in gross numbers (however difficulties in comparing these figures include, for instance, that a lower number of visits may in fact be due to better navigation which means less time spent finding information). In tandem, EFSA widened its use of different communication tools and channels under the period of review to address different information needs and preferences amongst stakeholders. For example, the website included videos, infographics and animations. Further, EFSA introduced a less formal and less technical house editorial style to simplify and make communication more accessible. The transfer of the EFSA Journal by Wiley into an open-access platform brought improvement in the accessibility of the Authority's final product.

Interviewed stakeholders (Forum and Bureau) corroborated the positive findings above, indicating that the communication initiatives undertaken supported EFSA's reputation. These include:

- The timely, relevant and more professional approach to social media – following the 2011 Social Media Strategy³²² – with greater staff engagement on Twitter;

³²⁰ Respondents could select all that apply. This resulted in 2,330 responses.

³²¹ The evaluation began after the overhaul was completed but this assessment is taken from EFSA's own reporting in its update on progress in relation to the 2012 Recommendations of the Management Board. EFSA RASA, REPRO, COMMS, BUS Departments, *Internal document follow-up on implementation of EFSA's Management Board recommendations, (Draft)*, 2017.

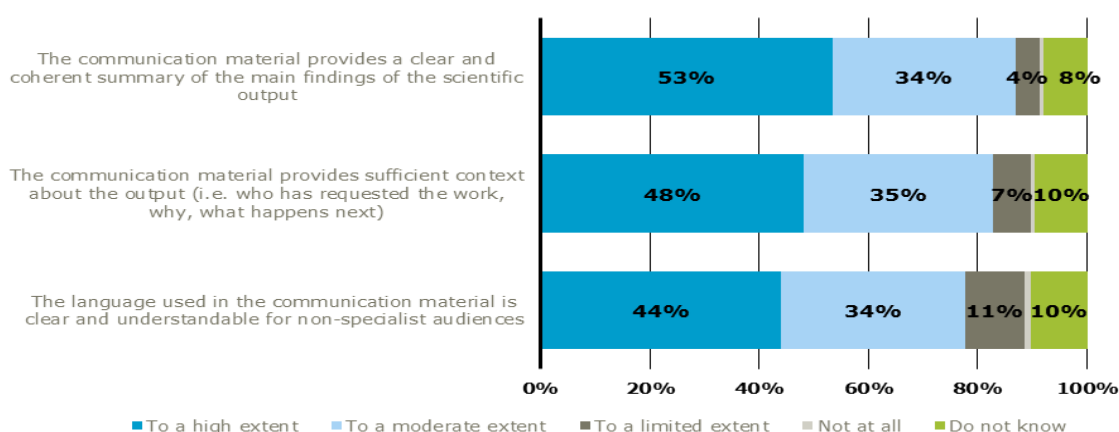
³²² European Food Safety Authority, *Annual Report 2011* (Parma, Italy, 2012).

- The increased development and use of other communication tools, such as educational videos, infographics, and factsheets;
- The improved website.³²³

There were overwhelmingly positive views from 1,230 stakeholders (not including EFSA staff) on the extent to which there is trust in the outputs that EFSA produces in the form of scientific opinions, reports, and press releases: 72% selected “to a high extent” and 22% selected “to a moderate extent” regarding trust in EFSA’s outputs (no significant differences were observed for distinct groups of stakeholders).

In addition, most respondents to the online survey indicated that they considered EFSA’s communication materials to be satisfactory. Respondents indicated that they found EFSA’s communication material to have at least moderate clarity (87%), provide at least moderately sufficient context (83%), and use at least a moderately understandable language for non-specialist audiences (78%) as shown in Figure 14.

Figure 14: To what extent do you agree with the following statements regarding EFSA’s communication materials (e.g. press releases, webstories, highlights, etc.)? (n=1,472)³²⁴



Source: Evaluation team based on survey results.

Some divergences in views were apparent. Management Board members were less likely to report that the communication material provided a clear and coherent summary of the main findings of the scientific outputs (13% selected “a limited extent” or “not at all”). Another divergent view was with respect to the language used in the communication material being clear and understandable for non-specialist audiences. Two of the six responding Stakeholder Bureau members selected “a limited extent”, which shows that two individuals from EFSA’s key stakeholders, who represent non-specialist audiences³²⁵, were not convinced EFSA’s communication materials were clear and understandable for non-specialist audiences. Open responses further supported this finding as 11% of comments³²⁶ concerned EFSA’s scientific opinions, indicating that although certainly not a majority view, there is scope for EFSA to increase its trustworthiness including by increasing the clarity of the language used in the opinions.

Notwithstanding achievements, tailored communication and targeting the public is an area for improvement. Linked to the above, survey respondents were asked what recommendations they had to help EFSA improve: 89 responses referred to communication

³²³ In addition, in September 2015, the website EFSA specifically created for its Second Scientific Conference received the international Euromediterraneo Award, a prize for institutional communication projects that enhance partnerships between the public and the private sector, concretely showing how an improved website can positively contribute to EFSA’s ability to engage with industry, and to its reputation.

³²⁴ The question was displayed to all respondents. This yielded a total of 1,472 responses.

³²⁵ The Stakeholder Bureau is intended to act as an advisor for EFSA on engagement with stakeholders and that the members are intended to act as representatives of the groups who nominate them.

³²⁶ The question about how trust in the information produced by EFSA could be increased was displayed to respondents who indicated that EFSA’s activities contributed to a limited extent or not at all to building trust in food safety over the period 2011-2016. This yielded a total of 288 responses.

activities, most notably in terms of getting the public to understand what EFSA does. A common message was that a large part of the current lack of understanding/ awareness of EFSA's work among the public lies in the complexity of outputs, and a need to reduce their complexity to make opinions easier to understand. This suggests that despite progress, EFSA's work is not done in this area. More generally 19% of comments raised on what EFSA could do to increase trust³²⁷ concerned communication activities: to address the lack of awareness of EFSA among the public, the Authority could improve its communication with the public on its role, providing clear explanation of its opinions and recommendations to consumers.

The documentary review revealed EFSA does not have an up-to-date dedicated operational communication strategy³²⁸ to delineate how different target groups should be reached and what level of effort should be expended. A related point regarding strategy was that there was scope to better leverage connections with national authorities' communicators, to provide information about EFSA and its work within the Member States. For example, interviewees suggested that EFSA could do more to encourage better communication about its activities at national level, especially since citizens may be more likely to go to their national authority rather than EFSA.

EFSA's communication is contributing to enhancing stakeholders' trust. Qualitative feedback gathered from stakeholders (Bureau and Forum) reported a more positive atmosphere when interacting with EFSA during the period under review, suggesting that the Authority's work to communicate with stakeholders had to some extent been effective. Three stakeholders (Forum and Bureau), considered that EFSA's management had made a real effort to try to find the right balance and to 'listen' to its stakeholders. This corresponds to Open EFSA's idea of engagement. Some examples of improvements cited were the Stakeholder Forum's proactivity; the publication of minutes within shorter timescales than before; and the introduction of targeted platforms to focus on certain topics, as this supports the highly technical nature of the work.

However, the application process for regulated products was highlighted as EFSA's main weakness by seven stakeholders interviewed (Bureau and Forum). The view presented was that the Authority needed to consider "the reality of business" and interact more with its stakeholders during this process. EFSA has already acted on this issue, as evidenced by the trial taking place at the time of the evaluation for dedicated support to SMEs³²⁹. More generally, 13% of survey respondents' comments³³⁰ concerned stakeholder engagement, indicating that EFSA could increase its trustworthiness by including stakeholders throughout the drafting of an opinion, from an earlier stage.

Further measures needed to improve trust

Targeting opinion influencers: The need to target opinion influencers was confirmed in documentary evidence. EFSA's commissioning of a Reputation Barometer looking at perceptions of EFSA in relation to key characteristics should provide insights in the areas of focus to improve EFSA's reputation. The 2017 Reputation barometer³³¹ found differences in how EFSA is perceived (Member States authorities had a positive view of EFSA, for all twelve attributes analysed³³², but

³²⁷ Survey respondents from across stakeholder groups who indicated that EFSA's activities contributed to a limited extent or not at all to building trust in food safety over the period 2011-2016 were asked how trust in the information produced by EFSA could be increased. This yielded a total of 288 responses.

³²⁸ The last Communication Strategy identified refers to the period 2010 - 2013 and updates the 2006 Communication Strategy.

³²⁹ In June 2017 EFSA launched a support initiative for applicants from small and medium-sized enterprises (SMEs) allowing SMEs in the areas of feed additives and novel foods (excluding traditional food) to request an administrative check of their draft dossiers prior to submission. The support was to be provided via teleconferences. See European Food Safety Authority – EFSA, 'Applications pilot: dedicated support for small and medium-sized enterprises', 2017 <<http://www.efsa.europa.eu/en/press/news/170606>> [accessed 4 May 2018].

³³⁰ Survey respondents from across stakeholder groups who indicated that EFSA's activities contributed to a limited extent or not at all to building trust in food safety over the period 2011-2016 were asked how trust in the information produced by EFSA could be increased. This yielded a total of 288 responses.

³³¹ Commissioned by EFSA and based on 109 stakeholders' opinions across the EU (Member State authorities, EC, EP, representative organisations from the food industry, consumer and environmental NGOs, and members of the scientific community involved in regulatory risk assessment for the food chain).

³³² EFSA's approach to providing scientific advice; quality of its risk assessment opinions; efficiency in producing risk assessments (timeliness and use of resources to carry out RA); identification and characterisation of emerging risks (role); work to harmonise RA methods (role); independence and objectivity; level of transparency; risk communication role; engagement with external partners; provision of scientific and technical assistance to Member States for crisis management (role); quality of governance (procedures and practices); innovativeness. See ICF, *Reputation Barometer* (London, UK, 2017).

consumers and thematic NGOs³³³ did not³³⁴). Despite the relatively small sample size, a valuable insight for EFSA is the importance of targeting public opinion influencers.

Framing and managing sensitive topics: The need for EFSA to improve the way it manages communication about sensitive topics was identified in the documentary review and interviews. One of the key activities planned as part of EFSA Strategy 2020 and its first strategic objective was to pilot and, if successful, set up a framework for the use of social science research in guiding the implementation of engagement measures in EFSA's mandates.³³⁵ Resulting from this, the transformation of the AFWGC to the Communications Expert Network (CEN), which focuses on 'the science of communications', aims to strengthen expertise in how social sciences can support risk communications and improve outreach on potentially sensitive or controversial topics, through meetings to share experiences and expertise in social sciences.³³⁶ The CEN is supposed to deliver risk perception surveys and other social science related activities.³³⁷ Staff within EFSA acknowledged that this remains an area for improvement, and that investing more resources in social sciences research would help to standardise approaches to tailoring risk communication. There is a need for further literature reviews on the best way to communicate about specific topics and how national and international organisations use social sciences to support risk communication. Members of the CEN and the Stakeholder Forum echoed this view.

Four interviewees from the Stakeholder Bureau and Forum considered that EFSA should be less defensive about its role and rely on the quality of its science. EFSA acknowledged in April 2017 that it could communicate in a manner that transparently defends EU priorities, supporting innovation and industry, presenting confidence of its scientific objectivity when facing criticism. EFSA also recognised it should create an internal culture of reputation management, based on its Panels and staff's status, to anticipate instead of dealing with this issue at a later stage.³³⁸

Harnessing future benefits of fewer limitations on transparency: The proposal for a targeted revision to the General Food Law Regulation identifies new measures to increase trust based on a revised legal framework.³³⁹ Although this does not fall within the period under review, the proposal would make changes that directly address issues relating to a lack of trust in the food safety system (including some of those mentioned here³⁴⁰). It also suggests that EFSA's room for manoeuvre in the current legal framework is not enough to meet some stakeholders' needs. Relevant elements of the proposal that would deal with some of the issues raised include:

- allowing citizens to have automatic and immediate access to all safety related information submitted by industry in the risk assessment process;
- requiring consultation of stakeholders and the public on studies submitted by industry to support product authorisation requests and strengthen risk communication to citizens, with common actions to enhance consumer confidence by promoting public awareness and understanding; and

³³³ Note that there were only five responses from this group though.

³³⁴ It generated a reputation score for each of the groups selected, on a scale from -100 (lowest) to 100 (highest). See ICF, Reputation Barometer (London, UK, 2017).

³³⁵ European Food Safety Authority, *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

³³⁶ European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017); EFSA Advisory Forum and Scientific Cooperation Unit, *Terms of Reference of the EFSA Communications Experts Network (CEN)* (Parma, Italy, 2016).

³³⁷ EFSA Advisory Forum and Scientific Cooperation Unit, *Terms of Reference of the EFSA Communications Experts Network (CEN)* (Parma, Italy, 2016).

³³⁸ EFSA RASA, REPRO, COMMS, BUS Departments, *Internal document follow-up on implementation of EFSA's Management Board recommendations, (Draft)*, 2017.

³³⁹ European Commission, Proposal for a Regulation of the European Parliament and of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002 [on general food law], Directive 2001/18/EC [on the deliberate release into the environment of GMOs], Regulation (EC) No 1829/2003 [on GM food and feed], Regulation (EC) No 1831/2003 [on feed additives], Regulation (EC) No 2065/2003 [on smoke flavourings], Regulation (EC) No 1935/2004 [on food contact materials], Regulation (EC) No 1331/2008 [on the common authorisation procedure for food additives, food enzymes and food flavourings], Regulation (EC) No 1107/2009 [on plant protection products] and Regulation (EU) No 2015/2283 [on novel foods] (Brussels, Belgium, 2018) <<https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=COM%3A2018%3A179%3AFIN>> [accessed 25 June 2018].

³⁴⁰ European Commission, 'Ban glyphosate and protect people and the environment from toxic pesticides', 2018 <<http://ec.europa.eu/citizens-initiative/public/initiatives/successful/details/2017/000002>> [accessed 30 May 2018].

- better explaining scientific opinions expressed by EFSA, as well as the basis of risk management decisions.³⁴¹

Summary of findings and progress relative to the baseline

EQ 3b (Effectiveness): To what extent has EFSA contributed to creating a European food safety system that enhances citizens' trust through its independence and transparency?

EFSA has taken an approach of continuous improvement and implemented updates to its policy on **independence** during the period under review, as well as more recently (in June 2017). It is effectively implementing the policy and reporting high levels of compliance as per evidence in KPIs and Annual Activity Reports. Despite being one of the most advanced systems for ensuring independence in the EU landscape, stakeholders continue to have concerns related to independence for different reasons, highlighting the importance of EFSA's efforts to promote awareness, understanding and manage expectations.

EFSA also carried out substantial initiatives aiming to increase **transparency** of the risk assessment process. The driving force behind these reinforced efforts (TERA) is not due to be completed until 2020. Its effectiveness cannot be fully assessed yet. Nevertheless, the direction of travel of EFSA's efforts, if EFSA continues to deliver effectively, would be a step change in how EFSA works and should mean that EFSA fully satisfies the recommendations made in this area. This progress is recognised by interviewees. The results of the survey confirm that EFSA can still improve, in line with the scheduled implementation of TERA.

Feedback from stakeholders through the survey and interviews shows that there is a perception that EFSA is improving its **communication with stakeholders**, and that the Authority has introduced changes to improve clarity and accessibility of its communication. However, the absence of an explicit communication strategy or roadmap with an explicit operational plan for managing communications and to focus efforts is a weakness.

Indeed, persistent challenges to EFSA's communication and trust in EFSA's work relate to the need to further tailor material, but EFSA must weigh the costs and benefits of efforts in relation to its key target audiences. The proposed targeted revision to the General Food Law to address concerns which relate to transparency and trust in the system demonstrates how powerful advocacy groups can be and the atmosphere of hostility among some groups. This is a reminder of the **continued challenges** which the Authority faces and must proactively address. Importantly, the measures proposed in the targeted revision will provide EFSA with the legal basis to be more transparent.

5.2.4 EFSA's governance model

To what extent is the Authority's governance model appropriate for ensuring the Authority's mission statement? (EQ 5)

Coverage of the question

This question specifically examines the extent to which EFSA's governance model has been appropriate for enhancing the Authority's day-to-day operations in line with its mission statement as formulated in Regulation (EC) N° 178/2002. The question focuses on EFSA's governance model through the composition and work of the Management Board (section 5.1.2 discusses EFSA's organisational structure and working practices/processes).

³⁴¹ European Union, 'Transparency and sustainability of the EU risk assessment in the food chain', 2018 <https://ec.europa.eu/food/safety/general_food_law/transparency-and-sustainability-eu-risk-assessment-food-chain_en> [accessed 4 May 2018].

Sources of evidence

Findings from the 2012 External Evaluation and ensuing recommendations from the Management Board were consulted to establish the baseline. To assess the extent to which EFSA's governance model complies with the Authority's mission statement, the evaluation consulted Regulation (EC) N° 178/2002 and the rules of procedure and code of conduct for the Management Board. Internal EFSA documentation such as Programming Documents and Annual Activity Reports were also consulted to review achievement of annual objectives and targets for the period under evaluation. The most relevant external reference source is the proposal for a targeted revision of the General Food Law which, although strictly outside of the period of review, includes a suggested change to the composition of the Management Board which is highly relevant. Online survey responses were a complementary source of evidence to assess the adequacy of the governance model.

Baseline

The 2012 External Evaluation of EFSA concluded that the Authority's governance model was compliant with EFSA's mission statement. The evaluation noted that EFSA's governance and structure had been conducive to fulfilling the Authority's obligations to operate in an independent manner, guaranteeing the separation between EFSA's scientific work and its strategic management.

Analysis of evidence

The governance model supports EFSA's mission statement

EFSA's governance model is different to those of other executive decentralised agencies. The Management Board is composed of 14 independent members appointed by the Council of the European Union (plus a representative of the Commission), rather than by representatives of the Member States as is the case in other EU agencies. This is a means of ensuring political independence. The primary body within EFSA representing Member States' interests is the Advisory Forum, which constitutes a mechanism for the exchange of information on potential risks and the pooling of knowledge between the Authority and competent bodies in the EU Member States.³⁴² See section 2.3.2 for further details on EFSA's bodies.

EFSA's strategy documents, as well as activity and monitoring reports for the period under evaluation provide evidence that **the Authority's governance model, and the composition and work of the Management Board, have been instrumental for observing the adequate implementation of EFSA's mission.** The report of the second External Evaluation provided an effective basis for the Management Board to anticipate challenges and evolving demands on the organisation and to formulate strategic recommendations to steer the direction of the Authority for later years. A review of the actions taken to address the 2012 recommendations was performed by EFSA's Management Board in 2014.

During this period, the Management Board provided strategic input and guidance on the elaboration of high-level programming documents (such as EFSA's Single Programming Documents) and strategic approaches (Open EFSA in 2014 and EFSA Strategy 2020, elaborated and subject to public consultation in 2014 and 2015). It adopted an anti-fraud policy for the organisation, undertook a review of EFSA's Independence Policy to further strengthen public trust (2015 and 2016), and endorsed EFSA Strategy 2020 and a new approach to engagement with stakeholders in 2016. Annual Reports confirm the Management Board's exchange of views and engagement in dialogue with other EFSA bodies, including the Advisory Forum and the Scientific Committee, and with various stakeholder groups, on issues related to transparency and independence.

A development relating to EFSA's governance model which is strictly outside of the assessment period is relevant to highlight given the question here: in April 2018, the European Commission officially proposed a targeted revision of the General Food Law including a **measure to**

³⁴² The Advisory Forum also advises the Executive Director.

incorporate Member States in the Authority's Management Board³⁴³, in line with the Common Approach on decentralised agencies. This amendment to the Management Board would grant Member States more responsibility for supporting EFSA and ensuring increased scientific cooperation. The proposal guarantees that EFSA's independence will continue to be observed with this measure, as the focus of the Management Board is on the Authority's administrative and financial aspects, and not on its scientific work. The suggested change is understood by this evaluation to be consistent with its finding on the effectiveness of the current governance model in supporting EFSA's mission. The focus of the change is rather on targeting the issue of sustainability which has been touched on elsewhere in this report (see section 5.2.1.1).

Summary of findings and progress relative to the baseline

EQ 5 (Effectiveness): To what extent is the Authority's governance model appropriate for ensuring the Authority's mission statement?

Documentary evidence confirms that **EFSA's governance model, and the composition and work of the Management Board, have been instrumental in ensuring the implementation of EFSA's mission statement.** During the period under assessment, the Management Board has carried out its main responsibilities, as outlined in Regulation (EC) N° 178/2002, and has assumed a strategic role through the provision of input and guidance on the elaboration of high-level programming documents and strategic approaches.

5.2.5 Measuring performance

Are the internal mechanisms for programming, monitoring, reporting and evaluating EFSA adequate for a) ensuring accountability and b) appropriate assessment of the overall performance of the Authority? (EQ 6)

Coverage of the question

The first part of this question covers the adequacy of EFSA's internal mechanisms for ensuring accountability of the Authority, and the second part covers their appropriateness for assessing its overall performance. A substantial portion of this section covers the appropriateness of EFSA's KPIs. The adequacy of EFSA's mechanisms for planning and prioritisation is further developed under section 5.3.2.2. Many of the issues highlighted in this section have been addressed since 2016, but as the evaluation focuses on the 2011-2016 period, they could not be disregarded. Improvements and changes made since 2016 are briefly referenced throughout the section.

Sources of evidence

The documentary review covers information on EFSA's mechanisms for programming, reporting and monitoring performance during the 2011-2016 period and beyond, including the legal basis of Regulation (EC) N° 178/2002. Internal EFSA documentation such as Programming Reports and Annual Activity Reports were used to assess the extent to which monitoring requirements were fulfilled by the Authority. Previous external evaluations and recommendations, including from the Commission REFIT evaluation of the General Food Law and European Court of Auditors (ECA) reports were also used to corroborate internal documentary evidence.

As programming, monitoring and reporting systems are specific to EFSA itself, only EFSA's staff and Management Board members were asked about the systems through the online survey and interviews. Although the small sample size for the interviews led to limited responses, they have been used to deepen the evidence where they support the findings from the online survey.

³⁴³ European Commission, *Proposal for a Regulation of the EP & of the Council on the transparency and sustainability of the EU risk assessment in the food chain amending Regulation (EC) No 178/2002, Directive 2001/18/EC, Regulation (EC) No 1829/2003, Regulation (EC) No 1831/2003, Regulation (EC) No 2065/2003, Regulation (EC) No 1331/2008, Regulation (EC) No 1107/2009, and Regulation (EU) No 2015/2283* (Brussels, Belgium, 2018).

Additionally, the small number of interviewees consulted (only staff members and EFSA's Management Board) did not provide comment on the issue of programming.

Monitoring and reporting systems are internal to the organisation and would not typically be an appropriate topic of concern for an independent academic article.

Baseline

The previous external evaluation of EFSA recommended that the Authority improve the monitoring system by (1) improving the readability of reporting documents by using a uniform nomenclature; (2) using the same indicators in strategic and reporting documents over the years; (3) inserting a column in the budget reconciling budget lines with activities; (4) limiting changes in budget, reporting documents, indicators, activity repartition and explaining them whenever they occur, enabling comparison across years; (5) establishing a system to reconcile mandates received, the questions produced and the outputs provided, and (6) increase the level of reliability and integrity of the data used.

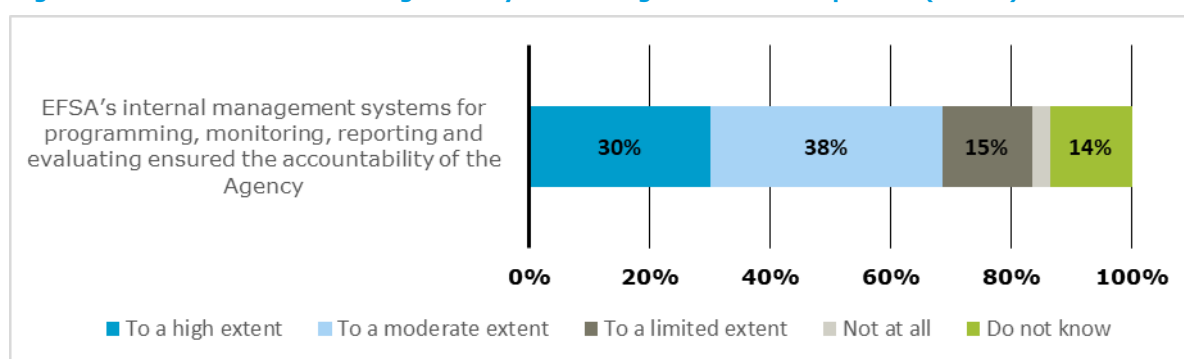
Analysis of evidence

Internal mechanisms for programming, monitoring, reporting and evaluating the Authority are adequate for ensuring accountability

EFSA has taken steps to improve internal mechanisms for programming, monitoring and reporting to ensure accountability of the Agency. For instance, in 2016, EFSA published its first forward-looking strategy document, EFSA Strategy 2020³⁴⁴. As outlined in section 2.3.1, EFSA defined five strategic objectives up to 2020. The formulation of these objectives, in addition to EFSA's regular (multi)annual programming documents, allows the Authority to set internal goals to be held accountable.

Similarly, results from the online survey highlight that the majority of EFSA staff and members of the Management Board agreed that the **internal management systems for programming, monitoring, reporting and evaluation ensured accountability** of the Authority (68% or 79% when discounting "do not know" responses). Interviewees did not comment on the issue of programming, and voiced their opinions about the adequacy of monitoring and reporting mechanisms to measure performance only.³⁴⁵

Figure 15: To what extent do you agree with the following statements regarding EFSA's internal organisational structure and management system during the 2011-2016 period? (n=235)



Source: Evaluation team based on survey results

In 2016, EFSA started to develop a system to translate EFSA's values into concrete processes and practices, coherent with integrated risk management and quality management systems, which was formally set up in 2017. This Accountability Framework encompasses four pillars: results-based management, assurance, governance and decision-making, as well as quality and improvement.³⁴⁶

³⁴⁴ European Food Safety Authority, *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

³⁴⁵ Three interviewees touched on the issue of programming, but in the context of EFSA's internal planning capabilities (i.e. in terms of the division of work and resources), which is discussed under the efficiency sections.

³⁴⁶ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017)

In this context, EFSA's process management capability was enhanced, roles and responsibilities were clarified, and new KPIs were defined to allow for more effective monitoring and reporting at all levels³⁴⁷. EFSA thus began introducing a process management approach after 2016; efforts in this direction were still ongoing at the time of writing and, as such, cannot be definitively assessed by the evaluation team. It is understood that workload and output production planning and monitoring were to be made as standardised and meaningful as possible, thereby allowing the Authority to manage and assess performance at the appropriate level of granularity in the areas where this is possible. EFSA also invested in risk prevention by further developing audit consulting and integrating its input into the design of processes and procedures and outsourcing the assurance audits as necessary.³⁴⁸ These changes show that despite the weaknesses in the KPIs identified, EFSA is taking a proactive approach to improvement.

