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THE 3RD INDEPENDENT EXTERNAL EVALUATION OF EFSA 2011-2016

FINAL REPORT - APPENDICES

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

Date **June 2018**

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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) Nº 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.

CONTENT

APPENDIX 1: EVALUATION QUESTION MATRIX

EFSA Evaluation Question Matrix
Final. Approved by EFSA.
26 September 2017

Evaluation questions		Subquestion		Indicators		Judgement criteria	Sources of evidence / tools												Conclusions from other EQs and subquestions
							Stakeholder consultation				Documentary review								
							Interviews		Surveys		EFSA				Other				
											Activity monitoring reports								
							EFSA	External	Online survey	Case study - Event survey	Monitoring data (KPIs)	Other monitoring / internal reporting	Annual activity reports, budgets	Governance / strategy docs / working practice	Policy / regulatory docs	Independent evaluation / recommendations	Other EU agencies	Other - literature search	
Relevance						For survey responses the judgement criteria is set at 75% of respondents providing a positive answer. This is based on the average of positive responses to the questions in the survey for the second external evaluation of EFSA in 2012 (Annex 1d of the evaluation report).													
1	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?	1.1	To what extent are the needs identified at the time of the adoption of Reg. 178/2002 (cf. intervention logic) still relevant?	1.1.1	Evidence (where readily available*) of continued relevance of original needs identified at the time of the adoption of the EFSA Founding Regulation	Evidence found in different types of documents confirming needs (a priori)							✔	✔			✔	
				1.1.2	Evidence (where readily available*) of procedures in place to confirm relevance of original needs	Evidence found in different types of documents of relevant procedures in place							✔		✔			
				1.1.3	Stakeholders' perceptions whether needs identified at the time of the adoption of the Regulation still exist	Different types of interviewees provide evidence of the continued validity of original needs	✔	✔										
		1.2	To what extent are EFSA's original objectives of Reg. 178/2002 deemed relevant vis-à-vis the current needs of its key target groups?	1.2.1	Stakeholders' opinions on the extent to which their needs are met	At least 75% of survey respondents are of the opinion that their needs are met			✔									
				1.2.2	Stakeholders' opinions on whether original objectives are (in)sufficient to meet needs of key target groups	Interviewees make reference to fact that original objectives are (in)sufficient to meet needs of key target groups	✔	✔										
		1.3	To what extent have new challenges, which can(not) be accommodated under the original objectives of Reg. 178/2002, emerged?	1.3.1	Evidence (where readily available*) of procedures in place to identify new challenges	Evidence found in different types of documents of relevant procedures in place							✔		✔		✔	
				1.3.2	Stakeholders' perceptions on new challenges which cannot be addressed	Interviewees do not provide examples of new challenges which cannot be addressed	✔	✔										
				1.3.3	Evidence (where readily available*) of new challenges which cannot be addressed through the original objectives	No evidence found in different types of documents which suggests new challenges which are out of scope / unaddressed									✔			✔	
2	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?	2.1	To what extent do EFSA's organisational structure and its working practices/processes enable it to meet identified current needs (EQ1)?	2.1.1	Stakeholders' opinions on the adequacy of EFSA's structure, working practices and scientific production system to its work	At least 75% of survey respondents are of the opinion that EFSA's structure, working practices and different parts of the scientific production system are adapted to its work			✔									
				2.1.2	Stakeholders' opinions on the adequacy of EFSA's organisational structure and working practices / processes to meet identified needs	Different types of interviewees make reference to the fact that EFSA's organisational structure and working practices / processes enable it to meet identified needs	✔	✔										
				2.1.3	Evidence (where readily available*) of coherence between organisational structure and working practices / processes; and the tasks and goals	Evidence found in different types of documents confirms that the organisational structure and working practices / processes match the tasks and goals of the Authority							✔	✔	✔			✔	
		2.2	To what extent are EFSA's organisational structure and working practices aligned with recognised good practices for executive decentralised agencies?	2.2.1	Evidence (where readily available*) on good practices and working practices of EFSA and other EU executive decentralised agencies	Evidence found in different types of documents that confirms that EFSA compares favourably with other executive decentralised agencies and applies recognised good practices							✔			✔	✔	✔	
		2.3	To what extent do mechanisms exist capable of ensuring that EFSA's activities identify and continue to meet emerging needs as these change over time ?	2.3.1	Stakeholders' opinions on the adequacy of EFSA's structure and working practices for responding to unforeseen challenges	At least 75% of survey respondents are of the opinion that EFSA's structure and working practices allow EFSA to respond to unforeseen challenges			✔									
				2.3.2	Evidence (where readily available*) on the flexibility of EFSA's working practices	Evidence found in different types of documents illustrating EFSA is taking steps to ensure it is adaptive and able to continue to meet (evolving) needs							✔	✔	✔			✔	
Effectiveness																			
3	a) 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, unbiased and fit-for-purpose scientific advice?	3a.1	To what extent does EFSA contribute to creating and maintaining a sustainable scientific system?	3a.1.1	Stakeholders' opinions on EFSA's scientific advice	At least 75% of survey respondents are of the opinion that EFSA's scientific advice and in particular the scientific opinions respond to the listed criteria			✔									
				3a.1.2	Evidence (where readily available*) of bottlenecks / divergences between needs and results of EFSA's scientific production system (which have not been addressed)	No evidence found in different types of documents of bottlenecks / divergences between needs and results of EFSA's scientific production system						✔		✔		✔		✔	
				3a.1.3	Stakeholders' perceptions of EFSA's contribution to creating and maintaining a sustainable scientific system	Different types of interviewees provide concrete examples of how EFSA contributes to creating and maintaining a sustainable scientific system	✔	✔										
				3a.1.4	EFSA's self-set KPIs (over the period 2011-2016 where comparable) • Number of scientific outputs adopted (within deadlines) • Number of technical reports finalised (within deadline) • Proportion of scientific outputs adopted within deadline • Proportion of experts with approved scientific DoI before participating in an EFSA meeting • Number of other publications (external scientific reports and event reports)	EFSA meets the targets for its self-set KPIs					✔								
		3a.2	To what extent does EFSA's panel system addressing general scientific questions respond to needs?	3a.2.1	Stakeholders' opinions and perceptions of EFSA's panel system addressing general scientific questions	• At least 75% of survey respondents are satisfied with the advice provided through this format • Interviewees provide concrete examples of ways in which the EFSA panel system addressing general scientific questions responds to needs		✔	✔									
				3a.2.2	EFSA's self-set KPIs (over the period 2011-2016 where comparable) • Number of closed scientific questions • Proportion of closed scientific questions	EFSA meets the targets for its self-set KPIs					✔								
		3a.3	To what extent does EFSA's panel system addressing authorisation dossiers respond to needs?	3a.3.1	Stakeholders' opinions and perception of EFSA's panel system addressing authorisation dossiers	• At least 75% of survey respondents are satisfied with the advice provided through this format • Interviewees provide concrete examples of ways in which EFSA panel system addressing authorisation dossiers responds to needs		✔	✔									
				3a.3.2	EFSA's self-set KPIs (over the period 2011-2016 where comparable) • Number of scientific outputs adopted • Proportion of scientific outputs adopted within deadline • Proportion of original budgeted committed / paid at year end	EFSA meets the targets for its self-set KPIs						✔							
		3a.4	To what extent does EFSA's peer-review system on pesticides dossiers respond to needs?	3a.4.1	Stakeholders' opinions and perceptions of EFSA peer-review system on pesticides dossiers	• At least 75% of survey respondents are satisfied with the advice provided through this format • Interviewees provide concrete examples of ways in which EFSA's peer-review system on pesticides dossiers responds to needs		✔	✔									
				3a.4.2	EFSA's self-set KPIs (over the period 2011-2016 where comparable) • Number of scientific outputs adopted • Proportion of outputs adopted within deadlines • Proportion of original budgeted committed / paid at year end	EFSA meets the targets for its self-set KPIs						✔							
		3a.5	To what extent does technical advice provided by EFSA's scientific staff respond to needs?	3a.5.1	Stakeholders' opinions on the technical advice provided by EFSA scientific staff	• At least 75% of survey respondents are satisfied with the advice provided through this means • Interviewees provide concrete examples of ways in which EFSA's technical advice responds to needs		✔	✔									
				3a.5.2	EFSA's self-set KPIs (over the period 2011-2016 where comparable) • Number of scientific outputs adopted • Proportion of outputs adopted within deadlines • Proportion of original budget committed / paid at year end	EFSA meets the targets for its self-set KPIs					✔								
		3a.6	To what extent are EFSA's scientific system, structure and mechanisms of scientific production able to adress emerging risks?	3a.6.1	EFSA's self-set KPIs (over the period 2011-2016 where comparable) • Number of scientific outputs adopted • Proportion of scientific outputs adopted within deadline.	EFSA meets the targets for its self-set KPIs					✔								
				3a.6.2	Stakeholders' opinions and perception on the adequacy of EFSA's scientific system, structure and mechanisms of scientific production to address emerging risks	• At least 75% of survey respondents are satisfied with the adequacy of EFSA's scienticic system, structure and mechanisms of scientific production to address emerging needs • Interviewees provide concrete examples of ways in which EFSA's scienticic system, structure and mechanisms of scientific production address emerging needs		✔	✔									
		3a.7	To what extent are the systems above (particularly the number, and the scientific excellence, of high level independent experts available and willing to contribute to EFSA) sustainable?	3a.7.1	Evidence (where readily available*) on the sustainability of EFSA's scientific systems (particularly the availability and scientific excellence of national experts and contributions of national scientific bodies)	Evidence found in different types of documents confirms the sustainability of systems Evidence found in different types of documents confirms the continued availability of a pool of excellent national experts contributions of national scientific bodies						✔	✔	✔		✔		✔	
				3a.7.2	Stakeholders' perceptions of the (un)sustainability of the EFSA scientific system	Different types of interviewees point to concrete evidence / examples of the ways in which the systems (particularly the availability of national experts and contributions of national scientific bodies) are (un)sustainable	✔	✔										
	b) To what extent has EFSA contributed to creating a European food safety system that enhances citizens' trust, through its scientific excellence, independence and transparency.	3b.1	To what extent do EFSA's activities contribute to enhancing citizen's trust through its scientific excellence, independence, and transparency?	3b.1.1	Extent to which EFSA's scientific excellence (i.e. the quality of the scientific output) show the potential to contribute to building citizens' trust, based on conclusions from other questions (EQ 3a.1)	Evidence found that EFSA's scientific excellence (i.e. the quality of scientific outputs) show the potential to enhance citizens' trust												✔	
				3b.1.2	EFSA's self-set KPIs for risk communication (over the period 2011-2016 where comparable) • Total number of press releases and news • Proportion of press releases / web news accompanying scientific outputs within 20 working days	EFSA meets the targets for its self-set KPIs					✔								
				3b.1.3	Stakeholders' opinions and perceptions of EFSA's independence and transparency	• At least 75% of stakeholders report they perceive the information produced by EFSA to be independent and transparent • Different types of interviewees indicate that they perceive the information produced by EFSA to be independent and transparent		✔	✔									
				3b.1.4	Evidence (where readily available*) of measures and actvities that EFSA undertakes to ensure its independence and transparency	Evidence found in different types of documents.							✔	✔					
				3b.1.5	EFSA's self-set KPIs for independence (over the period 2011-2016 where comparable) • Proportion of experts with approved annual declarations of interest before first meeting invitation • Proportion of experts with approved specific declarations of interest before participation in an EFSA meeting	EFSA meets the targets for its self-set KPIs					✔								
		3b.2	To what extent does EFSA have adequate systems in place to communicate with its stakeholders, partners, and citizens as a whole?	3b.2.1	Stakeholders' engagagement with EFSA's communication tools	At least 75% of survey respondents confirm that they use EFSA's different communication tools			✔	✔									
				3b.2.2	Stakeholders' engagement with EFSA's various outputs	At least 75% of survey respondents confirm that they use EFSA's different outputs			✔	✔									
				3b.2.3	Stakeholders' opinions and perceptions of EFSA's communicaton with its stakeholders, partners and citizens	At least 75% of survey respondents consider EFSA's communciation material to be clear and useful Different types of intreviewees refer to EFSA's communicaton with its stakeholders, partners and citizens as being appropriate	✔	✔	✔	✔									

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Evaluation questions		Subquestion		Indicators		Judgement criteria	Sources of evidence / tools												Conclusions from other EQs and subquestions
							Stakeholder consultation				Documentary review								
							Interviews		Surveys		EFSA				Other				
											Activity monitoring reports								
							EFSA	External	Online survey	Case study - Event survey	Monitoring data (KPIs)	Other monitoring / internal reporting	Annual activity reports, budgets	Governance / strategy docs / working practice	Policy / regulatory docs	Independent evaluation / recommendations	Other EU agencies	Other - literature search	
	c) To what extent has EFSA contributed to an improved harmonisation of methodologies and coherence of approaches on food/feed safety risks at EU and global level through its networking and cooperation with EU and global risk assessment authorities?		stakeholders, partners, and citizens as a whole?	3b.2.4	EFSA's self-set KPIs (over the period 2011-2016 where comparable) • Number of subscribers to online subscription products • Traffic to EFSA web content (web metrics) • Total number of subscribers to online subscription products (newsletter and alerts) • Impact score of the articles dedicated to EFSA • Number of Twitter followers • Traffic to EFSA web content from social media	EFSA meets the targets for its self-set KPIs				✔									
		3b.3	To what extent could EFSA's activities be enhanced to further contribute to building stakeholders' trust?	3b.3.1	Opinions of (i) stakeholders and (ii) participants at EFSA's events on the contribution of EFSA's activities to building stakeholders' trust	At least 75% of (i) survey respondents and (ii) participants at EFSA's events consider that EFSA's activities could be enhanced to further contribute to building stakeholders' trust			✔	✔									
				3b.3.2	Opinions and perceptions of (i) stakeholders and (ii) participants at EFSA's events of ways in which EFSA's activities could be enhanced to further contribute to building stakeholders' trust	Different types of (i) stakeholders and (ii) participants at EFSA's events provide concrete examples of ways in which EFSA's activities could be enhanced to further contribute to building stakeholders' trust		✔	✔	✔									
				3b.3.3	Evidence (where readily available*) of additional measures EFSA could take to build stakeholders' trust	Evidence found in different documents which shows specific measures are needed and have been identified								✔		✔		✔	
		3c.1	To what extent have the harmonisation of methodologies and coherence of approaches on food/ feed safety risks improved a) across the EU28 and b) at global level over the period 2011-2016?	3c.1.1	Stakeholders' opinions on the harmonisation of methodologies and coherence of approaches on food/feed safety risks across a) the EU28 and b) at a global level	At least 75% of survey respondents are of the opinion that in the EU there are harmonised methodologies and coherent approaches to food/feed safety in place			✔										
				3c.1.2	Evidence (where readily available*) of changes in the methodologies and approaches on food/feed safety risks across a) EU28 and b) at a global level	Evidence found in different types of documents of showing improvement of harmonisation of methodologies and increased coherence of approaches on food/feed safety risks across a) EU28 and b) at a global level								✔				✔	
		3c.2	Is it reasonable to infer that EFSA's activities (networking and cooperation with EU and global risk assessment authorities) have contributed to this harmonisation and increased coherence?	3c.2.1	• Stakeholders' opinions on EFSA's contribution to harmonisation and increased coherence • Stakeholders' perceptions of EFSA's activities connected to harmonisation of methodologies and increased coherence of approaches to food/feed risk assessment and risk communication.	• At least 75% of survey respondents are of the opinion that EFSA has contributed to harmonisation and increased coherence • Different types of interviewees provide concrete examples of ways in which EFSA's activities have contributed to harmonisation of methodologies and increased coherence of approaches to food/feed risk assessment and risk communication	✔	✔	✔										
4	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).	4.1	To what extent have different working practices (e.g. especially tools for pooling expertise, in particular the collaboration arrangements between EFSA and external expertise such as national experts and national scientific bodies, including Article 36 organisations) supported / hindered achievement of EFSA's mission?	4.1.1	Evidence (where readily available*) of coherence between EFSA's working practices and it's mission	Evidence found (i.e. concrete examples) of how EFSA's different working practices have supported / hindered achievement of EFSA's mission						✔	✔	✔					
				4.1.2	• Stakeholders' opinions on the contribution of EFSA's working practices to achievement of EFSA's mission • Stakeholders' perceptions of the extent to which EFSA's different working practices have supported / hindered achievement of EFSA's mission	• At least 75% of survey respondents consider that EFSA's different working practices have supported achievement of EFSA's mission • Different types of interviewees make reference to ways in which EFSA's different working practices have supported / hindered achievement of EFSA's mission	✔	✔	✔										
		4.2	Which factors (internal and external) have influenced what EFSA has achieved or failed to achieve (results corresponding to EFSA's strategic objectives and observed unintended effects (both positive and negative))?	4.2.1	Stakeholders' perceptions of factors that have influenced EFSA's ability to meet its strategic objectives, and the weight of those factors	• Different types of interviewees provide concrete examples of factors (internal and external) that have influenced what EFSA has achieved or failed to achieve in relation to EFSA's strategic objectives • Different types of interviewees provide views on weight of specific factors identified (internal and external) in influencing what EFSA has achieved or failed to achieve in relation to EFSA's strategic objectives	✔	✔											
				4.2.2	Evidence (where readily available*) of factors that have influenced EFSA's ability to meet its strategic objectives, and the weight of those factors	Evidence found in different types of documents confirming the existence of external factors of a relevant impact that influenced EFSA's effectiveness								✔		✔			
				4.2.3	Stakeholders' perceptions of and views on observed unintended effects (both positive and negative)	• Different types of interviewees provide concrete examples of observed unintended effects (both positive and negative) • Different types of interviewees provide views assigned to observed unintended effects (both positive and negative)	✔	✔											
				4.2.4	Evidence (where readily available*) of unintended effects of EFSA's activities	Evidence found in different types of documents of unintended (positive or negative) effects								✔		✔			
5	To what extent is the Authority's governance model appropriate for ensuring the Authority's mission statement?	5.1	To what extent has the Authority's governance model supported the Authority's mission statement?	5.1.1	Stakeholders' opinions on the management practices and governance structure	At least 75% of stakeholders are of the opinion that EFSA's management structure supports meeting objectives			✔										
				5.1.2	Evidence (where readily available*) of compliance or contradiction between governance model and mission statement	Evidence found in different types of documents confirming that the governance model supports the mission statement								✔	✔				
		5.2	To what extent has the Authority's organisational structure supported the Authority's mission statement?	5.2.1	Stakeholders' opinions on working procedures, division of work and resources	At least 75% of survey respondents consider working prodcures to be clear and appropriate, and division of work and resources to be appropriate			✔										
				5.2.2	Stakeholders' opinions on EFSA's access to experts - based on findings from 3a7	At least 75% of survey respondents agree that EFSA has access to the experts needed													✔
				5.2.3	Trends in EFSA's staff satisfaction surveys with regard to organisational structures	Surveys show a generally positive assessment of the organisational structures						✔							
				5.2.4	Evidence (where readily available*) of compliance or contradiction between organisational structure and mission statement	Evidence found in different types of documents confirming that the organisational structure supports the mission statement								✔					
		5.3	To what extent do the Authority's support structures support the Authority's mission statement?	5.3.1	EFSA's own relevant performance measurement (over the period 2011-2016 where comparable)	Data shows a positive assessment of the support structures (e.g. applicants feedback survey, experts calls performance)					✔	✔							
				5.3.2	Evidence (where readily available*) of compliance or contradiciton between support structures and mission statement	Evidence found in different types of documents confirming that the support structures support the mission statement								✔					
6	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?	6.1	To what extent are the internal mechanisms for programming, monitoring, reporting and evaluating the Agency adequate for ensuring accountability?	6.1.1	Stakeholders' opinions on the internal management systems capacity to ensure accountability	At least 75% of survey respondents are of the opinion that internal management systems ensure accountability			✔										
				6.1.2	Assessments of the Authority's internal mechanisms by the European Court of Auditors (ECA)	Evidence found in ECA's reports of positive assessments of the Agency's internal mechanisms												✔	
				6.1.3	Evidence (where readily available*) of EFSA's activities to folllow up on the ECA's recommendations	Evidence found in different types of documents that EFSA follows up on recommendations from the ECA							✔	✔				✔	
		6.2	To what extent do the internal mechanisms allow for an appropriate assessment of the overall performance of EFSA?	6.2.1	Stakeholders' opinions on the internal management systems' ability to ensure an appropriate assessment of performance	At least 75% of survey respondents are of the opinion that internal management systems ensure an appropriate assessment of performance			✔										
				6.2.2	Evidence (where readily available*) of EFSA's and other EU agencies' internal mechanisms and in particular good practices	Evidence found in different types of documents showing that compared to other EU agencies, EFSA provides a similar (or higher) standard of internal mechanisms to measure overall performance											✔	✔	
				6.2.3	Continuity of EFSA's internal monitoring data	KPIs are implemented, followed up and comparable over several years					✔								
				6.2.4	Stakeholders' acknowledgement and awareness of mechanisms to measure performance	Different types of interviewees make reference to internal mechanisms to measure performance	✔												
9	To what extent are the current practices for collecting scientific data and evidence adequate for EFSA's risk assessment?	9.1	To what extent do data collection and evidence management support risk assessment activities?	9.1.1	• Stakeholders' opinions on adequacy of the data collection and evidence management to support risk assessment activities • Stakeholders' perceptions of data collection and evidence management supporting risk assessment activities	• At least 75% of survey respondents are of the opinion that data collection and evidence management support risk assessment activities • Different types of interviewees provide concrete examples of how data collection and evidence management of EFSA support risk assessment activities	✔	✔	✔										
				9.1.2	Evidence (where readily available*) on the adequacy of data collection and evidence management to support risk assessment activities	Evidence found in different types of documents confirming the adequacy of the data collection and evidence management to support risk assessment activities							✔			✔			
		9.2	To what extent are the methodologies employed adequate to support risk assessment activities?	9.2.1	• Stakeholders' opinions on adequacy of the methodologies employed to suppot risk assessment activities. • Stakeholders' perceptions of the methodologies employed to suppot risk assessment activities.	• At least 75% of survey respondents are of the opinion that methodologies employed support risk assessment activities • Different types of interviewees provide concrete examples of how methodologies employed by EFSA support risk assessment activities	✔	✔	✔										
				9.2.2	Evidence (where readily available*) on the methodologies employed to support risk assessment activities	Evidence found in different types of documents confirming the adequacy of the methodologies employed to support risk assessment activities							✔			✔			
		9.3	To what extent is the expertise adequate and and properly sourced (taking into account appropriate roles and responsibilities) in order to support risk assessment activities?	9.3.1	• Stakeholders' opinions on the adequacy of expertise and expertise sourcing to support risk assessment activities. • Stakeholders' perceptions of expertise and expertise sourcing to support risk assessment activities.	• At least 75% of survey respondents are of the opinion that expertise is adequate and is being properly sourced, taking into account appropriate roles and responsibilities, to support risk assessment activities • Different types of interviewees provide concrete examples that point to the fact that expertise is adequate and is being properly sourced, taking into account appropriate roles and responsibilities, to support risk assessment activities	✔	✔	✔										
				9.3.2	Evidence (where readily available*) on the expertise and expertise sourcing to support risk assessment activities	Evidence found in different types of documents confirming the the adequacy of expertise and expertise sourcing to support risk assessment activities							✔			✔			
Efficiency																			
10 and 11	Are resources used for EFSA proportionate to the results achieved? If not, why not?	10.1	To what extent does an assessment of EFSA's spending compared to the results achieved (at the outcome level) show EFSA's activities are cost-effective?	10.1.1	Budget of the Authority	n/a - descriptive							✔				✔		
				10.1.2	EFSA's performance in achieving self-set KPIs on outputs (over the period 2011-2016 where comparable)	n/a - descriptive						✔	✔						
				10.1.3	Budget performance of EFSA and of EU agencies of similar size: • Annual budget • Sources of income (subsidy vs operational) • Expenditure lines (administrative, operational) • Share of operational expenditure (compared to other agencies) • Rate of budget execution/appropriation (compared to other agencies) • Human resources (staff costs, #staff) • Number of filled posts per year • Change in resources compared to change in outputs generated	EFSA's budget performance is similar to or better than that of other EU agencies of similar size					✔		✔				✔		
				10.2.1	Stakeholders' perception of external factors influencing EFSA's budget decision	Different types of interviewees make reference to factors (e.g. political, societal, media pressure) that influence EFSA's decisions (where funds allocated are disproportionate to results achieved)	✔	✔											

