Ex post Evaluation of the Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority (EFSA) and of its Implementing Rules on Declaration of Interest

Final Comprehensive Report

Final Comprehensive Report

15 March 2017

Contents

Table of Figures

Table of Tables

1 Introduction

This section outlines the key objectives of the assignment, its scope and the applied Analytical framework.

1.1 Objectives and purpose

The objective of this assignment was to examine EFSA's Policy on Independence and Scientific Decision-making Processes (2011) and the Rules on the Declarations of Interest (2014) and the implementation thereof in light of the following evaluation criteria: Effectiveness; Sustainability; Efficiency; and Relevance.

In accordance with the definitions of the EU's Better Regulation Guidelines[1], the evaluation criteria are framed as follows:

- **Effectiveness**: the extent to which EFSA's independence policy system is effective in achieving its objectives and results;
- **Sustainability**: the extent to which the outputs and results of EFSA's independence policy system are sustainable against the evolving financial, operational and political perspectives in the medium to long term;
- **Efficiency**: the extent to which the outputs/benefits are reasonable compared to the inputs/costs of EFSA's independence policy system; and
- **Relevance**: the extent to which EFSA's independence policy system is suitable to address relevant problems/needs.

The ex post evaluation took place in the **context of the EFSA "Independence Policy review"**, set up for the review of EFSA's Independence Policy and the alignment of EFSA's Rules on DoI with the new policy to be adopted in 2017. The results of the ex post evaluation are expected to contribute to the objectives of the review, with a view to increasing the levels of transparency, engagement, cost-effectiveness and efficiency of the independence policy system.

Therefore, the findings of the evaluation provide a basis to inform decisions of the Agency's Management Board on EFSA's future Independence Policy, by identifying inefficiencies, potential improvements of existing workflows and processes and suggesting initial orientations for an increased effectiveness of the system in place.

[1] European Commission: "Better Regulation Guidelines", SWD (2015) 111 final, 19.5.2015.

1.2 Evaluation scope

With regard to the time period in consideration, the evaluation covered the period **2014-2016**.

In terms of **legal scope**, EFSA's Founding Regulation (Regulation (EC) No 178/2002), in particular the relevant provisions on independence (Articles 22, 23, 28, 32 and 37), the Agency's Policy on Independence and Scientific Decision-making processes and Implementing Rules (the Rules on Declarations of Interest) were the key instruments for examination in the study. The EU's Staff Regulations were also taken into consideration.
On the basis of the **five evaluation criteria** (effectiveness, sustainability, efficiency, relevance and efficacy), the ToR provided the following **evaluation questions**:

Table 1: Overview of evaluation questions

1. To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 contributed to **EFSA's reputation**?
2. To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 contributed to a **high level of food safety and consumer protection**?
3. To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 provided **value for the money** the Authority invested to ensure the policy's implementation?
4. To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 **relevant, effective, efficient and proportionate** to the policy objective of ensuring compliance with the Independence requirements laid down in Regulation (EC) No 178/2002?
5. To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 **sustainable** against the evolving political and financial perspectives?

In addition, the ToR requested the evaluation team to assess EFSA's compliance with the Policy on Independence and Rules on Declarations of Interest in light of the **principles of proportionality and subsidiarity**, by taking into consideration the following questions:

- Whether the measure goes beyond what is necessary to achieve the objectives satisfactorily;
- Whether the form of action (choice of instrument) is as simple as possible and coherent with satisfactory achievement of the objective and effective enforcement;
- Whether the form of action (choice of instrument) is the most appropriate/necessary at EFSA level.

1.3 Analytical Framework

To structure the analysis, the evaluator used an Analytical Framework, consisting of four consequent levels of analysis. The Analytical Framework included the **evaluation questions**, **judgement criteria**, **indicators**, **main sources and methods**. It guided the data collection process during the different phases of the project, allowing the evaluator to produce conclusions that are evidence-based and objectively verifiable.