EFSA's consultative processes have resulted in the identification of key drivers and challenges, which have in turn allowed EFSA to delineate strategic areas of action and outcome-related objectives for the Authority as a basis for the elaboration of the annual work programmes and overall planning.³⁴⁹ The continued validity of ongoing and new challenges identified is assessed annually against EFSA's corporate KPIs, and any corrective actions are included in the multi-annual work programmes and annual management plans of the Authority. The strategies are reviewed regularly to adjust the strategic direction of the Authority in line with changes in the operating environment.

Over the period under review, the ECA produced five summaries of annual audits³⁵⁰, in addition to special reports³⁵¹. The summaries of the 2012-2016 annual audits showed overall satisfaction of the ECA with EFSA's internal mechanisms³⁵². According to the 2014 and 2015 review of Internal Control Standards (ICS) implementation, EFSA is effective and the system is compliant with the standards, thus providing the organisation with reasonable assurance on the reliability of the internal control environment.

These internal mechanisms did not allow for an appropriate assessment of EFSA's overall performance during the 2011-2016 period, but improvements are now being made

EFSA has a range of internal mechanisms for reporting, but there is a **lack of continuity** in what was reported on in 2011-2016 and therefore on what was easily accessible/visible to its stakeholders.³⁵³ Over the period under review, EFSA published five annual programming documents³⁵⁴, to which can be added the draft Programming Document 2018-2020 adopted in 2017³⁵⁵. While each follows a similar structure, they do not follow the same template nor the same publishing cycle which makes the review and comparison of them less straightforward. In 2011 and 2012, EFSA published Annual Activity Reports.³⁵⁶ They were complemented by Annual

³⁴⁷ European Food Safety Authority, *Consolidated Annual Activity Report 2017 (DRAFT)* (Parma, Italy, 2018).

³⁴⁸ European Food Safety Authority, *Consolidated Annual Activity Report 2017 (DRAFT)* (Parma, Italy, 2018).

³⁴⁹ Key challenges have been highlighted in EFSA's Strategic Plan 2009-2013, EFSA's Science Strategy 2012-2016 and EFSA Strategy 2020. These include globalisation, climate change, societal changes, increased nature and volume of scientific work, limited resources to face increased workload, emergence of new risks, etc. See Table 7 in section 5.1.1 on Relevance for a detailed overview.

³⁵⁰ European Court of Auditors, *Summary of Results from the Court's 2012 Annual Audits of the European Agencies and Other Bodies* (Luxembourg, 2013), *Summary of Results of the Court's 2013 Annual Audits of the European Agencies and Other Bodies* (Luxembourg, 2014), *Summary of Results from the Court's Annual Audits of the European Agencies and Other Bodies for the Financial Year 2015*, *Official Journal of the European Union*, 2016, *Summary of Results of the ECA's Annual Audits of the European Agencies and Other Bodies for the Financial Year 2016* (Luxembourg, 2017).

³⁵¹ European Court of Auditors, *Special Report No 15 – Management of Conflict of Interest in Selected EU Agencies* (Luxembourg, 2012).

³⁵² European Court of Auditors, *Summary of Results from the Court's 2012 Annual Audits of the European Agencies and Other Bodies* (Luxembourg, 2013), *Summary of Results of the Court's 2013 Annual Audits of the European Agencies and Other Bodies* (Luxembourg, 2014), *Summary of Results from the Court's Annual Audits of the European Agencies and Other Bodies for the Financial Year 2015*, *Official Journal of the European Union*, 2016, *Summary of Results of the ECA's Annual Audits of the European Agencies and Other Bodies for the Financial Year 2016* (Luxembourg, 2017).

³⁵³ EFSA is likely to have additional relevant data at hand but does not report on it externally in a consistent manner.

³⁵⁴ European Food Safety Authority, *Programming Document of the European Food Safety Authority 2014-2016 Incorporating Annual Management Plan 2014 and Multiannual Plan 2014-2016* (Parma, Italy, 2013), *Programming Document 2015-2017* (Parma, Italy, 2014), *Programming Document 2016-2018* (Parma, Italy, 2015), *Programming Document 2016-2019* (Parma, Italy, 2016).

³⁵⁵ European Food Safety Authority, *Programming Document 2018-2020 (DRAFT)* (Parma, Italy, 2017).

³⁵⁶ European Food Safety Authority, *Annual Activity Report of the European Food Safety Authority for 2011* (Parma, Italy, 2012), *Annual Activity Report of the European Food Safety Authority for 2012* (Parma, Italy, 2013).

Reports³⁵⁷, which stood alone in 2013 and 2014³⁵⁸. In 2015 and 2016, EFSA went back to Annual Activity Reports alone, but consolidated ones³⁵⁹, following the newly developed guidance and template by the Commission and the EU Agencies network. Although such changes are largely outside of EFSA's control, considering their legal obligation to align themselves with Commission guidelines, they point to a lack of consistency in EFSA's internal mechanisms for reporting.

Although changes were implemented in 2017 to the measurement and reporting on KPIs, which are now result-based and outcome-oriented, there was previously a **lack of consistency in the KPIs that were measured and reported**, which has made it problematic for the evaluation to meaningfully use this data. Only one KPI was used by EFSA continuously in its Annual (Activity) Reports over the period 2011-2016 (proportion of scientific outputs adopted within deadline). This does not mean that data for other KPIs did not exist for the entire period, but that they were not formally and consistently reported as KPIs throughout the period. Moreover, even the KPI on the proportion of scientific outputs adopted within deadline was not reported in a consistent way: it was reported jointly for Activities 1, 2 and 3 until 2013, and separately for each scientific Activity from 2014 onwards. As explained by EFSA, EFSA's work is variable by nature (i.e. questions to be answered, scientific complexity, scientific and social "divergence", methodological, data, expertise needed and available in qualitative and quantitative terms, the variable duration and progress rates of different questions), which makes the comparison on workload and output levels challenging based on simple metrics such as number of mandates, questions or outputs. According to EFSA, the lack of continuity in some of the KPIs used in the 2011-2016 period reflect EFSA's efforts to move away from such output-based indicators and towards the development of more meaningful indicators.

In fact, new KPIs were introduced during the period to monitor the performance of EFSA's evolving systems. For instance, in 2015, EFSA set up new KPIs for Activity 4 to assess its performance in terms of communication based on social media. While its introduction shows EFSA is moving with the times, **EFSA is not reporting in a way that facilitates direct comparisons over time**: in 2015, EFSA reported on the number of followers on Twitter, but in 2016, it reported on the number of followers on all social media combined, including Twitter. Similarly, for some KPIs EFSA made slight changes throughout the years, such as the proportion of scientific outputs finalised and published in the EFSA Journal, for which the target changed from "within 15 working days of adoption" to "within the agreed timelines" as to reflect the changes in workflow brought about by the move of the journal to Wiley in 2016 and the addition of typesetting, proof checking and editorial quality assurance steps. Although minor and necessary for on-going improvements, such discrepancies make it problematic to make a robust assessment of EFSA's effectiveness. This is especially true because the KPIs were largely quantitative, lacking a corresponding story or qualitative explanation, and it was not clear why certain things are measured the way they are or how targets are determined.

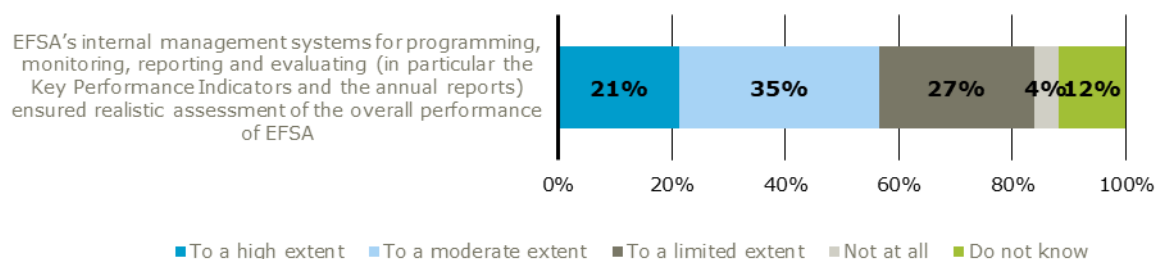
Parties consulted expressed **mixed views on the appropriateness of monitoring and reporting mechanisms to assess EFSA's overall performance** during the 2011-2016 period. There is a clear division of views among surveyed EFSA's management and staff in terms of the appropriateness of the Authority's internal management system for ensuring an appropriate assessment of its performance. As shown in the figure below, although 21% of EFSA's staff and management agreed to a high extent that the Authority's systems for programming, monitoring, reporting and evaluating ensured realistic assessment of its overall performance, and 35% to a moderate extent; 27% of respondents thought they were effective only to a limited extent, and 4% found they were not appropriate at all.

³⁵⁷ European Food Safety Authority, *Annual Report 2011* (Parma, Italy, 2012), *Annual Report 2012* (Parma, Italy, 2013).

³⁵⁸ European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014), *Annual Report 2014* (Parma, Italy, 2015).

³⁵⁹ European Food Safety Authority, *Consolidated Annual Activity Report 2015* (Parma, Italy, 2016), *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

Figure 16: To what extent do you agree with the following statements regarding EFSA's internal organisational structure and management system during the 2011-2016 period? (n=235)



Source: Evaluation team based on survey results

All negative responses to this question were provided by EFSA's staff. Among the 219 staff members who responded to this question, 64 indicated "to a limited extent" and ten "not at all". One of the 16 Management Board members responded: "do not know" to this question, while ten believed the systems were adequate "to a high extent", and five "to a moderate extent".

Nevertheless, **noteworthy progress was made** after 2016. EFSA made changes to the way in which performance is measured and reported, demonstrating a conscious effort to improve the systems, which is arguably more important than ensuring consistency in measuring and reporting on KPIs that may not measure the right things. In 2016, EFSA successfully delivered its first draft corporate performance dashboard. The dashboard provides strategic KPIs to guide the implementation of EFSA's strategy during 2016-2020 and represents the basis for the monitoring and reporting of data, thus strengthening a results-based management culture within the organisation³⁶⁰. This positive trend was acknowledged by staff and management, as all 13 interviewees who provided an opinion on this topic agreed that noteworthy progress had been made in the past few years. Yet, interviewed staff and management pointed to limitations of the former KPIs, indicating that **they were largely output driven** and did not include a means to accurately measure performance and efficiency. EFSA explained this is to be expected since EFSA was established as an executive agency with an emphasis on producing outputs, it means that the KPIs do not always provide a useful or meaningful means to measure the outcomes and impact of EFSA's work.

In response to such concerns, in 2016 EFSA established a performance framework that links strategic objectives to its portfolio of projects and processes and to its resources, and includes KPIs to monitor progress at input, output, outcome and impact levels. With this, EFSA has been leading the evolution towards a results-based approach. This approach was endorsed by the Heads of the EU Agencies Network during the second half of 2017 and acknowledged as providing a capability to allocate budget and resources based on expected workload and results, moving away from an input-based approach³⁶¹. The results-based performance improvement framework was adopted by the heads of the EUAN in 2018, evidencing that EFSA has made considerable progress that is also inciting change for other EU agencies. The extent to which this important change significantly impacts the usefulness of KPIs will need to be assessed in the next external evaluation.

³⁶⁰ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

³⁶¹ See p.29, European Food Safety Authority, *EFSA Performance Report, second reporting period 2017* (Parma, Italy 2017).

Summary of findings and progress relative to baseline

EQ 6 (Effectiveness): Are the internal mechanisms for programming, monitoring and reporting adequate for a) ensuring accountability and b) appropriate assessment of the overall performance of the Authority?

EFSA's mechanisms for programming, monitoring and reporting ensure accountability of the Authority, but there were obstacles to their ability to adequately measure overall performance during the 2011-2016 period.

EFSA has been proactive in following up on recommendations and improving internal mechanisms for reporting, programming and monitoring. This was corroborated by evidence from the interviews, as staff and management believe the internal mechanisms for programming, monitoring and reporting have significantly improved over the evaluation period. The Management Board is satisfied with the information it receives, and there is general agreement among staff and management that the reporting mechanisms are adequate for ensuring accountability.

However, the internal mechanisms for monitoring and reporting were not adequate to allow for a realistic assessment of the overall performance of the Authority during the 2011-2016 period. EFSA's KPIs have changed significantly over time, both in terms of what they measure and how they measure it. Although such changes are to some extent beyond EFSA's control due to its legal obligations as an executive EU agency, it made it more difficult to accurately evaluate performance across the years under review. Moreover, KPIs were largely output driven and did not allow for a meaningful measurement of efficiency, which is an important aspect of overall performance. As recently as 2017, however, EFSA introduced numerous improvements to its approach to monitoring and reporting, including through the definition of results-based KPIs that allow for a better assessment of performance at the appropriate level of granularity. This is likely to positively influence the adequacy and appropriateness of its future monitoring and reporting activities in the years to come but it is not in scope of the current evaluation to fully assess these on-going developments.

5.3 EFFICIENCY

This section seeks to assess the efficiency of EFSA, notably in terms of its cost-effectiveness, i.e. whether the desired effects are reached at a reasonable cost, as well as its operational efficiency, i.e. the degree to which EFSA's structures and processes are conducive to effective outputs and overall performance (nature and function of management systems, division of responsibilities in clear mandates, verifiable operating procedures, quality control mechanisms in place, etc.). However, there were limitations to the data available to assess the Authority's efficiency worth highlighting upfront. While EFSA had defined a few output-level KPIs to assess efficiency for the period under review, they failed to capture the complexity of its work across and within different scientific production systems. Further, they do not adequately capture the EFSA's contribution to the agri-food system through the analysis of trade data. At the time of writing, EFSA was undertaking further work to set appropriate quantitative and qualitative indicators through its Process Architecture process variant mapping of input/output indicators.

5.3.1 Cost-effectiveness

5.3.1.1 Overall cost-effectiveness of EFSA

Are resources used for EFSA proportionate to the results achieved? If not, why not? (EQ 10, 11)

Coverage of the question

This evaluation question assesses the extent to which EFSA's use of its resources is proportionate to the results achieved. To answer the question, costs and outputs were compared to assess EFSA's cost-effectiveness³⁶², assess the extent to which EFSA's organisation allows for an optimal use of resources and capabilities, and assess whether there have been any external factors that have influenced EFSA's resource allocation decisions.

This question addresses EFSA's cost-effectiveness overall, while the subsequent section explores the cost-effectiveness of different scientific production models. Due to the significant differences between EFSA's different scientific activities, it is difficult to compare its models and draw conclusions in this regard. To partially fill this gap, an analysis of the cost per output for each scientific production system is covered under EQ 18 below. However, EFSA's available data at the time of review and the complexities associated with its scientific work do not allow for a meaningful analysis of its cost-effectiveness.

The section begins with a general overview of EFSA's budget and expenditure compared to other EU agencies, and subsequently presents partial findings related to the overall efficiency of EFSA's scientific work depending on the availability of data.

Note: It is not within the agreed scope of this study (as defined in detail in the EQM – Appendix 1) to assess the cost-effectiveness of the Authority at a macro level by looking at, for example, EFSA's contribution to the agri-food system through the analysis of trade data. This is something that could be investigated as part of another study, while considering the difficulties involved in attributing any change directly to EFSA.

Sources of evidence

As this evaluation question addresses the proportionality of EFSA's resources to the results achieved, it is largely based on internal monitoring and reporting data on KPIs and expenditures. Comparative data on other EU agencies from ECA Audit Reports as well as agencies' own annual accounts and annual reports were consulted. Additional stakeholder consultation findings were used to fill gaps or offer explanations where relevant, particularly in relation to the use of resources and capabilities and external factors that may have influenced the results observed. In this context,

³⁶² EFSA's cost-effectiveness cannot meaningfully be measured with the available data, as there is a lack of outcome data to assess costs against, and EFSA's work is inherently complex and unpredictable. As a result, the analysis below looks at average costs per output to assess whether these have increased or decreased over time. Cost-effectiveness is here thus used to imply costs incurred compared to outputs produced.

responses from EFSA staff and Management Board were deemed particularly relevant and were therefore highlighted where appropriate.

The analysis of EFSA's costs versus outputs per Activity draws heavily on EFSA's Annual Activity Reports. The main limitation to the available data is in the inconsistency of reporting on KPIs and the lack of reporting on aspects such as workload, which make it difficult to assess the proportionality of EFSA's internal distribution of funds compared to results achieved. To partially account for this, the initial analysis is supplemented by an analysis of costs versus outputs *worked on* (as opposed to outputs *adopted*) in a given year, by using additional data supplied by EFSA in the context of this evaluation in March 2018. This additional data is not reported on in the Annual Activity Reports and is used to attempt to account for the inherent complexities associated with EFSA's work. Different scientific Activities produce different outputs, and not all outputs require the same amount of time and effort. A partial explanation of these complexities is outlined below and supplemented in Appendix 5.

Baseline

Over the 2007-2011 period, EFSA's expenditures on the provision of scientific outputs remained stable, while spending on scientific cooperation and networking increased and costs of risk communication decreased relative to the total budget. In 2011, EFSA's budget amounted to a total of 77.3 million EUR, of which EUR 53.9 million (70%) was allocated to its scientific production activities (Activities 1, 2 and 3).

The 2012 External Evaluation did not assess EFSA's cost-effectiveness or make any concrete conclusions on the proportionality of EFSA's spending compared to the results achieved. Nevertheless, the 2012 Management Board recommendations highlighted that EFSA needed to improve its efficiency, specifically in the context of tight resources.

Analysis of evidence

EFSA's spending was in line with its budget and distribution of costs remained stable

EFSA's commitment appropriations for 2016 totalled EUR 79.5 million EUR. Over the 2011-2016 period, the total budget of the Authority remained rather stable, increasing by only 3% in total from EUR 77.3 million in 2011 to EUR 79.5 million in 2016. The following table shows revenues and expenditures over the period under review. Subsidies from the European Commission account for the majority of EFSA's budget and, in 2016, represented over 99% of total revenue.

Table 11: EFSA's annual budgets (commitment appropriations) in EUR (2011-2016)

	2011	2012	2013	2014	2015	2016
Budget (commitment appropriations)						
Total	77,309,800	78,279,000	78,051,000	79,701,222	79,659,347	79,492,945
Executed commitment						
Personnel	37,097,113	38,563,788	39,366,197	37,685,246	39,437,577	40,513,288
Infrastructure	14,286,533	10,966,034	9,334,178	13,308,459	11,844,042	9,725,259
Operations	24,747,012	28,164,869	28,439,962	28,460,878	28,222,696	29,252,110
Total	76,130,659	77,694,691	77,140,337	79,454,583	79,504,315	79,490,657

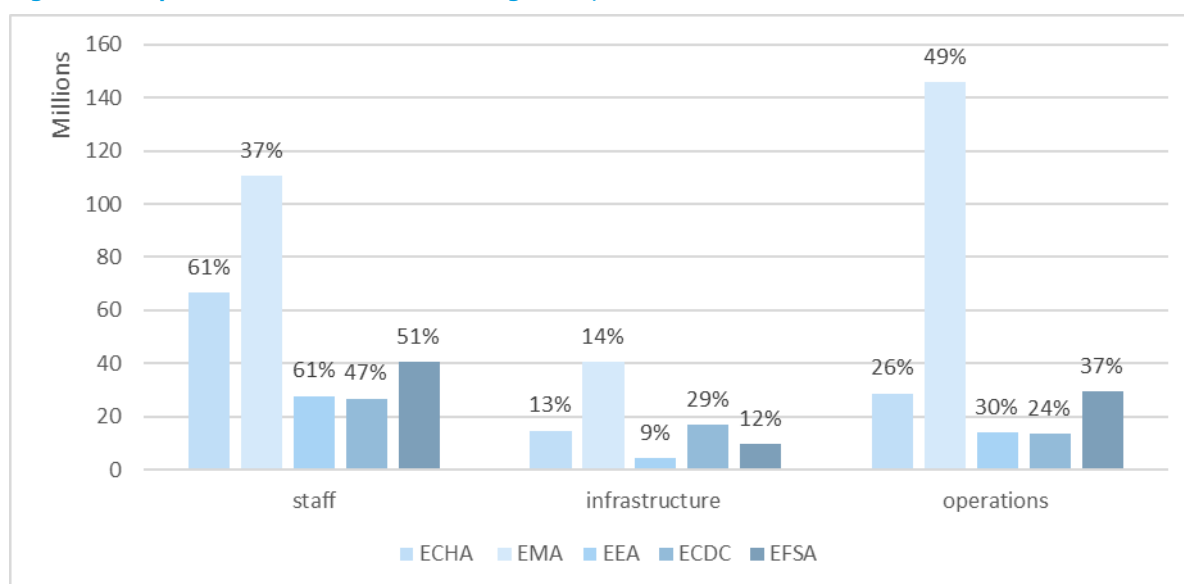
Source: Evaluation team based on EFSA Annual Activity Reports

EFSA spent most of its budget on staff (51% on average), followed by operational expenditure for the execution of its day-to-day work (36% on average) and infrastructure costs (13% on average), which were considerably lower across the period under review. The distribution of costs remained rather stable throughout the 2011-2016 period, as staff costs fluctuated between 48% and 51% of total spending, operational expenditure between 33% and 38%, and infrastructure costs between 11% and 18%.

Over the 2011-2016 period, **total expenditure increased by 3%**, in line with the 3% increase in overall budget. However, this masks significant changes in the allocation of expenditures: over the evaluation period personnel costs increased by 8% and operational costs increased by 14%, while infrastructure costs decreased significantly by 31%. Increased staff costs required reprioritisation in infrastructure³⁶³, but costs also reduced thanks to efficiency gains pertaining to IT infrastructure³⁶⁴. During 2014 and 2015, for example, EFSA consolidated all IT services under a single supplier to reduce costs.³⁶⁵

Compared to other EU agencies working in similar areas, EFSA's share of operational expenditure compared to its total spending was the highest (37%) in 2016. Spending on infrastructure (12%) was considerably lower than for ECDC and EMA, and personnel expenditure (51%) fell in the middle. However, conclusions cannot easily be drawn on the cost-effectiveness or efficiency of EFSA compared to other agencies as the budgets of EFSA and the other ENVI agencies are considerably different, they are located in different countries (with varying infrastructure and operational costs), and their work is of a different nature. Therefore, although comparing the distribution of costs within EFSA to that of the other agencies is interesting, it does not provide any meaningful picture of the adequacy of such distributions. A thorough comparative analysis in this regard falls outside the scope of this evaluation.

Figure 17: Expenditures of EFSA and other agencies, 2016



Note: percentages represent the share of each type of expenditure compared to total spending by the agency concerned in 2016.

Source: Evaluation team based on ECHA Annual Accounts 2016, EEA Annual Report 2016, EMA Annual Report 2016 and ECDC Annual Accounts 2016, EFSA Annual Activity Report 2016

EFSA's available data and the complexities associated with scientific work do not allow for a meaningful analysis of its cost-effectiveness

There was considerable fluctuation between EFSA's costs and scientific outputs. When looking at EFSA's scientific outputs over the 2011-2016 period, the trend is a clear decrease in the number of adopted outputs over time. However, changes over time in the definition of KPIs relating to scientific outputs (see section 5.2.5 for details), in combination with **complexities associated with the different elements of the scientific production system mean that KPIs measuring outputs do not adequately reflect the picture**. EFSA's work is highly variable by nature, which explains why KPIs relating to scientific outputs cannot be measured in a consistent manner and cannot be compared. Mandates and outputs differ in terms of the type and number of

³⁶³ EFSA, *Management Board Meeting presentation – 22 March 2017*, 2017.

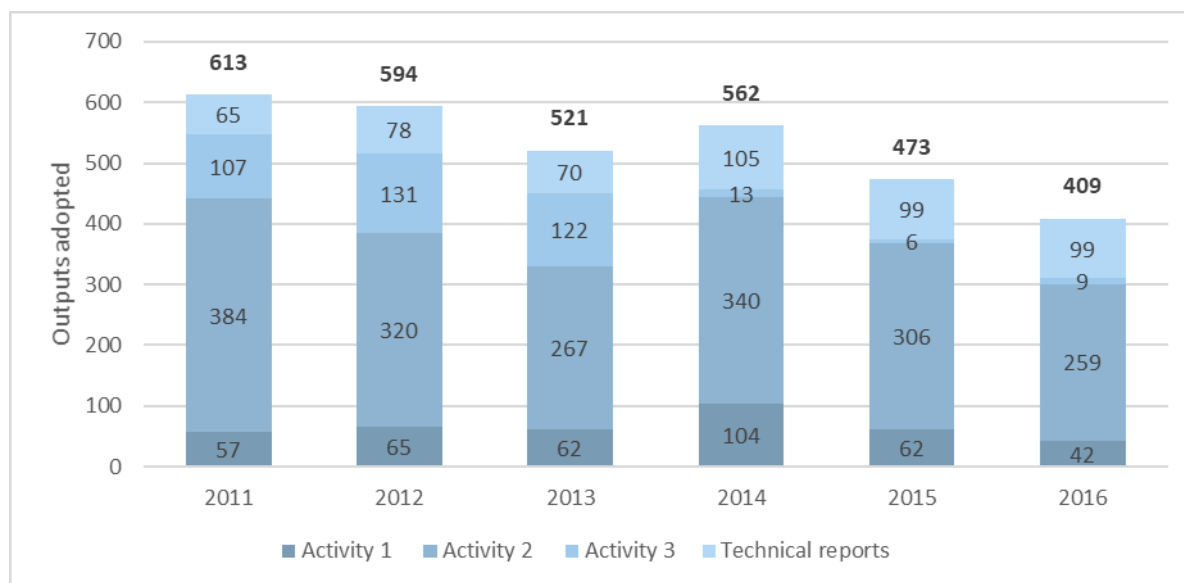
³⁶⁴ European Food Safety Authority, *Consolidated Annual Activity Report 2015* (Parma, Italy, 2017).

³⁶⁵ See p.20, European Food Safety Authority, *Consolidated Annual Activity Report 2015* (Parma, Italy, 2017).

questions to be answered, their scientific complexity, methods, data, and expertise needed to complete them, as well as the duration and progress rates of different questions.

The available data allow for a high-level year on year comparison of **how many scientific outputs were adopted**. This KPI was first put forward in 2004 (originally termed the “number of scientific opinions”).³⁶⁶ Definitions have changed over time; the definition of “scientific outputs” used here was adopted in 2010.³⁶⁷ The figure below depicts total scientific outputs adopted in 2011-2016 for Activities 1, 2 and 3, including technical reports.³⁶⁸

Figure 18: Number of scientific outputs and technical reports adopted, 2011-2016



Source: Evaluation team, based on data from EFSA's Annual Activity Reports 2011-2016

There is **no clear correlation between EFSA's budget and the number of scientific outputs (including technical reports) adopted under Activities 1, 2 and 3**. During the period under review, spending on Activities 1, 2 and 3 increased by 5% from EUR 53.9 million to EUR 56.5 million, while the total number of scientific outputs³⁶⁹ adopted decreased by 33% from 613 to 409 outputs. The graph below compares EFSA's expenditure and outputs *adopted* under Activities 1, 2 and 3 combined.