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											Activity monitoring reports			Governance / strategy docs / working practice					
							EFSA	External	Online survey	Case study - Event survey	Monitoring data (KPIs)	Other monitoring / internal reporting	Annual activity reports, budgets		Policy / regulatory docs	Independent evaluation / recommendations	Other EU agencies	Other - literature search	
		10.2	What external factors (e.g. political, societal, media pressure) influence EFSA's fund allocation decisions?	10.2.2	Stakeholders' perception of the importance of these factors	Different types of interviewees attribute a significant weight to specific factors (e.g. political, societal, media pressure) that influence EFSA's decisions (where funds allocated are disproportionate to results achieved)	✔	✔											
				10.2.3	Evidence (where readily available*) on budget decisions	Evidence found in different types of documents confirming external factors that influence EFSA's fund allocation decisions							✔	✔	✔			✔	
18	To what extent is EFSA's scientific production system cost-effective? *Note: This EQ was not in the TOR but has been added during the inception phase*	18.1	What are the costs and outputs of the different elements of the scientific production system?	18.1.1	Costs of the different elements of the scientific production system - Scientific committees and panels - Panel system addressing authorisation dossiers - Peer review system for pesticides - Scientific staff providing technical advice	n/a - descriptive							✔						
				18.1.2	Outputs of the different elements of the scientific production system according to KPIs (over the period 2011-2016 where comparable): - Scientific committees and panels - Panel system addressing authorisation dossiers - Peer review system for pesticides - Scientific staff providing technical advice	n/a - descriptive						✔	✔						
				18.1.3	Stakeholders' opinon on the functioning of the different elements of the scientific production system	At least 75% of survey respondents find the scientific prodcution system adopted to the challenges of EFSA's work Interviewees provide refer to the different elements of the production system as working optimally	✔	✔	✔										
		18.2	How do the different elements of the scientific production system compare to one another in terms of costs and outputs?	18.2.1	Comparison of the costs and outputs of the different elements of the scientific prodcution system (based on findings on 18.1)	n/a - descriptive						✔	✔						✔
7	Do established procedures minimise the administrative burden of the Authority and its stakeholders?	7.1	To what extent does EFSA's current organisation allow for an optimal use of capabilities and resources?: • Procedures are clear and light-touch • Hierarchy and decision-making processes are clear • Division of work / resources are appropriate • Infrastructure (including IT systems) are adequate • Internal initiatives for streamlining and simplification lead to change being implemented • Cooperation is encouraged and facilitated	7.1.1	Stakeholders' opinion on: -EFSA's working procedures -hierarchy within the Authority and decision making processes -the divison of work and ressources within the Authority -the infrastructure available to EFSA -internal initiatives for streamlining and simplificaiton	At least 75% of survey respondents are of the opinion that: - EFSA's working proceduresa are clear and appropriate to deliver on its objectives - the hierarchy within the Authority and decision marking processes is clear - the divison of work and ressources within the Authority is appropriate to deliver on EFSA's objectives - the infrastructure available to EFSA is adequate for its work - internal initiatives for streamlining and simplification lead to change being implemented			✔									
				7.1.2	Administrative expenditure of other EU agencies	Compared to other EU agencies EFSA has a similar (or lower) share of administrative expenditure							✔				✔		
		7.2	To what extent are there organisational obstacles preventing the delivery of EFSA's work or placing a disproportionate administrative burden on EFSA and its stakeholders (for example, in relation to applications for authorisations)?	7.2.1	Stakeholders' opinions on administrative burden in interacting with EFSA	At least 75% of survey respondents are of the opinion that the administrative burden involved in interacting with EFSA is of a reasonable level			✔										
				7.2.2	Evidence (where readily available*) on administrative burden within the Agency and for its stakeholders	No evidence found of administrative burden in different types of documents										✔		✔	
				7.2.3	Satisfaction data on expert management	Satisfaction data on expert management shows overall satisfaction with administrative procedures						✔							
8	Does EFSA undertake prioritisation of certain topics or tasks and, if so, has this been appropriate?	8.1	To what extent are there mechanisms in place to enable EFSA to prioritise topics / tasks?	8.1.1	Stakeholders' awareness about mechanisms enabling EFSA to prioritise topics/tasks	Different types of interviewees describe mechanisms enabling EFSA to prioritise topics/tasks	✔												
				8.1.2	Evidence (where readily available*) on internal working procedures and prioritisation processes	Evidence found in different types of documents on internal working procedures or mechanisms to enable EFSA to prioritise topics / tasks						✔	✔	✔						
		8.2	To what extent does EFSA prioritise topics / tasks?	8.2.1	Evidence (where readily available*) on usage of mechanisms in place to priorise topics or tasks	Evidence found in different types of documents that mechanisms to enable EFSA to prioritise topics / tasks are being used						✔	✔	✔					
		8.3	To what extent is EFSA's prioritisation of topics / tasks appropriate to meet changing needs in the EU?	8.3.1	Stakeholders' perception of EFSA's ability to prioritise topics or tasks to meet changing needs in the EU	Different types of interviewees make reference to the ability of EFSA to prioritise topics or tasks to meet changing needs in the EU	✔												
				8.3.2	Stakeholders' opinion on EFSA 's ability to respond to unforeseen needs	At least 75% of survey respondents are of the opinion that EFSA is able to respond to unforeseen needs			✔										
				8.3.3	Based on conclusions from other questions (EQ2)	Evidence found that EFSA 's working practices are fit-for purpose and meet evolving needs													✔
Coherence																			
12	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?	12.1	To what extent does EFSA's work contribute to promoting the EU's food and feed safety regulatory standards as a model to adopt at global level?	12.1.1	Evidence (where readily available*) of EFSA promoting EU standards on food and feed safety on an international level	Evidence found in several EU policy documents							✔	✔	✔				
				12.1.2	Evidence (where readily available*) of EU standards on food and feed safety being adopted internationally	Evidence found in several policy documents of third countries or at international level which show that EU standards are being adopted internationally												✔	
		12.2	To what extent are EFSA's tasks and activities aligned with the EU's political priorities?	12.2.1	Stakeholders' perception of alignment between EFSA's tasks and EU political priorites	Different types of interviewees make reference to alignment	✔	✔											
				12.2.2	Stakeholders' opinions on alignment between EFSA's tasks and activities and the EU's political priorities in the field of food safety	At least 75% of survey respondents indicate alignment			✔										
				12.2.3	Evidence (where readily available*) of EFSA's tasks and activities opposing EU political priorities	No or very limited evidence found in different types of documents that in comparing EFSA's tasks and activities with EU policy documents show that EFSA's tasks and activities oppose EU political priorities							✔		✔				
13	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?	13.1	To what extent do Member State risk assessment organisations share ownership of a harmonised European assessment outcome (and evidence of the factors)?	13.1.1	Evidence (where readily available*) of Member States taking up the outcome of harmonised European risk assessments based on EFSA's annual reports and external sources	Evidence found in different types of documents confirming that Member States take up the outcome of harmonised European risk assessments							✔					✔	
				13.1.2	Evidence (where readily available*) of engagement of Member State risk assessment organisations in EFSA's activities	Evidence found in different types of documents confirming engagement of Member State risk assessment organisations in EFSA's activities (participation in working groups, attendance at conferences, contribution of expertise and advice)						✔	✔						
				13.1.3	Stakeholders' perception of Member States' ownership of EFSA's risk assessments	Different types of interviewees provide examples of Member States' ownership of EFSA's risk assessments		✔											
				13.1.4	Evidence (where readily available*) of factors influencing Member States' ownership of a harmonised European assessment outcome and their involvement in the provision of scientific advice	Evidence found in different types of documents of factors (internal and external) influencing Member States' ownership of a harmonised European assessment outcome and their involvement in the provision of scientific advice						✔	✔						
		13.2	To what extent is the involvement of Member State risk assessment organisations in the provision of EFSA's scientific advice complementary to the activities of other public actors (and evidence of the factors)?	13.2.1	Evidence (where readily available*) of complementarities/overlaps between the work carried out by Member State risk assessment organisations in the provision of EFSA's scientific advice and the activities of other national public actors	Evidence found in different types of documents of complementarities between the work carried out by Member State risk assessment organisations in the provision of EFSA's scientific advice and the activities of other national public actors						✔	✔						
				13.2.2	Stakeholders' opinions on the alignment between EFSA's advice and the activities of other national public actors in the field of food stafety	At least 75% of survey respondents are of the opinion that EFSA's advice is aligned with the activities of other national public actors in the field of food safety (activities are complementary, do not overlap)			✔										
				13.2.3	Stakeholders' perception of complementarity between EFSA's scientific advice and that of other public actors	Different types of interviewees refer to the complementarity of EFSA's scientific advice to that of other public actors		✔											
14	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?	14.1	To what extent are EFSA's tasks and activities coherent with EU commitments at international level?	14.1.1	Evidence (where readily available*) of alignment between EFSA's tasks and activities and EU commitments at international level	Evidence found in different types of documents confirming alignment between EFSA's tasks and activities and EU commitments at international level						✔	✔					✔	
				14.1.2	Stakeholders' perceptions of coherence or overlaps between EFSA's tasks and activities and the EU commitments at international level	Different types of interviewees provide concrete examples of coherence/overlaps between EFSA's tasks and activities and the EU commitments at internatioanl level	✔	✔											
				14.1.3	Stakeholders' opinion on the aligment between EFSA's tasks and activities and the EU commitments at international level	At least 75% of survey respondents are of the opinion that EFSA's tasks and activities are aligned with the EU commitments at international level			✔										
15	To which extent is there overlap/complementarity/coherence with the work of other EU Agencies, notably EMA, ECHA, ECDC?	15.1	To what extent is there overlap between the work of EFSA and that of other EU agencies?	15.1.1	Documentation of the scope of EFSA's work and that of other EU agencies	No or only limited evidence found in different types of documents of overlaps between EFSA's work and the work of other EU agencies							✔			✔	✔		
		15.2	To what extent does EFSA's work complement the work of other EU agencies?	15.2.1	Documentation of the scope of EFSA's work and that of other EU agencies	Evidence found in different types of documents of complementarity between EFSA's work and the work of other EU agencies										✔	✔		
				15.2.2	Documentation of formal communication channels and cooperation/coordination between EFSA and other EU agencies	Evidence found in different types of documents confirming that formal communication channels and cooperation/coordination between EFSA and other EU agencies are in place						✔	✔	✔					
				15.2.3	Stakeholders' perceptions about communication channels and past cooperation between EFSA and other EU agencies	Different types of interviewees provide concrete examples of communication channels and past cooperation/coordination betweeen EFSA and other EU agencies	✔	✔											
				15.2.4	Stakeholders' opinion about the alignment of EFSA's tasks and activities with the work of EU agencies	At least 75% of survey respondents agree that EFSA's tasks and activities are aligned with the work of EU agencies			✔										
EU added value																			
16	What is the additional value resulting from EFSA's existence, compared to what could be achieved by Member States at national level?	16.1	To what extent do EFSA's activities add to what is being done by national authorities and food safety agencies in EU Member States (avoiding overlap and duplication of work and effort)?	16.1.1	Based on conclusions from other questions (EQ 13)	Evidence found of EFSA's activities that have added to what is being done at national level													✔
				16.1.2	Stakeholders' opinions whether the achievements of EFSA could have been made by other organisations	At least 75% of survey respondents are of the opinion that EFSA's achievements could not have been achieved at national/ international level			✔										
				16.1.3	Stakeholders' perception of EFSA's added value	Different types of interviewees provide examples of problems that EFSA has addressed which could not have been solved by Member States' authorities independently	✔	✔											
		16.2	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 concernd EU AV so has been integrated here*	16.2.1	Stakeholders' perception of the consequences of discontinuing EFSA	Different types of interviewees make reference to negative consequences of discontinuing EFSA	✔	✔											
				16.2.2	Stakeholders' opinion on consequences of discontinuing EFSA	At least 75% of survey respondents are of the opinion that discontinuing EFSA would have negative consequences for the provision of independent scientific advice on the food chain at EU level.			✔										
				16.2.3	Stakeholders' awareness of organisations that would take on EFSA's current work in case of discontinuation	Different types of interviewees are of the opinion that other organisations' (at national and international level) will not be able to take on work currently done by EFSA	✔	✔											
	To what extent is EFSA recognised as a leading regulatory	17.1	To what extent is EFSA recognised as a leading regulatory authority relating to independent scientific advice on the food chain?	17.1.1	Stakeholders' perception of EFSA	At least 75% of survey respondents consider EFSA to be the leading regulatory authority providing independent scientific advice on the food chain in the EU			✔										

EFSA Evaluation Question Matrix
Final. Approved by EFSA.
26 September 2017

Evaluation questions		Subquestion		Indicators		Judgement criteria	Sources of evidence / tools												Conclusions from other EQs and subquestions
							Stakeholder consultation				Documentary review								
							Interviews		Surveys		EFSA				Other				
											Activity monitoring reports								
							EFSA	External	Online survey	Case study - Event survey	Monitoring data (KPIs)	Other monitoring / internal reporting	Annual activity reports, budgets	Governance / strategy docs / working practice	Policy / regulatory docs	Independent evaluation / recommendations	Other EU agencies	Other - literature search	
17	scientific authority at national, European and global level? Which factors have the most important influence on the scientific recognition and the reputation of EFSA?		independent scientific advice on the food chain?	17.1.2	Based on conclusions from other questions (effectiveness)	Evidence found that EFSA is recognised as the leading regulatory authority relating to independent scientific advice on the food chain													✔
		17.2	To what extent are there factors that influence the scientific recognition and the reputation of EFSA?	17.2.1	Based on conclusions from other questions (effectiveness/efficency/coherence)	Evidence found that there are factors influencing the recognition of EFSA													✔

***Note: The reference to (where readily available*) throughout the evaluation question matrix refers to the fact that we will seek to identify relevant secondary data (be it from within EFSA or external data) within the confines of the approach agreed for the documentary review in the final, approved version of the inception report, section 4.2.1.**

APPENDIX 2: REFERENCE LIST

Type	Specific documents/data	Purpose of review
Policy and legal documents	Regulation (EC) N° 178/2002 of the European Parliament and of the Council of 28 January 2002 Laying down the General Principles and Requirements of Food Law, Establishing the European Food Safety Authority and Laying down procedures in Matters of Food Safety (2002) Regulation (EC) N° 1304/2003 on the procedure applied by the European Food Safety Authority to requests for scientific opinions referred to it (2003) Regulation (EC) N° 2160/2003 of the European Parliament and of the Council on the control of salmonella and other specified food-borne zoonotic agents (2003) Regulation (EC) N° 1333/2008 of the European Parliament and of the Council of 16 December 2008 on Food Additives (2008) Regulation (EU) 2015/2283 of the European Parliament and of the Council on Novel Foods, Amending Regulation (EU) N° 1169/2011 and Repealing Regulation (EC) N° 258/97 and Commission Regulation (EC) N° 1852/2001 (2015) Commission Decision of 12 June 2007 on a harmonised monitoring of antimicrobial resistance in Salmonella in poultry and pigs (2007) Commission Implementing Decision (EU) 2017/370 amending Commission Implementing Decision 2014/909/EU by extending the period of application of certain protective measures and amending the list of areas subject to protective measures in relation to small hive beetle in Italy (2017) Commission Implementing Regulation (EU) 2015/1375 of 10 August 2015 Laying down Specific Rules on Official Controls for Trichinella in Meat (2015) Commission Regulation (EC) N° 2230/2004 Laying down Detailed Rules for the Implementation of European Parliament and Council Regulation (EC) N° 178/2002 with regard to the Network of Organisations Operating in the Fields within the European Food Safety Authority's mission (2004) Commmission Regulation (EC) N° 2073/2005 of 15 November 2005 on Microbiological Criteria for Foodstuffs (2005) Commission Regulation (EC) N° 575/2006 amending Regulation (EC) N° 178/2002 of the European Parliament and of the Council as regards the number and names of the permanent Scientific Panels of the European Food Safety Authority (2006) Commission Regulation (EC) No 202/2008 amending Regulation (EC) N° 178/2002 of the European Parliament and of the Council as regards the number and names of the Scientific Panels of the European Food Safety Authority (2008) Commission Regulation (EU) N° 200/2010 implementing Regulation (EC) N° 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 of Gallus gallus (2010) Commission Regulation (EU) N° 517/2011 implementing Regulation (EC) N° 2160/2003 of the European Parliament	To gain a thorough understanding of the legal and policy framework of EFSA The review of these documents will feed into the assessment of the relevance and coherence of EFSA.

	and of the Council as regards a Union target for the reduction of the prevalence of certain Salmonella serotypes in laying hens of Gallus gallus and amending Regulation (EC) Nº 2160/2003 and Commission Regulation (EU) Nº 200/2010 (2011) Commission Regulation (EU) Nº 200/2012 concerning a Union target for the reduction of Salmonella Enteritidis and Salmonella typhimurium in flocks of broilers, as provided for in Regulation (EC) Nº 2160/2003 of the European Parliament and of the Council (2012) Commission Regulation (EU) Nº 1190/2012 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 (2012) Commission Regulation (EU) 2017/228 of 9 February 2017 amending Regulation (EC) Nº 178/2002 of the European Parliament and Council as regards the names and the areas of competence of the scientific panels of the European Food Safety Authority (2017) Consolidated Version of the Treaty on the Functioning of the European Union (2012) Joint Statement of the European Parliament, the Council of the EU and the European Commission on Decentralised Agencies (2012) Memorandum of Cooperation between the European Food Safety Authority and the Canadian Food Inspection Agency (2015) Memorandum of Cooperation between the European Food Safety Authority and the Food Safety Commission of Japan (2015) Memorandum of Understanding between the European Chemicals Agency and the European Food Safety Authority (2017) Memorandum of Understanding between the European Food Safety Authority and the European Centre for Disease Prevention and Control (2014) Memorandum of Understanding on Working Arrangements between the European Medicines Agency and the European Food Safety Authority (2012) 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, Directive 2001/18/EC, Regulation (EC) Nº 1829/2003, Regulation (EC) Nº 1831/2003 (2018)	
Previous or upcoming evaluations and impact assessments	Previous external evaluations: - Bureau van Dijk Ingénieurs Conseils with Arcadia International EEIG, Evaluation of EFSA – Final Report (2005) - Ramboll-Euréval-Matrix, Evaluation of the EU Decentralised Agencies in 2009 (2009) - Ernst&Young, External Evaluation of EFSA – Inception and Final Reports (2011, 2012) - Ex post Evaluation of the Policy on Independence and Scientific Decision-Making Processed of the European Food Safety Authority (EFSA) and of its Implementing Rules on Declaration of Interest – Final Comprehensive Report (2017) 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) - Food Chain Evaluation Consortium (for the European Commission), Evaluation of the Rapid Alert System for Food and Feed and of Crisis Management Procedures (2016) - The Refit Evaluation of the General Food Law (Regulation (EC) Nº 178/2002) and its Appendices (2018)	To set a baseline and ensure that the study takes into account and builds on earlier work that is necessary for the assessment of EFSA's performance and EFSA as an organisation