A full version of the Analytical Framework can be found in Annex C.

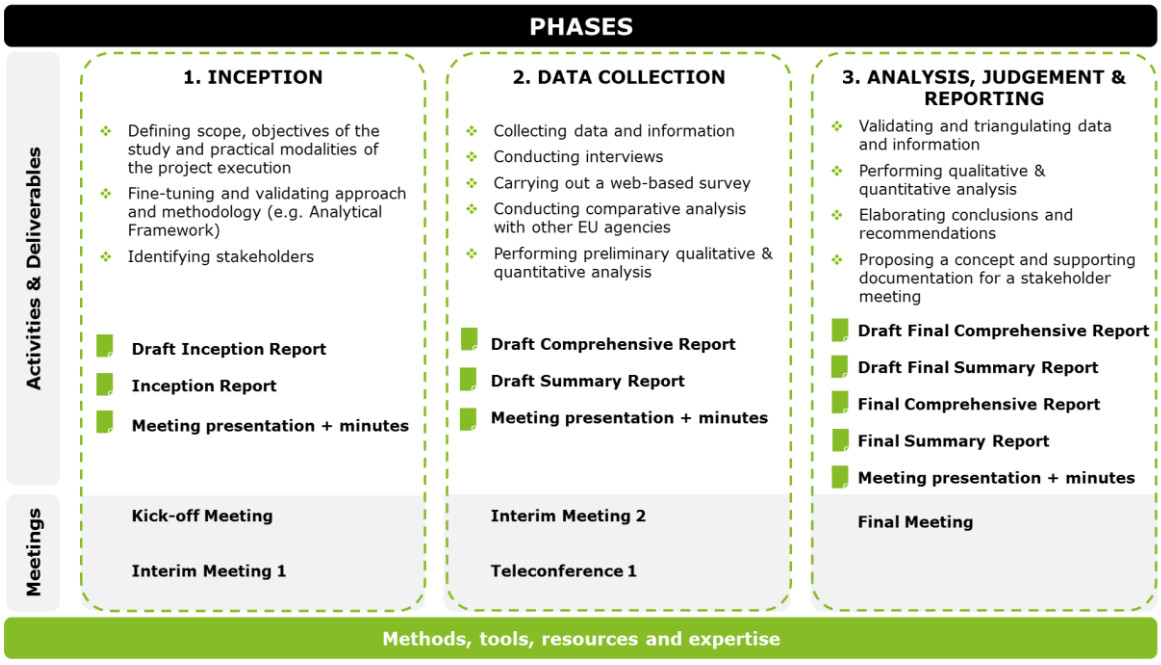
2 Approach and methodology

In this section we outline our approach to and design of the evaluation. Moreover, we describe the methodology used for data collection and analysis.

2.1 Approach

The evaluation was carried out between January and March 2017 in three phases, consisting of an inception, a data collection & analysis and a reporting phase. The figure below outlines the activities and the set of methodologies and tools used per phase. A full version of the work plan, including timelines and deliverables, and a detailed description of the phases at activity level can be found in Annex B.

Figure 1: Approach to the study



Source: Deloitte

The methodology used in support of the data collection and analysis will be presented in the following sections.

2.2 Methodology

2.1.1 Data collection

The evaluation team has collected quantitative data as well as qualitative information and insights on EFSA's independence policy system by using the following set of data collection methods:

- Document review;
- Interviews;
- Comparative analysis with similar organisations;
- Web-based survey.

Document review

The evaluation team has collected an extensive set of documentation on EFSA's independence policy system, including legal documents as well as EFSA strategies, work plans, activity reports, internal policies and procedures. The inventory was complemented with external information sources, i.e. audit and evaluation reports, independence-related documents of the EU institutions (e.g. European Parliament discharge reports, European Ombudsman decisions), academic publications and media articles.

A full and structured overview of the documentation can be found under Annex D.