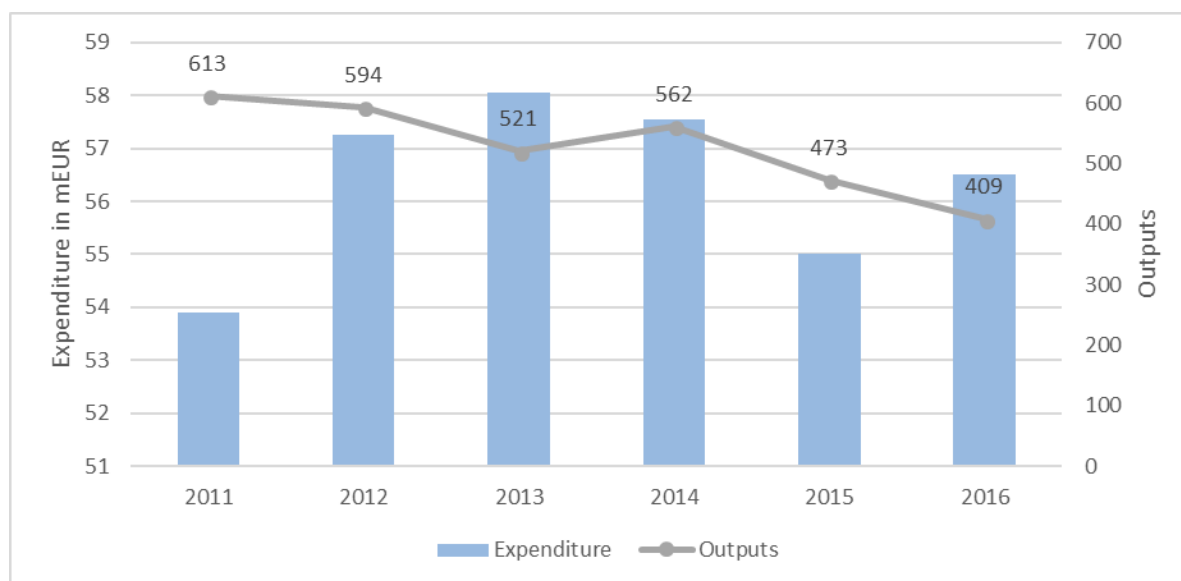
³⁶⁶ European Food Safety Authority, *EFSA Performance Indicators*, 2004.

³⁶⁷ European Food Safety Authority – EFSA, 'Definitions of EFSA Scientific Outputs and Supporting Publications' <<https://www.efsa.europa.eu/en/efsajournal/scdocdefinitions>> [accessed 4 May 2018].

³⁶⁸ Technical reports are presented separately to avoid overrepresentation of Activity 3 as reporting on them has changed over time. Prior to 2016, technical reports were reported on under Activity 3. Since 2016, technical reports are included under all three Activities.

³⁶⁹ Including all scientific outputs under Activities 1, 2 and 3 and technical reports but excluding event reports and external scientific reports. Technical reports are included because the costs are measured per Activity, and technical reports fall under the scientific Activities, whereas other supporting publications do not fall under EFSA's scientific outputs.

Figure 19: Outputs and expenditure (Activities 1, 2, 3 including technical reports), 2011-2016



Source: Evaluation team based on Annual Activity Reports 2011-2016

The graph shows that EFSA's outputs decreased between 2011 and 2016 (-33%), while spending on its three scientific Activities fluctuated but ultimately increased by 5%. Although this seems to imply that EFSA's average cost per unit of output increased over time, this reveals little about EFSA's cost-effectiveness during the 2011-2016 period due to the complexities and intricacies associated with its work (both within and between scientific Activities, which are not mutually exclusive, for example Activity 3 includes tasks which are necessary to support Activities 1 and 2).

For instance, Activities 1 and 2, which are concerned with the *provision of scientific opinions and advice and risk assessment approaches* and the *evaluation of products, substances and claims subject to authorisation* respectively, cover the production of scientific opinions, guidance documents, scientific reports, and statements by EFSA/scientific panels, but the **nature of these outputs differs significantly** (e.g. some scientific opinions are simple and require considerably less time and effort than others, see Appendix 5 for details). Activity 3 is concerned with *data collection, scientific cooperation and networking*, which covers the production of guidance documents and statements of EFSA and are therefore not comparable to Activities 1 and 2. Further, even within EFSA's Activities, **differences between panels/work areas in terms of legal deadlines and approaches lead to complexities that do not allow for a meaningful comparison** (this is discussed in more detail under section 5.3.1.2 and Appendix 5).

To partially control for the issue of comparing the number of *adopted* outputs per Activity, from 2016 EFSA launched several initiatives to improve the measurement of KPIs (making them more outcome-driven) and enhance the monitoring of workloads by, for example, assessing the **number of outputs worked on**³⁷⁰ (rather than outputs *adopted*) in any given year. The number of outputs *worked on* versus outputs *adopted* differs significantly because not all mandates received in a given year are finalised that same year, as some require more work or have longer deadlines. Hence, when considering the number of outputs adopted in relation to the money spent on scientific work in any given year, the comparison may be inaccurate if staff worked on outputs that were not adopted that same year. Nevertheless, even an assessment of the number of outputs *worked on* as opposed to the number of outputs *adopted* per Activity does not yield meaningful insights into EFSA's cost-effectiveness due to the differences between the Activities' mandates, and differences

³⁷⁰ Data on number of outputs worked on per year was provided by EFSA to the evaluation team in March 2018. The data is not reported on in Annual Activity Reports as EFSA previously only reported the number of adopted scientific outputs. The number of outputs worked on was calculated internally by EFSA based on a "productivity model". Outputs received and closed account for 100% of an output; outputs received but not closed in a year account for 55% of an output; and outputs closed in a year but not received that same year account for 45% of an output.

in the nature of outputs within the same Activity (this is discussed in more detail under section 5.3.1.2 and Appendix 5).

EFSA has become more efficient, though there is room for improvement

EFSA is actively pursuing efficiency gains, but the internal division of work and resources are insufficiently flexible. EFSA has undergone significant re-structuring and rationalisation processes since the 2012 External Evaluation.³⁷¹ The centralisation of tasks related to finance, procurement, planning and monitoring, among others, aimed to remove the burden from scientific units. A Quality Management System under ISO 9001/2015 (covering scientific and non-scientific activities) has been implemented. In addition, in 2011, EFSA was reorganised into five directorates, and an Applications Desk was created (see section 2.3.2), to make better use of resources to reflect a growing and diversifying workload, to increase efficiency, and to provide an improved service to clients.³⁷²

In recognition of the fact that EFSA's programming tools are better at capturing and managing large, stable, projects rather than at managing volatile, unpredictable, high frequency tasks, EFSA has begun a process of mapping all the key processes³⁷³, EFSA Process Architecture (EPA), including those in the scientific production system with the aim of exploring further potential for efficiency gains. The existence of resources within EFSA dedicated for measuring performance and efficiency (i.e. the Global Performance Services unit) is an indication of EFSA's commitment to improvement in this area.

EFSA also recognises the potential of IT systems. At the time of writing, EFSA is investing in developing and implementing IT systems to manage work-flows and applications where processes are sufficiently repetitive (e.g. work-flow system for submission of applications for regulated products and management of evidence submitted; data warehouse project, etc.). Other ideas are also under consideration, including forward-looking management of substances which are already on the market that need to be re-assessed in the future; mission management system, etc.

Despite EFSA's efforts to streamline procedures and centralise tasks to improve efficiency (see also section 5.3.2), there is a **lack of flexibility in terms of the allocation of work and resources**.

The starting point for EFSA's work is a complex legal framework embracing 19 different pieces of legislation³⁷⁴, which is an inherent constraint to streamlined procedures. However, the current set up does not allow for enough flexibility in resource sharing between units to manage peaks and troughs in workload (even though staff from some units may have the competencies needed to work across units). At the core of EFSA's resource management³⁷⁵ are its budgetary planning activities and time registration system (Sciforma), which were identified by EFSA staff as important tools for overall planning, management and reporting. Nevertheless, interviewed EFSA staff members noted that with the current systems, it is difficult to identify in real time whether a certain unit has spare staff, information which would be highly valuable to ensure flexible re-distribution of tasks and the management of volatile workloads. EFSA's organisational set-up is regarded as unnecessarily complex, and staff members called for more flexibility in resource sharing. Almost all interviewed EFSA staff and half of the interviewed members of the Management Board believed

³⁷¹ For example, the *Annual Activity Report of the European Food Safety Authority for 2011* states that "EFSA began rolling out its re-organisation programme in May 2011, with the objective of making better use of its resources to reflect an ever-increasing workload, strengthen efficiency and provide a higher-quality service to its clients". The re-structuring took place gradually throughout 2011 and was due to be completed by early 2012. Already in 2011, EFSA made structural savings of €1.98 million thanks to overall efficiency gains, particularly in specific areas such as interpretation, translation and meeting organisation.

³⁷² European Food Safety Authority, *Annual Activity Report of the European Food Safety Authority for 2011* (Parma, Italy, 2012).

³⁷³ The EFSA process architecture developed last year provides an overview of EFSA macro processes and EFSA is currently engaged in a process at to map further the level of sub-processes.

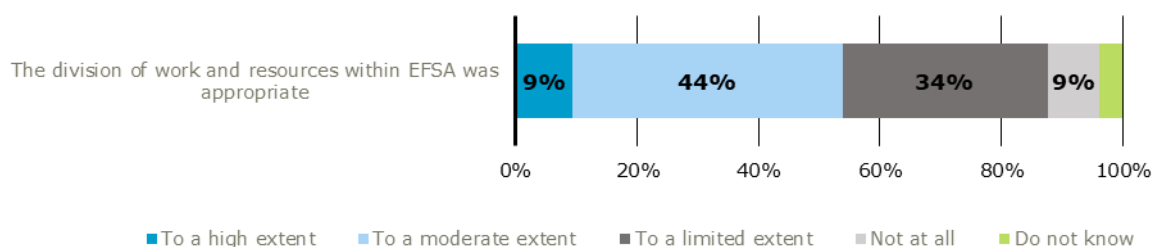
³⁷⁴ European Commission, *Impact Assessment on the Revision of Regulation 178/2002 Laying down the General Principles and Requirements of Food Law, Establishing EFSA and Laying down Procedures in Matters of Food Safety on the Establishment of Fees for EFSA*, 2016.

³⁷⁵ "In relation to strategic planning, the project and resource management initiative has been brought to fruition with the identification of EFSA's key processes and projects and associated resource allocations. This brings a range of benefits to the organisation including the ability to better match resource and delivery, plan resource allocation and identify bottlenecks and priorities in the work programme". European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014).

resources are not always properly allocated within the organisation due to this complex set-up and lack of flexibility.

Survey results show a similar picture: among the 234 staff and Management Board members surveyed, 99 believed the division of work and resources within EFSA was not at all, or only to a limited extent, appropriate during the 2011-2016 period. There was a split between EFSA's departments in terms of positive and negative views on this topic, highlighting the fact that the division of resources and work affects all parts of the organisation.

Figure 20: To what extent do you agree with the following statements concerning EFSA's organisational structure and working practices over the period 2011-2016? (n=234)



Source: Evaluation team based on survey results

Interviewed stakeholders involved in EFSA's work provided suggestions to improve the efficiency and ensure the optimal use of capabilities and resources. Interviewees from a range of stakeholder groups suggested decreasing the number of experts within each working group, making greater use of video-conferencing and increasing the scope of the work entrusted to working groups in the detriment of working at the level of the full Panel. EFSA's staff ought to be able to work across units if they have the relevant expertise and there is a need, as opposed to working in silos. Working groups could serve more than one panel (i.e. cross-panel working groups), and more preparatory work could be outsourced to ensure staff is not overburdened. However, a lot of experts were already spending a lot of their time on EFSA-related work, so placing them in several Working Groups or Panels may not be a viable solution.

No evidence on the degree to which societal and political pressures influence EFSA's fund allocation decisions

Through the documentary review, no factors were identified that suggest that external factors influence or do not influence EFSA's resource allocation decisions.³⁷⁶ On the contrary, evidence points to strengths of the current system for resource allocation. EFSA enjoys a regular income through EU funding³⁷⁷, which is supplemented by additional funding in the framework of activities to support candidate countries and as part of the European Neighbourhood Policy³⁷⁸.

Stakeholders' perceptions on the degree to which the Authority is influenced by societal and political pressures differed. Although many interviewees (19 of 34) believed political and societal pressures had led EFSA to invest in risk communication and transparency, almost all of them (28 of 34) were convinced external pressures did not affect EFSA's risk assessment activities. In fact, EFSA's spending on its core scientific work (Activities 1, 2 and 3) increased by 5% between 2011 and 2016 while its total spending increased by only 3% from EUR 77.3 million in 2011 to EUR 79.4 million in 2016. This suggests that even if EFSA increasingly invested in transparency and communications measures, it did not shift funds away from its core scientific work.

³⁷⁶ Both internal and external documents were searched, as further described in section 4.2.2.1.

³⁷⁷ See p.12-14, EFSA's Management Board, *Recommendations from EFSA's Management Board* (Parma, Italy, 2012).

³⁷⁸ EU-ANSA, *Overview of the Scientific Processes of the EU Agencies Network for Scientific Advice*, 2015.

Summary of findings and progress relative to baseline

EQ 10&11 (Efficiency): Are resources used for EFSA proportionate to the results achieved? If not, why not?

We cannot conclude whether EFSA's spending on scientific production was proportionate to the results achieved due to insufficient robust evidence from distinct types of sources.

A lack of consistency and adequacy in the measurement of KPIs during the 2016-2011 period, combined with complexities associated with the various aspects of EFSA's work make it impossible to accurately assess whether EFSA's spending on scientific production was proportionate to the results achieved. EFSA's scientific work differs significantly both within and across Activities, in terms of the type and number of questions, their scientific complexity, the methods, data and expertise needed to complete a given mandate, as well as the duration and legal deadline processes associated with a given mandate.

There is agreement amongst internal and external stakeholders that EFSA is working with limited resources, and that resources often are not allocated in the most efficient way. A considerable number of interviewees believed political and societal pressures had led EFSA to invest in risk communication and transparency. Although it is true that EFSA made considerable improvements to its transparency and communication between 2011 and 2016, the fact that spending on scientific work remained stable during that period implies that costs associated with these efforts did not take away from spending on EFSA's scientific work.

Moreover, there is insufficient flexibility in the internal division of work and resources sharing between units to manage peaks and troughs in the workload. Stakeholders believe there should be more flexibility in the way resources are allocated, for example by allowing for cross-panel Working Groups, cross-unit work for staff or outsourcing more work to Member States.

5.3.1.2 Cost-effectiveness of the scientific production systems

To what extent is EFSA's scientific production system cost-effective? (EQ 18)

Coverage of the question

This evaluation question builds on EQ 10 (section 5.3.1.1) and evidence from the detailed case study research into EFSA's scientific work by assessing in more detail the cost-effectiveness of the different elements of EFSA's scientific production system. Specifically, it breaks down the outputs and costs of the Panel system addressing general questions, the Panel system addressing authorisation dossiers, the peer review system for pesticides dossiers and scientific advice produced by EFSA staff, and compares them over time.

Due to a lack of data and evidence³⁷⁹, a thorough and robust analysis of the cost-effectiveness of EFSA's scientific production system could not be carried out. Instead, the section presents costs and benefits associated with each of the systems separately, reaching tentative conclusions on the extent to which their costs are proportionate to the results achieved.

Sources of evidence

As this evaluation question covers the cost-effectiveness of the scientific production system, it is largely based on output and cost monitoring data. Stakeholder consultations can provide little input on the matter, beyond their views on the effectiveness of the systems considering resources available. Hence, the main sources used to answer the question are EFSA's Annual Activity Reports, and additional data on outputs and costs per production system provided to the evaluators by EFSA for the purpose of this evaluation (as this data is not reported on in EFSA's Annual Activity Reports).

³⁷⁹ As described below and in section 5.2.5, EFSA's KPIs provide limited qualitative evidence in terms of outcomes; EFSA's work is complex so different aspects of the scientific production system cannot be compared; and limited evidence was collected from stakeholders through the online survey and interviews regarding the costs and benefits of the different models.

The data is different from that used in EQ 10 (above), which is at the level of EFSA's scientific Activities, rather than at the level of the scientific production systems themselves.

As explained under EQ 10, data on KPIs is limited in the sense that reporting changed over time and is solely output based, not considering workload and the complexity of the outputs. In addition, KPI data reported in Annual Activity Reports is grouped together under the different scientific activities and provides no breakdown per scientific production model. To account for this, additional data detailing outputs *worked on* and costs per model was provided by EFSA and used for this exercise.

While useful, even these additional data do not provide a comprehensive basis for assessment, as several qualitative factors come into play (including the degree of complexity, comprehensiveness, transparency and engagement, and the degree to which multiple questions are packaged in one output). Hence, no real cost-effectiveness analysis could be carried out because the available data cannot be compared. Rather, the ratio of costs over number of outputs *worked on* was assessed and interpreted, considering these qualitative factors.

Baseline

A breakdown of costs and outputs per scientific production model prior to 2014 was not available to the evaluation team, so there is no baseline for comparison prior to the period under review. Instead, the data from 2014 have been used as a baseline for comparison where relevant.

In total, across the four main scientific production models (panel system addressing general risk assessments, panel system for authorisation dossiers, pesticides peer review system and advice provided by EFSA staff), EFSA spent EUR 40.5 million in 2014, which was 51% of its total budget that year, for a total of 419 scientific outputs. *Note that these are different from the costs and outputs presented in the preceding question. Here we focus specifically on the four main scientific production models (so we exclude other costs and outputs not associated with these models).*

Analysis of evidence

Total costs for scientific production remained stable

The table below presents the total costs³⁸⁰ incurred by EFSA for all parts of the scientific production process, presented per system over the 2014-2016 period³⁸¹. Across the three years, the total costs for scientific production have remained relatively stable, though there have been minor fluctuations in the costs of the different production systems. Table 12 details the breakdown of costs associated with the different systems.

Table 12: Total costs associated with the scientific production process, 2014-2016 (in EUR)

	2014	2015	2016	Total
Panel system addressing general risk assessments	13,146,551	13,311,348	14,529,427	40,987,326
Panel system addressing authorisation dossiers	12,968,529	11,695,288	11,502,122	36,165,939
Pesticides peer review and MRL	3,741,213	4,005,192	3,967,358	11,713,764
Scientific and technical assistance to EC	10,638,153	9,618,730	8,873,509	29,130,392
Emrisk	959,688	728,393	1,607,675	3,295,756
Not Attributed ³⁸²	473,663	1,550,810	431,585	2,456,058
Total	41,927,798	40,909,761	40,911,675	123,749,234

Source: Cost data per scientific production system provided by EFSA in April 2018

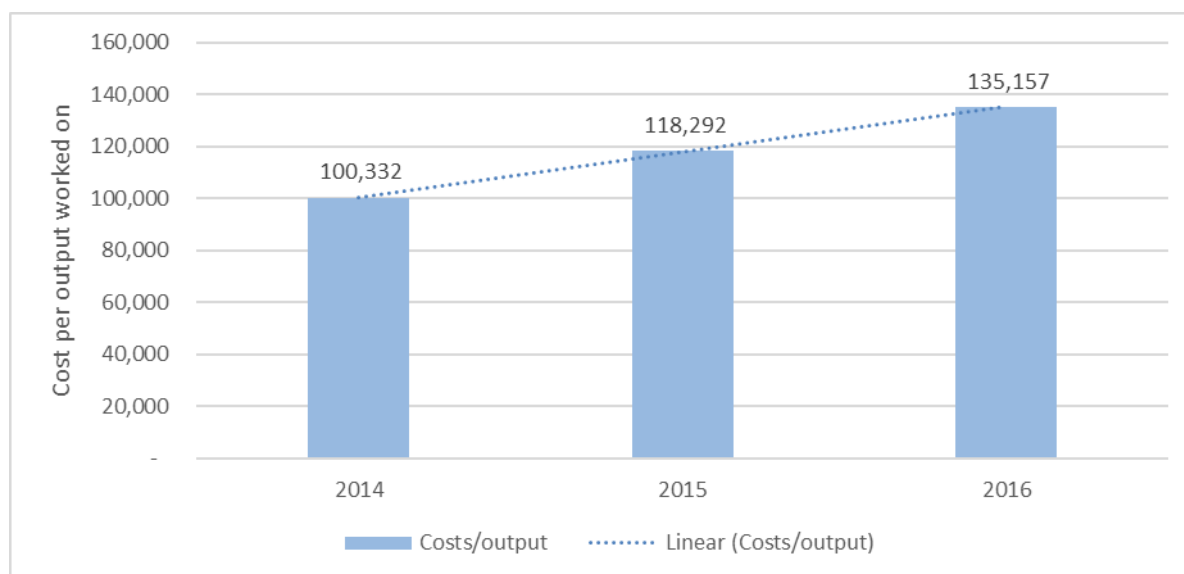
³⁸⁰ Based on additional data to that presented in the Annual Activity Reports and provided to the evaluation team by EFSA within the context of this study. Costs include all costs incurred for risk assessments and market applications, self-tasking, data collection, method/tool development for future opinions, training on expert knowledge, internal scientific coordination, handling of urgent requests, and technical assistance to the Commission.

³⁸¹ 2011-2013 is not covered as part of the cost-effectiveness analysis of the scientific production process due to a lack of data.

³⁸² Includes the TERA project, International conference 2015, organisation of scientific colloquia, Horizon 2020 work.

The benefits of the panel system addressing general risk assessments *appear to outweigh its costs*. EFSA's panel system addressing general risk assessments witnessed a **decrease in the number of outputs worked on**³⁸³ over the 2014-2016 period. At the same time, total costs associated with this scientific production system rose by 11% from EUR 13.1 million to EUR 14.5 million. As a result, the ratio of cost per unit of output *worked on* increased over time by 35%, rising from EUR 100,332 in 2014 to EUR 135,157 in 2016. This implies that over the 2014-2016 period, the production of scientific outputs through the panel system addressing general risk assessments became costlier.

Figure 21: Panel system addressing general risk assessments costs and outputs worked on, 2014-2016



Source: Evaluation team based on productivity data relating to this model provided by EFSA

However, this indicator (cost/output *worked on*) does not reflect the level of complexity or detail associated with each mandate and does not account for changes in the number of FTEs involved over time. It therefore cannot be used on its own to assess EFSA's processing capacity, efficiency and workload. For example, according to EFSA, the increase in average cost per output *worked on* is due to the complexity of customer requests and the "continuous increase of complexity of the scientific work, the demand for improved transparency and stakeholder engagement, and increased workload"³⁸⁴. Additionally, the decrease in outputs in many cases is due to streamlining the production of outputs by packaging more questions into a single output.

The panel system addressing general scientific questions accounts for the largest share of scientific production costs (EUR 14.5 million in 2016, or 35% of the total), and accounted for 19% of scientific outputs worked on in 2016.

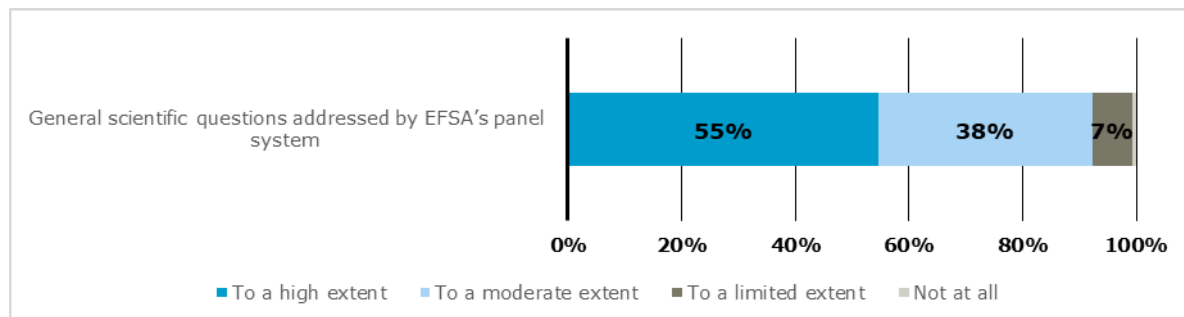
As discussed under section 5.2.1.1, the panel system addressing general risk assessments responds to needs by delivering state of the art scientific advice and is considered useful by a large majority of relevant customers (see Figure 22 below). However, the system is prone to some risks related to the availability and selection of experts. One of the main strengths is that the experts and the model for engaging experts enables EFSA to engage high quality experts ensuring high-level multidisciplinary expertise by its design, which in turn is of high importance for EFSA's effectiveness in achieving its objectives and producing assessments of the highest standards.

³⁸³ Data on number of outputs worked on per year was provided by EFSA to the evaluation team in March 2018. The data is not reported on in Annual Activity Reports as EFSA previously only reported the number of adopted scientific outputs. The number of outputs worked on was calculated internally by EFSA based on a "productivity model". Outputs received and closed account for 100% of an output; outputs received but not closed in a year account for 55% of an output; and outputs closed in a year but not received that same year account for 45% of an output.

³⁸⁴ See p.35, European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

Hence, if EFSA continues to engage the best high-quality expertise, the model's benefits outweigh its costs.

Figure 22: To what extent did the different kinds of advice provided by EFSA over the period 2011-2016 respond to your / your organisation's expectations in terms of usefulness? Please select "not applicable" if you or your organisation never used this type of advice (n=915)³⁸⁵

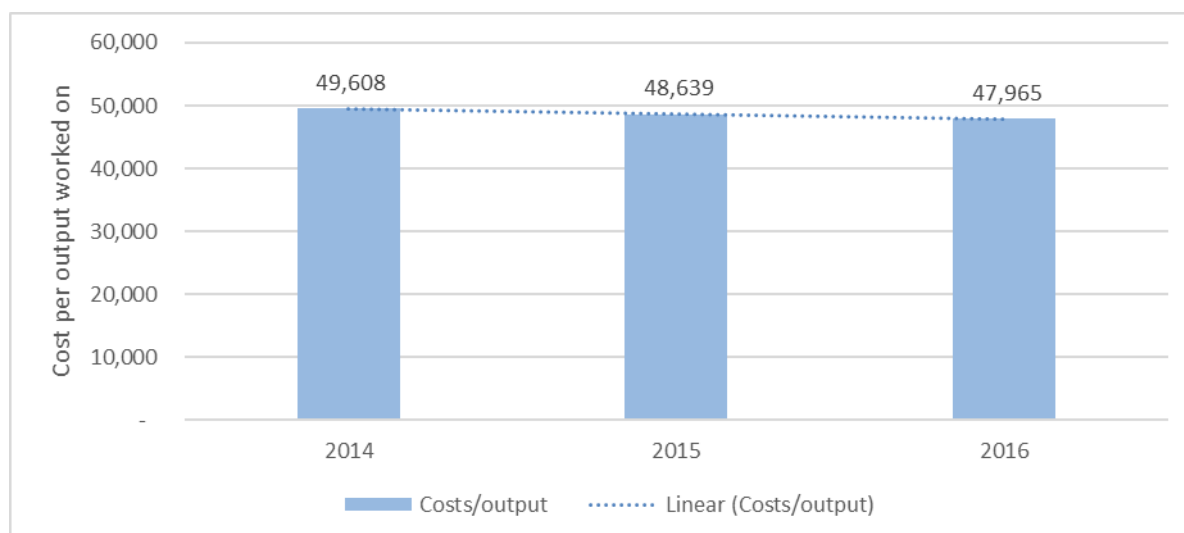


Source: Evaluation team based on survey results

The benefits of the Panel system addressing authorisation dossiers *appear to* outweigh its costs

In contrast to the panel system addressing general risk assessments, the panel system addressing regulated products saw a **decrease in both costs and outputs** over the period. The total cost for the system decreased by 11% from EUR 13.0 million to EUR 11.5 million between 2014 and 2016, while the number of outputs worked on fell by 8%, from 261.4 to 239.8 outputs.