	EFSA Communication and External Relations Department, *Stakeholder Engagement Approach – Interim Evaluation Report* (2017) EFSA Executive Director Office, Management Self-Evaluation (2017)	
Programming and activity monitoring reports	Progamming reports: - Management Board, Programming Documents 2014-2016, 2015-2017, 2016-2018, 2016-2019, 2017-2019, 2018-2020 (Draft) - Multi-annual Programme on International Scientific Cooperation 2014-2016 (2014) - Management Plans of the European Food Safety Authority for 2011, 2012 and 2013 - Work Plans 2011, 2012, 2013, and 2014-2016 - International Scientific Cooperation Work Plan 2017-2020 (Draft) Activity monitoring reports: - Annual Activity Reports of the European Food Safety Authority for 2011 and 2012 - Annual Reports 2011-2015 - Consolidated Annual Activity Report 2015 and 2016 - EFSA Consolidated Annual Activity Report 2017 (DRAFT) (2018) - Annual Report on Article 36 Activities 2011 (2012) - Article 36 Report 2012 – Activities on the Article 36 List and Networking with Article 36 Organisations (2013) - Article 36 Report 2013 – Activities on the Article 36 List and Participation of Article 36 Organisations in EFSA's Grant and Procurement Schemes (2014) - Focal Point Activities 2011-2013 (2012-2014) - Implemented Activities under the EFSA Pre-Accession Programme 2011-2014 (2015) - EFSA's Activities on Emerging Risks in 2016 (2017) Strategic documents: - EFSA Office of the Executive Director and the Management Board, EFSA Strategic Plan 2009-2013 (2008) - International Activities – a Strategic Approach (2009) - Science Strategy 2012-2016 (2012) - EFSA Strategy 2020: Trusted Science for Safe Food. Protecting Consumers' Health with Independent Advice on the Food Chain (2016) Scientific Cooperation Roadmap 2014-2016 (2014) Advisory Forum and Scientific Cooperation Unit, Mid-Term Report to EFSA's Management Board on the Scientific Cooperation Roadmap 2014-2016 (2015) Scientific Cooperation Annual Reports 2014, 2015 and 2016	To assess EFSA's performance over the period under review, notably drawing on KPIs at activity level and by considering EFSA's financials
Documents related to, or audits of, EFSA's working practices and procedures	European Commission – Internal Audit Service: - Final Audit Report on Performance Evaluation and Career Development in the European Food Safety Authority (2012) - Final Audit Report on Reporting and Building Blocks of Assurance in EFSA, and its Action Plan (2014) - IAS Audit on Reporting and Building Blocks of Assurance in EFSA – Action Plan (2014) - 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 (2015) - IAS Final Audit Report on IT governance and IT project management in EFSA (2016) European Court of Auditors: - Special Report No 15 – Management of Conflict of Interest in selected EU Agencies (2012)	To gain an in-depth understanding of EFSA's working practices and procedures and any limitations identified that can be followed-up on as part of this evaluation

	- Summary of Results from the Courts' Annual Audits of the European Agencies and Other Bodies (2012-2016) - Special Report No 12 – Agencies' use of grants: not always appropriate or demonstrably effective (2016) EFSA replies to the Special ECA Report – Agencies' use of grants: Not always appropriate or demonstrably effective (2016) Internal Audit Capability: - Data Protection Audit of EFSA video-surveillance system (2012) - Audit Report on Internal Control Standards Implementation (2014) Corporate Governance Audit on the Role of the Expert in the EFSA Scientific Decision-Making Processes (2016) Documents related to EFSA's working practices and procedures: - Advisory Forum and Scientific Cooperation Unit, Terms of Reference of the EFSA Communications Experts Network (2016) - Advisory Forum and Scientific Cooperation Unit, Background Document for Breakout Session Review of Focal Point Agreements (2017) - Advisory Forum Working Group on Communications (AFCWG) Terms of Reference (ToR) (2013) - EFSA Engagement Survey 2012 - EFSA Stakeholder Engagement Approach (2016) - External Relations Unit, Progress with the Implementation of the Stakeholder Engagement Approach (SEA) (2016) - EFSA's Independence Policy 2017 and its Implementing Rules (2017) - EFSA's Policy on Independence – How the European Food Safety Authority Assures the Impartiality to Its Operations (2017) - Best Practice for Crisis Communicators – How to Communicate during Food or Feed Safety Incidents (2016) - Closed Consultations (2018) Executive Director: - Decision of the Executive Director Concerning the Selection of Members of the Scientific Committee, Scientific Panels and External Experts to Assist EFSA in Its Scientific Work (2013, 2014, 2017) - Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management (2017) - Decision of the Executive Director on Declarations of Interest (2014) - Decision of the Executive Director of the European Food Safety Authority Concerning Pesticides Risk Assessment Peer Review (2015) Executive Directorate: - EFSA Progress Report (2015) - 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) Experts' Compensation Guide (2016) Human Capital Unit, Update on the Procedure for the Renewal of the ANS and CEF Scientific Panels (2016) Legal and Regulatory Affairs Unit, Note to the Attention of the Management Board - Renewal of ANS and CEF Panels (2016) Inaugural Meeting of EFSA's Stakeholder Forum, 30-31 May 2017 (2017) Information Governance Framework at EFSA (2017)	

	Internal Document Follow-up on Implementation of EFSA's Management Board Recommendations (2017) Monitoring and Risk Assessment of Antimicrobial Resistance in the Food Chain : EFSA's Role (2016) Open EFSA: - Discussion Paper – Transformation to an 'Open EFSA' (2014) - Preliminary Implementation Plan – Transformation to an "Open EFSA" (2015) - Final Phase Implementation plan to an "Open EFSA" (2016) Open Plenaries Statistics (2018) Public Consultation - Number of Comments and Responses (2018) Performance and workload management, BIOCONTAM case study report (2017) PPT - Panel Renewal 2018 - Management Board Meeting, 21st March 2018 (2018) Quality Management – Customer Feedback Mechanism (2013) Recommendations from EFSA's Management Board (2012) 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) Resources & Support Department, Concept Paper on the Review of EFSA's Policy on Independence and Scientific Decision-Making Process (2016) Scientific Committee and Emerging Risks Unit: - RAM-Pro: Risk Assessment Methodology Programme (2017) - Scientific Committee Minutes of the 87th Plenary meeting Held on 14-15 February 2018 (2018) - Network on Harmonisation of Risk Assessment Methodologies (2013) Annual Quality Manager's Reports 2013 Expert Database 5-Year Review Report (2014) Financial Statements Reports on the Implementation of the Budget 2011-2016 Management Board: - List of Competent Organisations Designated by the Member States Which May Assist EFSA with Its Mission (2017) - Decision of the Management Board of the European Food Safety Authority Concerning the Establishment and Operations of the Scientific Committee, Scientific Panels and of Their Working Groups (2017) - Transparency and Engagement in Risk Assessment (2015) EFSA Performance Indicators (2004)	
EFSA's projects	Australia Project 2014. Project Closure Report (2015) Agora Project. Project Closure Report (2015) EFSA Journal Project. Closure report (2017) PaRMa Project. Project Closure Report (2014) PRIME Project. Project Closure Report (2016) Process Management Project (PMP). Project Steering Committee (2017) STEP 2018 Project. Project Steering Committee (2017)	To better understand the horizontal project being carried out in relation to EFSA's strategic objectives and how these (are expected to) impact on EFSA's performance and EFSA as an organisation
EFSA data sources including EFSA Journal	EFSA's website EFSA's conference website *EFSA Journal* - **Scientific opinions** Lumpy skin disease (2015) Public health impact new target for the reduction of Salmonella in broiler flocks (2011 and 2012)	To get a better understanding of the Agency and its means of communication with its target groups

	Scientific Motivations and Criteria to Consider Updating EFSA Scientific Assessments (2017) Scientific Opinion on field trials for bovine tuberculosis vaccination (2013) Scientific Opinion on the Revised Exposure Assessment of Steviol Glycosides (E 960) for the Proposed Uses as a Food Additive (2014) Scientific Opinion on the Safety of Caffeine (2015) Scientific Opinion on the Safety of the Extension Use of Steviol Glycosides (E 960) as a Food Additive (2015) Scientific Opinion on the Safety of the Proposed Amendment of the Specifications for Steviol Glycosides (E 960) as a Food Additive (2015) The principles and methods behind EFSA's Guidance on Uncertainty Analysis in Scientific Assessment (2017) - **Scientific reports** An Update on the Risk of Transmission of Ebola Virus via the Food Chain – Part 2 (2015) Highly Pathogenic Avian Influenza A Subtype H5N8 (2014) Small hive beetle diagnosis and risk management options (2015) The European Union summary report on trends and sources of zoonoses, zoonotic agents and food-borne outbreaks in 2015 (2016) - **External scientific reports** EFSA APDESK Survey on Stakeholders' Satisfaction on Provided Services (2014) Gene Rowe and Fergus Bolger, Final report on 'the identification of food safety priorities using the Delphi technique' (2016) ICF GHK, *EFSA APDESK Questionnaire on Stakeholder Needs* (2013) ICF International, *External Review of the Impact of Scientific Grant and Procurement Projects on Delivering EFSA's Tasks - Review Report* (2014) Implementation of systematic reviews in EFSA scientific outputs workflow (2012) RAND Europe and VVA, *Impact Assessment of Specific Measures Aimed at Increasing Transparency and Engagement in EFSA Risk Assessment Process* (2016) - **Technical reports** EFSA's Catalogue of Support Initiatives during the Life-cycle of Applications for Regulated Products (2017) Identification of Emerging Risks: An Appraisal of the Procedure Trialled by EFSA and the Way Forward (2015) Outcome of the Public Consultation on EFSA's Draft Policy on Independence (2017) Outcome of the public consultation on the draft guidance on the agronomic and phenotypic characterisation of genetically modified plants (2015) Outcome of the public consultation on the draft Scientific Opinion of the EFSA Panel on Contaminants in the Food Chain (CONTAM) on acrylamide in food (2015) Scientific Data Management Framework (2017) Survey of Institutions Employing EFSA Panel Members (2017) The EFSA Data Warehouse Access Rules (2015) - **Event reports** EFSA and WHO, Review of the Threshold of Toxicological Concern (TTC) Approach and Development of New TTC Decision Tree (2016) Inaugural meeting of EFSA's Stakeholder Forum, 30-31 May 2017 (2017) Joint EFSA-DG SANTE Workshop – Strengthening regional cooperation in South East Europe and Middle East for prevention and control of Lumpy Skin Disease (2016)	

	- **Guidance** DRAFT for Public Consultation: Guidance on Risk Assessment of the Application of Nanoscience and Nanotechnologies in the Food and Feed Chain: Part 1, Human and Animal Health, Guidance (2018) Guidance on Uncertainty Analysis in Scientific Assessments (2017) - **Conclusion on Pesticides** Peer review of the pesticide risk assessment of the active substance glyphosate (2015) - **Editorial** Increasing robustness, transparency and openness of scientific assessments (2015) - **Statement of EFSA** Revised Exposure Assessment for Steviol Glycosides for the Proposed Uses as a Food Additive (2011) - **Reflection paper** Is Scientific Assessment a Scientific Discipline? (2017) - **Special issue** Harmonisation of monitoring zoonoses, antimicrobial resistance and foodborne outbreaks (2012) - **Supplement** Shaping the Future of Food Safety, Together: Proceedings of the 2nd EFSA Scientific Conference. Milan, Italy, 14-16 October 2015 (2015)	
Other (EFSA)	2015 Management Feedback: 1st Survey Jan-Feb 2015 (2015) EFSA: How We Communicate about Risk (2015) Non Paper: System for Providing Scientific Advice (2016) Register of Questions (2018) Twitter: @ESFA_EU Youtube: EFSAchannel	To complement the other types of documents listed above
External	Commission of the European Communities, *White Paper on Food Safety* (2000) European Commission: - Better Regulation Guidelines, Commission Staff Working Document (2017) - Communication from the Commission on the European Citizens' Initiative 'Ban Glyphosate and Protect People and the Environment from Toxic Pesticides (2017) - Food Safety and Animal and Plant Health in TTIP - From Farm to Fork: Safe and Healthy Food for Everyone, *The European Union Explained: Food Safety* (2014) - Glyphosate (2017) - Lessons Learned from the 2011 Outbreak of Shiga Toxin-Producing Escherichia Coli (STEC) O104:H4 in Sprouted Seeds (2011) - Roadmap on the follow-up to the common approach on EU decentralised agencies (2012) L. Miko (Deputy Director-General for the food chain), Commission Feedback Mechanism on EFSA's Scientific Opinions (2014) European Chemicals Agency, National Helpdesks (2017) European Food Safety Authority and European Chemicals Agency, Outline of Draft Guidance Document for the Implementation of the Hazard-based Criteria to Identify Endocrine Disruptors (2016) European Medicines Agency, Applying for EU Marketing Authorisation For Medicinal Products for Human Use (2015) European Parliament, The Cost of Non-Agencies with Relevance to the Internal Market (2016) European Union: - European Ombudsman Award for Good Administration 2017 – Winners and shortlisted nominations (2017)	To validate and provide external data to assess EFSA's relevance, effectiveness, coherence and efficiency.

- Ombudsman launches "Award for Good Administration" (2016)

EU-ANSA, Overview of the scientific processes of the EU agencies network for scientific advice (2015)

National agencies

All national agencies' websites were consulted.

Danish Agricultutre & Food Council, Danish Pig Producers and Food Safety (2017)

France - Agence nationale de la sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES) :

- Avis relatif à la révision de la définition des E. coli entéro-hémorragiques (EHEC) majeurs typiques, à l'appréciation quantitative des risques liés à ces bactéries à différentes étapes de la chaine alimentaire, selon les différents modes de consommation des steaks haches, et a la prise en compte du danger lie aux E. coli entéro-pathogènes (EPEC) dans les aliments (2011)
- Critères et Procédure de Nomination Des Experts de L'Anses Suite À Un Appel À Candidature (2011)

Istituto Zooprofilattico Sperimentale delle Venezie (Italy), *Aethina tumida in Italy: updates* (2017)

National Institute for Public Health and the Environment (Dutch Ministry of Health, Welfare and Sport), Nanomaterials in consumer products, Update of products on the European market in 2010 (2011)

UK:

- Department for Environment Food & Rural Affairs, The Strategy for achieving Officially Bovine Tuberculosis Free status for England (2014)
- Dr Walker, Food and Feed Law: Compendium of UK Food and Feed Legislation with Associated Context and Changes during January-March 2017 (2017)
- European Union Committee (House of the Lords), Counting the Cost of Food Waste: EU Food Waste Prevention (2014)

United States:

- Department of Agriculture (Food Safety and Inspection Service), Risk Profile for Pathogenic Non-0157 Shiga Toxin-Producing Escherichia coli (2012)
- Food & Drug Administration, The Global Coalition for Regulatory Science Research (2017)

International organisations

FAO:

- Code of Hygienic Practice for Meat, CAC/RCP 58-2005 (2005)
- Emergence of lumpy skin disease (LSD) in Europe (2015)

FAO/WHO:

- Enterohaemorrhagic Escherichia coli in raw beef and beef products: approaches for the provision of scientific advice (2011)
- FAO/WHO Global Individual Food Consumption Data Tool – GIFT (2017)
- Guidelines for the Control of Trichinella Spp. in Meat of Suidae, CAC/GL 86-2015 (2015)

World Health Organization, Integrated Surveillance of Antimicrobial Resistance in Foodborne Bacteria: Application of a One Health Approach (2017)

Fukuda, K., Food Safety in a Globalised World', *Bulletin of the World Health Organization* (2015)

International Agency for Research on Cancer, Some organophosphate insecticides and herbicides (2017)

Books and journal articles

A review of the systematic review process and its applicability for use in evaluating evidence for health claims on probiotic foods in the European Union, *Nutrition Journal* (2015)

Assessment of in vitro human dermal absorption studies on pesticides to determine default values, opportunities for read-across and influence of dilution on absorption, *Regulatory Toxicology and Pharmacology* (2014)

Challenges of Developing Countries in Complying Quality and Enhancing Standards in Food Industries, *Procedia - Social and Behavioral Sciences* (2016)

Comparison of the efficacy of Neethling lumpy skin disease virus and x10RM65 sheep-pox live attenuated vaccines for the prevention of lumpy skin disease – The results of a randomized controlled field study, *Vaccine* (2015)

Consumenten en voedselveiligheid, wat is acceptabel en wie is verantwoordelijk? -Consumers and food safety, what is acceptable and who is responsible?-, *LEI Wageningen UR* (2012)

Consumers and animal welfare. A comparison between European Union countries, *Appetite* (2012)

Emergence of Lumpy Skin Disease in Greece, 2015, *Transboundary and Emerging Diseases* (2016)

Epidemic Q Fever in Humans in the Netherlands, *Advances in Experimental Medicine and Biology* (book series) (2012)

Epizootology and Molecular Diagnosis of Lumpy Skin Disease among Livestock in Azerbaijan, *Frontiers in Microbiology* (2016)

EU animal welfare policy: Developing a comprehensive policy framework, *Food Policy* (2012)

Food Safety for Food Security: Relationship between Global Megatrends and Developments in Food Safety, *Trends in Food Science & Technology* (2017)

Foundations of EU Food Law and Policy – Ten Years of European Food Safety Authority (2013)

Impact of food and water-borne diseases on European population health, *Current opinion in food science* (2016)

Kontaminanten aus Lebensmittelverpackungen, *Bundesgesundheitsblatt* (2017)

Legal Requirements for Food Hygiene, *Encyclopedia of Food and Health* (2016)

Nanomaterials in Consumer Products, *NATO Science for Peace and Security Series C: Environmental Security* (2009)

OECD/EFSA Workshop on Developmental Neurotoxicity (DNT): The use of Non-Animal Test Methods for Regulatory Purposes, *Altex* (2017)

Parasite to patient: A quantitative risk model for Trichinella spp. in pork and wild boar meat, *International Journal of Food Microbiology* (2017)

Principles for the risk assessment of genetically modified microorganisms and their food products in the European Union, *International Journal of Food Microbiology* (2013)

Reflections on Bird and Mammal Risk Assessment for Plant Protection Products in the European Union: Past, Present, and Future, *Environmental Toxicology and Chemistry* (2017)

State of the art in benefit–risk analysis: Food microbiology, *Food and Chemical Toxicology* (2012)

The Emergence of Systematic Review in Toxicology, *Toxicological Sciences* (2016)

The Q fever epidemic in The Netherlands: history, onset, response and reflection, *Epidemiology & Infection* (2011)

Vaccination against tuberculosis in badgers and cattle: an overview of the challenges, developments and current research priorities in Great Britain, *Veterinary Record* (2014)

Reports

Deloitte, *Capitalizing on the Shifting Consumer Food Value* (2016)

Deloitte, *What's on Your Plate? Overview of Deloitte Research on Food Safety with a European Perspective* (2017)

	Fusions, *Review of EU Member States Legislation and Policies with Implications on Food Waste* (2015) *ICF, Reputation Barometer* (2017) Ipsos MORI, *EFSA Stakeholder Research – Final Report* (2015) Working Paper from the European Policy Centre Pre-Assessment ISO 9001:2015 – Report for EFSA (2015) QMS implementation Assessment for EFSA – European Food Safety Authority (2015) **Media** *France inter*, Marie-Monique Robin : « Sur le glyphosate, même les études menées par Monsanto montrent que c'est cancérigène » (2017) *Greenpeace*, EU chemicals agency sweeps glyphosate cancer evidence under the carpet (2017) *Libération*, Glyphosate: l'autorité européenne de sécurité des aliments sous influence de Monsanto ? (2017) *NutraIngredients*: EFSA Budget Plateaus despite Growing Workload (2016) *The Guardian*, EU report on weedkiller safety copied text from Monsanto study (2017) **Other** Egan, K., The Difference Between Facebook, Twitter, Linkedin, Google+, YouTube, & Pinterest (2017) Portier, C.J., Open letter: Review of the Carcinogenicity of Glyphosate by EChA, EFSA and BfR (2017) SAFE Annual Conference, *Workshop to identify recommendations for EFSA* (2017) ResearchGate: https://www.researchgate.net/ Web of Science: https://clarivate.com/products/web-of-science/	

APPENDIX 3: SURVEY QUESTIONNAIRE

Third independent external evaluation of the European Food Safety Authority (EFSA)

Stakeholder survey
28 September 2017

INTRODUCTION

Survey on EFSA's performance, governance and organisational structure

What is this survey about?

This survey is carried out in the context of the "Third independent evaluation of the European Food Safety Authority (EFSA)" conducted by Ramboll and Coffey for EFSA. Please find a letter from EFSA introducing the study here [link].

Responding to the survey should take about 25-30 minutes. To facilitate the process, you can start responding to the questions and return to the survey at a later stage by using your personalised link in the invitation email provided to you.