In addition, the evaluation team received – upon request for a set of indicators specified in line with the Analytical Framework – data from EFSA's performance management system (e.g. independence-related statistics; figures on human, financial and IT resources invested in the operation of EFSA's competing interest management system).

The information retrieved from the various documents and data sets is reflected in the evaluation part under Chapter 4.

The evaluator also performed a high-level screening of a sample of EU online media as well as of view-points published on websites of NGOs and consumer associations (mostly active at EU level). The references can be found under Annex D.

Interviews

The evaluation team has conducted a series of interviews with EFSA staff and management involved in the implementation of EFSA's independence policy during its visit to Parma on 24-25 January 2017. The interviews with management and staff from the Legal and Assurance Services Unit (LA), the Executive Office as well as the scientific departments allowed the team to collect critical information on the effectiveness, efficiency and sustainability of the current system in place and to identify main improvement points.

To complement EFSA internal views on the performance of the system with opinions of institutional stakeholders, the evaluation team interviewed officials of the European

Commission (DG SANTE) as well as a representative of the competent Committee of the European Parliament (ENVI Committee), involved in the annual discharge procedure.

Moreover, to capture opinions in regards to the effectiveness of EFSA's independence policy and its contribution to food safety and consumer protection, interviews have been arranged with representatives of industry associations active in the agri-food sector as well as non-governmental organisations (NGOs) and consumer associations.

The interviews were conducted in a structured manner, supported by an interview guide with a selection of evaluation (sub-) questions (presented under Annex E), which were adapted to the specific profile of the interview and its role in the implementation of EFSA's independence policy. Moreover, additional questions were asked to test findings from other interviews, clarify contradictions and to close information gaps.

The evaluator interviewed on average one to two representatives per stakeholder category (see Annex F). To ensure a well-balanced analysis of individual views expressed by the interviewees, the evaluator has warranted to triangulate the interview findings with data collected via other information sources.

Comparative analysis with similar organisations

To open the analysis to a comparison with independence policies and competing interest management systems of similar organisations (i.e. scientific decision-making EU bodies) and to identify good practices, the evaluation team looked at three organisations[2]:

- The European Chemicals Agency (ECHA);
- The European Medicines Agency (EMA);
- The Scientific Committees of the Directorate-General for Health and Food Safety (DG SANTE) of the European Commission (i.e. Scientific Committee on Consumer Safety (SCCS); Scientific Committee on Health, Environmental and Emerging Risks (SCHEER); Inter-Committee Coordination Group (ICCG)).

The analysis was based on the screening of publicly available information on these Agencies' websites and independence-specific webpages, such as the description of policies, procedures and working practices, as well as strategic plans, (Multi-)Annual Work Programmes and Activity Reports. In addition, interviews were set up with officers from ECHA and EMA to capture perceptions on the overall performance, (cost-) effectiveness and efficiency of the system set in place as well as suggestions for improvement.

[2] For the selection of the organisations, the following **criteria** were used:
- Governance structure and presence of Scientific Committees composed of external experts;
- Recognition at EU level for having a good independence policy;
- Recognition for good practices in terms of independence;
- Level of transparency;
- Data availability;
- Type of organisation (i.e. EU Agency or institution).

A selection of the most important findings of the comparative analysis is presented in Chapter 5.

Web-based survey with EFSA's scientific experts

Scientific experts who are involved in EFSA's Scientific Committee, Panels[3] and Working Groups and EFSA's Pesticides Steering Committee as well as officials of national competent authorities were consulted via a web-based survey. The survey questionnaire was designed in a way allowing to capture views on the Agency's reputation as an independently and transparently working organisation, the effectiveness and efficiency of the current competing interest management system, but also more specifically the impact of the current 2014 DoI Rules on the experts in terms of administrative burden, support and management of independence processes by EFSA and their involvement in EFSA's work.

The survey questionnaire, made available via the EUSurvey tool during a two weeks timeframe, was completed by 298 experts leading to a final response rate of 24.1%[4]. The evaluator considers the response rate as sufficient to use the results as one of the information sources for the analysis.