Figure 23: Panel system addressing regulated products costs and outputs worked on 2014-2016



Source: Evaluation team based on productivity data relating to this model provided by EFSA

As a result, the average cost per output *worked on* remained stable, only slightly decreasing from EUR 49,608 in 2014 to EUR 47,965 in 2016. This total decrease of 3% between 2014 and 2016 implies that each **scientific output from the panel system addressing authorisation dossiers has become less costly** to produce.

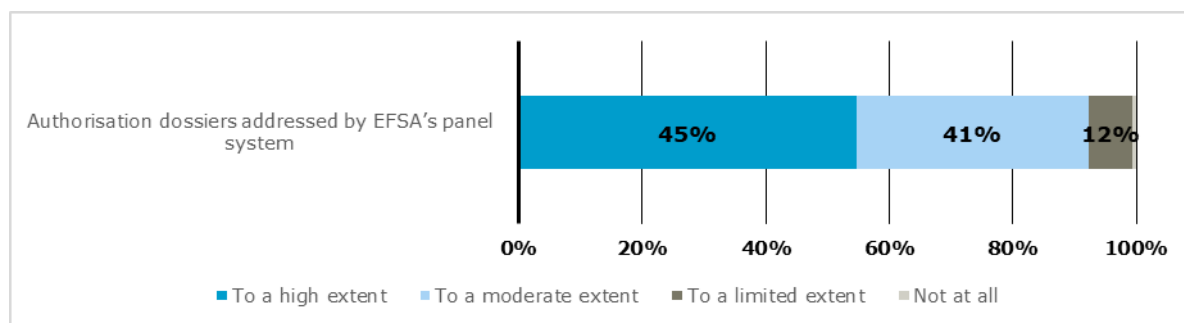
The panel system addressing authorisation dossiers is slightly less costly than the panel system addressing general risk assessments (EUR 11.5 million in 2016, or 28% of the total) but accounted for 40% of the outputs worked on in 2016.

Similar to the Panel system addressing general questions, this Panel system relies on the cumulative breadth of experience of experts with multidisciplinary expertise: academics, and those with experience in risk assessment authorities in different topic areas, and from several types of

³⁸⁵ "Do not know" (97) and "Not applicable" (281) responses were removed from the graph as respondents not familiar with this type of advice have no insight into its usefulness.

institutions, mainly universities, public research institutions and government bodies (see section 5.2.1.1). This allows the production model to provide state of the art scientific advice to EFSA's customers. As seen in Figure 24 below, relevant customers were highly satisfied with the usefulness of the authorisation dossier outputs. Hence, as above, if EFSA continues to engage the best high-quality expertise, the model's benefits outweigh its costs.

Figure 24: To what extent did the different kinds of advice provided by EFSA over the period 2011-2016 respond to your / your organisation's expectations in terms of usefulness? Please select "not applicable" if you or your organisation never used this type of advice (n=564)³⁸⁶

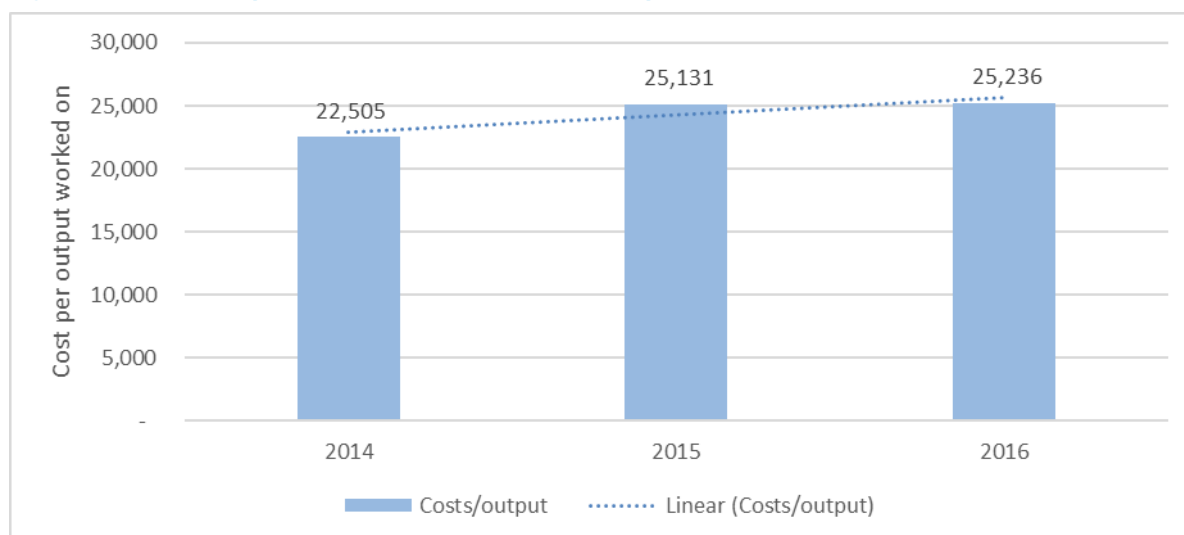


Source: Evaluation team based on survey results

The benefits of the pesticides peer review system *appear to* outweigh its costs

The peer review system for pesticides and Maximum Residue Levels (MRLs) is different from the other scientific production systems. Costs fluctuated and peaked in 2015, while the number of outputs worked on that year were lower than in 2014 and 2016. The costs associated with this model increased by a total of 6% between 2014 and 2016, rising from EUR 3.7 million to EUR 4.0 million. At the same time, the total number of outputs worked on decreased by 5%, from 166.2 in 2014, to 157.2 in 2016.

Figure 25: Pesticides peer review and MRL costs and outputs worked on 2014-2016



Source: Evaluation team based on productivity data relating to this model provided by EFSA

Because of the fluctuation between costs and outputs, the **average cost per output increased** from EUR 22,505 in 2014 to EUR 25,236 in 2016, implying that each unit of output of the pesticides peer review model became costlier to produce. This 12% increase in costs per output between 2014 and 2016 was largely a result of the large amount of work associated with the Glyphosate case. In addition, new short-term resources allocated to the Pesticides Unit (PRAS) to absorb the

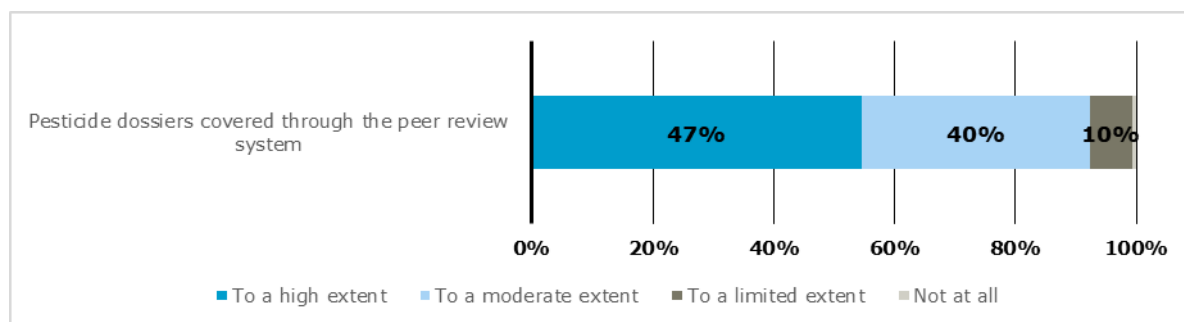
³⁸⁶ Do not know (247) and Not applicable (482) responses were removed from the graph as respondents not familiar with this type of advice have no insight into its usefulness.

inherited backlog of evaluations in pesticides dossiers only arrived between 2015 and 2016 and were not immediately fully operational.

The peer review system is the least costly system (EUR 3.9 million, or 10% of the total in 2016) and accounted for 36% of EFSA's scientific outputs worked on in 2016. This low cost is in part due to the fact that preparatory work is largely carried out by the Member States, as explained in more detail in section 2.3.4.3.

The peer review system is complex because it involves different actors (see 5.2.1.1) and its adequacy is under review. Although the survey conducted in the context of this evaluation shows a high degree of satisfaction with outputs from the pesticides system in terms of usefulness (see Figure 26 below), the system has been criticised due to differences in the quality of the Draft/Renewal Assessment Reports³⁸⁷, which was also mentioned by a small minority of interviewees. However, as discussed under section 5.2.1.1, EFSA has acknowledged that the system does not adequately respond to needs and has started working on an Action plan for improving the peer review process.

Figure 26: To what extent did the different kinds of advice provided by EFSA over the period 2011-2016 respond to your / your organisation's expectations in terms of usefulness? Please select "not applicable" if you or your organisation never used this type of advice (n=446)³⁸⁸



Source: Evaluation team based on survey results

The fact that EFSA is actively taking steps to improve the process highlights that its cost-effectiveness is likely to improve in years to come. However, considering that the peer review system is the least costly of EFSA's production models and only cost EUR 3.9 million in 2016, means that although there is room for improvement in terms of its benefits, the costs are already low. The benefits of the scientific and technical advice to the Commission appear to outweigh its costs

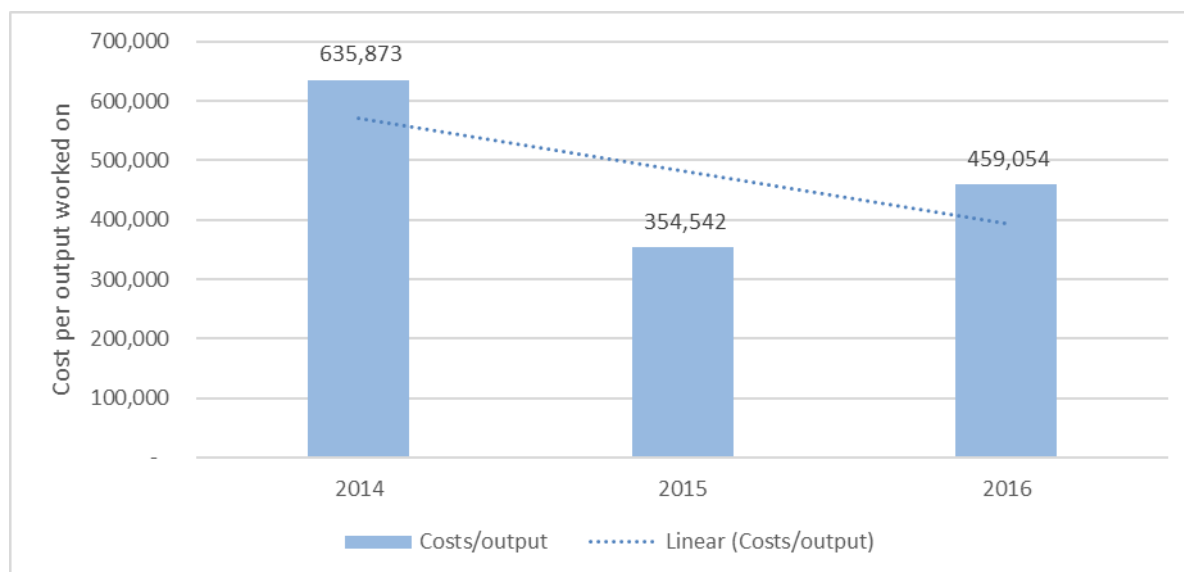
The benefits of EFSA's technical and scientific advice to the Commission system *appear to* outweigh its costs

Costs associated with the scientific and technical assistance provided to the Commission steadily decreased over the 2014-2016 period by a total of 17%, from EUR 10.6 million in 2014 to EUR 8.9 million in 2016. The number of outputs worked on increased by a total of 6%, from 16.7 outputs³⁸⁹ in 2014 to 19.3 outputs in 2016.

³⁸⁷ European Commission Internal Audit Service, 'Final Audit Report on Evaluation of Regulated Products: "Assessment" Phase in Pesticides Authorisation in the European Food Safety Authority (EFSA)', 2017.

³⁸⁸ Do not know (288) and Not applicable (559) responses were removed from the graph as respondents not familiar with this type of advice have no insight into its usefulness.

³⁸⁹ The total number of outputs worked on in 2014 is 29.7, but after adjusting by -13 to account for the change of classification of public consultation and other technical reports for NUTRI and PRAS, the total comes to 16.7 outputs.

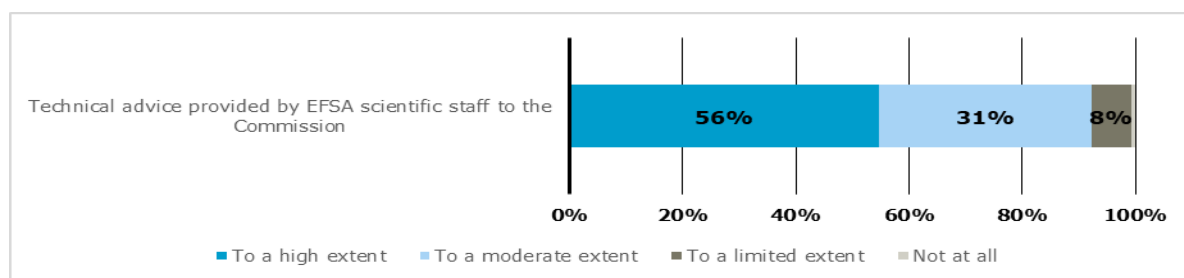
Figure 27: Scientific and technical assistance costs and outputs worked on 2014-2016

Source: Evaluation team based on productivity data relating to this model provided by EFSA

According to this metric, scientific and technical advice is the costliest system and accounted for only 3% of the outputs worked on in 2016. In absolute terms, a total of EUR 8.9 million (22% of the total in 2016) was spent on this system, despite the small number of 19.3 outputs *worked on*.

However, comparing costs and outputs over time within this category of outputs is not very meaningful due to the differences between requests. EFSA's scientific and technical assistance to the EU includes data collection, EU summary reports, surveillance activities, and article 31 generic requests, which range in size and cost. In 2016 alone, costs for individual mandates ranged from EUR 1,324 for data collection for IPCHEM, to EUR 1,362,740 for data collection and analyses processes on animal disease outbreaks and surveillance³⁹⁰. This highlights that costs vary significantly, depending on the mandate. Moreover, many mandates carry over several years, distributing the costs over time.

The Commission was largely satisfied with the advice provided by EFSA staff (see Figure 28), and there was widespread agreement among the interviewed Scientific Panel chairs that EFSA's staff are highly qualified, motivated and dedicated to supporting the production of high quality outputs (see 5.2.1.1). Hence, although the system is costly compared to the other systems, it is effective in providing high-quality scientific advice to the Commission, implying that its benefits outweigh the costs.

Figure 28: To what extent did the different kinds of advice provided by EFSA over the period 2011-2016 respond to your / your organisation's expectations in terms of usefulness? Please select "not applicable" if you or your organisation never used this type of advice (n=36)³⁹¹

Source: Evaluation team based on survey results

³⁹⁰ Based on additional data to that presented in the Annual Activity Reports and provided to the evaluation team by EFSA within the context of this study.

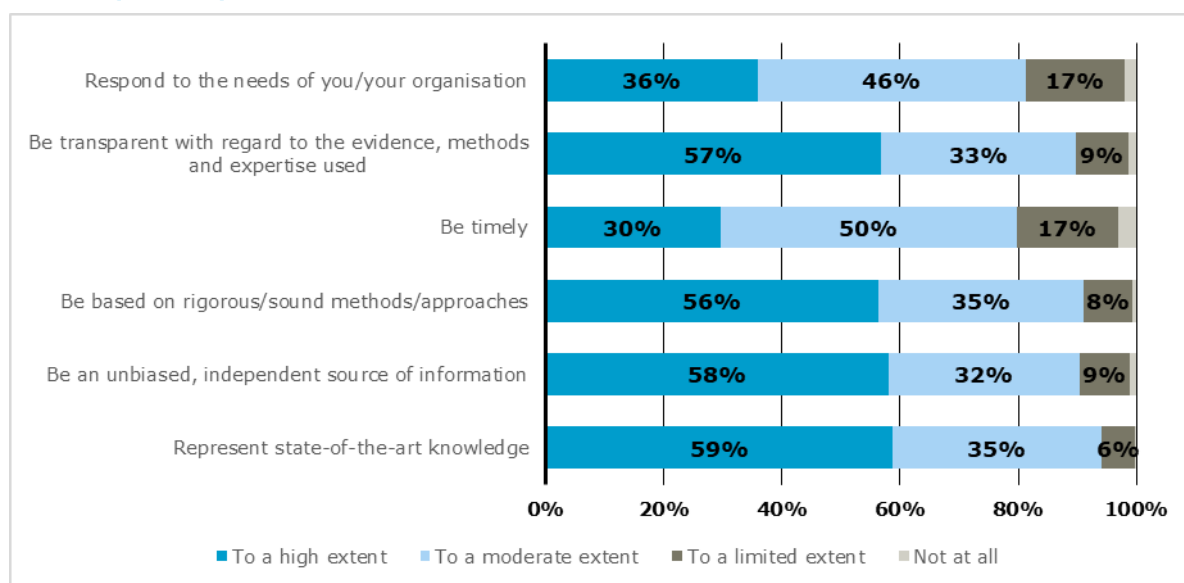
³⁹¹ The number of respondents for this question is low because it was only asked of Commission officials. "Not applicable" responses (4) were removed from the graph as respondents not familiar with this type of advice have no insight into its usefulness.

EFSA's scientific production systems appear to be cost-effective

Overall, even though costs and outputs are difficult to compare across and within scientific production models and there is limited outcome data available to assess the benefits of the different models, **the costs associated with EFSA's scientific production system do not appear to be disproportionate.**

As assessed above, qualitative evidence collected in the framework of this evaluation suggests that EFSA's customers are generally satisfied with the advice provided to them (see Figure 29). This, combined with the assessment that the costs associated with the different systems are not disproportionately high, means that EFSA's scientific production system is cost-effective.

Figure 29: To what extent do you consider the scientific advice provided by EFSA over the period 2011-2016 to: (n=1,309)³⁹²



Source: Evaluation team based on survey results

³⁹² The total number of respondents reported on in the graph differs per sub-question because Do not know/Not applicable answers were removed. The totals are as follows: represent state of the art knowledge (1246); be an unbiased, independent source of information (1247); be based on rigorous/sound methods/approaches (1241); be timely (1216); be transparent (1255); respond to needs (1131).

Summary of findings and progress relative to baseline

EQ 18 (Efficiency): To what extent is EFSA's scientific production system cost-effective?

The available data does not allow for a robust analysis of EFSA's cost-effectiveness. Hence, no conclusions could be drawn on the extent to which EFSA's spending on scientific production was proportionate to the results achieved.

Overall, EFSA's spending on the four scientific production models decreased by 4% between 2014 and 2016, from EUR 40.5 million to EUR 38.8 million. Compared to the 51% of the total expenditures in 2014, EFSA's spending on these four models accounted for 49% of total expenditures in 2016.

The average cost per output of production of the models differed: the cost per output *worked on* of the panel system addressing general scientific questions and the pesticides peer review system increased between 2014 and 2016, whereas the cost per output *worked on* of the panel system addressing authorisation dossiers and technical advice by EFSA staff decreased over time. However, average costs per output provide little insight into the comparative efficiency or cost-effectiveness of the models, as individual outputs across and even within a given model differ significantly in terms of their complexity, amount of time and effort required to produce them, and the legal deadlines which may affect prioritisation in times of limited resources to carry out the volume of work.

The differences between the different scientific production systems do not allow for a comparative analysis of their relative costs and benefits. In the absence of the possibility of conducting a full cost-benefit analysis, it can be tentatively concluded based on qualitative stakeholder satisfaction data obtained in the context of this evaluation that the benefits associated with EFSA's scientific production systems outweigh the costs incurred. Nevertheless, there is room to streamline processes to allow for more efficiency across the board.

5.3.2 Operational efficiency

5.3.2.1 Administrative burden for staff and stakeholders

Do established procedures minimise the administrative burden of the Authority and its stakeholders? (EQ 7)

Coverage of the question

Within the context of European institutions' drive to reduce the administrative burden imposed on staff and stakeholders, it is important for EFSA to understand the degree of administrative burden placed upon staff and stakeholders and whether its established procedures are adequate to ensure that it is proportionate. This question has a dual focus: it seeks to assess both the weight of administrative tasks undertaken by the Authority's staff, and the costs borne by EFSA's stakeholders because of administrative activities performed to comply with information obligations included in its legal rules. This question builds on EQ 10 and EQ 18 as it offers insight into the factors that influence EFSA's cost effectiveness.

Sources of evidence

A range of documentary sources were consulted, including EFSA's own internal reporting, data from other independent evaluations, and external sources. The main sources used were EFSA's Annual Activity Reports and planning documents, as they provide valuable insights in EFSA's investments in efficiency, and actual spending on administration.

However, documentary sources provide little evidence about the extent to which there is a (disproportionate) administrative burden associated with EFSA's procedures, both for staff and external stakeholders. Hence, as this question is highly subjective in nature, the views of consulted stakeholders weigh heavily in the assessment of the administrative burden associated with

interacting with EFSA. Views from EFSA staff and management have been used to assess administrative burden associated with their work.

Baseline

The 2012 External Evaluation of EFSA highlighted that during the 2007-2011 period, EFSA had begun to identify and reallocate resources to reinforce its scientific capacity and had successfully centralised several administrative tasks in light of its 2010 efficiency programme. The evaluation made no concrete conclusions or recommendations pertaining to the administrative burden associated with EFSA's working practices and procedures.

The resulting recommendation from EFSA's Management Board highlighted that regulatory workflows that are applicable to EFSA's work should be streamlined, with the objective of reducing unnecessary administrative burden.

Analysis of evidence

EFSA has made considerable investments to reduce staff's administrative workload

EFSA has undergone significant re-structuring and rationalisation processes since the last external evaluation.³⁹³ Tasks related to finance, procurement, planning and monitoring were centralised to remove the burden of administrative tasks from scientific units (see section 5.3.1.1). During 2014 and 2015, EFSA digitalised its administration to enhance productivity, and fully centralised grants, procurement and contract management as well as corporate control functions.³⁹⁴ The centralisation and improved planning and controlling of processes such as mandate review and planning, procurement (outsourcing) and grants management, and the centralisation of back office functions resulted in a saving of at least 21 posts between 2012 and 2017.³⁹⁵

Due to these improvements and the optimisation of roles, **scientific staff workload became less administrative over the period** and more focused on actively contributing to the drafting of scientific opinions and to the development of guidelines, protocols and standards disseminated to Scientific Panels and Member States.³⁹⁶ In line with the objectives of the STEP 2018 project, there was a reduction of 17.5 FTEs for the performance of administrative tasks, as well as an improvement in the ratio of effort spent on operational versus support activities from 74%/26% in 2015 to 73%/27% in 2017.³⁹⁷

Administrative tasks impact operational work

These investments were recognised by interviewees to have improved internal working procedures and enhanced efficiency, and 58% of staff and management who responded to the survey indicated that internal initiatives for streamlining and simplification led to change being implemented. EFSA staff highlighted the increased efficiency through increased use of technology and automation: data collection and management is being automated; EFSA put in place a project management system and is generally advancing in its use of IT tools to improve efficiency. Hence, investments for efficiency gains are being made, but there is room for improvement, as survey results show that 76% of EFSA staff and management still believed the administrative burden imposed on them negatively affects their ability to carry out operational work.

³⁹³ For example, the *Annual Activity Report of the European Food Safety Authority for 2011* states that "EFSA began rolling out its re-organisation programme in May, with the objective of making better use of its resources to reflect an ever-increasing workload, strengthen efficiency and provide a higher-quality service to its clients". The re-structuring took place gradually throughout 2011 and was due to be completed by early 2012. Already in 2011, EFSA made structural savings of €1.98 million thanks to overall efficiency gains, particularly in specific areas such as interpretation, translation and meeting organisation"

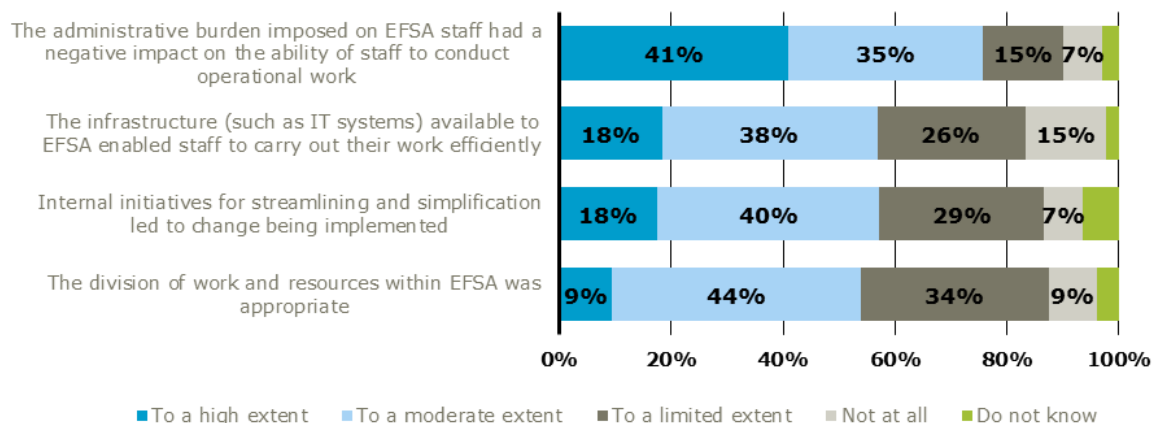
³⁹⁴ See p.20, European Food Safety Authority, *Consolidated Annual Activity Report 2015* (Parma, Italy, 2017).

³⁹⁵ EFSA, *Consolidated Management Evaluation*, 2017.

³⁹⁶ Ibid.

³⁹⁷ European Food Safety Authority, *Consolidated Annual Activity Report 2017 (DRAFT)* (Parma, Italy, 2018).

Figure 30: To what extent do you agree with the following statements concerning EFSA’s organisational structure and working practices over the period 2011-2016? (n=234)



Source: Evaluation team based on survey results

No disproportionate administrative burden for stakeholders

The 2011 Scientific Expert Satisfaction Survey, conducted among 1,700 experts associated with EFSA, bore overwhelmingly positive responses: 91% of the respondents were either satisfied or very satisfied with the overall support provided by EFSA, and specifically with the level of administrative support (93%), the scientific support (89%), and the level of communication support (85%).³⁹⁸ The 2015 Expert Satisfaction Survey, conducted among 767 experts, produced similar, though slightly less positive results: satisfaction was indicated by 89% regarding support provided by EFSA travel management staff, 87% for scientific support, 60% for EFSA’s financial compensation, 54% with training opportunities and access to free scientific literature, and 53% with the application and selection process.