Who should answer?

The survey invites all with an involvement/interest in the work of EFSA to provide their assessments.

Please note that this survey is strictly confidential - your identity will not be disclosed, and the survey will be anonymous. No personal information will be shared with EFSA.

How will this survey make a difference?

The survey data will contribute to the assessment of EFSA over the period 2011 to 2016 and the identification of recommendations for the improvement of EFSA's performance and governance in the future.

Thank you for taking the time to respond to this survey - we highly appreciate your feedback!

BACKGROUND QUESTIONS

Please select the option which best categorises you / your relationship with EFSA. You can select several options. Please indicate current and/or past positions and memberships (between 2011 and 2016): (multiple choice)

(1) ❑ Staff member of EFSA
(2) ❑ Member of EFSA's Management Board
(3) ❑ Member or observer of EFSA's Advisory Forum
(4) ❑ Member of Advisory Forum Communications Working Group (AFCWG)
(5) ❑ Representative or observer of an EFSA National Focal Point
(6) ❑ Member of EFSA's Scientific Panels or Committee
(7) ❑ Pesticides peer review expert
(8) ❑ Member of EFSA's scientific working groups
(9) ❑ Member of an EFSA Scientific Networks
(10) ❑ Member of EFSA's Stakeholder Bureau
(11) ❑ Members of EFSA's Stakeholder Forum
(12) ❑ 'Article 36' competent organisation (competent organisations designated by the Member States which may assist EFSA with its mission)
(13) ❑ Representative of a national risk management or risk assessment body of an EU Member State, an EEA country or an accession or candidate country
(14) ❑ Representative of a third country
(15) ❑ Representative of one of the European institutions or bodies
(16) ❑ Representative of an international organisation
(17) ❑ Journalist or other media representative
(18) ❑ Other. Please specify _____

For those who selected Management Board, Advisory Forum, Advisory Forum Working Group on Communications, Focal Point, Scientific Panels of Committees, Pesticides peer review expert, Scientific working group, scientific network, Stakeholder Bureau, Stakeholder Forum

Are you a current or a past member of the selected organisation/body?

(1) ❑ I am currently a member
(2) ❑ I was a member during the period 2011-2016 but am no longer a member
(3) ❑ I was a member before 2011 but am no longer a member

If selected option 3 above – will exit the survey.

All except EFSA staff and European institutions or bodies

Please select the country in which you are based for your work.
(Use drop down menu)

(1) ❑ Albania
(2) ❑ Austria
(3) ❑ Belgium
(4) ❑ Bosnia and Herzegovina
(5) ❑ Bulgaria
(6) ❑ Croatia
(7) ❑ Cyprus
(8) ❑ Czech Republic
(9) ❑ Denmark
(10) ❑ Estonia
(11) ❑ Finland
(12) ❑ Former Yugoslav Republic of Macedonia

(13) ❑ France
(14) ❑ Germany
(15) ❑ Greece
(16) ❑ Hungary
(17) ❑ Iceland
(18) ❑ Ireland
(19) ❑ Italy
(20) ❑ Latvia
(21) ❑ Lithuania
(22) ❑ Luxembourg
(23) ❑ Malta
(24) ❑ Montenegro
(25) ❑ Netherlands
(26) ❑ Norway
(27) ❑ Poland
(28) ❑ Portugal
(29) ❑ Romania
(30) ❑ Serbia
(31) ❑ Slovakia
(32) ❑ Slovenia
(33) ❑ Spain
(34) ❑ Sweden
(35) ❑ Switzerland
(36) ❑ Turkey
(37) ❑ United Kingdom
(38) ❑ Other

For those selecting other:

Please indicate the country in which you are based for your work _____

Only for EFSA staff

Which of EFSA's departments are you currently working in?

(1) ❑ Scientific evaluation of regulated products
(2) ❑ Risk assessment & scientific assistance
(3) ❑ Communications & external relations
(4) ❑ Business services
(5) ❑ Executive Director Office

Only for EFSA staff

How long have you been working for EFSA?

(1) ❑ < 1 year
(2) ❑ 1 – 3 years
(3) ❑ 4 - 5 years
(4) ❑ 6 - 10 years
(5) ❑ > 10 years

For representatives of EU institutions/bodies

Which of the EU institutions or bodies do you represent?

(1) ❑ European Commission – DG SANTE
(2) ❑ European Commission – Joint Research Centre
(3) ❑ European Commission – Other DG
(4) ❑ European Parliament
(5) ❑ European Medicines Agency (EMA)

(6) ❑ European Chemicals Agency (ECHA)
(7) ❑ European Centre for Disease prevention and control (ECDC)
(8) ❑ European Environment Agency (EEA)
(9) ❑ Other. Please specify _____

For representatives of international organisations

Which international organisation do you work for?

(1) ❑ World Health Organisation (WHO)
(2) ❑ Food and Agriculture Organisation of the United Nations (FAO)
(3) ❑ World Organisation of Animal Health (OIE)
(4) ❑ Organisation for Economic Co-operation and Development (OECD)
(5) ❑ European and Mediterranean Plant Protection Organization (EPPO)
(6) ❑ Other. Please specify _____

For members of EFSA's Management Board, Member or observer of EFSA's Advisory Forum, Member of Advisory Forum Working Group on Communications, Representative of a Focal Point, Member of a Scientific Committee or Panel, EFSA Scientific Networks, Member of the Stakeholder Bureau, Members of EFSA's Stakeholder Forum, 'Article 36' competent organisation, pesticides peer review experts

Which sector do you work in? Please select all that apply. *(multiple choice)*

(1) ❑ National public administration
(2) ❑ European bodies and institutions
(3) ❑ Academia / Research
(4) ❑ Consumer organisation
(5) ❑ NGOs and advocacy groups
(6) ❑ Business and food industry
(7) ❑ Distribution and HORECA
(8) ❑ Practitioners' associations (medical doctors, dieticians, nurses, veterinarians etc.)
(9) ❑ Farmers and primary producers
(10) ❑ Other. Please specify _____

For Representative of a national risk management or risk assessment body, representative of a third country

What is your main area of work? Please select all that apply. *(multiple choice)*

(1) ❑ National risk management body
(2) ❑ National risk assessment body
(3) ❑ Health, nutrition and food safety
(4) ❑ Animal health
(6) ❑ Plant health
(7) ❑ Research and development
(8) ❑ Other. Please specify _____

For members of the European Parliament, other EU agencies, representatives of international organisations, representative of a national risk management or risk assessment body, third countries, journalists

To what extent are you aware of EFSA as an organisation and the work it undertakes?

(1) ❑ To a high extent
(2) ❑ To a moderate extent
(3) ❑ To a limited extent
(4) ❑ Not at all

If selected option 4 above – will exit the survey.

For Article 36 competent organisations

During the period 2011-2016, have you/ has your organisation applied for an EFSA grant or procurement contract?

(1) ❑ Yes
(2) ❑ No

If selected option 2 above and "Article 36 organisation" was the only response in Question 1 – will exit the survey.

If selected option 1 above

Was your/ your organisation's grant or procurement application successful?

(1) ❑ Yes
(2) ❑ No

If selected option 2 above and "Article 36 organisation" was the only response in Question 1 – will exit the survey.

EFSA'S PERFORMANCE AND ORGANISATIONAL STRUCTURE 2011-2016

This survey which covers EFSA's activities, performance and organisational structure over the period 2011-2016. The questions follow the evaluation criteria: relevance, effectiveness, efficiency, coherence and added value. Responses will be used for the external evaluation of EFSA. Please consider EFSA's activities over the period 2011-2016 when providing answers to the following questions.

RELEVANCE

All

Over the period 2011-2016, to what extent: (EQ1.2.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
Was there a need among risk managers /stakeholders to have access to independent and tailored scientific advice developed at EU level?	❑	❑	❑	❑	❑
Was there a need to increase trust in food safety through an independent, transparent and open EU level scientific agency?	❑	❑	❑	❑	❑
Was there a need to share views on food/feed safety risks at the EU level?	❑	❑	❑	❑	❑

All

Were there any needs in the food/feed safety area (other than those listed above) that should have been responded to by an organisation at EU level such as EFSA but were not listed in EFSA's Founding Regulation? (EQ1.2.1)

(1) ❑ Yes
(2) ❑ No
(3) ❑ Do not know

For those indicating "yes" in the question above

What other needs in the EU should have been responded to by an organisation at EU level such as EFSA? (EQ 1.2.1) _____

For EFSA staff/management, members of EFSA's Management Board, Member or observer of EFSA's Advisory Forum, AFCWG

To what extent do you agree with the statements below regarding EFSA's organisational structure (e.g. organisation in departments and units, reporting lines)? (EQ 2.1.1, 2.3.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
EFSA's current organisational structure is well adapted to the work it is expected to carry out	❑	❑	❑	❑	❑
EFSA's current organisational structure allows it to respond to unforeseen challenges	❑	❑	❑	❑	❑

For those indicating "to a limited extent" or "not at all" in the question above

Please explain why you think that EFSA's organisational structure is not fully fit for purpose. (EQ 2.1.1, 2.3.1)

For EFSA staff/management, members of EFSA's Management Board, Member or observer of EFSA's Advisory Forum, AFCWG*, Representative of a National Focal Point, Member of a Scientific Committee or Panel, pesticides peer review experts, working groups, scientific networks*

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)? (EQ 2.1.1, 2.3.1, 4.1.2)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
EFSA's working practices/procedures are well adapted to the work it is expected to carry out	❑	❑	❑	❑	❑
EFSA's working practices/procedures allow it to respond to unforeseen challenges.	❑	❑	❑	❑	❑

For those indicating "to a limited extent" or "not at all" in the question above

Please explain why you think that EFSA's working practices are not fully fit for purpose. (EQ 2.1.1, 2.3.1, 4.1.2)

EFFECTIVENESS

Scientific advice and opinions

For all except EFSA staff and MB

To what extent do you consider the scientific advice provided by EFSA over the period 2011-2016 to (EQ3a1.1, 3a7.2, 3b1.3):

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know	Not applicable
Represent state-of-the-art knowledge	❑	❑	❑	❑	❑	❑
Be an unbiased, independent source of information	❑	❑	❑	❑	❑	❑
Be based on rigorous/sound methods/approaches	❑	❑	❑	❑	❑	❑
Be timely	❑	❑	❑	❑	❑	❑
Be transparent with regard to the evidence, methods and expertise used	❑	❑	❑	❑	❑	❑
Respond to the needs of you/your organisation	❑	❑	❑	❑	❑	❑
Have involved, considered and engaged appropriately with the various stakeholder groups and citizens in the process of risk assessment	❑	❑	❑	❑	❑	❑
Have involved, considered and engaged appropriately with the various stakeholder groups and citizens in the process of risk communication	❑	❑	❑	❑	❑	❑

For all except EFSA staff and MB, option 4 (technical advice) should only be visible to Commission staff

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. (EQ 3a3.1,3a4.1, 3a5.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know	Not applicable
General scientific questions addressed by EFSA's panel system	❑	❑	❑	❑	❑	❑
Authorisation dossiers addressed by EFSA's panel system	❑	❑	❑	❑	❑	❑
Pesticide dossiers covered through the peer review system	❑	❑	❑	❑	❑	❑
Technical advice provided by EFSA scientific staff to the Commission	❑	❑	❑	❑	❑	❑

If indicated "to a limited extent" or not at all" in the above question.

Please explain why you are not completely satisfied with the advice provided (EQ3a3.1,3a4.1, 3a5.1)

_____

All except EFSA staff, MB, experts

To what extent do you agree with the following statements regarding EFSA's scientific opinions? (Added by EFSA, relevant for the external evaluation: 3a.1.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know	Not applicable
The opinions allow for a full understanding of the uncertainties and assumptions	❑	❑	❑	❑	❑	❑

The opinions allow for a full understanding of the weight of evidence	❑	❑	❑	❑	❑	❑
The opinions provide a clear basis for regulatory action	❑	❑	❑	❑	❑	❑
The level of clarity and detail in the opinions facilitate decision making, specifically risk management	❑	❑	❑	❑	❑	❑
The opinions adhere to and provide a clear answer to the terms of reference	❑	❑	❑	❑	❑	❑
The conclusions are consistent with the evidence and methods presented in the opinion	❑	❑	❑	❑	❑	❑

For all except EFSA staff/management and MB

To what extent did the different kinds of services and outputs provided by EFSA over the period 2011-2016 respond to your / your organisation's expectations in terms of usefulness? (EQ3a3.1, 8.3.2)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know	Not applicable
Urgent advice and crisis support	❑	❑	❑	❑	❑	❑
Identification of and response to emerging risks	❑	❑	❑	❑	❑	❑
Methodological approaches and guidance documents	❑	❑	❑	❑	❑	❑
Structured and unstructured data (e.g. data warehouse, EU summary reports)	❑	❑	❑	❑	❑	❑

For EFSA staff/management, members of EFSA's Management Board, Member or observer of EFSA's Advisory Forum, AFCWG*, Representative of a National Focal Point, Member of a Scientific Committee or Panel, pesticides peer review experts, working groups, scientific networks*

To what extent are the different elements of EFSA's scientific production system adapted to the challenges of EFSA's work? (EQ18.1.3)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know	Not applicable
Scientific committees and panels addressing generic risk assessments	❑	❑	❑	❑	❑	❑
Panel system addressing authorisation dossiers	❑	❑	❑	❑	❑	❑
Peer review system for pesticides	❑	❑	❑	❑	❑	❑
Scientific staff providing technical advice	❑	❑	❑	❑	❑	❑

For those indicating "to a limited extent" or "not at all" in the question above

Please explain why you think that EFSA's scientific production system is not fully fit for purpose. (EQ18.1.3)

Communication

For all

How often do you access EFSA's website? (Added by EFSA, relevant for the external evaluation EQ3b2.1)

(1) ❑ Daily
(2) ❑ Weekly
(3) ❑ Monthly
(4) ❑ A few times per year
(5) ❑ Less than once a year

For all

Do you follow EFSA on any of these services and social networks? Please select all that apply. (Added by EFSA, relevant for the external evaluation EQ3b2.1) *Multiple choice*

(1) ❑ Twitter
(2) ❑ LinkedIn
(3) ❑ RSS feeds
(4) ❑ Email alerts
(5) ❑ Newsletter
(6) ❑ YouTube
(7) ❑ Other. Please specify
(8) ❑ None of the above

Not for those who indicated in Question 28 "less than once a year".

To what extent do you / does your organisation consider the following EFSA products to be useful? (Added by EFSA, relevant for the external evaluation EQ3b2.2)

	To a high extent	To a moderate extent	To a limited extent	Not at all	I do not use these products	Do not know/
About EFSA, corporate information	❑	❑	❑	❑	❑	❑
Event information	❑	❑	❑	❑	❑	❑
News	❑	❑	❑	❑	❑	❑
Topics (Discover section)	❑	❑	❑	❑	❑	❑
Videos	❑	❑	❑	❑	❑	❑
Infographics, data visualisations and other multimedia products	❑	❑	❑	❑	❑	❑
Newsletter – EFSA Highlights	❑	❑	❑	❑	❑	❑
Requests and mandates (Register of Questions)	❑	❑	❑	❑	❑	❑
Declarations of Interests (DOI database)	❑	❑	❑	❑	❑	❑
Glossary	❑	❑	❑	❑	❑	❑
Other (please specify)	❑	❑	❑	❑	❑	❑

For all

To what extent do you agree with the following statements regarding EFSA's communication materials (e.g. press releases, web stories, highlights etc.)? (Added by EFSA, relevant for the external evaluation EQ3b2.3, EQ3b3.2)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know

The communication material provides a clear and coherent summary of the main findings of the scientific output	❑	❑	❑	❑	❑
The language used in the communication material is clear and understandable for non-specialist audiences	❑	❑	❑	❑	❑
The communication material provides sufficient context about the output (i.e. who has requested the work, why, what happens next)	❑	❑	❑	❑	❑

Trust in information from EFSA

For all <u>except</u> EFSA staff/management and MB

To what extent do you / does your organisation trust the outputs that EFSA produces in the form of scientific opinions, reports, press releases? (EQ3b3.2)

(1) ❑ To a high extent
(2) ❑ To a moderate extent
(3) ❑ To a limited extent
(4) ❑ Not at all
(5) ❑ Do not know _____

All

To what extent have the following activities contributed to building trust in food safety over the period 2011-2016? (EQ3b3.2)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know	Not applicable
EFSA's communication activities	❑	❑	❑	❑	❑	❑
Activities to increase access to, and the transparency of, data	❑	❑	❑	❑	❑	❑
Activities to increase access to, and the transparency of, scientific methods	❑	❑	❑	❑	❑	❑
Activities to increase access to, and the transparency of, the scientific output production process	❑	❑	❑	❑	❑	❑
Activities to increase access to, and the transparency of, the actors involved throughout the scientific output production process	❑	❑	❑	❑	❑	❑
Activities to strengthen the engagement of stakeholders throughout the scientific output production process	❑	❑	❑	❑	❑	❑

For those indicating "not at all" or "to a limited extent" in one or several of the options in the question above

How could trust in the information produced by EFSA be increased? (EQ3b4.1)

_____

Harmonisation

For all except EFSA staff/management and MB

To what extent do you agree with the following statements? (EQ3c1.1, 3c2.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
Across the EU, harmonised methodologies and coherent approaches to food/feed safety are in place	❑	❑	❑	❑	❑
At a global level, harmonised methodologies and coherent approaches to food/feed safety are in place	❑	❑	❑	❑	❑
Over the period 2011-2016, EFSA contributed to increasing the harmonisation of methodologies across the EU 28 and at a global level	❑	❑	❑	❑	❑
Over the period 2011-2016, EFSA contributed to increasing the coherence of approaches across the EU 28 and at a global level	❑	❑	❑	❑	❑

Working practices, governance and organisational structure

For EFSA staff, management and MB, Members or observer of EFSA Advisory Forum, Representative of a National Focal Point, Member of a Scientific Committee or Panel, pesticides peer review experts, working groups, scientific networks

To what extent do you agree with the following statements? (EQ9.1.1, 9.2.1, 9.3.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
Over the period 2011-2016, EFSA had access to the data and evidence needed to provide useful risk assessments to policy makers at national and EU level	❑	❑	❑	❑	❑
Over the period 2011-2016, EFSA had access to the methods needed to provide useful risk assessments to policy makers at national and EU level	❑	❑	❑	❑	❑
Over the period 2011-2016, EFSA had access to the expertise needed to provide useful risk assessments to policy makers at national and EU level	❑	❑	❑	❑	❑

All

To what extent do you agree with the following statements? (EQ5.1.1, 5.2.1, 5.3.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
The composition of the Management Board (as laid down in the Founding Regulation) supports EFSA in meeting its objectives	❑	❑	❑	❑	❑
The current role and responsibilities of the Advisory Forum support EFSA in meeting its objectives, as set out in its Founding Regulation	❑	❑	❑	❑	❑

EFSA's management practices (e.g. setting of work programmes, targets, division of work) support it in meeting its objectives, as set out in its Founding Regulation	❑	❑	❑	❑	❑
The size of EFSA is appropriate for the work entrusted to it and is adapted to the actual workload	❑	❑	❑	❑	❑
EFSA manages to involve the best experts in their field in its work for the appropriate roles or tasks (e.g. staff, independent experts, Member State representatives)	❑	❑	❑	❑	❑

For EFSA staff and MB

To what extent do you agree with the following statements regarding EFSA's internal organisational structure and management system during the 2011-2016 period? (EQ6.1.1, 6.2.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
EFSA's internal organisational structure (e.g. organisation in departments and units, reporting lines) supported it in meeting its objectives, as set out in its Founding Regulation	❑	❑	❑	❑	❑
EFSA's internal management systems for programming, monitoring, reporting and evaluating ensured the accountability of the Agency	❑	❑	❑	❑	❑
EFSA's internal management systems for programming, monitoring, reporting and evaluating (in particular the Key Performance Indicators and the annual reports) ensured realistic assessment of the overall performance of EFSA	❑	❑	❑	❑	❑

EFFICIENCY

For EFSA staff and MB

To what extent do you agree with the following statements concerning EFSA's organisational structure and working practices over the period 2011-2016? (EQ7.1.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
The administrative burden imposed on EFSA staff had a negative impact on the ability of staff to conduct operational work	❑	❑	❑	❑	❑
The division of work and resources within EFSA was appropriate	❑	❑	❑	❑	❑
The infrastructure (such as IT systems) available to EFSA enabled staff to carry out their work efficiently	❑	❑	❑	❑	❑
Internal initiatives for streamlining and simplification led to change being implemented	❑	❑	❑	❑	❑

For all except EFSA staff and MB, media

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? (EQ7.2.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know	Not applicable
Completing contractual requirements	❑	❑	❑	❑	❑	❑
Taking part in meetings on EFSA's premises	❑	❑	❑	❑	❑	❑
Getting travel costs reimbursed	❑	❑	❑	❑	❑	❑
Becoming a member of EFSA's expert groups (e.g. a member of a scientific committee, a panel, a working group)	❑	❑	❑	❑	❑	❑

COHERENCE

For national authorities (Advisory forum, AFCWG, national risk management and assessment bodies, Focal Points), European institutions and bodies and EFSA Management Board

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? (EQ12.2.2)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
Food safety	❑	❑	❑	❑	❑
Feed safety	❑	❑	❑	❑	❑
Animal health	❑	❑	❑	❑	❑
Animal welfare	❑	❑	❑	❑	❑
Plant health	❑	❑	❑	❑	❑
Nutrition	❑	❑	❑	❑	❑
Environmental aspects related to authorisation of pesticides, GMO and feed additives and environmental plant health aspects	❑	❑	❑	❑	❑

For national authorities (Advisory forum, AFCWG, national risk management and assessment bodies, Focal Points) and third countries

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? (EQ 13.2.2, 13.2.3)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
Food safety	❑	❑	❑	❑	❑
Feed safety	❑	❑	❑	❑	❑
Animal health	❑	❑	❑	❑	❑
Animal welfare	❑	❑	❑	❑	❑
Plant health	❑	❑	❑	❑	❑
Nutrition	❑	❑	❑	❑	❑
Environmental aspects related to authorisation of pesticides, GMO and feed additives and environmental plant health aspects	❑	❑	❑	❑	❑

To what extent do you agree with the following statements, concerning EFSA's tasks and activities over the period 2011-2016? (EQ 13.2.2, 13.2.3)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
EFSA's tasks and activities maximised the sharing of knowledge/resources creating a high impact and value.	❑	❑	❑	❑	❑
EFSA's tasks and activities maximised the sharing of knowledge/resources leading to higher efficiency					

For national authorities (Advisory forum, AFCWG, national risk management and assessment bodies, Focal points), European Commission, European Parliament and EFSA Management Board

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? (EQ 13.2.2, 13.2.3)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
Food safety	❑	❑	❑	❑	❑
Feed safety	❑	❑	❑	❑	❑
Animal health	❑	❑	❑	❑	❑
Animal welfare	❑	❑	❑	❑	❑
Plant health	❑	❑	❑	❑	❑
Nutrition	❑	❑	❑	❑	❑
Environmental aspects related to authorisation of pesticides, GMO and feed additives and environmental plant health aspects	❑	❑	❑	❑	❑

For representatives of other EU agencies, international organisation 3rd countries, DG JRC

To what extent do you agree with the following statement concerning EFSA's tasks and activities over the period 2011-2016? (EQ 15.2.4)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
EFSA's tasks and activities were aligned (i.e. support, do not contradict) with the work of my organisation	❑	❑	❑	❑	❑
EFSA's tasks and activities maximised the sharing of knowledge/resources creating a high impact and value.	❑	❑	❑	❑	❑
EFSA's tasks and activities maximised the sharing of knowledge/resources leading to higher efficiency	❑	❑	❑	❑	❑

EU ADDED VALUE

All

To what extent do you agree with the following statements concerning EFSA's achievements over the period 2011-2016? (EQ16.1.2)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know	Not applicable
The same - in terms of quality, relevance and timeliness - could have been achieved at national level at the same or a lower cost	❑	❑	❑	❑	❑	❑
The same - in terms of quality, relevance and timeliness - could have been achieved at international level at the same or a lower cost	❑	❑	❑	❑	❑	❑

If selected "to a high extent" or "to some extent" in previous question.