2.1.2 Data analysis

The evaluation team performed an analysis of the data collected from the multiple information sources in line with the parameters set out in the Analytical Framework. The findings are presented, discussed and assessed per evaluation criteria and (sub-)questions in Chapter 4, following the same structure:

- **Introduction**: Describing the evaluator's understanding and the scope of the evaluation question;
- **Main analysis:** Presenting and analysing quantitative and qualitative information; visualising and interpreting the results of the online survey with EFSA's experts.

The main findings of the **comparative analysis** with independence policy systems of similar organisations are addressed separately in Chapter 5.

The **conclusions** per evaluation question and the evaluator's **main recommendations** are presented in Chapter 6.

All supporting evidence can be found in the Annexes which are referenced throughout the report.

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

[4] Timeline of the web-based survey: 18.01.2017 (start date) – 27.01.2017 (end date).

3 Current state-of-play of EFSA's independence policy

This section presents the legal framework of EFSA's Independence Policy and Declaration of Interest rules as well as EFSA's conceptual approach to independence. Moreover, it outlines the key aspects and processes of the Agency's current competing interest management system as well as its main target groups. Finally, the section highlights the main challenges of the current system for EFSA's operations and the main priorities for the review of EFSA's Independence Policy, which is discussed in parallel to this ex post evaluation.

3.1 Legal framework of EFSA's Independence Policy

The European Food Safety Authority (EFSA) was established in 2002, as a response to a series of food crises in the late 1990s and early 2000s, the result of which was a negative reputational impact to the EU's perceived ability to ensure the safety of the food chain, which in turn also affected the optimal functioning of the EU internal market, thereby causing important damage to concerned food business operators. Aside from one of its strategic objectives, to contribute to a high level of food safety and consumer protection, EFSA was set up to restore public confidence in the EU's food safety system. EFSA's mission is to contribute to the safety of the EU food chain by providing scientific advice to risk managers, by communicating on risks to the public, and by cooperating with Member States and other parties to deliver a coherent, trusted food safety system in the EU. Therefore, securing independence from undiligent external influence on its scientific risk assessment process was set as one of its main priorities. Independence moreover forms part of the Authority's core values, together with scientific excellence, openness and transparency[5]. Setting up EFSA, not only as an authority independent from industry but also from political interference in the scientific decision-making process, took the form of a structural as well as functional separation between the risk assessment and risk management spheres within the risk analysis process[6].

One of EFSA's main activities is to provide objective and independent scientific advice to the EU risk managers, i.e. the European Commission, European Parliament and Member States, on various aspects related to food and feed safety.

[5] Article 22 of Regulation (EC) No 178/2002, *supra*.

[6] Article 6 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1-24, as last amended.

EFSA's Founding Regulation ((EC) No 178/2002) provides the legal basis for EFSA's independence policy. The independence requirements were translated by EFSA into a policy on independence and scientific decision-making processes. The current policy was adopted in 2011, succeeding EFSA's Policy and Guidance on Declarations of Interest of 2007[7] and its 2008 Implementing Rules as well its 2003 Guidance on Declarations of Interest. Moreover, EFSA's Declarations of Interest (DoI) system, one of the key instruments of its independence policy, has been detailed in 2012 with the adoption of revised Rules on Declarations of Interest. Today, the 2011 Independence Policy and the 2014 recast of the Rules on DoIs constitute the operational framework for EFSA's competing interest management system.

EFSA is committed to regularly review the effectiveness of its competing interest management system and to align it with the evolving institutional and scientific context, as well as with financial and policy priorities. The main challenge that EFSA is facing is not only to maintain a well-functioning and effective system but also to find the right balance between a high level of independence and the availability of best scientific and specialist expertise. This *ex post* evaluation of the implementation of EFSA's independence policy system is part of the review process of EFSA's independence policy, which is currently discussed within the organisation and at governance level, i.e. EFSA's Management Board. A dedicated Working Group has been established to review the policy and a project team within the Agency has been set up to provide input to the discussions[8].