In contrast, a 2016 Ipsos MORI study³⁹⁹ commissioned by EFSA specifically soliciting stakeholder views on administrative burden associated with interacting with EFSA resulted in some negative feedback from a small number of industry representatives⁴⁰⁰ on the application process more specifically. The process was reported to be impersonal and not clear enough, and clarifications were reportedly difficult to obtain.

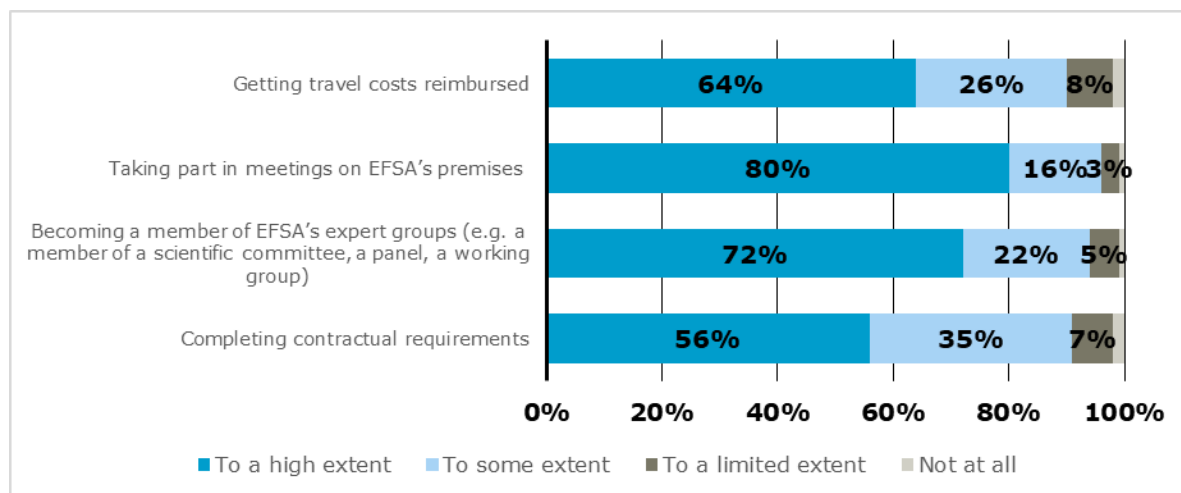
However, the same size for the IPSOS MORI study was very small (five interviewees), and stakeholders consulted within the framework of this evaluation were overwhelmingly positive in their assessment of the extent to which administrative tasks were appropriate considering the outputs achieved. When considering only those who provided an opinion, 90% or more of respondents believed all four administrative tasks listed in the figure below were appropriate to a high or moderate extent.

³⁹⁸ European Food Safety Authority, *Annual Report 2011* (Parma, Italy, 2012).

³⁹⁹ Ipsos MORI, *EFSA stakeholder research – Final report* (London, UK, 2015).

⁴⁰⁰ In total, 5 people from industry and industrial associations were interviewed. The report concludes that “there was an overall sense however that the application process is much too bureaucratic where EFSA is more focused on process than they are with relationships”. A survey was also carried out, but the report makes no reference to the number of respondents from industry/industrial associations.

Figure 31: To what extent were the administrative tasks associated with the following interactions (that you/your organisation may have had with EFSA) appropriate, considering the outputs achieved? (n=1,191)⁴⁰¹



Source: Evaluation team based on survey results

Although requirements for experts have changed significantly since 2011, the positive trend in results over the period under review implies that EFSA's stakeholders have consistently been satisfied with the level of support provided to them, implying that there is no disproportionate administrative burden imposed on stakeholders when interacting with EFSA.

Summary of findings and progress relative to baseline

EQ 7 (Efficiency): Do established procedures minimise the administrative burden of the Authority and its stakeholders?

EFSA has made considerable investments to improve the efficiency of its work, including projects to better allocate work and resources within the organisation and mechanisms to shift administrative work away from its scientific staff. These efforts are recognised by stakeholders, however, there is room to further improve efficiency, e.g. by further centralising administrative work and investing in IT solutions to reduce the administrative burden on EFSA staff. Despite improvements, the clear majority (76%) of staff and management still believed the administrative burden imposed on them negatively affected their ability to carry out operational work, and only 7% believed the administrative burden did not impact their ability to conduct operational work at all, suggesting scope for further efficiency improvements.

When it comes to external stakeholders, they were satisfied with the support provided by EFSA in relation to several administrative tasks required of them, and no disproportionate administrative burden was identified when interacting with EFSA.

5.3.2.2 Prioritisation of work

Does EFSA undertake prioritisation of certain topics or tasks and, if so, has this been appropriate? (EQ 8)

Coverage of the question

It is important for EFSA to prioritise tasks to fulfil all mandates within their respective deadlines and in a satisfactory manner. This evaluation question assesses the extent to which EFSA has

⁴⁰¹ The total number of respondents to this question was 1,191. However, as a significant percentage of responses was "do not know" or "not applicable", these responses were removed from the graph. Hence, the total number of respondents differs between sub-questions. The total number of respondents included in the graph is: 696 for getting travel costs reimbursed; 1,013 for taking part in meetings; 949 for becoming a member of expert groups; and 885 for completing contractual requirements.

mechanisms in place that allow it to prioritise and the extent to which these are used in practice and assesses the appropriateness of its prioritisation of topics considering EU political priorities.

Sources of evidence

The mechanisms in place to prioritise and the extent to which EFSA prioritises were assessed with reference to Regulation (EC) N° 178/2002, as well as Annual Activity Reports and strategy documents, and consultations with relevant stakeholders (EFSA staff and DG SANTE). EFSA's internal reporting and strategy documentation was especially relevant, as it provides insights into EFSA's priorities and investments in planning and prioritisation mechanisms over the period under review. Stakeholder views complement this as they offer insights as to whether EFSA's staff and stakeholders themselves believe the investments made have positively affected the Authority's ability to prioritise work and improve efficiency.

As an assessment of the appropriateness of EFSA's prioritisation is highly subjective and difficult to assess through documentary evidence, the documentary review focuses on assessing EFSA's ability to respond to emergency needs through its internal reporting, which offers a good proxy to assess EFSA's ability to shift priorities and resources when necessary. Stakeholder views acquired through the online survey and interviews provided insights on the appropriateness of EFSA's prioritisation more generally.

Baseline

The previous external evaluation of EFSA concluded that the Authority should increase its programming and prioritisation capacity. It found that EFSA works in a very complex context where the workload is increasing, not easily foreseeable and becoming more challenging. Hence, it was deemed important that EFSA and its clients increase the level of information exchange for EFSA to tackle the increasing workload in an efficient way, and that EFSA strengthen its internal capacity to anticipate challenges and emerging risks and prioritise activities/tasks. The evaluation also suggested that EFSA should first recognise that it has extended its sphere of activities to fit risk managers' needs and that the Commission could give more detailed feedback on the usefulness of EFSA's outputs to help it identify priority areas and focus available resources.⁴⁰²

The resulting recommendations from EFSA's Management Board were as follows: (i) EFSA should continue to enhance its efficiency and its ability to set priorities; (ii) EFSA should maintain its focus on general health issues and emerging risks in a context where the workload and the complexity of the assessment of regulated products are continuously increasing; (iii) EFSA should proactively identify scientific fields where there is a need for self-tasking and communicate clearly on this aspect of its work to all stakeholders.

Analysis of evidence

EFSA remains committed to the effective and efficient prioritisation of its work

EFSA's structural re-organisation in 2011, including the creation of planning and monitoring teams for each directorate, was one of the steps to enhance internal coordination and long-term planning capabilities within the organisation. A further centralisation of services followed in 2016 in the areas of transaction, processing, sourcing, planning, monitoring and reporting under the STEP 2018 project. This tailoring of planning and monitoring resources and tools has proved instrumental in supporting EFSA's scientific and communication departments to focus on their planned activities and tasks and to monitor them more closely.

There was a strategic commitment to prioritisation in EFSA's Science Strategy 2012-2016, which planned for the development of a clear prioritisation framework taking into consideration needs for review of regulated products, health and emerging issues.⁴⁰³ This commitment continued in the EFSA Strategy 2020, where EFSA will define a prioritisation scheme for its resources, in close

⁴⁰² Ernst&Young, *External Evaluation of EFSA – Final Report*, 2012.

⁴⁰³ European Food Safety Authority, *Science Strategy 2012-2016* (Parma, Italy, 2012).

cooperation with risk managers and assessment partners. It will also anticipate risk assessment priorities and related methodology and evidence needs. Finally, it will proactively identify priority areas of intervention in collaboration with its partners and stakeholders.⁴⁰⁴ This Strategy was still in the early phase of execution at the time of writing, so it is too early to assess outcomes.

EFSA has various mechanisms in place that enable it to prioritise topics/tasks

The starting point for EFSA's ability to prioritise work is Regulation (EC) N° 178/2002. As per EFSA's founding Regulation, the Management Board is tasked with the adoption of (multi)annual work programmes, and needs to ensure that these are consistent with the Community's legislative and policy priorities in food safety.⁴⁰⁵ The Advisory Forum advises the Executive Director on the drafting of a proposal for the Authority's work programme and the prioritisation of requests for scientific opinions.⁴⁰⁶ At the same time, the Regulation tasks EFSA with the monitoring and identification of emerging risks in the fields within its mission.⁴⁰⁷ If a crisis were to emerge, EFSA needs to respond quickly, even if this means setting aside priorities initially agreed on.

Between 2011 and 2016 EFSA identified research priorities in consultation with the Advisory Forum and the Scientific Committee/Panels and units, but it also established other mechanisms to assist in the prioritisation of topics/tasks:

- In 2012, EFSA set up a working group to establish priorities for the review of existing guidance documents on risk assessment and the preparation of new ones.⁴⁰⁸
- In 2013, the EC-EFSA roadmap was re-established to focus on resource outlook and prioritisation, leading to the identification of EFSA's key processes and projects and associated resource allocations.⁴⁰⁹
- In 2014, a review of the methodology of risk ranking for prioritisation of food and feed related issues based on their anticipated health impact was carried out to ensure proper prioritisation of important topics.⁴¹⁰
- In 2014, EFSA concluded the Project and Resource Management approach (PaRMa), which put in place a system for portfolio management with the aim to place planning and prioritisation at the heart of EFSA's activities to allow EFSA to better manage its resources.⁴¹¹ It provided EFSA with better insight into the use of its resources and, in parallel, project/process managers and teams were supported by professional planning and monitoring tools that facilitate the execution of projects and tasks.⁴¹²
- In 2014, EFSA set up the STEP 2018 initiative, which aimed to improve operational efficiency and effectiveness. By the end of 2015, the project had centralised, standardised and modernised several controlling and support processes, improved the ratio of operational to administrative resource, and delivered efficiency gains of nine full-time-equivalent resources.⁴¹³ The STEP 2018 project achieved more than the expected savings (17.5 FTEs out of the 14 planned over the years 2015 and 2016), thereby contributing to the reduction of the effort dedicated to support activities.⁴¹⁴
- In 2016, the development of the EFSA process architecture (EPA) and a process mapping and documentation methodology increased EFSA's maturity in process management. This strengthened EFSA's planning and analytical capability regarding resource management and optimisation, with a focus on efficiency. The EPA was set up in 2016 in recognition of

⁴⁰⁴ EFSA Strategy 2020: *Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

⁴⁰⁵ Article 25(8) of Regulation (EC) N° 178/2002.

⁴⁰⁶ Article 27(3) of Regulation (EC) N° 178/2002.

⁴⁰⁷ Article 34 of Regulation (EC) N° 178/2002.

⁴⁰⁸ European Food Safety Authority, *Annual Report 2012* (Parma, Italy, 2013).

⁴⁰⁹ European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014).

⁴¹⁰ European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015).

⁴¹¹ P21, European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015).

⁴¹² EFSA, *PaRMa Project: Project Closure Report*, 2014.

⁴¹³ European Food Safety Authority, *Consolidated Annual Activity Report 2015* (Parma, Italy, 2016).

⁴¹⁴ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

the fact that EFSA's programming tools are better at capturing and managing large, stable, projects rather than at managing volatile, unpredictable, high frequency tasks. It aims to map all EFSA's key processes⁴¹⁵ to explore further potential for efficiency gains through appropriate planning and prioritisation. The existence of resources within EFSA dedicated to measuring performance and efficiency (i.e. the Global Performance Services unit) is a good indication of EFSA's commitment to improvement in this area.

- At the core of EFSA's resource management⁴¹⁶ are its budgetary planning activities and time registration system (Sciforma), which were identified by interviewed EFSA staff as important tools for administrative overall planning, management and reporting.
- In 2016, EFSA developed a performance measurement system which enforces results-based management and, to a certain extent, process management (EFSA will continue along this path by piloting results-based budgeting and management via flexible resource allocation in 2019). The documentary review uncovered evidence that EFSA is working based on a vision that aligns working practices with tasks and goals⁴¹⁷ as well as a wide range of activities to further develop working practices and organisational structure, suggesting a willingness to adapt to meet evolving needs.⁴¹⁸

Despite these initiatives, nine interviewees from DG SANTE and EFSA (of 19 in total) noted that the **Authority was lacking a concrete model for setting priorities** during the 2011-2016 period. That is not to say that EFSA did not prioritise topics and tasks, but rather that there was no consistent way in which prioritisation decisions were made. Priorities largely depended on circumstances (e.g. emergencies), making it difficult for EFSA to plan. As described in section 5.2.5, however, EFSA has shifted towards a results-based approach enabling to track on a regular basis progress made against EFSA's strategic objectives⁴¹⁹, which in turn allows the Authority to track performance and improve its prioritisation. Although there is no way to assess at this stage the results the recent planning and prioritisation mechanisms will have, EFSA has clearly **taken steps to improve the planning process and resource utilisation** during the 2011-2016 period that have positively impacted its capacity to plan and allocate resources to be better prepared in the future.

EFSA has been successful at responding to urgent requests

A majority (70%) of the 690 survey respondents who were asked about EFSA's ability to respond to urgent requests and crises believed EFSA was prepared to do so to a high or moderate extent. EFSA has **mechanisms in place to efficiently prioritise topics or tasks in case of an urgent need** emerging in the EU that have allowed it to adequately respond to an urgent request or crisis over the 2011-2016 period, as exemplified by the following examples:⁴²⁰

- During the 2011 E. coli outbreak, EFSA gave urgent scientific advice and technical assistance to France and Germany. It issued urgent outputs and fast-track risk assessment, and it set up a special Task Force to trace back the cause of the crisis.⁴²¹

⁴¹⁵ The EFSA process architecture developed last year provides an overview of EFSA macro processes and EFSA is currently engaged in a process at to map further the level of sub-processes.

⁴¹⁶ "In relation to strategic planning, the project and resource management initiative has been brought to fruition with the identification of EFSA's key processes and projects and associated resource allocations. This brings a range of benefits to the organisation including the ability to better match resource and delivery, plan resource allocation and identify bottlenecks and priorities in the work programme". European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014).

⁴¹⁷ European Food Safety Authority, *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

⁴¹⁸ E.g. (i) Selection and implementation of a set of transparency and engagement measures throughout the risk assessment workflow; (ii) Establishment and implementation via regular review of a multiannual plan of support activities; (iii) Development of an e-submission workflow on application dossiers for regulated products which will be gradually implemented from 2018; a collaboration tool for the preparation of regulated product opinions will be developed by 2020.

⁴¹⁹ See p.29, European Food Safety Authority, *EFSA Performance Report, second reporting period 2017* (Parma, Italy 2017).

⁴²⁰ The examples listed do not offer an exhaustive list of EFSA's response to emergencies.

⁴²¹ European Food Safety Authority, *Annual Report 2011* (Parma, Italy, 2012).

- In 2012, the Commission requested urgent assistance from EFSA on the Schmallenberg virus. EFSA then published reports and updates based on data shared with the Commission and Member States, and assisted Member States with the risk management approach.⁴²²
- In 2014, aside from its regular scheduled work, EFSA provided an emergency response to the Ebola crisis, outbreaks of hepatitis A, avian flu, and African swine fever. Following the outbreak, EFSA published reports on the risk of transmission of the Ebola virus and updated the information published, and gave urgent advice following cases of African Swine Fever on pigs and wild boars in Poland and Lithuania, and on sheep and goat pox in Greece and Bulgaria.⁴²³
- In 2015, EFSA's plant health specialists provided scientific and technical advice to the European Commission regarding the outbreak of *Xylella fastidiosa*, a plant pathogen affecting large populations of olive trees in southern Europe.⁴²⁴ They established a host plant database, providing risk assessment data on the pathogenicity of the Apulian strain and the efficacy of hot water treatment for grapevine, and assessed claims regarding other causative agents of the olive decline and supported the Commission in developing guidelines for the EU territory survey.
- In 2016, EFSA responded to an urgent request for advice on lumpy skin disease (LSD), and carried out an assessment of the effect of combinations of different eradication and vaccination options on the spread of the LSD virus, using a mathematical model to simulate the spread of LSD between farms.⁴²⁵

Summary of findings and progress relative to baseline

EQ 8 (Efficiency): Does EFSA undertake prioritisation of certain topics or tasks and, if so, has this been appropriate?

EFSA has invested in mechanisms for prioritisation in response to the 2012 External Evaluation of EFSA, leading to improvements over time. EFSA identified research priorities in consultation with the Advisory Forum and the Scientific Committee/Panels and units; initiated the set-up of research clusters and a working group to establish priorities for the review of existing guidance documents on risk assessment and the preparation of new ones; rolled out the PaRMA project with the main aim of improving planning and prioritisation; and set up the STEP 2018 initiative to centralise, standardise and modernise a number of support and controlling processes. Stakeholders believed EFSA's prioritisation has improved over time as a result of these investments, and will continue to do so into the future.

Recent examples of emergencies or urgent requests EFSA has responded to (e.g. Ebola virus, lumpy skin disease, *Xylella fastidiosa*) show that it has successfully managed to allocate resources to emerging requests when necessary, implying that its mechanisms to prioritise topics or tasks in such situations are adequate. Nevertheless, there is room for improvement as resources are not always allocated in the most efficient manner (see 5.3.1.1 and 5.3.2.1), and further efficiency gains can be explored.

⁴²² European Food Safety Authority, *Annual Report 2012* (Parma, Italy, 2013).

⁴²³ European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015).

⁴²⁴ European Food Safety Authority, *Consolidated Annual Activity Report 2015* (Parma, Italy, 2016).

⁴²⁵ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

5.4 COHERENCE

This section assesses the coherence between EFSA's work and the EU's political priorities and the EU's international commitments in the areas relevant to EFSA's work. It also assesses the degree of coherence and complementarity between EFSA's work and that of other EU agencies working in similar fields, and between EFSA's work and national risk assessment organisations and other competent bodies.

5.4.1 EFSA and EU political priorities

To what extent does EFSA's work contribute to the EU's political priorities? To what extent does EFSA's work contribute to the promotion of the EU food and feed safety regulatory standards on a global level? (EQ 12)

Coverage of the question

This question seeks to address the extent to which EFSA's work is aligned with and contributes to the EU's political priorities. It specifically covers the extent to which EFSA's work has or has not had an influence on global regulatory standards on food and feed safety through its support to the EU, and the extent to which EFSA's work has been aligned with EU political priorities. This question does not address EFSA's support to the EU's international commitments like the Codex, OIE and IPPC, which are covered under EQ 14 (section 5.4.2). This evaluation question is of fundamental importance as it is part of the Authority's purpose to contribute through the provision of support on scientific matters to the EU's role in the development and establishment of international food safety standards and trade agreements.⁴²⁶

Sources of evidence

A variety of documentary sources, specifically policy and regulatory documents and EFSA's Annual Activity Reports were assessed to answer the evaluation question, as they help set out what EFSA is intended to do, as well as how it has performed in this regard. Independent evaluations, including the 2012 external evaluation of EFSA to measure progress against and the REFIT evaluation of the General Food Law, as well as external documentation by other organisations like FAO has also been consulted for evidence, especially to assess the extent to which EFSA's work has contributed to the promotion of EU food and feed safety regulatory standards at a global level.

In addition, stakeholder consultations through interviews and the online survey helped provide additional evidence of the degree to which stakeholders believe priorities are aligned. Their views were especially useful in the assessment of the degree to which EFSA's work has helped promote EU food and feed standards and the assessment of the degree to which stakeholders believe EFSA's work is aligned with EU priorities, as this is difficult to measure through documentary evidence alone.

Baseline

The 2012 External Evaluation of EFSA recognised that EFSA worked closely with the Commission and had implemented different measures (e.g. agreed roadmap) to ensure alignment of priorities. In this context, recommendations from EFSA's Management Board highlighted the need for continued enhancement of interaction and dialogue with risk managers, and that EFSA should work closely with the EU Institutions to ensure that risk assessment needs are addressed in an adequate manner.

Analysis of evidence

EFSA's tasks and activities are in line with EU political priorities

EFSA's tasks and activities are aligned with the EU's political priorities. As outlined in section 2.1.1, the provision of safe, nutritious, high quality and affordable food to Europe's

⁴²⁶ Recital 39, Regulation (EC) N° 178/2002.

consumers is the central objective of EU food safety policy.⁴²⁷ The table below sets out the three core priorities of the EU, and links these to EFSA's tasks and activities.

Table 13: Alignment between EFSA's tasks/activities and EU priorities

EU priorities	EFSA's tasks/activities
To ensure that food and animal feed are safe and nutritious	Provision of independent, science-based advice on food and feed safety Evaluation of pesticides and applications for biological hazards, food ingredients and food contact materials, feed additives, GMO, and nutrition before market authorisation Data collection and evidence management to ensure advice is up-to-date Transparency, openness and communication on risks and threats to food and feed safety Identification of (emerging) risks to public health/food safety Crisis management in the event of a food-related crisis Cooperation with other EU agencies, Member States, and third country risk assessment organisations
To ensure a high level of animal health, welfare and plant protection	Provision of independent, science-based advice on animal health, animal welfare, and plant health Transparency, openness and communication on risks and threats to animal health and welfare and plant health Data collection and evidence management to ensure advice is up-to-date Evaluation of pesticides and biological hazards Identification of (emerging) risks to animal health and welfare and plant protection Cooperation with other EU agencies, Member States, and third country risk assessment organisations
To ensure adequate and transparent information about the origin, content/labelling and use of food.	Risk communication Provision of independent scientific advice for risk managers as a basis for drafting legislation Cooperation with other EU agencies, Member States, and third country risk assessment organisations

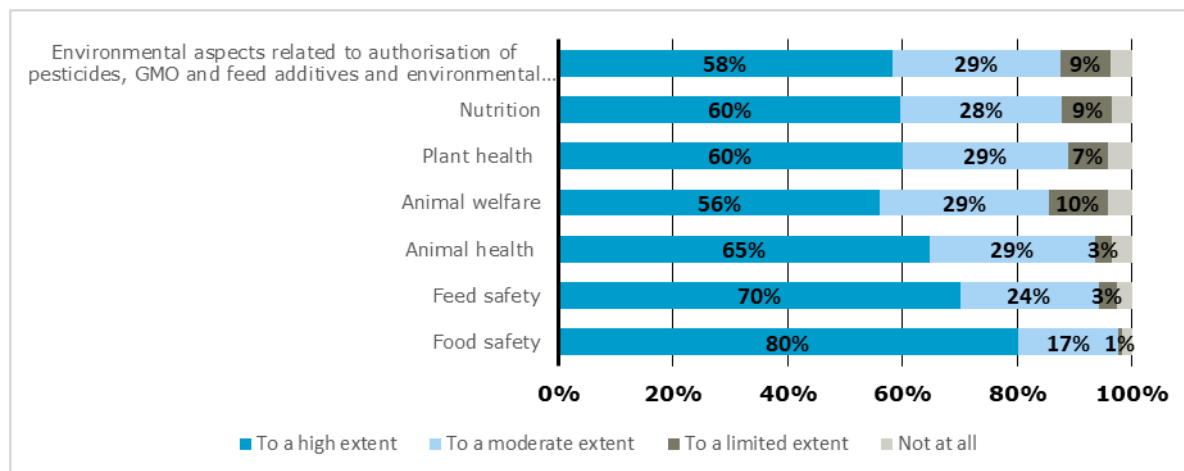
Source: Evaluation team based on 'From Farm to Fork: Safe and Healthy Food for Everyone' in *The European Union Explained: Food Safety and White Paper on Food Safety*, and Regulation (EC) N° 178/2002

Findings from the survey, which asked questions of national authorities, EU institutions and EFSA's Management Board about the extent to which EFSA's tasks were aligned with EU political priorities, show a high degree of agreement that **EFSA's tasks and activities are aligned with EU political priorities**. Amongst those who provided a response, a high or moderate extent of alignment was indicated by 98% in terms of food safety; 94% in terms of feed safety; 94% in terms of animal health; 88% in terms of environmental aspects⁴²⁸ related to authorisation of pesticides, GMO, and feed additives; 88% in terms of nutrition; 89% in terms of plant health; and 86% in terms of animal welfare.

⁴²⁷ European Commission, 'From Farm to Fork: Safe and Healthy Food for Everyone', in *The European Union Explained: Food Safety*, ed. by European Union (Luxembourg, 2014).

⁴²⁸ Including environmental plant health aspects.

Figure 32: To what extent were EFSA's tasks and activities over the period 2011-2016 aligned with (i.e. supported, did not contradict) the EU's political priorities in the following fields? (n=382)⁴²⁹



Source: Evaluation team based on survey results

This is in line with interview findings. According to interviewed EFSA staff and DG SANTE representatives, EFSA's regulatory framework prevents it from steering away from priorities at EU level. Moreover, as more than 80% of mandates come from the Commission, alignment of political priorities is inevitable. DG SANTE interviewees found that priorities were coherent because the work programmes were collaboratively discussed.

EFSA's international engagement helps promote EU standards on food and feed safety

EFSA has different mechanisms in place to engage with third countries and international organisations, and through which it can **help promote EU regulatory standards on food and feed safety**.