Please specify how comparable achievements could have been made at the same or a lower cost, and specify which national/international body could have achieved these. (EQ161.2)

_____

All except EFSA staff, management and MB

To what extent do you agree with the following statements (EQ16.2.2, 17.1.1)

	To a high extent	To a moderate extent	To a limited extent	Not at all	Do not know
Discontinuing EFSA would lead to negative consequences for food safety in Europe	❑	❑	❑	❑	❑
EFSA is recognised as the leading scientific authority at EU level, providing independent scientific advice on the food chain	❑	❑	❑	❑	❑

If indicated "to a high extent" on the first option in the previous question

Please elaborate on what these consequences would be: (EQ16.2.2)

_____

All

Do you have any recommendations on how EFSA can be improved in order to provide greater added value? Are there any other observations / comments you would like to make?

_____

Thank you very much for your contribution to the external evaluation of EFSA undertaken by Ramboll and Coffey! Your answers have been saved.

APPENDIX 4: INTERVIEW GUIDES

Topic Guide

BACKGROUND INFORMATION	
Interviewee	
Interviewer	
Data of interview	
Type of interview	

Note: This questionnaire contains a comprehensive list of questions which are to be covered through interviews with the diverse set of EFSA stakeholders. Not all questions are relevant to each respondent. Some questions provide an indication as to whom they should be / not be addressed to.

1. BACKGROUND QUESTIONS (WARM-UP)	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
1. As an introduction, please describe your own history of working with EFSA and/or in the field of food safety (length of time in the organisation/working in this field, role(s), main responsibilities)?	☑ (only members of management board)	☑	☑	☑	☑	☑	☑

[Probes]: - *What is the nature of that work?* - *What tasks do you carry out day to day?*

3. EFFECTIVENESS	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
1. To what extent do you believe EFSA is **achieving** the objectives it was set-up to achieve? Can you provide **concrete examples** of ways in which EFSA's activities have contributed to these objectives? [EQ 3c.2.1] *[Prompt:* *- The objectives of EFSA are:* *- To establish a system with sufficient capacity to deliver excellent, independent and fit for purpose advice to respond to the needs / demands of risk managers* *- To contribute to the trust in the food safety system by its*	☑	☑	☑	☑	☑	☑	☑

3. EFFECTIVENESS	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
independence, transparency and openness *- To build a system creating coherence and shared views on food / feed safety risks at EU & Global level (cooperation with EC and MS to ensure coherence of RA, RM and risk communication functions)]*							
2. What do you see as the main causes behind EFSA achieving, or failing to achieve, its mission? [4.2.1] ***Prompt**:* *EFSA's mission is to ensure a higher level of protection of human life and health, taking account of animal health and welfare, plant health and the environment* *[Follow-up:* How important are these main causes for the success/failure of EFSA's mission relative to each	☑	☑	☑	☑	☑	☑	☑

3. EFFECTIVENESS	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
other? [EQ 4.2.2]							
3. What contributions has EFSA made to a more coherent approach to food/feed safety risks assessment and communication across the EU member states? [EQ 3c.1.1] **Please provide concrete examples.**		☑	☑	☑	☑	☑	
4. Would you say that EFSA has had any unintended (negative or positive) effects that go beyond the objectives stated above? [EQ 4.2.3] *[Probe:* *How significant are these unintended effects?]*		☑	☑	☑	☑	☑	
5. To what extent do you believe that EFSA's data collection and evidence management activities support risk assessment activities? [EQ 9.1.1]		☑				☑	☑ specifically, staff dealing with scientific work (not all support staff or communication staff, for example)

3. EFFECTIVENESS	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
6. To what extent do you believe that EFSA has adequate systems in place to communicate with its stakeholders? [EQ 3b.2.3] *[Probe:* - *What can be improved, how?*	☑	☑	☑	☑	☑	☑	☑
7. [For external stakeholders only]: To what extent do you perceive the information produced by EFSA to be independent and transparent? [EQ 3b.1.3]			☑		☑		
8. What would you say EFSA could do better in terms of its communication to become more trustworthy to the **public** [EQ 3b.4.2]? *Follow up:* What about in terms of becoming an important source of information/advice to scientists and national decision-makers Follow up: How do you think EFSA's activities could be enhanced to further contribute to building **stakeholders**' trust	☑	☑	☑	☑	☑	☑	☑

3. EFFECTIVENESS	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
9. What factors would you say are influencing EFSA's scientific recognition and reputation? [EQ 4.2.2] **Prompts: Internal factors? External factors?**	☑	☑	☑	☑	☑	☑	☑
10. [EQ 6.2.4] <internal staff only> Are the internal mechanisms for programming, monitoring, reporting and evaluating EFSA adequate for a) ensuring accountability of EFSA' b) providing an appropriate assessment of the overall performance? **Probe: Why? Why not? What more could be done?**	☑						☑

4. EFFICIENCY (COST-EFFECTIVENESS)	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
11. To what extent do you believe that EFSA's scientific opinion production system, in particular the collaboration arrangements between EFSA and external expertise (national experts, national scientific bodies including Article 36 organizations), works optimally? **Probe: Why / Why not? How could it be improved?**	☑			☑		☑	☑ Probably not a question for all internal staff but for staff dealing with the hiring of experts or scientific production system
12. Are there any factors that prevent EFSA's scientific production system from working optimally? [EQ 3a.1.3] *[Prompt: EFSA's scientific production system relies (mainly) on work produced by external, independent experts working in the framework of Scientific Panels. EFSA's Scientific Panels of experts are responsible for the bulk of EFSA's scientific assessment work. Each of the 10 Panels is dedicated to a different area of the food and feed chain. The Scientific Committee has the task of supporting the work of the Panels on cross-cutting scientific issues. It focuses on developing*							

4. EFFICIENCY (COST-EFFECTIVENESS)	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
harmonised risk assessment methodologies in fields where EU-wide approaches are not yet defined. The membership of EFSA's Scientific Committee and Panels is renewed every three years][1]							
13. To what extent do you believe that EFSA's scientific systems, structures and mechanisms for scientific production address emerging needs? [EQ 3a.6.2]		☑	☑	☑		☑	☑
14. Do you find EFSA's scientific systems, including the EFSA peer-review system and panel system, sustainable? Why? Why not? [EQ 3a.7.2] 15. Can you provide concrete evidence / examples of the ways in which the systems are (un)sustainable? *[Probe:* - *Can/Should EFSA's scientific system continue using independent national*	☑	☑		☑		☑	☑

[1] See: https://youtu.be/nIrJois4NSY

4. EFFICIENCY (COST-EFFECTIVENESS)	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
experts and national scientific bodies in the way it is using them now (i.e. panel system via independent experts in the panels and MS organisation in outsourcing work). Why? / Why not? - *What do you see as the Pro's and Con's (strengths and weaknesses) of the peer review/panel systems?* - *What would be the alternatives?*							
16. [Only for external stakeholders] To what extent are you familiar with EFSA's panel system addressing general scientific questions? <If responded is familiar>: To what extent are you satisfied by the quality of the advice provided by EFSA? [Q3a.2.1]		☑	☑		☑	☑	
17. [Only for external stakeholders] Are you familiar with EFSA's panel system for addressing authorization dossiers? <If responded is familiar>: To what extent do you find this system responds to the		☑	☑			☑	

4. EFFICIENCY (COST-EFFECTIVENESS)	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
needs of EFSA's stakeholders? [Q3a.3.1]							
18. [Only for external stakeholders] Are you familiar with EFSA's peer-review system on pesticides dossiers? <If responded is familiar>: To what extent do you find this system responds to the needs of EFSA's stakeholders? [3a.4.1]		☑	☑			☑	
19. [Only external stakeholders] Are you familiar with the technical advice provided by EFSA's scientific staff? <If responded is familiar>: To what extent are you satisfied by the quality of the advice provided by EFSA? [3a.5.1]		☑	☑			☑	
20. Would you say that there are any external factors (e.g. political, societal, media pressure) that influence EFSA's activities or decisions? If so, which ones, why, how and to which extent?	☑	☑	☑	☑	☑	☑	☑

4. EFFICIENCY (COST-EFFECTIVENESS)	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
[EQ 10.2.1, 10.2.2] *[Probe:* - *Does this influence make EFSA allocate funds inefficiently?* - *What other implications do these external factors have on EFSA's work?]*							
21. How has EFSA responded to these external factors? 22. What are/have been the consequences of this response? [EQ 10.2.2]	☑	☑	☑	☑	☑	☑	☑

2. RELEVANCE	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
23. Would you say that the needs and problems EFSA was set up to address still exist? [EQ 1.1.3] *[Prompt:*	☑	☑	☑	☑	☑	☑	☑

2. RELEVANCE	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
- The needs EFSA was set up to address are: *- Ground food law-making in a solid evidence-base, at EU level, which required systematic risk analysis and the definition of a cooperative and systematic methodology;* *- Strengthen the scientific capacity of the institutions protecting health and other interests;* *- Strengthen the confidence in the scientific basis underpinning food law;* *- Develop effective data collection and comprehensive, feasible and up-to-date risk assessment methodologies; and identify emerging risks]*							
24. Would you say that EFSA's original objectives remain relevant vis-à-vis the current needs of its key target groups? [EQ 1.2.2] *[Prompt:*	☑	☑	☑	☑	☑	☑	☑

2. RELEVANCE	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
- The objectives of EFSA are: *- To establish a system with sufficient capacity to deliver excellent, independent and fit for purpose advice to respond to the needs / demands of risk managers* *- To contribute to the trust in the food safety system by its independence, transparency and openness's* *- To build a system creating coherence and shared views on food / feed safety risks at EU & Global level (cooperation with EC and MS to ensure coherence of RA, RM and risk communication functions)]*							
25. Can you name any new challenges the food-system in the EU is facing that are currently not addressed by EFSA and which, arguably should be tackled by EFSA? [EQ 1.3.2]	☑	☑	☑	☑	☑	☑	☑
26. <Only for internal staff> What procedures does EFSA have in place to identify new challenges facing its stakeholders? [EQ 1.3.2]	☑						☑

2. RELEVANCE	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
<If applicable>: Do you feel the procedures in place to identify new challenges allow EFSA to respond adequately to unforeseen challenges? [EQ 2.3.1] *[Probe:* - *Such as how to respond to unforeseen workloads and tight deadlines?]*							
27. How does EFSA ensure it prioritises tasks in accordance with changing needs in the EU? [EQ 8.3.1] *[Probe:* **Has EFSA prioritised tasks in line with your needs or should other tasks have been prioritised instead?**	☑	☑	☑	☑			☑
28. <Internal staff only> What are the internal working procedures or mechanisms that enable EFSA to prioritise topics / tasks? [EQ 8.1.1] ***Follow-up: Would you say they are working optimally? – Why? Why not?***							☑

2. RELEVANCE	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
29. Does EFSA's current organisational structure adequately enable the agency to meet its mission and respond to the needs discussed above? [EQ 2.1.2] *[Probes:* - *Are there any goals that are consistently unmet? Why?* - *Does the organisation lack expertise or personnel to carry out certain tasks? (e.g. internal staff; availability/access/readiness of independent experts (Panels/WGs) and MS organisation expertise (networks/outsourcing)* - *Is communication and cooperation between departments adequate?]*	☑	☑	☑	☑			☑
30. <Only for internal staff> Over the period 2011-2016, have changes to EFSA' organisational structure and working structure improved or decreased its ability to meet its mission and respond to unforeseen challenges? *[Follow-up:* - *In what way,*				☑			☑

2. RELEVANCE	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
- *Can you provide examples?*							
31. Does EFSA's current working practices (excluding EFSA' scientific production system, which will be discussed separately) adequately enable the agency to meet its mission and/or to respond to the needs discussed at the questions above? [EQ 2.1.2] *[Follow-up:* - *In what way,* - *Can you provide examples?*							☑

5. COHERENCE	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
32. Do you believe that EFSA's tasks and activities are aligned with the EU's current political priorities? [EQ 12.2.1]	☑	☑	☑				☑
33. Do you believe that EFSA's tasks and activities are coherent with	☑	☑	☑				☑

EU commitments at international level? [EQ 14.1.2]							
34. Do you believe that EFSA's tasks and activities are coherent with those of national organizations/institutions? [EQ 13.2.2]	☑	☑	☑	☑	☑	☑	☑
35. Can you provide any examples demonstrating that EFSA's work has been complementary to the work of other EU agencies and International Organisations? [EQ 15.2.3] *[Probe:* - *Such as the European Medicines Agency.]*		☑	☑				☑
36. <Internal staff and EU Agencies only> What measures are in place for EFSA to communicate with other EU agencies? *Follow-up*: Do you find these sufficient to ensure coherence between them? [EQ 15.2.3]			☑				☑

6. EU ADDED VALUE	EXECUTIVE DIRECTOR AND MB	DG SANTE	OTHER EU AGENCIES, PARLIAMENT INTERNATIONAL ORGANISATIONS	ADVISORY FORUM AND FOCAL POINTS	STAKEHOLDER FORUM, BUREAU MEDIA COMM. EXPERT NETWORK	SCIENTIFIC COMMITTEE PANELS AND ART 36 ORGANISATIONS	MANAGEMENT AND STAFF
37. Can you give examples of food safety problems EFSA has addressed, which could not be solved independently by Member States' national authorities? [EQ 16.1] *[Probe:* - *Why could they not have been solved by national authorities?*	☑	☑	☑	☑	☑	☑	☑
38. What consequences (positive or negative) would result from discontinuing EFSA? [EQ 16.2.1]	☑	☑	☑	☑	☑	☑	☑
39. In your view, can EFSA's work be carried out by other existing international or national organisations? [EQ 16.2] If so, which ones and why these?	☑	☑	☑	☑	☑	☑	☑

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APPENDIX 2: EFSA'S COST-EFFECTIVENESS

There are considerable differences between and within EFSA's scientific activities in terms of the number of outputs *adopted*. This is due to complexities associated with the type of work, and the unpredictable nature of requests. Looking at the number of outputs *worked on* during a given year, even if the request dates from a previous year, or if the question is not answered in the same year, mitigates this problem. It is helpful when assessing the degree to which EFSA delivers on its KPI related to the adoption of outputs within the legal deadline, but it is not without limitations either.

In fact, the number of outputs *worked on* does not allow for an analysis of the cost-effectiveness of EFSA's work over time. Indeed, workload changes considerably over time between and within activities, and even within the same Panel between two years. When comparing costs over the years and comparing it to the number of outputs, the lack of outcome and workload information makes it impossible to draw accurate conclusions about EFSA's efficiency or cost-effectiveness. For this reason, the analysis in the main report was limited to a comparison over time of average cost per unit of production.

This appendix sets out the limitations associated with looking at outputs *adopted* and offers examples to illustrate the complexities associated with EFSA's work.

EFSA's scientific Activities and associated self-set KPIs

Over the period under review, in its Annual (Activity) Reports, EFSA divided scientific production into two distinct categories[2]:

1. Scientific advice and risk assessment methodologies in the areas of food and feed safety, animal health and welfare, and plant health, which is reported as *"Activity 1: Provision of scientific advice and risk assessment approaches"*;
2. Work produced in relation to regulated products within food and feed, food contact materials and pesticides, genetically modified organisms, food-related processes and processing aids, recorded under *"Activity 2: Evaluation of regulated products".*

Over the 2011-2016 period, EFSA reported, for each of these scientific activities, information on the number and types of scientific outputs produced, the overall costs related to each activity, and the proportion of scientific outputs adopted within deadline.

While the process of tracking and comparing these aspects of performance over the years provides a good understanding of the quantitative nature of outputs, the approach is not without limitations. Some of them are explained below.

The **KPIs do not account for differences in the level of complexity and unpredictability associated with EFSA's work, which is an explanatory factor behind some of the variances observed**. Distinct types of requests and outputs require various levels of effort in terms of the amount of time and resources invested in them. Additionally, mandates received in one year might not be finished the same year, depending on the deadline. As one mandate may lead to more than one questions registered in the "Register of questions" tool, EFSA began reporting on the number of questions closed each year, rather than the number of outputs adopted, from 2017 onward. However, the number of questions closed still does not account for differences within activities (between different areas) in terms of workload and complexity.

- **Activity 1**

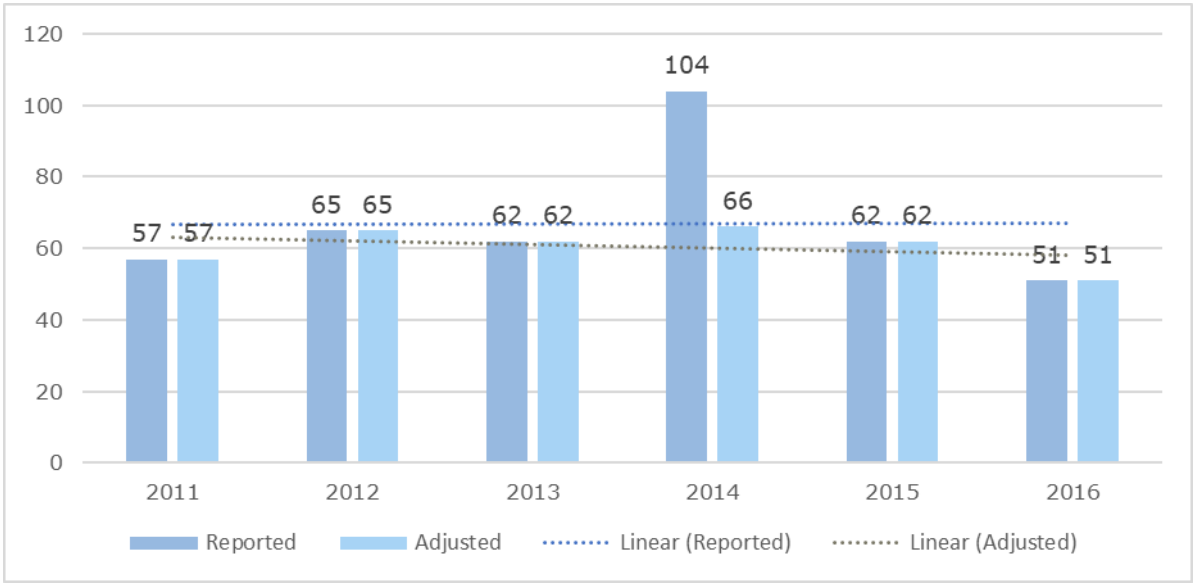
Between 2011 and 2016, EFSA adopted a total of 401 scientific outputs (including technical reports) under Activity 1. The number of outputs *adopted* was stable across all years (between 51 and 65 outputs), aside from a spike in 2014 (104 outputs).