3.2 Key aspects of EFSA's Policy on Independence and Scientific Decision-Making Processes (2011) and DoI Rules (2014)

Main features of EFSA's 2011 Independence Policy

The objective of the Policy on Independence and Scientific Decision-Making Processes (2011) is to ensure the independence of EFSA's scientific decision-making processes. The policy details the independence requirements of the Founding Regulation and provides the conceptual framework for EFSA's Conflict of Interest management.

The main objective of EFSA's policy is to promote a high level of trust among the public in the independence, impartiality and excellence of its scientific advice by preventing the occurrence of Conflicts of Interest. Therefore, the Agency has established a comprehensive

[7] EFSA Policy on Declarations of Interests (MB 11.09.07 - 5.2); EFSA Guidance on Declarations of Interests (MB 11.09.07 - 5.3) and Procedure for identifying and handling potential conflict of interests (MB 11.09.07 - 5.4).

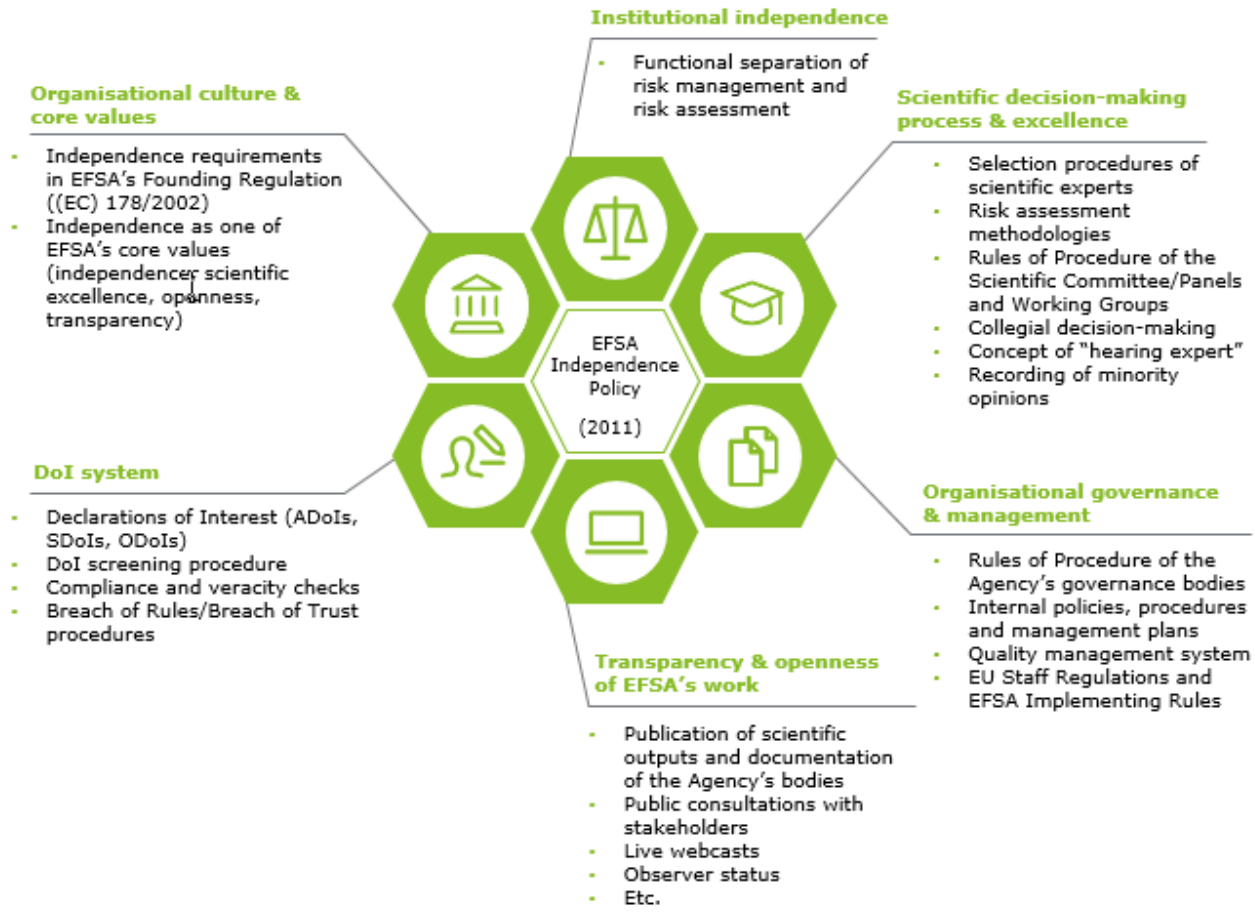
[8] EFSA, Note to the Management Board, "Concept paper on the review of EFSA's Policy on independence and scientific decision making process", 15.06.2016.