First, **EFSA's scientific and technical advice supports the EU's bilateral trade priorities**. EFSA's Multi-Annual Programme on International Scientific Cooperation (published in 2014) committed EFSA to supporting the EU's trade policy by developing bilateral collaboration with third countries that have concluded agreements with the EU.⁴³⁰ Most recently, EFSA's International Scientific Cooperation Work Plan (2017–2020) referred to EFSA's role in providing support in case of trade disputes, by providing the "scientific state-of-play of specific subjects for which trade problems between a particular country and the EU exist"⁴³¹. Trade policy provides the opportunity to shape globalisation according to European values and interests, including high standards for consumer protection and environmental rules⁴³², which is why EFSA's role is significant. The EU's bilateral trade ties with Japan and Canada, for example, are complemented by EFSA's work through its partnerships with the Food Safety Commission of Japan and the Canadian Food Inspection Agency based on Memoranda of Cooperation.⁴³³

Second, EFSA supports the promotion of EU food and feed regulatory standards within the neighbourhood and enlargement region through **capacity building for accession countries and potential candidates**, supporting them to anticipate and respond effectively to food safety risks

⁴²⁹ The total number of respondents for this survey question was 382. However, there was a large amount of "do not know" responses, that was excluded from the graph and analysis. As a result, the total respondents differed between sub-questions: 289 for food safety; 224 for feed safety; 201 for animal health; 187 for animal welfare; 188 for plant health; 206 for nutrition; and 218 for environment.

⁴³⁰ EFSA Advisory Forum and Scientific Cooperation Unit, *Multi-Annual Programme on International Scientific Cooperation 2014-2016* (Parma, Italy, 2014).

⁴³¹ EFSA Advisory Forum and Scientific Cooperation Unit, *International Scientific Cooperation Work Plan 2017-2020 (Draft)*, 2017.

⁴³² European Union, 'A balanced and progressive trade policy to harness globalisation', 2018

<https://ec.europa.eu/commission/priorities/balanced-and-progressive-trade-policy-harness-globalisation_en> [accessed 4 May 2018].

⁴³³ EFSA and Food Safety Commission of Japan, *Memorandum of Cooperation between the European Food Safety Authority and the Food Safety Commission of Japan*, 2015; EFSA and the Canadian Food Inspection Agency, *Memorandum of Cooperation between the European Food Safety Authority and the Canadian Food Inspection Agency*, 2015.

and prepare them to integrate existing EU structures and adopt the relevant EU legal order.⁴³⁴ For instance, representatives of these countries can participate as observers in EFSA's meetings when relevant for them.

Third, according to its Scientific Cooperation Annual Reports, and in line with its Multiannual Programme on International Scientific Cooperation 2014-2016, EFSA **maintains visibility and promotes EU standards by participating in international fora and events**, hosting and visiting third countries to explore opportunities for collaboration, and cooperating with third country risk assessment organisations through established multilateral activities, such as International Liaison Groups or in the Global Coalition for Regulatory Science Research.⁴³⁵ EFSA is also involved in liaison groups, including the International Food Chemical Safety Liaison Group (IFCSLG) and the International Microbial Food Safety Liaison Group (IMFSLG), where it shares information on ongoing scientific activities in the area of contaminants and in the area of microbiological risk assessment, as well as the International Health Claims Liaison Group, together with Food Standards Australia New Zealand (FSANZ), Health Canada and New Zealand Ministry of Primary Industries (NZMPI), to exchange experience in terms of scientific evaluation.⁴³⁶ These groups involve international food authorities spanning the globe, indicating a broad reach of EFSA's work.

EFSA's work has influenced food and feed safety standards beyond EU borders

There is considerable evidence to conclude that **EFSA's work has influenced regulatory standards on food and feed safety at international level**. While an in-depth study is not possible within the scope of the present study, the documentary review⁴³⁷ highlighted several examples of EU standards being adopted internationally by the FAO and WHO, namely the Code of Hygienic Practice for Meat⁴³⁸ and the Guidelines for the Control of *Trichinella* Spp. in Meat of Suidae⁴³⁹.

The REFIT evaluation of the General Food Law concluded, based on parties consulted, that the European food safety framework has served, in some cases, as "a source of inspiration" for non-EU countries developing their national legislation.⁴⁴⁰ Interviews corroborated this sentiment, as 16 of 23 interviewees from all different stakeholder groups highlighted that **EFSA is seen as a model even beyond EU borders**. Two examples mentioned were national risk assessment agencies in Turkey and Switzerland which, according to external interviewees, had willingly adapted to EFSA's risk assessment model.

⁴³⁴ EFSA Advisory Forum and Scientific Cooperation Unit, *Multi-Annual Programme on International Scientific Cooperation 2014-2016* (Parma, Italy, 2014); European Food Safety Authority – EFSA, 'International' <<https://www.efsa.europa.eu/en/partnersnetworks/international>> [accessed 4 May 2018].

⁴³⁵ More detail on EFSA's cooperation at international level is included under EQ 14.

⁴³⁶ EFSA Advisory Forum and Scientific Cooperation Unit, *International Scientific Cooperation Work Plan 2017-2020 (Draft)*, 2017.

⁴³⁷ To figure out whether EU standards on food and feed safety are being adopted internationally, a search of Codex Alimentarius standards was performed

⁴³⁸ See p.51, FAO, *Code of Hygienic Practice for Meat*, CAC/RCP 58-2005, 2005.

⁴³⁹ FAO and WHO, *Guidelines for the Control of Trichinella Spp. in Meat of Suidae*, CAC/GL 86-2015, 2015.

⁴⁴⁰ Examples mentioned are the Canadian and Japanese systems. See European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002)* (Brussels, Belgium, 2018).

Summary of findings and progress relative to baseline

EQ 12 (Coherence): To what extent does EFSA's work contribute to the EU's political priorities? To what extent does EFSA's work contribute to the promotion of the EU food and feed safety regulatory standards on a global level?

EFSA's work is inherently aligned with EU political priorities: most of EFSA's mandates come from the Commission, and the Authority's work programmes are jointly established. EFSA's tasks and activities cover a broad range (i.e. ranging from the provision of independent scientific advice to identifying emerging risks and responding to crises), fulfilling the three core objectives of the EU's food safety policy: to ensure that food and feed are safe and nutritious, to ensure a high level of protection of animals and plants, and to ensure adequate and transparent information about food.

EFSA cooperates with scientific organisations in third countries that are important trading partners for the EU, supports accession countries through capacity building for risk assessments, and participates in international fora and events. All three of these mechanisms improve EFSA's international visibility, which in turn helps promote EU standards on food and feed safety. These efforts have been successful, as there are examples of third countries that have adapted to EFSA's model of work, as well as take-up of EFSA's work at the WHO and FAO.

5.4.2 EFSA and EU commitments at international level

To what extent is EFSA's work coherent with EU commitments at international level (e.g. CODEX, OIE, and IPPC)? Which aspects are not coherent, if any, and why? (EQ 14)

Coverage of the question

In its Multi-Annual Programme on International Scientific Cooperation 2014-2016, EFSA identified three main objectives in the field of international cooperation, of which the first consists of supporting the EU in its international commitments through multilateral scientific cooperation, by participating in international organisations' activities, enhancing its involvement in the work of Codex Alimentarius, improving scientific cooperation with the Secretariats of the Joint FAO/WHO Expert Committees.

This question assesses the extent to which EFSA's work is coherent with EU commitments at international level, specifically scientific and technical advice provided to the Commission on food safety issues in the context of the Codex Alimentarius, animal health issues in the context of OIE and plant health issues in the context of IPPC. It builds on EQ 12 (section 5.4.1), which covered the alignment between EFSA's work and the EU's political priorities, as well as the degree to which EU standards subsequently influenced the global sphere.

Sources of evidence

The starting point for this question were the EU's international commitments in the areas of food and feed safety, animal health and plant health, as these are areas within EFSA's competence, as well as background information on EFSA's cooperation with international organisations, including any relevant agreements between them that are relevant for this question, were drawn upon. To assess the degree of coherence between EFSA's work and the abovementioned EU commitments, reports from EFSA's Advisory Forum and Scientific Cooperation Unit, as well as documentation from other relevant organisations (WHO, FAO, EPPO) were consulted. EFSA's Founding Regulation was also consulted to provide the background to EFSA's role in terms of providing support to the Commission in this context.

The documentary evidence was further supplemented by evidence acquired through findings from in-depth case study investigation on EFSA's cooperation and networking at international level, as well as through interviews and the online survey.

Baseline

No specific conclusions were drawn as part of the 2012 External Evaluation of EFSA on the coherence between EFSA's work and EU commitments at international level. Instead, the baseline is taken as the international commitments that have been made:

- In 2003, the EU became a member of the Codex Alimentarius Commission (dealing with food safety), and thereby committed to fulfilling its associated obligations.⁴⁴¹
 - Since 2008, the EU is party to the IPPC which means it contributes to plant health data collection, sharing, and analysis. Under the IPPC, EPPO (an intergovernmental organization responsible for cooperation and harmonisation in plant protection within the European and Mediterranean region) is the regional plant protection organization for Europe.
 - In 2011, the European Commission signed a Memorandum of Understanding with the World Organisation for Animal Health (OIE), committing to further developing their relations in relation to animal health.⁴⁴²
-

Analysis of evidence

EFSA's work supports EU international commitments

EFSA supports the EU in its international commitments by providing scientific and technical advice to the Commission. EFSA mentions supporting EU international commitments in several strategic documents, from its Multi-Annual Programme on International Scientific Cooperation 2014-2016 to its International Scientific Cooperation Work Plan 2017-2020.⁴⁴³

For example, EFSA provides the Commission with technical and scientific advice on matters related to plant health and animal health in the context of IPPC and OIE. EFSA also continues to participate in Codex Alimentarius activities, providing scientific and technical advice to the Commission, meeting with different Committees such as the Codex Committees on Pesticide Residues, Nutrition, and Coordinating Committee for Europe, amongst others.⁴⁴⁴ As touched upon in section 5.2.2, EFSA also cooperates with international organisations that the EU has made commitments to, including WHO, FAO, OIE and EPPO.⁴⁴⁵ In 2016 EFSA registered 18 multilateral engagements with international organisations providing scientific advice or setting international standards, which included collaboration with organisations such as WHO, FAO, EPPO, OECD and OIE. The EU has made commitments to these international organisations, and the fact that EFSA supports its work in these context leads to inevitable alignment.

EFSA's activities in these fields are coherent with the EU's commitments according to stakeholders. The survey findings from national authorities, EU institutions, and EFSA's Management Board members, indicate that there is at least moderate alignment between EFSA tasks and activities and EU's commitments at international level in all relevant fields listed below (85% agreement or more, though there was a high degree of "do not know" answers).

⁴⁴¹ European Union, Directive 2003/99/EC of the European Parliament and of the Council of 17 November 2003 on the monitoring of zoonoses and zoonotic agents, 2003.

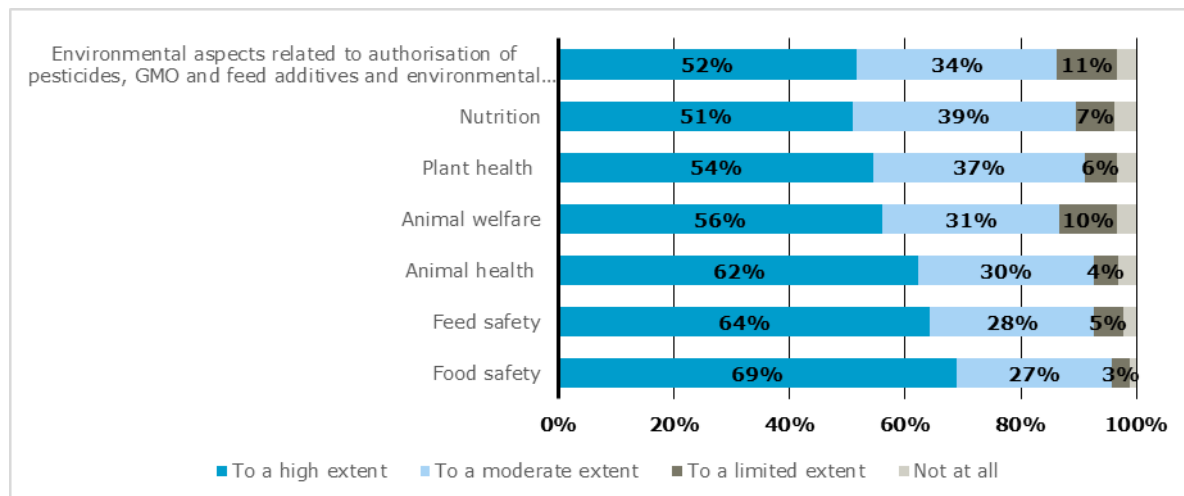
⁴⁴² European Union, Memorandum of Understanding between the European Commission and the World Organisation for Animal Health (OIE) concerning their general relations, 2011/C 241/01, 2011.

⁴⁴³ European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017); EFSA Advisory Forum and Scientific Cooperation Unit, *International Scientific Cooperation Work Plan 2017-2020 (Draft)*, 2017; EFSA, *Management Plan of the European Food Safety Authority for 2013, 2012*; European Food Safety Authority, *Annual Report 2014* (Parma, Italy, 2015); EFSA Advisory Forum and Scientific Cooperation Unit, *Multi-Annual Programme on International Scientific Cooperation 2014-2016* (Parma, Italy, 2014).

⁴⁴⁴ European Food Safety Authority, *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

⁴⁴⁵ EFSA Advisory Forum and Scientific Cooperation Unit, *Multi-Annual Programme on International Scientific Cooperation 2014-2016* (Parma, Italy, 2014).

Figure 33: To what extent were EFSA's tasks and activities over the period 2011-2016 aligned with (i.e. supported, did not contradict) the EU's commitments at international level in the following fields? (n=339)⁴⁴⁶



Source: Evaluation team based on survey results

Interview findings corroborate this positive view, as a total of sixteen interviewees (out of 21, including EFSA staff and management, the Commission, and international interviewees) believed that **EFSA's work is coherent with the EU's commitments at international level**, and both EFSA staff and Commission officials were confident that both entities were helping each other at international level.

Summary of findings and progress relative to baseline

EQ 14 (Coherence): To what extent is EFSA's work coherent with EU commitments at international level (e.g. CODEX, OIE, and IPPC)? Which aspects are not coherent, if any, and why?

EFSA's work is coherent with EU commitments at international level, based on the efforts made to provide scientific and technical advice to the Commission, in line with its legal base and commitments made in the Multi-Annual Programme on International Scientific Cooperation 2014-2016. This includes EFSA's support for the Commission's work on Codex Alimentarius activities, contributions to the IPPC through data collection and analysis, and support to EU work on plant health matters in line with commitments made to the OIE. EFSA also formally cooperates with international organisations, including WHO, FAO, OIE and EPPO, through the publishing of joint guidance, or through work on harmonisation of methods and approaches.

Stakeholders agree that EFSA's work is aligned with EU international commitments and believe this has improved over time as EFSA has focused more on international engagement. Notably EFSA's support to the Commission on Codex Alimentarius activities was referred to in this regard.

5.4.3 EFSA and Member State risk assessment organisations

To what extent is the involvement of Member State risk assessment organisations in the provision of EFSA's scientific advice adequate for ensuring Member States' ownership of a harmonised European assessment outcome and to what extent has the involvement been complementary to other public actors' activities? Which factors weighed on this adequacy and complementarity? (EQ 13)

⁴⁴⁶ The total number of respondents for this survey question was 339. However, there was a large amount of "do not know" responses, that was excluded from the graph and analysis. As a result, the total respondents differed between sub-questions: 241 for food safety; 179 for feed safety; 162 for animal health; 150 for animal welfare; 140 for plant health; 161 for nutrition; and 180 for environment.

Coverage of the question

Member States have their own risk assessment organisations, and other national public actors also operate in the fields within EFSA's mission. Without coordination there is a risk of duplication of work, which is why EFSA cooperates and networks with relevant competent authorities in the Member States through several mechanisms to ensure coherence and complementarity.

This question covers the extent to which EFSA's work is coherent with and complementary to the work of EU national risk assessment organisations. It assesses the extent of alignment between EFSA's work and political priorities in the Member States, the ways in which EFSA engages with other relevant bodies in the Member States, and the extent to which these come together to avoid duplication of work. This question is important to establish whether EFSA is carrying out work that is of benefit to Member States and does not duplicate work at national level (or vice-versa).

Sources of evidence

The answer to this question is based on a variety of documentary sources. To evaluate the mechanisms in place for EFSA to cooperate and involve Member States and other relevant actors in its work, a range of EFSA's internal documentation including Scientific Cooperation Roadmaps, the 2011-2013 Annual Reports on Article 36 Activities, 2011-2013 Focal Point Annual Activity Reports, and 2014-2016 Scientific Cooperation Annual Reports were consulted. External documentation from national risk assessment organisations and Commission Regulations were used to assess the degree of take-up of EFSA's work by national risk assessment organisations. Additionally, the 2014 review of EFSA's grants and procurement proved useful for this question.

The documentary sources were complemented by stakeholder consultation through the online survey and interviews with internal and external stakeholders, as well as findings from in-depth case study research on EU cooperation and networking. Stakeholder views were particularly relevant in the assessment of alignment of EFSA's work and individual Member States' political priorities, as well as insights on the degree of duplication or overlap of work. Views from respondents from national risk assessment organisations and Article 36 organisations were considered most relevant in this context and have been singled out where appropriate.

Baseline

The 2012 external evaluation of EFSA highlighted that it seemed impossible to prevent national risk managers from relying on national agencies, though increasing EFSA's credibility was seen as the key factor to ensure national agencies consult with EFSA to avoid overlap and duplication of work. It concluded that cooperation remained an area for improvement to better share responsibilities, priorities and future workloads, and to avoid duplication and misalignments with Member States.

EFSA's Management Board subsequently recommended that EFSA cooperate further with Member States to enable better priority setting and more efficient and effective use of resources. In particular, it recommended EFSA enhance the coordination of work programmes with national authorities, including through the Advisory Forum, to enable better sharing of data and scientific studies and better planning of joint projects. At the same time, it recommended Member State authorities contribute to defining a common EU risk assessment agenda, reinforce cooperation and networking on a multiannual perspective, and be willing to share data and methodologies with EFSA in order to build long-term partnerships.

Analysis of evidence

Mechanisms for scientific cooperation with Member States are conducive to shared ownership of a harmonised assessment outcome

EFSA has **mechanisms in place to engage with national risk assessment agencies**, namely the Advisory Forum, the Advisory Forum Communications Working Group (became the Communications Expert Network (CEN) in 2017), the Focal Point network, cooperation with Article

36 organisations, and Scientific Networks (see section 2.3.2 for explanations of all five channels of scientific cooperation).

These mechanisms of engagement are a **means to ensure Member States' ownership of a harmonised EU outcome on risk assessments**. This is clearly something EFSA is working towards, as confirmed by the Scientific Cooperation Roadmap 2014-2016. Its vision was "to move beyond the operation of specific cooperation tools towards building a common risk assessment agenda", based on priorities defined and shared by the 28 Member States and on which EFSA could partner.⁴⁴⁷

From a scientific point of view, the Advisory Forum is required "to prevent or at least identify at an early stage potential divergence between scientific opinions of EFSA and of a national competent authority"⁴⁴⁸. The Communications Expert Network and Focal Point network support EFSA in collaborating with Member States to promote coherence in the risk communication process and to support scientific cooperation and networking, including the exchange of information between EFSA and relevant bodies in the Member States respectively. EFSA's Scientific Networks facilitate the exchange of information and best practices, and for the development and implementation of joint projects, which stimulate scientific cooperation with Member States.⁴⁴⁹

For example, in 2016, EFSA and members of the Advisory Forum established the common EU Risk Assessment Agenda, outlining a list of priority topics to be addressed in a collaborative manner by EFSA and Member States in the years to come.⁴⁵⁰ Advisory Forum/Focal Point members highlighted possible joint projects, which organisations in their Member States proposed to work on with others in the same or a different EU country⁴⁵¹. As explained in academic literature on the subject, regular cooperation and daily contact between EFSA and Member State risk assessment organisations leads to a feeling of shared ownership of a harmonised European assessment outcome.⁴⁵²

Additionally, there is evidence of the take-up of EFSA's assessments by Member States, which is another indication of shared ownership of a harmonised European assessment outcome. For example, Member States have taken up the outcome of harmonised risk assessments as a result of the publication of the Regulation on the control of Salmonella and Other Specified Food-Borne Zoonotic Agents⁴⁵³ and its implementing measures⁴⁵⁴. These Regulations are based on several EFSA opinions dealing with risk assessments for Salmonella, from 2009 for breeding hens, 2010 for laying hens, 2011 for broilers and 2012 for turkeys.

Similarly, the UK's Department for Environment Food & Rural Affairs (DEFRA) commissioned the design of field trials for bovine tuberculosis vaccination, based on EFSA's opinion from December 2013.⁴⁵⁵ Then, in 2014 DEFRA used EFSA's advice as scientific evidence for its Strategy for Achieving Officially Bovine Tuberculosis Free Status for England, indicating for instance being

⁴⁴⁷ European Food Safety Authority, *Scientific Cooperation Roadmap 2014-2016* (Parma, Italy, 2014).

⁴⁴⁸ See p.80, Alberto Alemanno and Simone Gabbi, *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority*, 2014.

⁴⁴⁹ European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017); EFSA (2016), European Food Safety Authority, *Scientific Cooperation Annual Report 2015* (Parma, Italy, 2016).

⁴⁵⁰ European Food Safety Authority, *Scientific Cooperation Annual Report 2015, Consolidated Annual Report 2015* (Parma, Italy, 2016).

⁴⁵¹ At the end of 2016, 117 projects from 23 countries had been identified. European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017).

⁴⁵² See p.81, Alberto Alemanno and Simone Gabbi, *Foundations of EU Food Law and Policy: Ten Years of the European Food Safety Authority*, 2014.

⁴⁵³ European Union, Regulation (EC) No 2160/2003 of the European Parliament and of the Council of 17 November 2003 on the Control of Salmonella and Other Specified Food-Borne Zoonotic Agents, 2003.

⁴⁵⁴ European Union, Commission Regulation (EU) No 200/2010 of 10 March 2010 Implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as Regards a Union Target for the Reduction of the Prevalence of Salmonella Serotypes in Adult Breeding Flocks; European Union (2011), Commission Regulation (EU) No 517/2011 of 25 May 2011 Implementing Regulation (EC) No 2160/2003 of the European Parliament and of the Council as Regards a Union Target for the Reduction of the Prevalence of Certain Salmonella Serotypes in Laying Hens of G; European Union (2012), Commission Regulation (EU) No 1190/2012 of 12 December 2012 Concerning a Union Target for the Reduction of Salmonella Enteritidis and Salmonella Typhimurium in Flocks of Turkeys, as Provided for in Regulation (EC) No 2160/2003 of the European Parliament and of the Council; European Union (2012), Commission Regulation (EU) 200/2012 of 8 March 2012 Concerning a Union Target for the Reduction of Salmonella Enteritidis and Salmonella Typhimurium in Flocks of Broilers, as Provided for in Regulation 2160/2003 of the European Parliament and of the Council, 2010.

⁴⁵⁵ M. A. Chambers et al., 'Vaccination against Tuberculosis in Badgers and Cattle: An Overview of the Challenges, Development and Current Research Priorities in Great Britain', *Veterinary Record*, 175/4, 2014.

"Based partly on that advice [EFSA's opinion]"⁴⁵⁶. The UK government also referred to EFSA (40 times) in its *Food and feed law* update of March 2017.⁴⁵⁷

Limited duplication or overlap of work

The close cooperation between EFSA and the Member States ensures the sharing of scientific data, methodologies and information concerning food and feed safety risks, promoting mutual understanding and minimising the risk of duplication of work. As per the REFIT evaluation of the General Food Law, from a total of more than 4,500 scientific opinions, divergences between EFSA and national risk assessment organisations emerged only in 11 cases, seven of which were solved immediately at the level of the Advisory Forum.⁴⁵⁸

Nineteen interviewees (of 45) consulted as part of this evaluation explicitly agreed that the existing mechanisms in place to ensure communication and cooperation with the Member States were **effective means to avoid duplication and overlap of work**, which is in line with EFSA's 2014 SWOT analysis of the Focal Point Network, which concluded that the network contributed to avoiding diverging scientific opinions between EFSA and Member States.⁴⁵⁹ Interviews also pointed to an increase in coherence over time, as EU Member States increasingly align themselves with EFSA to ensure coherence on food and feed safety standards.

A total of 19 (of 45) interviewees highlighted that there have been instances where national risk assessment bodies have carried out their own assessments, because some countries (notably France and Germany) prefer performing their own risk assessments. Seven of these interviewees, however, explicitly highlighted that cases of duplication were **minor, happened in rare cases, and had reduced in number over the past years**. They found that, where duplication does take place, it is mostly for political reasons, not because EFSA's excellence is challenged or because of divergent opinions, i.e. Member States might disagree with EFSA's assessments regarding politically sensitive issues and might want to carry out the work themselves. This was confirmed by the REFIT evaluation of the General Food Law, which found that scientific divergences were confirmed in only four cases, two of which concerned the same substance (bisphenol A), which is a politically sensitive matter that attracted considerable public attention.⁴⁶⁰ In other cases, Member States do not necessarily disagree with EFSA's opinions but rather want to cross-check EFSA's evaluation outcomes against their national context or their own exposure data.

As highlighted in EFSA's two most recent strategic documents, there is **scope to further improve coordination with Member States' organisations** through the sharing of work programmes and use of joint initiatives to maximise benefits from available European capacity and resources.⁴⁶¹ Also, according to almost half of the stakeholders consulted (21 out of 45 interviewees from different groups), there is a need for closer and deeper collaboration between EFSA and national risk assessment organisations. Suggestions by interviewees included closer cooperation in the form of better communication from the start of the risk assessment procedure or through sharing of work between EFSA and national risk assessment agencies.

High degree of complementarity between EFSA's work and activities of other actors

EFSA has several mechanisms in place to cooperate with other competent public organisations in the Member States which **positively influence the degree of coherence and complementarity** between their respective activities.

⁴⁵⁶ Department for Environment, Food & Rural Affairs, *The Strategy for Achieving Officially Bovine Tuberculosis Free Status for England*, 2014.

⁴⁵⁷ Dr. Michael Walker, *Food and Feed Law: Compendium of UK Food and Feed Legislation with Associated Context and Changes during January-March 2017*, 2017.

⁴⁵⁸ See p.33, European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002)* (Brussels, Belgium, 2018).

⁴⁵⁹ EFSA Advisory Forum and Scientific Cooperation Unit, *Background Document for Breakout Session Review of Focal Point Agreements*, 2017.