[2] "Activity 3: data collection, scientific cooperation and networking", is also related to EFSA's scientific production. However, no exceptional circumstances were identified in this Activity, hence it is not described here in detail.

This considerable spike in 2014 reflects differences in the work conducted by the different Panels. Specifically, in 2014, there were many pest categorisations. For these opinions, the Plant Health (PLH) Panel follows a two-step approach: an initial assessment takes place to develop a "simplified" opinion, based on which the requestor can decide whether to request a more detailed "full opinion".[3] Over the period under review, the PLH Panel produced around 10 such pest categorisation opinions per year, that were usually full opinions. In 2014, however, it produced a total of 34. This reflected a specific mandate from 2014 (M-2014-1909)[4], which asked only for a standard, partial and mainly qualitative risk assessment to be carried out for 38 plant pests. The mandate specified that a "full" assessment would only be required in specific cases based on the content of the original output. It was required in only 7 of the 38 cases. The other 31 cases were sufficiently covered through the one-step procedure, and hence required less effort. Yet, when looking at the number of outputs *adopted*, they are reported in the same way as "full" opinions.

To mitigate this, EFSA adjusted its reporting of output data based on exceptional circumstances. In this case, that led to a decrease of 38 scientific outputs in 2014. The figure below compared the officially reported number of outputs *adopted* to the adjusted numbers. As a result, the number of outputs *adopted* each year remained more stable.

Figure 1: Adjusted outputs – Activity 1



Source: evaluation team based on data provided by EFSA

However, even when adjusting for exceptional circumstances, the number of outputs *adopted* still does not give an accurate representation of the complexities associated with EFSA's work. For example, different procedures are applicable for different areas depending on the regulatory framework (as seen above for instance), and different legal deadlines to adhere to. As a result, the number of outputs tells us nothing about the required workload, which in turn makes it impossible to accurately assess EFSA's cost effectiveness or efficiency.

To illustrate this point, data provided by EFSA on the estimated workload of the PLH Panel in 2014 and 2016 shows that the **deviation in scientific outputs *adopted* between the two years is significantly higher than the deviation in the estimated production effort**. This means that relative to 2014, the average effort per output was significantly higher in 2016, despite fewer outputs being adopted (see **Error! Reference source not found.** below). In 2014, a total of 55 o utputs were adopted, compared to 15 in 2016, which means a decrease of 73%. In terms of the

[3] EFSA Panel on Plant Health, *Guidance on a harmonised framework for pest risk assessment and the identification and evaluation of pest risk management options by EFSA*, 2010.
[4] EFSA Acting Executive Director, *Request to provide a scientific opinion on the risk to plant health of 38 regulated harmful organisms, for the EU territory – Ref.: Ares(2014)970361 – 28/03/2014/Acceptance letter* (Parma, Italy, 2014) [accessed through EFSA's register of questions].

estimated required total effort in FTEs[5], the difference was significantly smaller. In 2014, a total of 9.6 FTEs was allocated to the 55 outputs, whereas in 2016 the total was 7.9 FTEs, a reduction of only 18%. Despite the large decrease (-73%) in the number of outputs *adopted* between 2014 and 2016, the total estimated effort in terms of FTEs only decreased by 18%. For this reason, it is difficult to base conclusions on EFSA's cost-effectiveness based on the number of outputs *adopted*, as all outputs differ and require different time and effort to address.

Table 1: PLH 2014/2016 output production and effort comparison

YEAR 2014			
	Number of outputs *adopted*	Estimated effort per output – FTEs	Total (estimated) effort – FTEs
Pest categorisation	38	0.1	3.8
Normal art 29	16	0.3	4.8
complex art 29 (Xylella)	1	1	1
	55		**9.6**
YEAR 2016			
Pest categorisation	4	0.1	0.4
Normal art 29	5	0.3	1.5
complex (Xylella)	6	1	6
	15		**7.9**
Deviations	**-73%**		**-18%**

Source: Table provided by EFSA in March 2018

- **Activity 2**

Between 2011 and 2016, EFSA adopted a total of 1,938 scientific outputs (including technical reports) under Activity 2. The number of outputs was less stable than Activity 1, showing more year-on-year variability.

However, compared to Activity 1, there were considerably more exceptional circumstances to take into consideration for Activity 2.

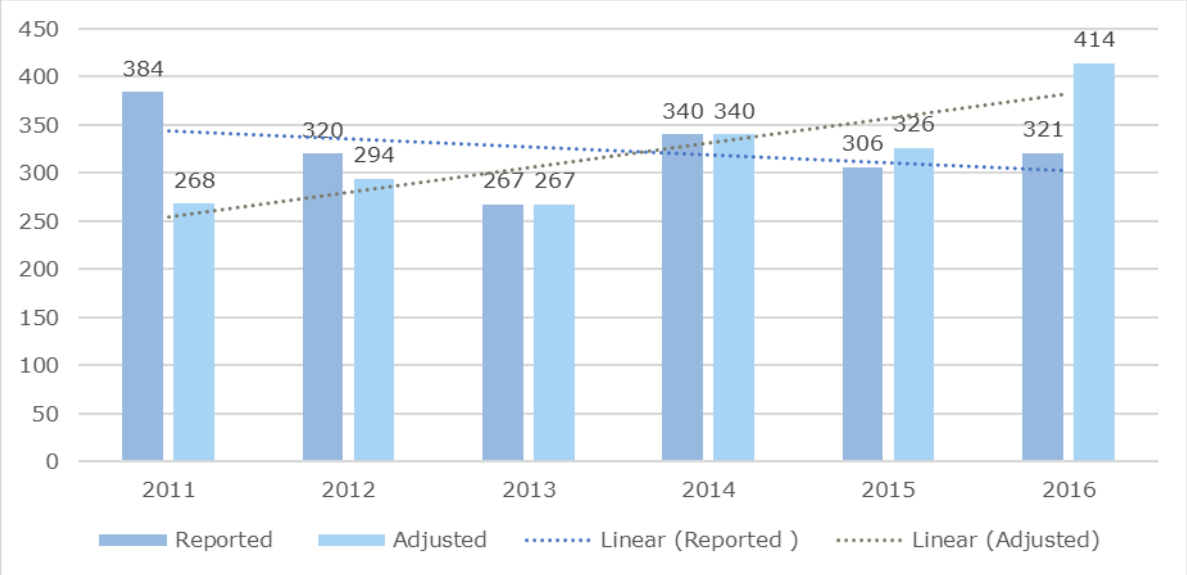
For instance, 2011 is not the most appropriate baseline: in 2011 and 2012 EFSA finalised the adoption of functional health claims, which accounted for almost 116 outputs in 2011 alone, and an additional 26 in 2012. Health claims are regulated according to Regulation (EC) Nº 1924/2006, and different workflows are foreseen according to the nature of the health claim. The production of outputs related to Article 13.1 health claims ("general function claims") was less work intensive than standard outputs (including outputs related to health claims following Article 13.5 and Article 14 of Regulation (EC) Nº 1924/2006). In 2011, 116 NUTRI outputs related to the "general function" health claims process were delivered. The main amount of work for these "general function" health claims was carried out in previous years and this kind of output was less work intensive than the average according to EFSA. During this time, some other work was deprioritised in agreement with the Commission to finalise this task, such as Dietary Reference Values (DRVs), which do not constitute many outputs, but are costly to produce.

The figure below presents the number of outputs *adopted* as reported in EFSA's Annual Reports and the adjusted outputs. It clearly shows an upward trend in the number of outputs after adjustments, compared to an initial downward trend as per the reported number of outputs *adopted*. In addition to the 2011 and 2012 adjustments outlined above, 20 outputs were added in 2015 as the result of exceptional stop-the-clock occurrences. The additional 93 in 2016 result of clock stops in flavourings (+20), feed (+40), ongoing feed guidance (+3), and exceptional question/output ratio in PRAS. As a result, in contrast to the cost/output results presented in Figure

[5] There is no available data on FTEs used for specific tasks, so the table is based on estimations of FTEs provided by EFSA.

2: Adjusted outputs – Activity 2, the general trend over the years is a slight decrease in cost per output, by 15% in total. This means an increase in productivity, granted the adjusted outputs offer an accurate representation of workload.

Figure 2: Adjusted outputs – Activity 2



Source: evaluation team based on data provided by EFSA

As in the case of Activity 1, the example below of scientific outputs *adopted* compared to effort in the Nutrition (NUTRI) area shows how the number of outputs *adopted* cannot be accurately used to estimate workload. The table below shows the variation in the effort allocated to health claims in the years 2011 and 2012, and the distinct types of health claims outputs, which allows for an assessment of the different effort required for outputs related to different type of claims. The percentage of "general function" health claims outputs decreased from 78% in 2011 to 41% in 2012. At the same time, the production of health claims outputs dropped by 59% from one year to another, and the effort per single output increased by 125%.

Table 2: NUTRI-health claims output production and effort comparison

YEAR 2011			
	Number of outputs *adopted*	Estimated effort per output - FTES	Total (estimated) effort – FTES
Health Claims of which: functional (Art 13.1): 78% Art 13.5 and 14: 22%	149	0.09	13
	149	0.09	**13**
YEAR 2012			
Health Claims of which: functional (Art 13.1): 41% Art 13.5 and 14: 59%	61	0.20	12
	61	**0.20**	**12**
Deviations	**-59%**	**+125%**	**-8%**

Source: Table provided by EFSA in March 2018

Workload in different areas within the same Activity might be completely different. Hence, they cannot be compared.

APPENDIX 6: EFSA MANAGEMENT SELF-EVALUATION

Management Self-Evaluation

Contents

Preamble

This paper intends to provide a concise reflection on EFSA's current and future operations within the context of a set of evolving external forces, and will present a number of questions and possible evolutions EFSA is facing or may face in the mid-term. Specifically, the paper will highlight EFSA's key achievements since the 2012 external evaluation[1], and its progress toward the objectives described in the last external evaluation.

In preparation for the 2018 external evaluation, EFSA's management has conducted a review of EFSA's achievements since 2012 during the first half of 2017, drawing the following conclusions:

- Operational roles across European Member State organisations and scientific organisations have been optimised, within the limits established by the current regulation, in order to face increasing workload and complexity of the scientific questions put to EFSA.
- Efficiency programmes executed since 2012 in both operations and in administration have delivered real economic and personnel savings which have, in turn, benefited the scientific collaboration and engagement activity within EFSA remit. Notably, EFSA's research and development (internal mandates) and scientific network collaboration establish common research priorities in order to address evolving risk assessment needs in a timely manner.
- Significant improvement has been proven in the area of independence, transparency and communication, which, in turn, positively impact EFSA's reputation and attractiveness.
- Much progress has been made in the maturity and modernisation of EFSA's data management and information systems, including data collection, reporting, communication, publication, dissemination and human capital management systems.

Whilst much progress has been made, EFSA's Strategy 2020[2] describes a challenging context which presents both threats and opportunities for EFSA in the near and mid-term perspective. Through its management self-evaluation, EFSA notes that, despite progress toward the objectives set by the 2012 external evaluation, there are a number of areas that deserve continued attention:

- The scientific questions that EFSA receives continue to increase in complexity, if not volume, mainly due to the pace of global innovation, globalisation, and the exponential growth of the body of knowledge and data to be reviewed in risk assessment procedures. This increment supersedes the pace of policy and practice. A focus on streamlining regulated workflows and on leveraging even closer European cooperation mechanisms may be needed to face these challenges.
- Efficiency improvements have contained inflationary forces and allowed a focus on new scientific and cooperation instruments, but may not be sufficient in the near term to meet all European risk assessment mandates in a timely manner. A continued focus on efficiency and innovation, professional development, and re-prioritisation of EFSA activities may be required to face these challenges.
- While independence, transparency and engagement activities have matured and improved, the social and political forces in the 21st century may create tensions between public opinion and science that threaten EFSA's and the European Commission's reputation. A continued focus on public outreach, internal transparency, and building a common European agenda should be considered.

[1] http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/efsafinalreport.pdf
[2] https://www.efsa.europa.eu/sites/default/files/151008.pdf

- Data management, analytics and other information systems have improved and continue to improve, but resource constraints may not permit timely investment in a quickly changing IT requirement involving very large data sets and intense computational capability. Addressing some of these information technology needs at a European level or through joint projects could provide support to EFSA's work within existing financial constraints.

In response to such challenges, this paper explores lines of action that go beyond the EFSA Strategy 2020. The aim of the paper is to trigger a discussion with EFSA's main stakeholders which could serve as the foundation for the next five year strategic planning cycle.

1. Background – 2012 External Evaluation

EFSA's mission, established by its Founding Regulation[3], is to contribute to the safety of the EU food and feed chain and to a high level of protection of human life and health, mainly by:

- Providing EU risk managers with independent, up-to-date and fit-for-purpose scientific advice on questions related to food and feed safety, animal health and welfare, plant health, nutrition and sector-specific environmental aspects;
- Communicating to the public on its outputs and the information on which they are based;
- Cooperating with Member States (MS), institutional partners and other interested parties/stakeholders in the EU to promote coherent advice and increase trust in the EU food safety system;
- Developing uniform methodologies and collecting, analysing and summarizing data to allow the identification, characterisation and monitoring of emerging risks that have a direct or indirect impact on food and feed safety.

As an essential component of the EU food safety system, EFSA must also ensure that it supports the overarching objectives of the European Commission, such as "contributing to a high level of public health while enhancing the competitiveness of the Union food and feed industry and favouring the creation of jobs."

As an essential component of the EU food safety system, EFSA is an EU evidence-based agency responsible for consumer protection while enhancing EU competitiveness trough trust in the industry and EU market.

The 2012 external evaluation concluded that EFSA was fulfilling its mandate and was operating in an independent, open and transparent manner, providing high quality advice to underpin and add value to the EU system of food and feed law. At the same time, EFSA's Management Board (MB) took note of the Authority's evolving role in facing the challenges of the increasing complexity in risk assessment questions and the increasingly multi-disciplinary scope of the mandates. Consequently, the MB requested EFSA to address four key improvement areas while continuing to provide risk managers and stakeholders with independent, high quality, timely, fit-for-purpose and clear scientific advice, following open and transparent processes, and while communicating clearly to all interested parties.

The four key areas that were identified as a matter of priority for the period 2013-2017 were:

- Enhancing the EU risk assessment capacity
- Improving the clarity and accessibility of EFSA's communication
- Increasing trust by ensuring independence, and increasing transparency and openness
- Securing the long-term sustainability of EFSA's operations

The following section will highlight the progress made, and the state of play, for the main recommendations made by the Management Board in 2012.

[3] http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF

2. Highlights of key achievements with regards to the 2012 External Evaluation

2.1. Enhancement of EU risk assessment capacity

Significant progress has been made by EFSA in enhancing the EU risk assessment capacity:

- A joint European Risk Assessment Agenda has been developed by and with EFSA's Advisory Forum. Multinational and regional projects have been co-financed and implemented by EFSA together with Member States. An array of new grant instruments has been developed to foster collaboration, innovation and staff exchange among European public organisations.
- Meetings and exchanges with DG SANTE, the Commissioner for Health and Food Safety as well as with MEPs of the ENVI committee were intensified, in order to review priorities, adjust work programmes, and align expectations. In parallel, EFSA renewed cooperation programmes and partnership agreements with Member States' and international risk assessment organisations, to promote common planning of research and risk assessment activities and better work-sharing. It extended the mandates and functions of the Advisory Forum (AF) and Focal Points as drivers of EU food safety cooperation.
- In addition to the existing international liaison group on food chemical safety, EFSA has been instrumental in setting up international liaison groups on microbiological food safety risk communication. Cooperation in this area makes EFSA both a contributor and a recipient of support from sister organisations in third countries and international scientific assessment bodies for the development of risk assessment methods. Experts from third countries are invited to join or observe working groups, particularly when it concerns the development of horizontal guidance. Similarly, EFSA contributes to the work of international assessment bodies such as the Organisation for Economic Co-operation and Development (OECD), European and Mediterranean Plant Protection Organisation (EPPO), World Organisation for Animal Health (OIE), Food and Agriculture Organisation (FAO) and World Health Organisation (WHO) in the development or revision of guidance. The objective is to further strengthen this cooperation with the FAO and WHO secretariats, supporting committees such as JECFA, JEMRA and JMPR as well as to explore areas of common interest with the WHO's IARC. The focus will be on tangible results leading to scientifically based harmonisation of assessment methods.
- Up to the end of 2016, EFSA has signed 11 cooperation agreements with scientific assessment organisations in non-EU countries.
- EFSA often participates in workshops and scientific conferences which promote the setting of science-based international standards. For example, EFSA is now an active member of the US-FDA-led Global Coalition on Regulatory Science Research (GCRSR). Cooperation with third countries is also important to provide training towards building scientific assessment capacity in third countries. These can be EU candidate-countries, EU neighbouring countries, as well as other countries which the EU wishes to support. This training is often delivered in close cooperation with the European Commission.
- EFSA organises every three years a scientific conference to take stock of new developments and challenges in food safety and human health. The 2nd one was organised in Milan in 2015 on the occasion of the WorldExpo. The 2018 EFSA Conference is under preparation.
- Since 2012, EFSA has made considerable progress in improving data sharing and data quality for Member States and the public through modern online information technology systems. EFSA completed the development of its web-based Scientific

Data Collection Framework (DCF), which harmonises all data collection with standardised data models, and its Scientific Data Warehouse (SDWH), which provides standard and customised reporting and analytical tools in graphical and statistical formats to Member States and members of the public. The IT supporting these tools has consolidated 16 separate older software systems that were not publicly available and not integrated with geographic visualisation and statistical analysis capabilities. The DCF tool also provides validation rules that operate on incoming data to verify the quality of the transmitted data. The underlying IT systems are prepared on quality standards verified by ISO 9001 certifying authorities. Furthermore, EFSA has provided financial and technical support to Member States to implement the standard sample description model (SSD) and FoodEx2, which establish minimum baseline quality for all data exchanges.

- EFSA re-aligned its SDWH architecture to open standards of the European Commission through support from the European Commission ISA[2] (Interoperability solutions for public administrations, business and citizens) Programme and has made open data available on platforms such as OpenTox.
- Alongside these achievements, efforts to improve collaboration and access to scientific data has resulted in EFSA scientific data availability on the EU Open Data Portal, the Information Platform for Chemical Monitoring Data and the OECD's (Organisation for Economic Cooperation and Development) eChemPortal.
- Beyond the technical solutions, EFSA provided training to the scientific networks with which it works, including country visits, to improve the quality of collected data. For the collection of data on food additives, food contaminants and food chemical occurrence, EFSA also provided training to industry to improve the quality of this important area of data collection.
- Ongoing efforts which should improve information technology supporting scientific data collection, analysis and dissemination include collaboration with the European Joint Research Centre (JRC) to establish web-services between databases to expand the capability of analysis on joint data sets. Also ongoing are pilots ("circle of trust") to expand data sharing between EU Member States, and training to Member State data providers on data collection and dissemination tools and methods for BSE/TSE.
- In the area of regulated products, new technology and process solutions are being built in order to automate and structure regulated dossiers and the scientific data provided by industry applicants. Integration of these dossier data sets with EFSA's scientific data warehouse will expand EFSA's ability to validate submitted data.
- More innovative data and technology initiatives in the area of machine learning and other applied artificial intelligence mechanisms for data analysis and insight are ongoing in pilot modes.

In 2012, EFSA acknowledged three forces that have progressively imposed themselves as strategic drivers: the increasing scrutiny of food safety policy and science by civil society, an increased EU focus on stimulating industry, and the global financial crisis and consequent pressure on public budgets. These external forces led EFSA to intensify interaction with risk managers and stakeholders. This has served to boost scientific quality, and to balance public support for the EU policy agenda. EFSA has aimed to enhance transparency and independence while ensuring stakeholder and Commission needs are met by fit-for-purpose scientific advice. To this aim, EFSA has regularly reviewed its governance, its policies and procedures. These, in turn, have led to efficiency gains and to increased capacity for closer cooperation across European organisations in the public sector.

2.2. Clarity and accessibility of EFSA communication

- Since 2014, EFSA reviewed its approach to external relations by consolidating all competencies in the areas of communications, customer, stakeholder and media relations. In this context, meetings and exchanges with DG SANTE, the Health Commissioner as well as with MEPs were intensified.
- In 2016, EFSA's redesigned its web content for user-friendliness, reducing the number of webpages and deleting redundant content. A more accessible editorial style and a richer choice of communications tools to explain EFSA's activities to the public (video, flash news videos, infographics, animations, and data visualisation tools) were introduced, improving understanding and impact among users. The IT services underpinning EFSA's new website were outsourced to the EC/DG-Informatics using technologies for website development that are standard across DG-DIGIT, DG-CONNECT and other EC institutions.
- EFSA has been promoting the use of social media as engagement channels to reach a larger audience when disseminating information.
- Efforts to further improve search and information access are currently ongoing and EFSA is aware that increasing the volume of data shared with the public may have a significant impact on quality control and reputation management.
- During the same period, the EFSA Journal was migrated to a dedicated professional platform (Wiley online library) which enabled EFSA to improve the quality of its scientific production. Layman summaries have also been enclosed to the scientific outputs. The new platform increases the rights to open information dissemination by adopting Creative Commons open licensing rights for EFSA Journal documents and data.
- Target audience research projects have been carried out since 2015 with the results feeding into improving best practice and prioritisation of communication activities, now following a thematic approach and targeting specific stakeholders. Through the Communication Experts Network (CEN) EFSA proactively seeks communication synergies with Member States' authorities to strengthen consistency of information on food and feed safety. This coordination ensures that messages are not provided in isolation, but provide a broader context that is meaningful to consumers and that advises on risk management measures. Regular contact with DG SANTE's and sister agencies' communication team ensures reciprocal understanding of planned communication priorities and activities.
- In 2016, EFSA launched a new and more flexible Stakeholder Engagement Approach as well as pilot projects to assess EFSA's reputation and public perception of its work.