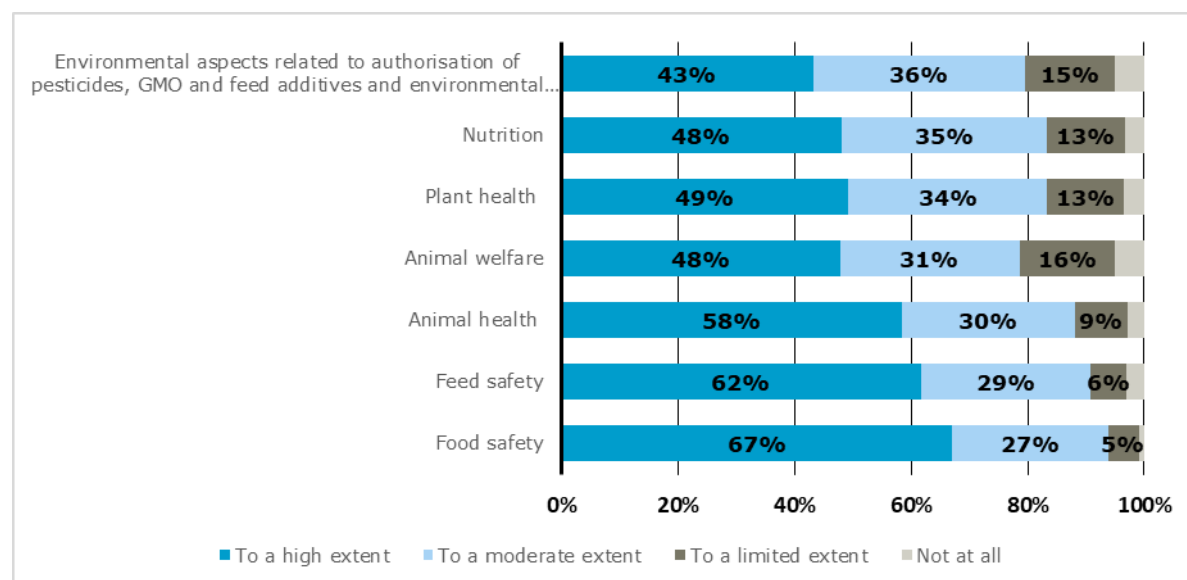
⁴⁶⁰ See p.33, European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002)* (Brussels, Belgium, 2018).

⁴⁶¹ European Food Safety Authority, *Science Strategy 2012-2016* (Parma, Italy, 2012); *EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Scientific Advice on the Food Chain* (Parma, Italy, 2016).

An important objective of this cooperation is to promote synergies. To do so, EFSA allocates grants to Article 36 organisations and externalises some of its scientific work to competent organisations in the Member States.⁴⁶² EFSA's grants are tools to foster scientific cooperation between and among Article 36 competent organisations of a public nature and EFSA.⁴⁶³ As highlighted in the 2014 External Review of EFSA's grants and procurement, there was a strong, positive networking and cooperation benefit from science projects supported by EFSA for both beneficiaries and contractors, and "EFSA science projects stimulated new cooperation, rather than just providing an opportunity for organisations who regularly worked together to continue to do so".⁴⁶⁴

The 2013 review of the Focal Point network concluded that it is a strong and operational network that strengthens cooperation and networking between **Member States' risk assessment organisations and other national actors**.⁴⁶⁵ This is confirmed by the stakeholder survey, in which a total of 277 respondents from the Focal Points, Advisory Forum, and AFCWG⁴⁶⁶ point to moderate to high **alignment between EFSA tasks and activities in all relevant fields**.

Figure 34: To what extent were EFSA's tasks and activities over the period 2011-2016 aligned with (i.e. supported, did not contradict) your country's political priorities in the following fields? (n=277)⁴⁶⁷



Source: Evaluation team based on survey results

Although this is not a direct proxy for complementarity of activities, the high degree of alignment between political priorities noted by surveyed stakeholder highlights that the relevant organisations from different Member States can indeed contribute to EFSA's work in a way that is in line with their national priorities. For all the relevant fields of EFSA's work listed in Figure 34, the rate of agreement amongst those who provided a response was 79% or higher.

⁴⁶² In the period 2011-2015, 40 grant agreements amounting to about €8.7 million and, annually, 30 Focal Point agreements amounting to about €4.36 million were successfully awarded to Member States, Norway and Iceland. During the same period, EFSA also signed over 500 scientific procurement contracts amounting to about €35.84 million. Globally, EFSA allocates a little more than 10 million per year to the scientific cooperation, corresponding to around 13% of its annual budget. European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002) - Appendices* (Brussels, Belgium, 2018).

⁴⁶³ European Food Safety Authority, *Annual Report on Article 36 Activities 2011* (Parma, Italy, 2012)

⁴⁶⁴ See p.10, ICF International, *External review of the impact of scientific grants and procurement projects on delivering EFSA's tasks*, 2014.

⁴⁶⁵ Note that these conclusions were only available in other reports, such as: European Food Safety Authority, *Focal Point Activities 2013* (Parma, Italy, 2014).

⁴⁶⁶ Note that this includes both private and public actors, though the two cannot be distinguished between.

⁴⁶⁷ This survey question rendered a lot of "do not know" responses, which were excluded from the graph and analysis. As a result, the total number of respondents differs per category: 225 on food safety; 162 on feed safety; 144 on animal health; 140 on animal welfare; 144 on plant health; 156 on nutrition; and 162 on environment.

Summary of findings and progress relative to baseline

EQ 13 (Coherence): To what extent is the involvement of Member State risk assessment organisations in the provision of EFSA's scientific advice adequate for ensuring Member States' ownership of a harmonised European assessment outcome and to what extent has the involvement been complementary to other public actors' activities? Which factors weighed on this adequacy and complementarity?

EFSA has effective mechanisms in place to engage with national risk assessment bodies, ensuring coordination between them to avoid overlaps in the work undertaken. These mechanisms include direct communication with national risk assessment authorities through the Advisory Forum, as well as engagement with wider stakeholder groups (including other competent actors) through the Focal Point network, Article 36 activities, and the Scientific Networks.

These efforts have increased Member States' ownership of EFSA's assessment outcomes and reduced duplication of work. On rare occasions, duplication of assessments did take place, though this is mainly because a Member State wanted to cross-check EFSA's evaluation with its own national context or data, or simply because some topics are politically sensitive (e.g. bisphenol A). There was widespread agreement, however, that activities were largely complementary, as stakeholders believed EFSA's work on all areas within its remit was largely aligned with priorities in their countries, and that collaboration had improved over the period under review.

5.4.4 EFSA and other EU agencies

To what extent is there overlap/complementarity/coherence with the work of other EU Agencies, such as EMA, ECHA, ECDC? (EQ 15)

Coverage of the question

This question assesses the extent to which EFSA's work is coherent with or complementary to the work of other EU agencies in related fields. It specifically addresses cooperation with the European Medicines Agency (EMA), the European Chemicals Agency (ECHA) and the European Centre for Disease Prevention and Control (ECDC) because their work covers topics related to EFSA's remit and the agencies have MoUs in place. The answer assesses the way in which EFSA cooperates with these agencies, and the extent to which there has been overlap or duplication in their work. Where pertinent, the question refers to the sole "sister agency"⁴⁶⁸ not referred to explicitly in the evaluation question, namely the European Environment Agency (EEA), given that cooperation between the EEA and EFSA has intensified in recent years.

Sources of evidence

The answer to this evaluation question draws on previous independent evaluations and external documentation on other EU agencies, as well as EFSA's internal monitoring and reporting, Annual Activity Reports, and strategy documents. The starting point for this answer was the legal bases of the EU agencies listed above, and the MoUs outlining work arrangements and issues of common interest between them and EFSA. As an evaluation of the coherence of their work is largely subjective in nature, stakeholder views collected through interviews and the online survey provided a useful source of evidence. For this purpose, the views of respondents and interviewees from other EU agencies as well as EFSA's own staff were singled out where appropriate.

An important source of evidence for this question was EFSA's Interagency Scientific Cooperation 2015 Annual Report, which provides a detailed overview of the Authority's cooperation with the other "ENVI Agencies" (ECDC, EMA, ECHA and EEA)⁴⁶⁹, including the topics jointly worked on. Unfortunately, such a detailed report only exists for 2015. The 2016 Scientific Cooperation Annual

⁴⁶⁸ See 2.3.3.1 for the definition of sister agency.

⁴⁶⁹ At the time of writing, there was no formal MoU between EFSA and the EEA, though the agencies are exploring ways of working together in the future.

Report is broader and lacks the specific focus on EU agencies, and no such reports were produced in preceding years.

Baseline

The 2012 External Evaluation of EFSA highlighted the need to strengthen data sharing and access agreements with other EU agencies. It found that cooperation was not fully effective and required additional efforts.

In this context, EFSA's Management Board recommended that EFSA cooperate further with other EU Agencies in relation to planning EU work in the areas within its remit, to enable better priority setting and more efficient and effective use of resources.

Analysis of evidence

Limited overlap/duplication of work, resulting from clear scope of action defined in sister agencies' legal bases

The fact that EFSA and its sister agencies have different legal mandates inherently minimises overlap or duplication of work: EFSA's remit covers food and feed safety, nutrition, animal health and welfare, plant protection and plant health, while EMA is responsible for authorisations and safety monitoring of medicines for human or veterinary use, ECHA for the safe use of chemicals, and ECDC for the risk assessment of infectious diseases (see Table 14 below).

Table 14: Scope of action of EU agencies

Agency	Scope of action	Potential for cooperation with EFSA
EFSA	Food safety, feed safety, nutrition, animal health, animal welfare, plant health, plant protection	
EMA	Public health, animal health	Public health, animal health, anti-microbial resistance, emergency response
ECDC	Infectious diseases, disease prevention, disease control, human health	Public health, anti-microbial resistance, food-borne diseases, emergency response
ECHA	Chemicals, human health, environment	Pesticides, endocrine disruptors, nanomaterial safety

Source: Websites of EFSA, ECHA, EMA and ECDC

Most interviewees across stakeholder groups found that there was **barely any duplication between the above-mentioned agencies**, or that in the case of inconsistencies, EFSA dealt with them in a satisfactory manner. They found that any apparent duplication that takes place is inevitable and justified by the fact that the agencies have different approaches to related topics within their respective legal bases.

Thus, although there are cross-cutting topics (e.g. zoonoses, food-borne diseases, antimicrobial resistance, pesticides), the legal bases make complete overlap or duplication impossible. And, importantly, such issues are collaboratively addressed, and there is no evidence to suggest that that this is not done in a satisfactory manner.

MoUs and related mechanisms for cooperation ensure coherence

EFSA has several mechanisms in place that allow the organisation to cooperate with its sister agencies to ensure their work is coherent. EFSA collaborates closely with ECHA, EMA and ECDC on exposure assessment and joint evaluations, and to ensure a consistent, harmonised approach to risk assessment in the EU.⁴⁷⁰ The MoUs and subsequent close cooperation between agencies ensure early identification of potential sources of conflict, allow for coordination as to the handling of

⁴⁷⁰ European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014); *Annual Report 2014* (Parma, Italy, 2015).

scientific questions of common interest⁴⁷¹ and for cooperation in the event of an emerging health threat that may affect or concern public health, zoonotic animal diseases or food safety.

In 2012, **EFSA and EMA** signed a MoU that aims to enhance cooperation and avoid duplication through the exchange of information and views, the implementation of specific joint projects, and the development of scientific guidance on relevant topics, among others. Both agencies are invited to attend their respective meetings or participate in respective working groups in relevant matters.⁴⁷² EFSA and EMA collaborated on joint mandates, including on measures to reduce the need for and use of antimicrobials in food-producing animals and analysis of the resulting impacts on AMR in 2016, and worked together on risk assessment during the horsemeat crisis in 2013.⁴⁷³ The publication of the Joint Scientific Opinion on measures to reduce the need to use antimicrobial agents in animal husbandry in the European Union, and the resulting impacts on food safety constitutes a recent illustration of their cooperation.

In 2017, **EFSA and ECHA** updated their 2009 MoU with the aim of intensifying cooperation in the areas of risk and hazard assessment of chemical substances, including application and further development of the methodologies applied, scientific advice, risk communication, data and IT governance, and capacity building.⁴⁷⁴ EFSA and ECHA, in turn, have started developing scientific guidance to enable endocrine disruptors to be identified, at the request of the Commission.⁴⁷⁵ In 2015, the agencies collaborated on a range of topics, namely Bisphenol A, nanomaterial safety, open data, and pesticides.⁴⁷⁶

EFSA also has a MoU with ECDC, which they renewed in 2014⁴⁷⁷, to enhance cooperation on matters of mutual interest⁴⁷⁸, through active information exchange, sharing of knowledge, to develop synergies and better mutual understanding, and to increase collaboration. They aim to keep each other informed on strategic matters of common interest and partake in common activities like joint communications on issues of common interest, staff exchange, training of staff and recruitment procedure. The agencies have joined forces on issues such as zoonoses, antimicrobial resistance, food-borne outbreaks, microbial risk assessment, surveillance/monitoring, epidemiological investigation, rapid alert, early warning, identification of emerging risks, emergency response and risk communication.⁴⁷⁹ As per the Refit Evaluation of the General Food Law, EFSA and ECDC have enhanced their cooperation over time to ensure a high level of protection of public health in areas of common interest, e.g. in the area of food safety, control of communicable diseases, infectious diseases prevention and emergency response.⁴⁸⁰

At the time of writing, there was **no formal MoU in place with the EEA**, as it does not carry out risk assessments and is thus different in nature from EFSA and the above-mentioned sister agencies. In the past, priorities for cooperation were placed on EMA, ECHA, and ECDC, but joint activities with EEA have intensified in recent years. For instance, throughout 2015, EEA observed the work of EFSA's Scientific Committee on overarching elements of environmental risk

⁴⁷¹ Areas of common interest include zoonoses, antimicrobial resistance, consumption of veterinary antimicrobial agents, residues in foodstuff of animal origin, maximum residue limits and scientific approach to safe limits for residues, methodologies for risks assessment of substances, genetically modified organisms, indications/health claims for products containing herbal ingredients, and food supplements and additives. EMA and EFSA, Memorandum of Understanding on Working Arrangements between the European Medicines Agency and the European Food Safety Authority, 2012.

⁴⁷² EMA and EFSA, *Memorandum of Understanding on Working Arrangements between the European Medicines Agency and the European Food Safety Authority*, 2012.

⁴⁷³ European Food Safety Authority, *Annual Report 2013* (Parma, Italy, 2014), *Consolidated Annual Activity Report 2016* (Parma, Italy, 2017).

⁴⁷⁴ ECHA and EFSA, *Memorandum of Understanding between the European Chemicals Agency and the European Food Safety Authority*, 2012.

⁴⁷⁵ ECHA, 'Endocrine disruptors: ECHA and EFSA start work on guidance', 2016 <<https://echa.europa.eu/-/endocrine-disruptors-echa-and-efsa-start-work-on-guidance>> [accessed 4 May 2018].

⁴⁷⁶ See p.10, EFSA, *Interagency Scientific Cooperation Annual Report 2015*, 2016.

⁴⁷⁷ The MoU was signed in 2008 and previously renewed in 2010.

⁴⁷⁸ Including communicable disease matters and food and feed safety, zoonoses, antimicrobial resistance, food-borne outbreaks, scientific advice, surveillance/monitoring, epidemiological investigation, rapid alert, early warning, identification of emerging risks, emergency response, communication issues related to the areas identified above, and any other matter falling within both of their remits.

⁴⁷⁹ EFSA and ECDC, *Renewed Memorandum of Understanding between the European Food Safety Authority and the European Centre for Disease Prevention and Control*, 2014.

⁴⁸⁰ See p.110, European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002)* (Brussels, Belgium, 2018).

assessment, and indicated an interest in contributing to the EFSA-JRC project to develop a landscape risk/impact assessment tool for mapping environmental risk at EU level.⁴⁸¹ EEA also participated in a workshop on future research priorities on bee health and pollution, and the identification of emerging risks is considered an interesting area for future collaboration.⁴⁸² Hence, signing an MoU with EEA could be of interest to further formalise cooperation between EFSA and EEA.

Interviewees believed the **MoUs had positively contributed to the effectiveness of cooperation** between EU agencies because they clarified means of cooperation. It was highlighted by staff from other agencies and EFSA that an effort is made to share best practices during inter-agency meetings, in some fields scientists can be seconded from one agency to another (e.g. staff exchange with ECDC⁴⁸³), be invited to each other's working groups or panels (e.g. joint meetings with EMA⁴⁸⁴), and work on joint projects. These are seen by interviewees from EU agencies and EFSA staff as positive contributions to ensuring coherence and complementarity between EFSA and its sister agencies.

Efforts made to increase and improve collaboration

As mentioned above, the previous evaluation called for more cooperation with other EU agencies. EFSA has since made efforts to address these shortcomings through its close collaboration with ECHA, EMA and ECDC.

As outlined above, since the previous external evaluation, a new MoU with EMA was signed in 2012, and the MoUs with ECDC and ECHA were renewed in 2014 and 2017 respectively, highlighting the agencies' **continuous efforts to work together**. Between 2014 and 2016, EFSA held the Chair of the EU Agencies' Network on Scientific Advice (EU-ANSA), a network to address horizontal topics/challenges relevant for European agencies providing scientific advice. In 2016, the Executive Directors of EFSA, ECHA and ECDC set the basis for a new strategic approach through the network in areas such as data exchange and interaction⁴⁸⁵, highlighting that efforts to work together and streamline procedures are likely to continue.

In addition, EFSA's shortlisting for its collaborative work with the European Commission, EMA, and ECDC, for the "Award for Good Administration"⁴⁸⁶ is an indication of the progress being made. Indeed, EFSA was shortlisted in the category 'Excellence in collaboration' for its inter-institutional collaboration to fight antimicrobial resistance.⁴⁸⁷

Complementarity between EFSA and sister agencies but room to further strengthen ties

Despite the considerable efforts to cooperate and the limited evidence of overlap, there is **room to further strengthen ties between EFSA and its sister agencies to improve coherence and complementarity**.

Stakeholders working for EFSA's sister agencies (EMA, ECHA, ECDC) were divided in their opinions on the extent to which their work was coherent with that of EFSA, and on the extent to which their work allowed for the sharing of knowledge/resources to maximise impact and efficiency. The figure below shows how surveyed EU agency representatives responded: a large majority of respondents believed EFSA's tasks and activities were aligned with the work of their organisation (72%), but a lesser majority believed EFSA's work maximised the sharing of knowledge and resources (57-58%). Clearly, the general sentiment is that the cooperation works well and there is a high degree of coherence and complementarity, though there is room for improvement.

⁴⁸¹ See p.11, EFSA, *Interagency Scientific Cooperation Annual Report 2015*, 2016.

⁴⁸² European Environment Agency, *Consolidated Annual Activity Report 2016* (June 2017).

⁴⁸³ Point IV (b) of the Memorandum of Understanding between EFSA and ECDC.

⁴⁸⁴ Point 4 of the Memorandum of Understanding between EFSA and EMA.

⁴⁸⁵ See p.20, European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017).

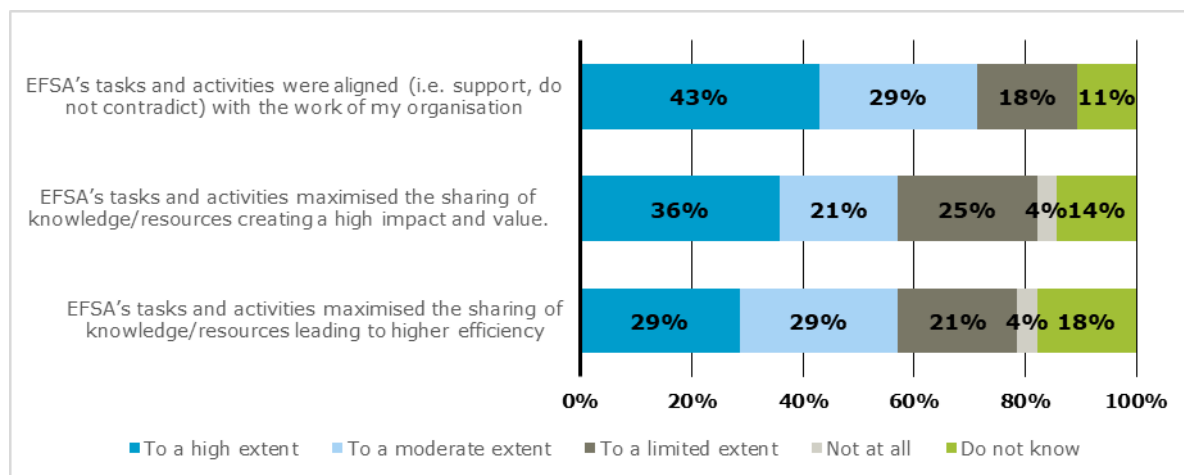
⁴⁸⁶ The European Ombudsman launched this award within the EU institutions, agencies and bodies in 2016 to recognise EU staff who bring high standards of public service to their work, including high standards of ethics, transparency and accountability.

⁴⁸⁷ European Union, 'Ombudsman launches "Award for Good Administration"', 2016

<<https://www.ombudsman.europa.eu/press/release.faces/en/72245/html.bookmark>> [accessed 4 May 2018]; European Union, 'European Ombudsman Award for Good Administration 2017 – Winners and shortlisted nominations', 2017

<<https://www.ombudsman.europa.eu/en/activities/eventdocument.faces/en/77458/html.bookmark>> [accessed 4 May 2018].

Figure 35: To what extent do you agree with the following statement concerning EFSA's tasks and activities over the period 2011-2016? (n=28)⁴⁸⁸



Source: Evaluation team based on survey results

This was apparent in interviews as well. Although interviewed staff from ECHA, EMA, and EEA believed the cooperation generally worked well, they also unanimously agreed that there is room for improvement, notably in terms of harmonising methodologies and practices. A total of 15 out of 18 interviewees from EFSA and EU agencies highlighted that EFSA needs to collaborate with other agencies to ensure efficiency. Related topics are often dealt with by several agencies, and efficiency ought to be maximised by further collaborating on cross-cutting issues, when permitted by the Agencies' respective legal bases. Although they believed that progress had been made already, five interviewees suggested that there needed to be clear systems in place to divide the work and avoid duplication, for example by establishing a regulatory framework to clarify the remit of different agencies dealing with related topics, or better coordinating on methodologies and approaches, including IT systems and data management.

Summary of findings and progress relative to baseline

EQ 15 (Coherence): To what extent is there overlap/complementarity/coherence with the work of other EU Agencies, such as EMA, ECHA, ECDC?

EFSA has MoUs in place with EMA, ECHA, and ECDC, which allow for collaboration and cooperation to avoid duplication of work. The MoU with EMA was signed in 2012 and the MoUs with ECHA and ECDC (which were in place before 2011) have been reviewed and updated, signifying an investment in stronger relations between EFSA and these agencies over time. The agencies have increasingly been working together on cross-cutting topics, and EFSA has been actively involved in the EU-ANSA network, trying to find new ways to cooperate, including through data sharing. Hence, a clear improvement was made relative to the previous evaluation, which recommended a formalisation of relations with sister agencies and further cooperation to improve coherence.

The cooperation is found to be working well by all parties involved, and there is limited evidence of overlap or duplication of work. Aside from the agencies having different legal bases that delineate the scope of their work, conscious efforts are being made to collaborate on cross-cutting topics where relevant. As a result, where apparent overlap exists, it is largely justified by the different contexts of the agencies' work, and their different approaches to related topics. Nevertheless, staff from EFSA and sister agencies alike agree that their organisations could mutually benefit from further harmonisation of practices and by working together on issues that concern more than one party.

⁴⁸⁸ This includes survey responses from EMA, ECHA, and ECDC staff only, which have been singled out because they are the most relevant respondents for this question

5.5 EU ADDED VALUE

This section addresses the extent to which there is an added value associated with EFSA's existence at EU level.

What is the additional value resulting from EFSA's existence, compared to what could be achieved by Member States at national level? (EQ 16)

Coverage of the question

The question considers the extent to which EFSA's existence has achieved EU added value. The EU added value refers to added benefits of the presence of EFSA at EU level, compared to what could be achieved, in the absence of the Authority, by Member States. This evaluation of EU added value presents the arguments on causality and draws conclusions, based on the evidence to hand, about EFSA's performance, and whether it is still justified.⁴⁸⁹ One cross-cutting area covered as part of the additional value of EFSA is its reputation at national, European and international level.

Sources of Evidence

There was no separate documentary review for EU added value. Rather, evidence is based on findings and conclusions from other evaluation questions including documentary evidence (see sections 5.2.2 and 5.4.3 in particular). Conclusions are drawn from qualitative insights, including survey results and interviews. Indeed, such analysis is often limited to qualitative research, given the difficulties in identifying a counterfactual. Because there was little evidence of the added value of EFSA's existence, consideration was given to its abrogation. This evaluation of EU added value presents the arguments on causality and draws conclusions, based on the evidence to hand, about EFSA's performance, and whether it is still justified.⁴⁹⁰

Baseline

The 2012 External Evaluation of EFSA found that EFSA had achieved EU added value in comparison with national agencies 1) in the provision of pan European scientific opinions on specific products; and 2) in the capacity to hire the best experts to address new challenges and 3) propose opinions that include minority opinions and to increase visibility of Europe for external stakeholders.

National food safety authorities benefited from EFSA's activities, but the gains varied from one Member State to another. Stronger efforts to facilitate the alignment of work programmes were required for EFSA to achieve greater EU added value.⁴⁹¹ The Management Board recommendations included that EFSA enhance its coordination activity and reinforce cooperation and networking. It also recommended that the international role and reputation of EFSA be enhanced.

Analysis of evidence

Pan European cooperation in the field of food safety continues to provide EU added value

EFSA's activities add to what is done at national level, facilitating cooperation between all 28 national risk assessment bodies and the production of EU level scientific opinions. Key aspects are:

- Between 2011 and 2016, EFSA has produced a total of 2,656 EU level **scientific outputs**.
- In addition, EFSA's activities led to **a common risk assessment agenda**, established in 2016 with members of the Advisory Forum⁴⁹² based on priorities defined and shared by the 28 Member States.⁴⁹³ EFSA's activities have also enhanced national authorities' ownership of its outputs over the period of review, leading to less disagreement within the EU. The

⁴⁸⁹ European Commission, *Better Regulation Guidelines, Commission Staff Working Document* (Brussels, Belgium, 2017) <<https://ec.europa.eu/info/sites/info/files/better-regulation-guidelines.pdf>>.

⁴⁹⁰ European Commission, *Better Regulation Guidelines, Commission Staff Working Document* (Brussels, Belgium, 2017).

⁴⁹¹ Ernst&Young, *External Evaluation of EFSA - Final Report*, 2012.

⁴⁹² European Food Safety Authority, *Scientific Cooperation Annual Report 2016* (Parma, Italy, 2017).

⁴⁹³ See p.33, European Food Safety Authority, *Scientific Cooperation Roadmap 2014-2016* (Parma, Italy, 2014).

European dimension of EFSA's scientific work ensures a harmonised level of protection based on high quality and independent scientific advice.⁴⁹⁴

EFSA adds value to the food safety activities of national risk assessment organisations

There is qualitative evidence confirming the added value of EFSA vis-à-vis activities of national risk assessment organisations. Parties consulted for the evaluation believed these achievements could not have been made by other organisations at national level. Out of a total of 958 survey respondents (not including EFSA staff and Management Board), 78% indicated that it would not be possible (or at least only to a limited extent) to achieve the same quality, relevance, and timeliness of scientific outputs at the national level.

Interviewees opined that the role of the Authority has become increasingly important given the globalisation of the food chain and resulting challenges. 15 interviewees provided examples of work that Member States could not address in the absence of EFSA. The most cited one was that of Glyphosate, with five interviewees from distinct groups indicating that given the complexity of this case, collaboration was essential to give a coordinated scientific answer and to have consistency in communication of risks. Several interviewees also mentioned EFSA's crucial role during the 2011 E. coli outbreak, mapping and exchanging information at EU level. Interviewees believed that the development of risk assessment methodologies and standards could not be achieved in the absence of EFSA because Member States individually lack the overview, scale and capacity to develop these.