EFSA's reputation is often challenged as we witness the rise of anti-EU, anti-establishment, as well as anti-science and technology trends. Communicating openly, effectively and promptly on EFSA scientific work helps foster trust in EFSA and the EU food safety system. As new communication tools became available, a better integration of social science, consumer insight and target audience research in risk communication are desirable. EFSA's investment in the interface between in-house scientists and communication officers has been very successful in involving EFSA's scientific staff in the development of messages, which has ensured high accuracy and quality standards for the dissemination of knowledge. This work could be further strengthened through the establishment of a specific social science function, reflecting a trend seen in international (e.g. WHO) and national (e.g. ANSES, BfR and UK FSA) organisations.

2.3. Increased trust ensuring independence and enhancing transparency and openness

Transparency and openness are fundamental aspects of EFSA's work enshrined in its Founding Regulations. Until 2012, EFSA informed stakeholders of its work and consulted on major draft opinions. Since 2012, demand for higher levels of transparency and openness from stakeholders and the public have significantly increased and set expectations relating both to how the scientific decision-making process works, as well as to the underlying data and methodologies that support the scientific recommendations. Improvements in transparency and openness at different stages of the risk assessment process have been an important focus for EFSA during the last five years.

- Following an Open EFSA concept paper[4] (2014), a comprehensive set of 35 measures have been implemented through the Transparency and Engagement in Risk Assessment (TERA) project[5]. The project covers all stages of the risk assessment cycle, including the way EFSA interacts with stakeholders, manages data and seeks input from a wider pool of scientific expertise. In parallel, an Information Management Programme (IMP) was established to consolidate, coordinate, steer and monitor development projects related to EFSA data, evidence and knowledge. The programme is investing EUR 24 million in projects that improve openness, transparency and analytical capability.
- With regards to independence, EFSA has continuously updated its rules in line with recommendations from the European Parliament. EFSA's approach in this area is one of continuous improvement: repeated cycles of policy development, implementation of rules, assessment of results, and consideration on further revisions. This has, for example, led to the centralisation of the screening of declarations of interest in an organisational unit separate from the scientific operations, allowing for a more consistent implementation of the rules. Another example of improvements in the area of independence is the introduction, in 2014, of compulsory training for all external experts and staff.

Looking at the outcome of the latest policy update[6] in 2017, it is fair to say that EFSA has a comprehensive, robust and impactful system to avoid real and reasonably perceived conflicts of interest in all of its populations. It might be seen as the most advanced system within the European Agencies and Institutions landscape. Whether these initiatives have increased trust in EFSA is however difficult to measure. A first pilot of a "reputation barometer" commissioned in 2017 has revealed relatively high scores assigned by Member State authorities, the scientific community and the European Commission, medium positive scores by industry and farmers, and a neutral rating by consumers and thematic NGOs. Trust in EFSA should be viewed in the context of eroding trust in European institutions and the Union. A recent social force to contend with is also the influence of social-media driven, "post-truth" parallel universes. EFSA's reputation and trust in its scientific process and output will remain a major point of attention.

2.4. Long-term sustainability of EFSA's operations

Within a sealed "financial and staff envelope" (a budget of approx. EUR 80 million per year solely covered by EU funding and an establishment plan set by the budgetary authorities), EFSA's scientific workload is essentially driven by EC mandates for generic risk assessment and by the processing of industry applications in the area of regulated

[4] http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/openefsadiscussionpaper14.pdf
[5] https://www.efsa.europa.eu/sites/default/files/160615-d3.pdf
[6] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

products which require EFSA's safety assessment and authorization. EFSA's output each year consists approximately of 500 scientific papers responding to European demand, and a marginal influence on the workload balance stems from EFSA's self-mandates. Internal mandates are used to fund the research and development of guidance documents and to ensure risk assessment methods are kept fit for evolving scientific demand. Since EFSA's establishment, the workload for the assessment of regulated product authorisations steadily increased, representing by 2012 more than two-thirds of EFSA output. This regulated product workload remained high in the following years and was aggravated by increasing scientific complexity and public scrutiny. Until 2012, EFSA was able to absorb this increase due to annual budget and establishment plan growth.

Since 2013, institutional budgets have been frozen and EFSA's establishment plan was reduced by 10%. Increases in the workload of the regulated products area have been met at the expense of the other three pillars of EFSA: generic risk assessment, communication and business support.

In 2017, EFSA will spend approximately 52.8% of its overall resources to cover staff cost (EUR 42 million). The share of staff cost has risen steadily from 49% in 2012 and will reach 59% in 2019. Assuming a fixed budget, and an overall average annual cost increase of approximately 2% due to inflation and career progression, EFSA loses purchasing power each year worth EUR 1.6 million. This loss has to be addressed by reducing labour cost or by spending less money on non-salary expenditures (such as scientific meetings, infrastructure, information technology, and scientific cooperation). Efficiency projects are continuously implemented to counterbalance the effect of increasing staff-related costs:

- A number of efficiency projects and structural adaptations have been implemented from 2013 to 2017 to transfer resources from administrative activity to science and communication tasks, resulting in a current ratio of roughly 25/75.
- At the same time, efforts were made to move from traditional administration and transactional support to expertise management and strategic advisory services. This shift enables the administration to better leverage existing resources and to add capabilities supporting the scientific advice production process (i.e. result-based management, project and process management, quality and change management, corporate planning, strategic steering and control linked with improved risk management, etc.).
- Centralisation of back office and administration function has led to the reduction of administrative labour for scientific officers, which has resulted in labour savings equivalent to 21 posts. Centralisation projects enhancing efficiency addressed finance, corporate controlling, grants management, activity planning, travel and events management, recruitment and scientific expert selection, and information technology. These centralisation projects and their resulting process implementation reduced the non-scientific workload of scientific officers of EFSA.
- Financial savings from centralisation, and other efficiency improvements and financial controls, led to an increase in outsourcing, from EUR 2.18 million (2012) to EUR 5.2 million (2016), via grants and scientific collaboration activities with Member States.
- The centralisation of administrative work and the additional labour dedicated to operational work has allowed EFSA to introduce and manage new outsourcing tools. New types of grants have been developed to diversify outsourcing and to support partnership building between competent organisations in Member States.
- EFSA implemented a corporate portfolio management and controlling system that will enable clear classification and monitoring of its operational portfolio and allows for analysis and management evaluation of operational fit based on business case, urgency and expertise capacity and availability.

- The implementation of a quality and continuous improvement practice certified to ISO 9001 standard enables targeted efficiency-improvement projects and set baseline and target improvement metrics for operations and administration.
- EFSA created an Application Desk and centralised to a single unit all of the administrative and applicant interaction for applications on regulated products so as to focus scientific units only on the related risk assessment processes. The net benefit of the centralisation is reduced unnecessary clock-stop (such as those resulting from quality validation), and acceleration and consistency of application lead times.

Further projects are being run to reduce administrative burden from operational units via centralisation and/or outsourcing of non-critical tasks. Notwithstanding these efforts, a growing mismatch between supply and demand is producing backlogs in the area of regulated products, and lower than anticipated preparedness and innovation in the area of generic risk assessment.

EFSA's scientific work is mainly carried out by independent European scientific experts who are members of one of EFSA's 10 scientific panels or its Scientific Committee. They are supported by scientific working groups, EFSA scientific staff and public institutions. Independent scientific experts are not employed by EFSA. They do not, therefore, receive a salary but a daily allowance when engaged in EFSA scientific risk assessment. Surveys show a high engagement in EFSA panel membership, and recognition this brings, through co-authorship of the scientific opinions that are published in the EFSA Journal. Networking opportunities provided through EFSA are also appreciated by scientific experts. However, EFSA management notes several problems with the current system:

- While there are many highly-skilled scientists in Europe who could potentially serve on an EFSA panel, membership requires deep knowledge of, and skill in, an increasingly broad set of guidance, methods and processes that are specific to risk assessment. EFSA has offered training modules on specific aspects of risk assessment, particularly to introduce new guidance, in order to ensure that current EFSA experts and staff keep abreast of new developments.
- As scientific experts can devote only a limited amount of time to EFSA, it is necessary to use them judiciously. In the area of regulated products, experts face a large workload of repetitive application assessments which stretches their allowed time budget and decreases the attractiveness of EFSA from a scientific point of view. Hence, there is consensus that EFSA staff need to provide the scientific support and take responsibility for routine scientific tasks and for preparatory work. While some preparatory and routine work might be possible to outsource, there is no immediate solution to implement this shift of responsibility from panels to EFSA and its collaboration partners due to policy and EU regulation. Furthermore, outsourcing routine and preparatory work would require additional financial resources and increased scientific support of EFSA's staff to working groups and panels, which are already considerably constrained.
- Attractiveness to serve on an EFSA panel is also influenced by the degree of efficiency EFSA can provide for administrative and logistical issues. Without a fully-functioning international airport or a connection to a high-speed train, Parma is at a clear disadvantage. While travel to Parma takes time, shuttle service, which comes at a cost of EUR 1 million a year, has improved scientific expert satisfaction. Tele-meetings have increased to 20% of all meetings, reducing both travel cost and scientific expert inconvenience, and are targeted to reach 25% in 2018.
- The challenges with regard to attracting skilled staff are in part similar to those described for scientific experts. Despite being viewed by its staff as an attractive place to work (engagement level >75% according to the 2015 EU staff survey),

EFSA has experienced difficulties in attracting staff from across EU (43% of staff are Italian nationals). The upcoming Brexit may also drain EFSA of skilled staff (6% of EFSA's staff). A number of initiatives addressing this issue and aiming at strengthening EFSA's brand have been implemented (EU FORA, capacity-building initiatives, traineeships, relationships with universities.)

- To increase EFSA attractiveness, EFSA implemented authorship rights for contributing staff and external scientific experts in 2016. EFSA supports presentation of scientific work at conferences and now permits publication in peer-reviewed scientific journals and staff exchange with sister organisations.
- In order to continue to attract, retain and develop its human capital, EFSA has recognised that its work force, be external experts or internal staff, needs to be integrated into a comprehensive talent management approach. The organisation has thus moved from an administratively focused approach of providing traditional personnel services, to modern HR practices including business partnering fully aligned with EFSA's strategic objectives. EFSA has thus designed an Expertise Management Programme (EMP) with an overall budget of EUR 10 million aiming to enhance talents as EFSA's key asset in delivering safer food for European citizens (modern IT environment to recruit, manage and develop talents, common expertise pool, quality index, predictive workforce model of competencies and capabilities, etc.).

Despite having achieved significant results and made substantial improvements over the past years, the sustainability of EFSA's model remains at risk, being strongly dependent of a set of external and internal factors deserving serious consideration.

3. EFSA in a changing landscape: Challenges impacting EFSA's efficiency and relevance and the ambitions of EFSA 2020

3.1. Emerging challenges

Contemporary social, cultural, economic and environmental problems are becoming increasingly complex. Addressing issues such as food safety, social inequality or environmental sustainability requires multi-agency and cross-sector responses. Factors such as fragile economic growth, demographic change, globalisation, reduction in public expenditure, and increasing public expectation, accentuate the challenge of securing appropriate outcomes to these issues. In this context, and with increased interdependency and ambiguity, complexity is no longer a phenomenon only of European scientific risk assessment questions. Complexity introduces itself into the approach one must take to apprehend, evaluate, and adjust to, if not anticipate, the emerging issues.

The main challenges confronting EFSA can tentatively be summarised as follows:

- Relevance: the knowledge society, the global economy and the technological revolution have resulted in a business environment with levels of complexity, uncertainty, and dynamism not previously experienced. This environment is also characterized by increasing risk and ambiguity and decreasing ability to forecast. Public service organizations are challenged to demonstrate their added-value to society as a whole or to the Community project. This reinforces the need for enhanced result-orientation and advocacy strategies targeting the scientific community, and the policy decision-makers.
- Preparedness: in light of (i) an increasingly globalised trade and the subsequent flow of hazards and risks, (ii) a more complex food supply chain, and of the tripod approach in food: food safety, nutrition and food security.
- Cooperation: In a world marked by increasing interdependence, technological innovation and societal demands, the resource limitations contribute to a growing recognition of the need for greater collaboration within and between sectors. Such collaboration requires organizations to work together across traditional, institutional and professional silos, leveraging pooled resources and assets, and with clear focus on delivering cross-cutting outcomes.
- Efficiency: considering that the risk assessment landscape is driven by Member States, there is scope for better tapping into, leveraging and optimizing the resources and assets available within the MS (competencies, knowledge, data, methods).
- Transparency: in the face of data ownership by Member States, confidentiality claims of applicants and overall conflicting provisions in existing legislation both at national and European Union level.
- Innovation: when public service organisations struggle to keep pace with the advancement of data and exposure science in a world spinning at Internet speed.
- Comprehensiveness and accuracy: with the growing recognition that scientific decisions alone cannot, in most cases, provide all the information on which risk management decisions should be based - societal, economic, ethical and environmental factors needing consideration as well.
- Communication: in times of post-truth and intense scrutiny with the increased impact of social media and of less centralised and possibly more polarised channels.
- Reputation: in an environment characterised by emerging and vocal anti-EU, anti-establishment and anti-science and technology trends in Member states and globally.

- Resource scarcity: with a steadily decreasing operational budget, the sustainability of EFSA's current model is at risk, raising the necessity to ring fence a suitable amount of financial resources for its core operations (generic risk assessment, scientific and technical assistance, preparedness, innovation, collaboration, risk communication) and of adequate expertise and competencies to perform its tasks.

Some of these challenges influenced the EFSA Strategy 2020, developed in 2015 and approved by the MB in early 2016. The introduction of a result-based approach, and of quality and process management methods, enable EFSA to specify the impact expected from EFSA's interventions, the role of its customers and stakeholders in supporting both product and service delivery but also to develop forecasting, environment-scanning and scenario-planning capacities.

The European and global landscape have however already shifted considerably since 2015. EFSA-EC cooperation should be further improved in relation to assessing near and mid-term resource outlook and prioritisation, and on aligning question definition and expected output format (Terms of Reference Frontloading Initiative, for example), and also in identifying mandates that should be put to public consultation underpinned with information from social science research.

3.2. The ambitions of EFSA Strategy 2020

EFSA's strategy document captures the Authority's ambitions up to 2020, taking particular account of the obligations outlined in its Founding Regulations, the overarching priorities of the EC and feedback from its partners and stakeholders. A number of drivers expecting to influence significantly EFSA's operations have been considered, ranging from high-level issues such as public expectations of greater transparency and engagement and the impact of globalisation, to closer-to-home concerns such as internal efficiency and attraction of scientific expertise.

As part of its strategy, EFSA has revisited and refined the core values driving its development until 2020, namely: (i) scientific excellence (high-quality scientific advice based on quality of expertise, science-based information and methodologies grounded in internationally recognised standards); (ii) independence (safeguarding the independence of its experts, methods and data from undue external influence); (iii) openness (communicating openly and promptly, engaging civil society and connecting with untapped scientific potential); (iv) innovation (anticipating new challenges, being pro-active and forward-looking; and, (v) cooperation (working and exchanging knowledge between food safety experts in the EU and globally).

Five overarching strategic objectives have been defined, guiding the organisational development over five years, namely:

- Prioritise public and stakeholder engagement in the process of scientific assessment: Promoting an enhanced dialogue with stakeholders on mandates in collaboration with the risk managers, making documentation on information gathering and the evaluation process available, fostering engagement throughout the development of scientific assessments, and ensuring clarity and accessibility/usability in the communication of findings.
- Widen EFSA's evidence base and optimise access to its data: Adopting an Open Data approach to foster reusability of EFSA data, improving data interoperability to facilitate data exchange, and migrating towards structured scientific data.
- Build the EU's scientific assessment capacity and knowledge community: Strengthening capacity building and capacity sharing with Member States, fostering the growth of the EU risk assessment community in collaboration with

international organisations, and reviewing and further developing EFSA's scientific assessment model.

- Prepare for future risk assessment challenges: Strengthening EFSA's resilience and ability to anticipate and respond effectively to food safety risks in cooperation with EU and international partners, developing and implementing harmonised methodologies for risk assessment across the EU and internationally, and becoming a hub in methodologies and tools for risk assessment.
- Create an environment and culture that reflects EFSA's values: Building a culture putting EFSA's values into practice and fostering an environment focused on improving organisational performance and capabilities.

On these core values and strategic objectives, EFSA has built a plan for its operations and its development that addresses many of the challenges that were identified in 2015. However, mid-way in the current 5-year strategy plan, we might consider the changing context and reflect on a medium-term response where feasible, and on possible long term impacts.

The following section invites the Management Board to reflect on some of the main areas that might be instrumental for a sustainable mid-term and long-term response.

4. EFSA's evolution: Key areas for consideration

EFSA's 5-year strategic planning cycle for the period 2021-2025 will begin in Q2 2018. The work from 2018 to 2019 will provide the MB with a comprehensive analysis of the objectives and work programmes that will contribute to food safety well into the 21st century. The external evaluation of EFSA's performance during 2011-2016, and the 3rd EFSA scientific conference, both of which will deliver recommendations during 2018, will also be major contributors to the strategic planning.

This paper aims only at highlighting, as part of a reflective management evaluation, the four most critical dimensions of EFSA strategy that are important areas for further reflection and strategic orientation.

4.1. Data and Evidence management

It is widely acknowledged that some 90% of the data in the world today has been created in the last two years and about 75% of this data is unstructured. While EFSA is already making progress on tackling the issue of big data and open data, and is exploring approaches to the management and exploitation of big data sets, such as in the whole genome sequencing mandate, the scope and acceleration of the volume of data relevant to its risk assessment mandate is becoming so large and complex that soon both new tools and new approaches will be needed to make the most of them.

The EFSA website, Journal, and Scientific Data Warehouse, are EFSA's main "shop front" for stakeholders of the information EFSA publishes. EFSA's Strategy 2020 has and will continue to implement machine-readable interfaces to permit more automated access by algorithms that will enable automated exchange of information between organisations. The Wiley platform, which hosts the EFSA Journal, and the Zenodo platform, which hosts EFSA's Knowledge Junction, both have open-access machine interfaces. These platforms have allowed EFSA to increase access to its scientific output and supporting evidence. To date, however, EFSA has not yet implemented its own application programming interface (API) to automatically 'expose' all of its available data.

Furthermore, the nature of EFSA's scientific work increasingly requires access to data that is not traditionally collected by the agency. Today almost 60% of data needed and used in risk assessment is not collected in the traditional data collection modes[7]. It is, therefore, timely to consider a shift in focus from data collection to data connection. EFSA's Strategy 2020 partly addresses the evolving challenge by implementing solutions such as R4EU and Food Chain Lab (BfR), but may not sufficiently address the speed with which raw data, big data, and multi-disciplinary data is needed in the risk assessment processes. Exploration of all plausible data streams, including from the general public, could generate useful information to inform our future scientific work.

The exponential growth and acceleration of new data, different types of data, and public access to data sources force a consideration of EFSA's approach not only to data management but to risk assessment methods. Advances in computation capability and in biology and biotechnology (NGS, CRISPR[8]), will shift risk assessment methods in the 21st century toward empirical whole plant or whole organism modelling to complement (or replace) traditional rational epistemological approaches to scientific risk assessment. It is still unclear, based on the latest breakthroughs in genomics, artificial intelligence and

7 https://www.efsa.europa.eu/sites/default/files/event/180606-ax11.a.PDF

8 Ibidem

computer science, if such tools will be accessible to EFSA, considering its resources, if policy will permit a non-deterministic approach, and how international public and private-public organisations will collaborate toward the development of shared large-resource projects and manage the data and the models which make use of the data.

Cognitive analytics such as machine learning and natural language processing can discover patterns and relationships in information from millions of texts, books, online articles and other sources (e.g. social media), harvesting information that could take researchers (humans) decades to discover, retrieve and digest. Big data would be extremely valuable for EFSA if methods, competencies and tools were in place to harness and harvest new data paradigms. EFSA 2020 strategy maintains a focus on innovation, collaboration, and on specific topics in big data, but this does not necessarily guarantee relevance for risk assessment by 2025. In all scenarios, EFSA's current data collection and dissemination approach, constrained by the regulation and by agreements or lack thereof between Member States, will eventually undermine the relevance of its scientific output if not transformed to leverage the new technological and scientific methods that are developed to address the data explosion.

As EFSA progresses with achievement of strategic milestones, however, it is discovering that methodological and organisational capabilities are as equally important as the scientific and technological tools available or in development. Data connection and semantic interoperability, for example, will require a significantly more coordinated approach between European institutions, both for the harmonisation of data management and modelling methods, and a potentially more directive and coordinated approach from the EC with regard to semantic interoperability and data method harmonisation between entities that have until now been in functional silos that large data, open data, and their relevant methods are beginning to stitch together in increasingly multi-disciplinary approaches.

4.2. Expertise and Competences

In accordance with Regulation 178/2002, EFSA's scientific production system is mainly built on ten scientific panels and one Scientific Committee. Over 200 individual scientists are appointed by open call, competency evaluation and independence verification, and the cost of travel, daily allowance and indemnities is EUR 4 million/year. The panel work is supported by: (i) scientific working groups (EUR 5 million), (ii) EFSA staff (approx. 330 staff), (iii) scientific cooperation with Member States organisations (via 15 scientific networks), (iv) outsourcing of preparatory work via grants to Art. 36 organisations and via public procurement (approx. EUR 10 million).

Even though ensuring a sound level of multidisciplinary expertise and guaranteeing the involvement of MS national agency and experts in EFSA output, this system also entails important limitations impacting the organisation's sustainability. Recent calls have shown the difficulties encountered in attracting new panel members. The current trend of diminishing public administration budgets is also impeding the ability of national bodies to contribute to EFSA's work.

Experts in panels voluntarily contribute in their personal capacity for a mandate of three years, without formal contract, and receive in exchange only a reimbursement and indemnity. 50% of scientific experts are employed by national agencies (the other half are members of academia or work for public research institutes.) EFSA is therefore highly dependent on the willingness of national bodies to lend their experts' working time to EFSA. This expert capacity risk is further aggravated by a low level of attractiveness to EFSA by young scientists due to workload, and lack of financial or career reward. This risk is leading to the "ageing" of panels. Even more critically, availability of top-drawer

scientific resource is further hindered by a lack of attractiveness for senior scientific experts due to the routine nature of authorisation work, the lack of impact points for scientific publications, and the absence of research funding to support RA development. Finally, EFSA sets a high standard for expertise in scientific RA approaches and very strict requirements on independence that fails to take into account the increasing trend of public-private partnerships in scientific research. This further limits the pool of interested and eligible scientific experts.

Several non-mutually exclusive options could be explored to overcome these shortcomings and increase the efficiency of the existing model, but they carry considerable financial implications.

- Within the provision of the existing regulation, EFSA could explore the following changes:
  - Change panel focus, directing work on strategic and complex issues such as the peer-review of preparatory work which could be carried out either by EFSA staff directly or by Art. 36 national scientific bodies. This would increase national agency participation and reduce the cost and time of working group meetings in Parma.
  - Increase preparatory work by the Member State, exploiting fully the provision of the Founding Regulations, amending Art. 36 Commission Regulation and optimising the use of grants. Resources dedicated to the outsourcing of EFSA's tasks to national risk assessors are however considered by the MS as a limiting factor (EUR 10 million per year, 13% of EFSA's total budget).
  - Review the efficiency of the model by putting in place working groups to serve one or multiple panels. Cross-panel working groups (e.g. on genotoxicity) would as well contribute to foster consistency.
  - Increase the level of indemnities allocated to experts and/or to their employers. According to the most recent survey, an increase in financial compensation was mentioned as a high priority in maintaining EFSA’s attractiveness to the experts and their employers.
  - Enhance the collaboration within the Commission landscape (DG RTD, JRC, other agencies) to optimise working processes and cross-sector collaboration but also to improve the attraction for young scientists.
  - Openup collaboration with research institutes, which might require mechanism to allow for the co-management of research grants.
  - Increase the reward and value of working group contribution via formal recognition of authorship of panel opinions and similar measures.
- Other options would require a change of regulation:
  - Redefining the roles, responsibilities and competencies within the panel system, for example: (i) having all or part of the panels hired as temporary staff, which could be an incentive for both young and experienced scientists, (ii) replacing external experts by EFSA staff to reduce the dependency on external organisations and the perception of alleged conflicts of interests (apart from the financial implications, this would however diminish the involvement of national agencies in EFSA work and raise opposition by the MS). In any and all cases, the role of the scientific staff at EFSA could be further optimised and harmonised across units and panels. In particular, EFSA staff could focus on being the guardians of both materials and methods, ensuring consistency across EFSA output. Any shift in role and responsibilities requires a clear definition and management of critical competencies as they evolve.

- Defining and delineating routine files to be evaluated by staff, and sensitive or complex files, by the panels. This option would require some changes in the subsequent regulations and directives on authorisations.
- Establishing a system where each Member State would appoint an expert, ensuring therefore their involvement and a more even representation in panels. A similar set-up was however rejected by the Commission after the BSE crisis and could be perceived as jeopardizing the independence of the scientific advice.
- Leveraging Art. 7 and Art.23 of the Financial Framework Regulation to allow receipt of ad-hoc grants, therefore increasing the possibilities for further collaboration with research institutes and world-class experts in advancing risk assessment (RA) methodologies.
- Assigning the preparation of a draft assessment report to a competent Member State Organisation and organising a peer review with all Member States risk assessment bodies, followed by final conclusions adopted by EFSA (extension of the Pesticides model to other food sector areas). The capacity of Member States to cover adequately all areas under EFSA's remit may be a limiting factor.

Safeguarding an appropriate level of expertise within the panels is an important concern which could be partially addressed by:

- Extending the assignment from 3 to 5 years. Panel membership pay-off typically starts only after two years of exposure to RA methods and panel procedures. A 5-year nomination, as is the case for DG-SANTE scientific panels, could enhance scientific returns.
- Not being a full-time occupation, panel membership implies that other activities may represent a potential conflict of interest. EFSA has to strike the delicate balance of exploring the latest innovation and technology pursued by industry (e.g. engineered nanomaterials, new genetic modification technologies), while simultaneously delivering advice unbiased by stakeholder influence. Access to industry expertise remains however important and the use of "hearing experts" providing their knowledge without influencing the drafting of scientific opinions could be further explored in order to stay abreast of the latest advances.
- Actively scouting for additional and different competencies, and anticipating emerging trends and risks that require different skills (developments in data require for example new roles such as data curators or bio-informaticians).
- Because new experts may not be versed in the methodologies and guidelines that are relevant for EFSA's scientific work, it could be beneficial to open up the working groups to observers nominated by the Member States. Alternatively, staff from Member State institutions could join EFSA on a temporary basis. Study visits and fellowships could be further explored, complementing already established seconded national expert (SNE) and guest scientist schemes.
- Even though EFSA created a platform for the delivery of learning and development activities with a focus on specialised scientific training sessions (such as computational toxicology, modelling tools or uncertainty analysis), a formal virtual hub for risk assessment knowledge acquisition and exchange in the form of an "EFSA Academy" could be a distinctive feature. This hub could also evolve in supporting universities in developing courses in scientific assessment.
- Similar initiatives have been taken by national RA organisations. Enhanced cooperation with other EU agencies should therefore be sought to join forces. EFSA is currently considering organising, together with Member State institutions, a training programme in order to build adequate risk assessment and risk communication capacity in Europe.

EFSA will have to carefully and comprehensively assess these factors – as well as the sustainability of, and possible improvements to – its current operating model as a whole, and address them in cooperation with EU and international partners, and within its budgetary limitations.

4.3. Cooperation, collaboration, management of knowledge for integrated responses: The risk assessment delivery model

EFSA faces an increasing demand for additional services. These services span the range of better and more intensive support for applicants for regulatory products, to mandates focused on innovative new scientific risk assessment methods that respond to topics such as whole genome sequencing.

As highlighted in the study commissioned by the European Commission on future scenarios for food safety and nutrition[9], new risks in food production will continue to emerge, thereby increasing the need for data, methodologies, expertise and scientific advice on new and complex food safety questions. EFSA and its partners, at EU and international level, will have to address these new developments through an integrated "one health" approach. Cooperation and collaboration for integrated responses will be needed to adequately meet societal expectations for broader, sustainable levels of protection of human, animal, plant and environmental health.

At the same time, scientific knowledge continues to evolve rapidly. As already explored, new methodologies, information and data are growing exponentially. To illustrate that, new findings in biomedical research, in neurotoxicity, in reproductive toxicity, in the role of gut microbiota, in genomics and in epigenetics, in metabolic biomarkers, or in the cumulative effects of compounds and antimicrobial resistance, will directly affect the nature of EFSA's scientific assessments. EFSA's Strategy 2020, with the external environment, addresses the challenges of cooperation, collaboration and knowledge management through collaborative digital platforms that help to further standardise and automate routine tasks of the agency.

These new digital collaboration platforms can increase efficiency and ease the effort and speed for enhanced cooperation, for example, by facilitating a richer and more continuous exchange between Member States, international scientific assessment bodies, risk managers, and risk assessment partners on topics such as prioritisation schemes to address resource bottlenecks. They do not however, necessarily address the need for a different approach to knowledge management. To illustrate the need, consider the following potential increase in EFSA collaboration and coordination activities:

- EFSA and its partners will have to monitor and take stock of new scientific developments, thus ensuring that its work, and particularly its risk assessment methodologies and evidence, continues to reflect the newest scientific developments available. In this arena, EFSA will increasingly be exposed to private research and industry, and will need mechanisms for managing the research output.
- EFSA collects and analyses existing evidence and data but it does not generate primary evidence to carry out its risk assessment. In this arena, partnering with research bodies and project consortia, with risk managers and with funding bodies will be increasingly important in order to prioritise research funding for generating scientific knowledge.
- Member States could take on scientific tasks of exploratory nature or routine tasks that have well established methodologies and guidelines, including common risk assessment priorities as established in the Risk Assessment Agenda, and as

[9] https://ec.europa.eu/food/safety/future_en

agreed by the Advisory Forum. The preparatory work of such programmes could also be outsourced, similar to the rapporteur system for pesticides. Further cooperation with MS institutions could be further enhanced by leveraging new types of grants and by simplifying and optimising Art. 36 modalities.

- Member State organisations may have built expertise in specialised domains that may be leveraged beneficially across the whole of Europe. For example, the development of software for estimating exposure to mixtures of chemicals is a specialised endeavour that does not need to be present in each State but that does require a sustained investment in software maintenance by a centre of excellence that may be recognised as an EU Reference Lab for this purpose.
- The risk of diverging scientific opinions can be mitigated by better coordinating national research and risk assessment activities and by further developing the Risk Assessment Agenda by giving it a concrete form, such as the one a knowledge management approach could deliver.

There are evident challenges associated with these proposals. Deeper and closer collaboration requires an important investment in shared processes, tools and competence. But such developments would enable EFSA to progressively adjust to a changing global context and to scale its 2020 ambitions to the next level. Cooperation and collaboration, even if digitally enhanced, would benefit from a strategic European approach to knowledge generation, knowledge exploitation, and knowledge management in the area of risk assessment and risk management topics. These approaches would better enable EFSA to anticipate, and respond to emerging issues by ensuring broader, more efficient and more rapid access to knowledge.

The recommendations from the 2012 External Evaluation explicitly suggest enhancing EFSA's role in developing harmonised quality-based data collection and exploitation systems and processes. This fundamental aspect of EFSA's work may not have been fully gleaned. EFSA could play an enhanced role in managing and making sense of the collective scientific knowledge available within its remit, responding via a dual operating model to different typology of requests for: (i) the provision of scientific advice (knowledge production) and, (ii) the identification, aggregation and delivery of knowledge that furthers risk assessment method and practice across Europe (i.e., knowledge management).

Knowledge management involves activities related to the capture, use and sharing of knowledge. It supports the management both of external linkages and orchestrates the flow and dissemination of knowledge. To do so, it develops methods and procedures for seeking, sharing and using knowledge and for establishing closer relationships with other stakeholders. This would mean for EFSA further focus on:

- Developing common platforms for the use of data, information and knowledge available to MS in support to policy making, infrastructure to support big data, and new ways of exploiting and managing knowledge;
- Developing knowledge sharing and collaboration mechanisms that support cross-disciplinary communities of interest and communities of practice;
- Supporting knowledge generation, development of skills in meta-analysis and sense-making, systematic review and anticipation, strengthening horizon-scanning capabilities in close cooperation with the scientific community and the MS;
- Enforcing knowledge-based communications and targeted visibility and impact by means of knowledge-based content, expanding the understanding of the interfaces between science and policy, and between science and politics;
- Investing in capacity building, coordinating a digital network of academic institutions and public sector bodies on RA matters, (i) collecting and mapping relevant knowledge sources covering: data, tools, methods, knowledge and

competency centres, partnerships and communities of practice and, (ii) closing competency gaps in new fields such as bio-informatics, bio-mathematics, -omics, behavioural insight, social sciences, etc. A possible focus for an EFSA Academy could be the support for forward-looking research analysis and synthesis.

EFSA's positioning as a knowledge hub for risk assessment methodologies would have an impact on its delivery model and it might enable EFSA further to:

- Provide an integrated and more cohesive and efficient system for panel and working group output, leveraging a possible redefinition of MS' tasks;
- Exploit knowledge input and output, further developing environment-scanning and analytics capabilities on emerging risks and trends, and strengthen cooperation with the MS (applicants included) as well as with European and international stakeholders.

4.5. Resources and ways of funding

The legislative framework has an impact on EFSA's capacity to adequately plan and allocate its resources, partly due to limited interactions between the EU institutions during the legislative process[10]. No extra budget nor staff was for example foreseen in the financial fiches accompanying the new authorisation procedures, adopted following the establishment of EFSA. Since 2015, only 10 extra contractual short-term posts were created in order to reduce EFSA's backlog.

To address the impact of the high workload in the area of authorisations, the Commission undertook an impact assessment on the establishment of fees for EFSA in 2012[11]. Although acknowledging its benefits, it concluded that such a mechanism in a complex framework embracing 19 different EU legislations provided only limited income and could undermine perceptions of EFSA's independence.

In the mid-term, the EU will have to decide on "ring fencing" a suitable amount of resources for generic RA enhancing preparedness, innovation, collaboration, and risk communications. For regulated products, further efficiency gains will have to be found and harvested. Negotiating timelines and priorities, however, will also have to be a consideration. Considering the current economic and political context (e.g. EU focus on security, defence, and migration; Brexit, etc.) EFSA may need to establish and apply negative priorities, decrease the volume or quality of its services, or seek additional funding mechanisms.

Revising EFSA's funding mechanisms may require change to the regulation, even in the context of a larger funding reform. The increased pressure on EU budget for more efficiency has led the high level group on EU resources chaired by Mario Monti[12] to suggest enlarging the resource base and exploring alternative revenues.
Along these lines, EFSA could consider leveraging:

- Additional revenues: Art. 23 of the Framework Financial Regulation (FFR) allows agencies to receive: (i) financial contributions from Member States and third countries to certain activities including in both cases public agencies, entities or natural persons; (ii) revenue earmarked for a specific purpose from foundations, subsidies, gifts and bequests; (iii) financial contributions from third countries or various non-Union bodies from ad-hoc grants referred to in Art. 7 and from delegation agreements referred to in Art. 8); (iv) revenue from fees and charges referred to in Art. 6.2 when provided for in the constituent act; (v) internal assigned revenue ancillary to revenue referred to supra from third parties in

10 https://ec.europa.eu/food/safety/general_food_law/fitness_check_en
11 http://ec.europa.eu/smart-regulation/impact/ia_carried_out/docs/ia_2013/sanco_efsa.pdf
12 https://ec.europa.eu/commission/publications/reflection-paper-future-eu-finances_en

respect of goods, services or work supplied at their request, with the exception of fees and charges, proceeds from the supply of goods, services and works for Union institutions or other Union bodies. In combination with Art.7 FFR, it could be considered to enlarge these possibilities, particularly in:

- Participating in open tenders' competition in order to carry out certain tasks leveraging on EFSA's expertise. Art. 7 and 23 of the FFR could allow enlarged possibilities to receive ad-hoc grants and engage in research activities.
- Developing knowledge products (research papers, data warehouses) from ad-hoc demands funded by requestors (industry, NGOs, research centres, MS, international stakeholders, etc.) and/or from increased public-private partnership.
- Providing knowledge products and services to dedicated stakeholders (e.g. certification or standardisation bodies). Along the same line, active dissemination of RA methodologies and training for non-EU member states could be considered.

- Fees and charges: EFSA Founding Regulation offers the possibility to levy fees for activities performed for the benefit of private parties, and in the context of risk assessment, for certification or property rights operations. Fees are meant to cover the cost of services following a non-profit principle. The Commission is conducting a review of the fee system for a number of agencies (ACER, EMA, ECHA) and this should complete in 2017. The conclusion of the Commission (covering the areas of rationale, costing logic, management of incurred resources, and the regulatory framework) could inform similar application of uniform principle to all EU agencies. Charges on the other hand, apply for additional optional services, proposed by the agency and upon request. Both fees and charges require an adequate regulatory framework; and EFSA, unlike ECHA, EMA, EASA and EUIPO, which have similar mandates, does not have a Fee Regulation, despite the provisions of Art. 25 of the FFR.
- Shared services: Joint EU agency endeavours that provide significant economies of scale and efficiencies could be further exploited. Services and their related cost recovery mechanisms that are fully exploited by institutions such as DG BUDG, DG HR, and DIGIT are supported by the FFR, could serve as a model for EU agencies. For example, five joint calls conducted in 2016 and 2017 under EFSA's lead have been able to generate an overall saving of EUR 6.2 million for all the agencies.
- Other revenue: As developed in the paper on the future of EU Finances, using the provisions of the TFEU, other revenues for agencies could be generated through mechanisms linking, for instance, the agency size and financing to the sector of activities it belongs to and serves. These revenues have a more flexible legal character as not being ruled and established through the Own Resources Decision (ORD) which enacts the Treaty provision, but rather in secondary law not requiring ratification by all Member States. They could therefore be envisaged and enacted through normal legislative process. Along that line, the Commission has just published a legislative proposal for the reform of the three European Supervisory Authorities (EBA, ESMA, EIOPA) introducing a new funding system supported by the respective sectors, and allowing resources to be commensurate with the tasks performed.

The enlargement of fees and charges and assigned other revenues will require regulatory review for full leverage. It is however critical to note that the full scope of EU financial and staff rules would need consideration. They have proven to be impeding EFSA as well as other agencies from maximizing the utility of their budget and staff allocations. Calls for greater flexibility in terms of budget management and establishment plan, which should not be constrained by rigid headcount ceilings, should be enforced. Results-based

management and budgeting should be strengthened to allow the agency to manage with more flexibility its resources against previously agreed-upon outcomes.

Conclusion

Observing the evolution of EFSA operations and of the external context both since the Authority's establishment in 2004, and specifically since 2012, it is fair to say that EFSA has met many of the challenges it has faced and is operating in a manner that fulfils its mandate. One might also observe that, despite a record of achievement in improving transparency and efficiency, and in optimising, within the reach of its legislative remit, the roles of the respective stakeholders in the EU food safety system, scientific complexity, politics, and resource scarcity are increasing the tension between expectation and capability.

Indeed, EFSA's long term sustainability remains a delicate issue. The progress made between 2012 and 2017, summarised in section 1 of this paper, has been made largely in collaboration with the Commission, Member States and international partners. One should note, however, that these organisations face the same external challenges as EFSA. Nevertheless, EFSA's remit fundamentally depends on access to independent scientific expertise, and the basic fact of being dependent on volunteer public organisations whose employers are not compensated for time spent on EFSA's remit significantly limits the pool of expertise available to EFSA panels. Add to this a relatively shrinking budget that does not allow salaried experts or further outsourcing of relevant parts of the scientific work to Member State organisations, and some form of radical reform might be envisaged. EU reflections on budgetary reform may be relevant to EU agencies seeking alternative funding mechanisms that can help address increased public demand. EFSA could meet the ever increasing demand from the EC and Parliament (respectively focused on more scientific output and speed, and greater transparency and independence) if additional resources were provided or if a reasonable degree of flexibility were secured for alternative sources of funding, alternative allocation of task, ways of working or significant simplification of the heterogeneous landscape of regulation that constrains the efficiency of risk assessment in the area of food safety. In the triangle of scope, cost, and time, and with quality a given, modifying one angle of the triangle would allow EFSA to better prepare for and swiftly address increased demands in transparency, independence, preparedness, and advice. Leaning and continuous efficiency initiatives will continue, but with diminishing returns due to financial and political forces outside of EFSA's control.

Evaluating the last 5 years of EFSA evolution while at the same time beginning the reflection for the next 5 years, one finds that, in addition to honing the focus on the objectives and work programme of EFSA Strategy 2020, management may ask the following key questions that were explored in sections 3 and 4 of this paper:

- How can increased and continuously increasing demand for capacity of independent scientific expertise be met balancing the policy objectives, the budgets, and the reputational aspects of the food safety system?
- Following the 'Fitness Check' approach for the Regulation (REFIT) report[13], which was generally positive, how can EU food legislation be standardised and streamlined, especially in the area of regulated products, to allow for better planning and utilisation of resources, especially through collaborative and partnering relations between the Commission, the Agencies, and Member States?
- Recognising that 15 years after its creation, EFSA is facing a maturity crisis which could challenge its long-term relevance, how might the organisation shift focus on knowledge management, coordination and on emerging topics that anticipate

13 https://ec.europa.eu/food/safety/general_food_law/fitness_check_en

food safety issues, and possibly shift the production model to enable a strategic balance within European budgetary constraints?

- Can a dual operating model, with a focus on peer-review and knowledge production on the one hand, and knowledge management and exploitation on the other, be supported by a differentiated financing model?

Illustrating these key questions, the paper has explored topics that are both within its remit, as well as those that are outside its remit. Putting these to action would require considerable alignment between the various actors and stakeholders of the European food safety system. The ambition of the paper is to highlight the achievements over the past 5 years while at the same time inviting the Management Board to provide recommendations for the areas of focus that might be the starting point for the initial draft of EFSA Strategy 2025, complemented with the external evaluation 2017 and Commission directives.

The Management Board is therefore invited to take stock of the progress, to validate, limit or expand the strategic reflections this paper puts out, and to advise EFSA's management team on future recommendations for action through its work programming or its strategic planning process.

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