However, there was a suggestion that EFSA's added value is not well recognised at national level. Interviewed members of the Stakeholder Bureau suggested that EFSA should focus on better coordinating EU messages and on encouraging communication about its work at national level to reflect and promote its EU added value.

Negative consequences would result from discontinuing EFSA

There is qualitative evidence suggesting that negative consequences would result from discontinuing EFSA. Out of a total of 1,188 survey respondents (not including EFSA staff and Management Board), 77% agreed to a high extent that discontinuing EFSA would have negative consequences for food safety in Europe. Their comments pointed to the potential damage to the provision of independent advice on the food chain both at EU and national levels, with 18% of them indicating it would weaken the scientific basis for decision making, with some also highlighting the risk of political interference or industry lobbying at a national level.⁴⁹⁵ EFSA's independence is a clear element of its added value.

Interviewees from across the distinct groups (38 out of 53) agreed that there would be no positive consequences from discontinuing EFSA. They stated that it would adversely impact the coherence of food safety and risk assessments; undermine informed policymaking; reduce the EU's capacity for crisis response; fragment the internal market; and have negative repercussions for the EU's scientific reputation. The view that the quality of EFSA's work and standards could not be matched by other organisations was shared by interviewees from distinct groups. A consistent message was that most Member States do not have the capacity to take on the role either. Indeed, some of the small or less active Member States, with more limited resources and risk assessment capacity, save resources by benefitting from EFSA's work. This was confirmed by interviewees from all categories consulted, who considered that EFSA works in an environment characterised by significant differences in the levels of risk assessment capacity and commitment of Member States to the Authority's work. EFSA provides a valuable service to Member States that would otherwise be unable to produce their own risk assessments to the same level of rigour and quality.⁴⁹⁶ At the same time, this potentially makes them more dependent on the work of the Authority and may discourage them from building their own scientific capacity, on which EFSA's system is, in return, dependent. Indeed, EFSA was set up with the view to be able to utilise the work of national

⁴⁹⁴ European Commission, *The Refit Evaluation of the General Food Law (Regulation (EC) N° 178/2002) - Appendices* (Brussels, Belgium, 2018).

⁴⁹⁵ These survey respondents were asked to specify what these consequences were in an open question, which received 541 responses.

⁴⁹⁶ ICF, *Reputation Barometer* (London, UK, 2017).

authorities, by gaining access to their expertise, available data and information, to avoid duplication of work and to combine efforts. Nevertheless, interviewees from the Advisory Forum, the Stakeholder Bureau and Forum suggested that national agencies, especially from smaller and less active Member States, see their risk assessment capacity effectively increased by EFSA.

EFSA is recognised as the leading regulatory authority regarding independent scientific advice on the food chain. As concluded elsewhere (section 5.2.2), EFSA has had a positive role in contributing to ensuring high standards in risk assessment methodologies and this is recognised by stakeholders from within and outside the EU. The main factor which stakeholders return to is the scientific excellence that characterises EFSA's work (as also mentioned above).

As indicated in the 2017 Reputation barometer, EFSA's reputation is particularly high among Member States' authorities, across all twelve attributes analysed⁴⁹⁷. They positively assessed EFSA's engagement with their organisation, risk communication, efficiency in risk assessments, assistance for crisis management, and the CoI policy.⁴⁹⁸ Commission representatives consulted positively assessed transparency, independence, efficiency in risk assessments, and (risk) communication.⁴⁹⁹ The study concluded that political factors are an important driving force within the EU, and this context influences EFSA's reputation at EU level. Examples include:

- EFSA's Opinion not being followed by its customers;
- EFSA's Opinion at odds with national/EU level political priorities;
- Highly politicised or controversial topic at national level or among consumers – such as Glyphosate or Neonicotinoids;
- High scientific uncertainty or contradictory evidence;
- Any significant incident that could be construed as a challenge to one of EFSA's opinions.⁵⁰⁰

Interviewed members of the Stakeholder Forum corroborated this and indicated that national authorities need to do their part to support EFSA's work.

Summary of findings and progress relative to baseline

EQ16 (EU Added Value): What is the additional value resulting from EFSA's existence, compared to what could be achieved by Member States at national level?

EFSA's EU added value is perceived to be strong by the different parties consulted. It still resides in the production of pan European high quality scientific outputs, through the pooling of experts from all Member States. Its facilitation role also provides great EU added value. In addition, EFSA fills capacity gaps in risk assessment, particularly for Member States less active in food safety, and ensures consistency in risk assessment approaches across the EU. Specific recommendations from the Management Board – following the 2012 External Evaluation –, including the enhancement of its coordination activity and the reinforcement of cooperation and networking were achieved, as illustrated by the creation of a common risk assessment agenda for example.

⁴⁹⁷ EFSA's approach to providing scientific advice; quality of its risk assessment opinions; efficiency in producing risk assessments (timeliness and use of resources to carry out RA); identification and characterisation of emerging risks (role); work to harmonise RA methods (role); independence and objectivity; level of transparency; risk communication role; engagement with external partners; provision of scientific and technical assistance to Member States for crisis management (role); quality of governance (procedures and practices); innovativeness.

⁴⁹⁸ The barometer generated a reputation score for each of the groups selected, on a scale from -100 (lowest) to 100 (highest). With 46, Member States gave the highest score.

⁴⁹⁹ Their score was 33, also high across all attributes.

⁵⁰⁰ ICF, *Reputation Barometer* (London, UK, 2017).

6. CONCLUSIONS

6.1 Overarching conclusion

EFSA has come a long way since its inception in 2002. The case for an independent authority able to provide high quality scientific advice at the EU level established in Regulation (EC) N° 178/2002 was confirmed in each independent evaluation to date, including this one.

The previous External Evaluation of EFSA, in 2012, pointed to key weaknesses and opportunities for improvement, such as the **efficiency** of the provision of scientific advice, **cooperation**, which could be improved through better sharing responsibilities and harmonising methodological approaches and data collection, and a need to further strengthen EFSA's **international** engagement, and the risk **communication** mandate, which lacked clarity, with messages not being readily accessible to the public.

This evaluation found that, during the 2011-2016 period, EFSA made progress in addressing the weaknesses previously identified:

- EFSA strengthened its mechanisms for cooperation and engagement with partners and stakeholders at national, EU and international level, contributing to an enhanced **risk assessment capacity at the EU level**.
- In response to demands (and a need to maintain trust), EFSA has committed to reinforcing and refocusing efforts on **transparency** and **independence**. EFSA strengthened its independence policy and rules and set out a plan to move towards an "Open Science organisation", through its "Transparency and Engagement in Risk Assessment" project. Linked to this, EFSA improved mechanisms for engagement with stakeholders.
- **Cross-cutting communication** activities have generated greater clarity, accessibility and professionalism of materials.

The above findings are coherent with EFSA's management self-evaluation (which can be found in Appendix 6).

Notwithstanding these achievements, the present evaluation identified remaining challenges and areas for further improvement:

- EFSA's long-term ability to **continue to produce scientific advice at the current level** is a risk. The model for engaging experts has limitations, not least that it depends on the willingness of experts (and their home institutions) to support EFSA without adequate pay. EFSA's management also identified this risk to the long-term sustainability of the Authority's operations in their self-evaluation.
- Notwithstanding the importance of having established Key Performance Indicators (KPIs), during the period under review, EFSA's **monitoring system** had shortcomings, which meant it was not adequate for a realistic or meaningful assessment of performance over time, which also made it difficult to assess efficiency and cost-effectiveness. EFSA's management did not comment on the (in)adequacy of the monitoring system in their self-evaluation, but we understand these issues are already being addressed by EFSA indicating the consistency of our findings with EFSA's own assessment.
- EFSA faces challenges in terms of **resource allocation** and competing demands; the most pressing issue being to ensure a proper balance of resources between its core scientific activities – the authorisation dossiers and the general scientific questions. In addition, significant resources are being allocated to openness, which could create imbalances in the long term. Further, during the period under review, there was limited flexibility in the internal allocation of work and human resources and therefore a need to streamline processes where possible and better mechanisms for prioritisation. Given the fragmented legislative framework, further harmonisation or flexibility may not be fully within the control of EFSA as it may require legislative changes.
- Despite headway, tailored **communication** remains an area where continued efforts are needed to continue to foster trust and proactively explain EFSA's work and address misunderstandings.

In addition, EFSA's management self-evaluation identified big data and evidence management as a critical area, which also featured in the present evaluation, but not as prominently. In terms of resources and ways of funding, EFSA's self-evaluation looked at the options for additional funding, including changing the legislative framework, which was not within the scope of this evaluation.

The points covered by this evaluation are expanded on in the assessment below, setting out EFSA's key strengths, weaknesses, opportunities and threats.

6.2 SWOT analysis⁵⁰¹

Table 15: EFSA's strengths, weaknesses, opportunities and threats

Strengths	Weaknesses
Independence/neutrality. EFSA is an independent agency without political or commercial bias. This allows it to produce independent scientific outputs without external influence from politics or industry. This independence is ensured through EFSA's rigorous DOI criteria.	Limited flexibility in the internal allocation of work and human resources. The main challenges for EFSA's organisational structure to adequately address its mission statement relate to the lack of flexibility in the distribution and assignment of EFSA staff across departments and Scientific Panels to manage volatility in workloads.
High quality, fit-for-purpose scientific advice. EFSA is a leading scientific authority in food and feed safety, its outputs are perceived to be of high scientific quality and are meeting risk managers' needs.	Fixed budget. EFSA's budget is fixed and yet its workload is volatile, difficult to plan and increasingly complex. The organisation is often put under pressure to deliver (increasingly complex) mandates on time and with fixed resources. This forces EFSA to apply a system of prioritisation involving negotiations with risk managers on the expected deadlines.
Capacity building. EFSA promotes the development of a common risk assessment agenda, thereby improving risk assessment capacity at Member State level, and building capacity in accession countries. The main strength in this regard is EFSA's role as a forum where Member States can exchange knowledge, methods and ideas, contributing to less fragmented risk assessment at EU level.	Office location in Parma. EFSA's location in Parma, Italy impacts its ability to attract external expertise. The location is not easily accessible by public transportation which acts as a disincentive for scientists to apply as external experts.
European dimension. In line with the above, EFSA has a unique position as the European agency for food safety. The transnational nature allows for a wide range of expertise from different Member States and ensures independence from national politics or other interference. Many Member States or international organisations could not carry out EFSA's work to the same level of rigour, and if they did there would be no guarantee of consistency in approach.	Fragmented Regulatory Framework. EFSA's regulatory framework is complex, embracing 19 different pieces of legislation. This makes the organisation and its ways of working difficult to understand and limits the organisation's efficiency due to considerably different working practices.
Contribution to higher food and feed safety standards. Outputs from EFSA's work are an essential information source for risk managers to formulate policy. EFSA's work is aligned with the EU's political priorities and to some extent contributes to the promotion of EU food and feed safety regulatory standards at international level.	The absence of an up-to-date communications plan is found to be a weakness, harming the full realization of potential benefits. Communication efforts and materials are not sufficiently tailored to the public and media.
Strong relationship with stakeholders. EFSA's investments in transparency and openness have been fruitful. In comparison to working practices and organisational structures of other EU agencies, EFSA does particularly well in the fields of communication, transparency and dialogue with its key stakeholders.	
Opportunities	Threats
Continued access to a pool of experts. If scientists are incentivised to work with EFSA, i.e. by making the positions more attractive for experts and their home organisations by providing remuneration or publishing outcomes in highly renowned scientific	Talent gap and lack of sustainability of the scientific production system. The lack of financial incentives for home institutions and scientists leads to a limited pool of experts. The best scientists may not apply due to limited incentives and/or stringent

⁵⁰¹ The SWOT analysis was carried out by the evaluation team on the basis of findings derived from a triangulation of the different collection methods.

journals, it will continue to have access to a pool of credible experts. EFSA could also expand the pool of applicants by making the selection criteria less rigorous and time consuming. Incentives ought to take into account the specific needs of young, mid-career researchers, in particular their focus on career growth.

application procedures, which means that EFSA may not be able to recruit the best / most suitable experts for their Panels and Working Groups. The reliance on unpaid external experts is a long-term risk to sustainability. Although efforts are made to make internal adjustments (for example to adjust the proportion of preparatory work done in house and by experts), the relationship with external experts represents a real challenge to sustainability.

Addressing new challenges. New issues and challenges are continuously emerging. There is a need for EFSA to keep with the times and tackle the increasing societal demands and challenges arising from globalisation, including on issues related to trade, nutrition and climate change. Closer collaboration with partners, including building on existing levels of cooperation with Member States and other EU agencies, and the development of more innovative approaches in its working methods will continue to be essential to achieve efficiency gains to adequately address current and future needs and challenges.

Political sensitivity. The nature of EFSA's work on politically sensitive topics like nutrition, GMO and pesticides makes it prone to criticism about its independence.

Cross-border coordination. EFSA could strengthen its coordination role at EU level by acting as a facilitator during emerging crises and as a knowledge coordinator to facilitate the exchange of best practice and increase the capacity of those Member States in need.

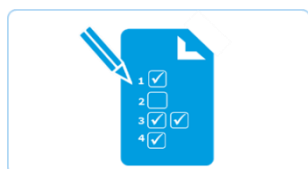
Standardisation and harmonisation. EFSA can further capitalise on its role as the European food safety authority to encourage harmonisation of methods and standards across and beyond EU borders. This would help foster integration, increase trust, and lead to a more effective and efficient system for the management of food and feed safety in the future by avoiding future overlap and duplication.

Awareness raising. Reflecting weaknesses identified, there is an opportunity for EFSA to improve communications with the media, the public and international organisations to enhance understanding and trust in the Authority.

6.3 Specific conclusions by criterion

6.3.1 Relevance

Conclusion 1: There is a continued need for independent scientific advice at EU level



EFSA's original objectives as set out in Regulation (EC) N° 178/2002 are sufficiently broad to have allowed the Authority to identify and adapt to evolving needs and future challenges in line with its mandate. The evaluation confirms a continued need for an independent and EU level provider of scientific and technical advice on EU food and feed safety. It also highlighted the continued importance of EFSA's role in *preparing*

for crises and *responding* to risk assessment demands in times of crisis.

Conclusion 2: EFSA is an increasingly outward looking organisation, engaging better with stakeholders and risk managers



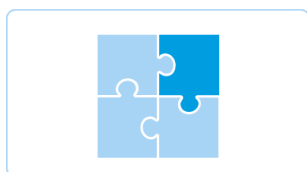
EFSA, as an organisation, has matured considerably since 2011. During the period under evaluation, EFSA adapted to better understand and respond to stakeholders' needs. Institutional mechanisms were strengthened and working practices and procedures streamlined and harmonised to engage more effectively with a broader base of

stakeholders. The Authority initiated a formal feedback mechanism to ensure its scientific advice meets risk managers' needs. The organisation has also committed to a transformation into an "Open Science organisation", which constitutes a significant undertaking.

Despite EFSA's flexibility and proactivity, the Authority operates in an increasingly complex context and faces growing demands, which it must respond to within available resources. Closer cooperation with partners (i.e. Article 36 organisations) and a constant focus on working methods will continue to be critical to adequately address current and future needs and challenges.

6.3.2 Effectiveness

Conclusion 3: High quality, fit for purpose scientific advice is being delivered, long-term risk to sustainability confirmed



The evaluation found EFSA's scientific system has successfully delivered high quality, fit for purpose scientific advice, that is responding to risk managers' needs. Specific concerns were raised regarding the adequacy of the peer review system for pesticides, which is the subject of ongoing assessment. However, there are long-term risks to the scientific production system, which may jeopardise EFSA's ability to effectively

provide scientific advice in the future, most importantly the reliance on unpaid experts (and willing home institutions) to produce scientific advice.

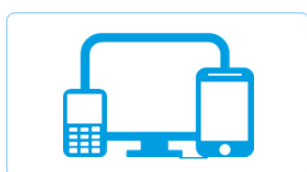
Conclusion 4: Effective cooperation at EU and progress at international level

EFSA has contributed to the harmonisation of methodologies and coherence of approaches on food safety at the EU level. EFSA has successfully enhanced its international engagement, and actively cooperates with third countries and international organisations following previous recommendations.



Nevertheless, the evaluation found a misinterpretation among international organisations of EFSA's global engagement and ambition, of which the Authority ought to be aware going forward.

Conclusion 5: Commitment to core values and communication mandate



EFSA has reinforced its policy on independence. Despite being one of the most advanced bodies in the EU in this regard, EFSA continues to face criticism highlighting the importance of strategic communication on this issue. Likewise, EFSA has committed to becoming an "Open Science organisation". Although this journey is not complete, the progress made is significant. Complementing these changes are efforts

to improve communication activities (including an upgraded website and numerous communications channels). However, the absence of an up-to-date dedicated operational strategy for communications is considered a weakness, harming the full realisation of potential benefits in a targeted and efficient manner. Specifically, communication is not tailored enough to EFSA's different audiences, particularly the public and media.

Conclusion 6: Scope to further improve monitoring systems for assessment of performance

To measure its performance, EFSA has internal mechanisms for programming, monitoring, reporting and evaluating. Notwithstanding the importance of having developed KPIs, this evaluation found that the monitoring mechanisms did not allow for a meaningful assessment of the Authority's performance over the evaluation period. KPIs were largely output-based, have changed significantly over time and were not sufficiently qualified. KPIs were largely quantitative, lacking a corresponding story or



qualitative explanation. EFSA itself recognises these shortcomings as, at the time of writing, EFSA was undertaking further work to set appropriate quantitative and qualitative indicators through its Process Architecture process variant mapping of input/output indicators, with the aim of improving the utility of its performance management.

6.3.3 Efficiency

Conclusion 7: Better mechanisms for prioritisation needed given limited resources



EFSA has made considerable investments to improve planning since 2011 but still lacks an adequate system for prioritisation of tasks based on available human and financial resources. Priorities are inherently difficult to set because of differences between sectors and areas, and because of the difficulty of estimating how much staff time or money a certain task will require. As part of EFSA Strategy 2020, the Authority

began developing a prioritisation scheme for its resources, which will anticipate risk assessment priorities and related methodology and evidence needs, as well as proactively identify priority areas of intervention, in collaboration with partners and stakeholders. In this context, it is important EFSA consider internal mechanisms to allow for more flexible allocation of resources to increase potential efficiency gains.

Conclusion 8: EFSA's complex legal basis and associated processes obstruct a meaningful evaluation of comparative cost per output



There are inherent differences in the costs of the different scientific production systems, resulting from their legal set-up. The differing levels of complexity associated with the work of the systems make a meaningful comparison between different outputs within the same system, let alone across systems, impossible. During the period under review (2011 – 2016), EFSA did not measure or report on such complexities and the workload associated with different outputs or production systems, which did not allow for a meaningful evaluation of their efficiency. From the data available, EFSA's *total* spending on the four main scientific production models remained stable between 2014-2016⁵⁰², though the costs associated with the different systems fluctuated. Crude measurement of cost/output fails to acknowledge the significant variances in the level of effort involved in producing outputs so cannot be taken as a reliable measure of cost-effectiveness.

6.3.4 Coherence

Conclusion 9: EFSA's work is complementary to that of national risk assessment organisations and mechanisms for cooperation can be enhanced

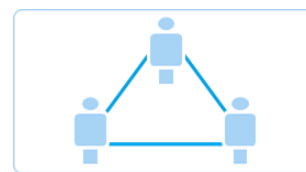


EFSA's mechanisms for engaging with national risk assessment organisations, like the Advisory Forum, CEN and the Focal Point Network allow for an early identification of potential divergence between scientific opinions and increase the degree of complementarity of work across the EU. Nevertheless, there are instances where there is a need for more regular and structured communication on specific programmes

or topics to avoid a loss of efficiency on either side. This suggests continued efforts to ensure cooperation and alignment are critical.

⁵⁰² Data unavailable for 2011-2013

Conclusion 10: EFSA's work is coherent with and complementary to that of its sister agencies, and additional collaboration is required to maximise effectiveness and efficiency



The mechanisms for collaboration and sharing of best practices have improved over time and the evaluation found little to no duplication of work. Memoranda of Understanding and related mechanisms for collaboration have greatly enhanced the effectiveness of cooperation between EFSA and its sister agencies, but there is scope to further capitalise on these to maximise impact and efficiency, notably in terms of harmonisation of methods and approaches.

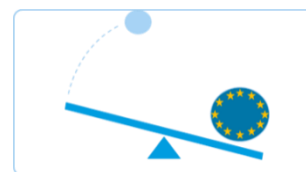
Conclusion 11: EFSA's work has indirectly influenced standards and methods on food and feed safety beyond EU borders



EFSA is not mandated to promote EU standards at international level. Through its role as the Commission's main scientific adviser on food and feed safety, combined with its cooperation with international and third country organisations, it helps the EU promote regulatory standards and assessment methods in the international sphere. EU standards have been adopted by the WHO and FAO, and national risk assessment agencies in some non-EU countries have willingly adapted to EFSA's risk assessment methods.

6.3.5 EU Added Value

Conclusion 12: EFSA provides strong added value



EFSA's EU added value mainly lies in its core role in delivering fit for purpose pan European scientific advice to support risk management measures and policy-making. EFSA has a reputation for scientific excellence. In its absence, there would be negative impacts on food safety in the EU, as there would be less independent and coherent advice on the food chain, both at EU and national levels. The scientific basis for decision-making would be weaker and more fragmented, leading to greater risks of political interference and inconsistencies in risk assessment, and ultimately risk management, across the EU.

EFSA's EU added value is also the result of its role as a facilitator of cooperation between and within Member States, including national authorities and a broad range of food safety organisations. EFSA's work increases the Member States' risk assessment capacity through harmonisation of methodologies. By undertaking this work at EU level, EFSA ensures a common approach to risk assessment across all Member States, filling a gap in capacity that exists at Member State level, especially in those that are less active in the field of food safety. The added value lies in providing a valuable service to Member States that would otherwise be unable to produce their own risk assessments to the same level of rigour, quality and consistency.

7. RECOMMENDATIONS

Below are six specific recommendations. These, separately and in different ways, tackle components of the challenges that EFSA faces. However, a more fundamental overarching recommendation arising from this evaluation is the need to address EFSA's resource challenges more holistically and periodically. For example, as new legislative requirements bring new competencies or greater duties into EFSA's remit, the extent to which EFSA's budget remains adequate should be systematically examined.

Recommendation 1: Explore options to address the structural risks to the sustainability of the scientific production model



It is recommended that EFSA further considers ways to organise its scientific work more sustainably. The most important aspect being to ensure the system continues to provide the necessary expertise and competence to support EFSA's work in the medium to long term. As a start, EFSA should consider:

- a model of distinct categories of experts for several types of work, appropriate to their expertise and availability. For example, preparatory work or more routine work (such as elements of literature reviews) could be outsourced to mid-career experts (through grants and/or procurement to Member State organisations), while higher level experts would be able to focus on work where more experience is needed.
- exploring new mechanisms of involving "home" organisations⁵⁰³ in the scientific production process without adding additional burden, for instance, through a rotation of hosting working groups meeting in Member States instead of in Parma, with the logistics and organisation of meetings supported by EFSA. Member States should be consulted on this idea to gauge interest and to ensure it would not in fact impose additional burden upon them.
- new systems to support the institutions releasing experts to minimise inconvenience or provide benefits that counteract any inconvenience caused. For example, EFSA should consider if setting up staff exchange agreements for experts with national food safety bodies is feasible, or whether more training could be provided by EFSA based on a consultation of capacity gaps among national staff performing risk assessments.

Recommendation 2: Ensure a wide pool of experts is maintained

Closely linked to the above, it is recommended that EFSA undertake measures to ensure a wide pool of experts is maintained. EFSA should make the proposition of acting as an expert more appealing. At the same time, EFSA should be mindful to strike the right balance between the need to maintain an appropriate level of independence and the scientific expertise required, and ensure that the system is not made stricter than it already is. As a starting point EFSA should:



- offer the opportunity to publish more in-depth articles on research related to risk assessments carried out for EFSA in high-impact journals, in addition to, not instead of, the EFSA Journal;
- maximise the potential to streamline and shorten the application process for experts applying to EFSA's Scientific Panels, by introducing a staggered process with a short pre-application screening process for example to allow those unsure if they may have a conflict of interest to establish this before embarking on a full application (and thereby ensure this is not a deterrent).

Both recommendation 1 and 2 are in line with one of the main objectives of the Commission's proposal for a targeted revision of the General Food Law Regulation to "strengthen the ability of EFSA to maintain a high level of scientific expertise in the different areas of its work, especially its capacity to attract excellent scientists to be members of its Scientific Panels".

⁵⁰³ Meaning those organisations that release staff to support EFSA's scientific work.

Recommendation 3: Use a competency-based approach to internal resourcing



There is a need for more flexibility to respond to peaks and troughs in workload and to priorities as they emerge. EFSA should ensure more flexibility in working procedures to allow staff to work across units where common skillsets and competencies can apply and where availability allows. To fulfil this recommendation, EFSA should first carry out a comprehensive assessment of the distinct roles and competencies needed and the ones at its disposal in its different units, and on that basis, identify where there is scope for staff to be shared across units⁵⁰⁴. This also requires mechanisms for clear priority setting and resetting.

Recommendation 4: Continue efforts to develop more fit for purpose KPIs



There is a need for greater continuity in the gathering of monitoring data over time, as well as in how it is reported. Quantitative data should be complemented with sufficient qualitative narrative to understand and explain changes over time. This will serve to enable a more meaningful understanding of EFSA's activities. Where KPI targets are changed, the reasons should be fully explained, again to allow for meaningful interpretation over time. In addition, EFSA's efforts to better measure efficiency and cost effectiveness of its different scientific activities over time, which are on-going at the time of writing, should be prioritised.

Recommendation 5: Continue to maximise potential for collaboration with sister agencies and Member States' authorities



Building on the successful collaboration that exists between EFSA and sister agencies, as well as between EFSA and national authorities, EFSA should continue to look for opportunities to benefit from potential synergies. This is especially important considering the need to address shared challenges, such as the need for ever more openness, and harvesting and managing big data.

Recommendation 6: Identify strategic priorities for communication activities



EFSA needs to have and regularly update a communications workplan to make the relevant elements of its Strategy 2020 operational, and guide its work in this area, to effectively fulfil its second mandate. The workplan should be based on a cost-effectiveness analysis for these activities. It should provide a comprehensive roadmap linking audiences with materials tailored to their needs. It should include more proactive communication and engagement with the media. EFSA should build solid relationships with journalists such that they feel comfortable seeking clarification on issues to be covered, for example. The website should include a section dedicated to the rapid publication of press releases, directed to the media only, and aiming to help them write about news from EFSA.

⁵⁰⁴ We understand that a competency library has been developed and used to deploy staff, however this has been developed outside of the period of review and was not reviewed here.