set of organisational solutions and procedures to effectively prevent or manage conflicts of interest. EFSA's Independence Policy describes the contribution of these solutions and procedures to secure the independence of its scientific work.

The conceptual approach of EFSA's independence policy is holistic: EFSA's core value of "independence" is reflected in other aspects of its set-up, i.e. organisational governance, operational management, scientific governance, organisational culture and transparency. The 2011 Independence Policy departs from an exclusive focus on the individual expert's independence and the individual's responsibility to ensure compliance with the independence requirements set out in the Founding Regulation.

The key elements of EFSA's 2011 Independence Policy are presented in the figure below:

Figure 2: Key elements of EFSA's 2011 Independence Policy



Source: Deloitte

One of the key instruments of EFSA's competing interest management system are Declarations of Interest (DoIs). The disclosure of interests via the DoIs allows to identify potentially conflictual interests and to take appropriate actions to mitigate the occurrence of CoIs. EFSA's current DoI system will be described in more detail in the following sections.

2014 DoI rules and procedures applicable to EFSA's scientific experts

The main target group of the DoIs are the scientific experts (i.e. members and external experts) participating in the work of the Agency's Scientific Committee, Panels and Working Groups, which deliver opinions on scientific risk assessment to the Commission. A comprehensive set of DoIs has been put in place for scientific experts, who have to declare their interests at three different moments in times, i.e. Annual Declarations of Interest (ADoIs)[9] which are drafted/updated once a year, Specific Declarations of Interest (SDoIs), required for every meeting of a specific Panel, Committee or Working Group, and Oral Declarations of Interest (ODoIs)[10]. ODoIs are performed at the start of each meeting and complement ADoIs and SDoIs (all interests which have not been declared prior to the meeting in written form). In some instances, for example Working Groups with only one specific mandate, the current system of SDoIs and ADoIs leads to a duplicative effect. In addition, a declaration concerning confidentiality and declaration of commitment has to be signed by scientific experts.

As EFSA acts as Appointing Authority for scientific experts in the Panels and Working Groups, which are selected via an open call for expression in application of transparent and predetermined criteria, the Agency is requesting prior to their selection the submission of an ADoI in order to prevent any potential Conflict of Interest (CoI).

The DoI Rules stipulate the responsibility of the individual expert to provide correct and complete information on any current declarable interest or activity as well as those which occurred within the past five years.

The 2014 DoI Rules define specific interest categories: economic interests, management or scientific advisory functions, employment, occasional consultancy, research funding, intellectual property rights, other membership or affiliation or other relevant interests falling in the remit of EFSA's mandate and activities. To facilitate the Declarations of Interest for the scientific experts, the current DoI Rules have clarified the definition of the interests and of the cases leading to the insurgence of conflicts. Moreover, the rules specify the screening criteria and the consequences applicable in case a competing interest is identified. The acceptability of an interest might differ with regard to the status of the organisation the expert is / has been working for. In fact, EFSA's DoI rules makes a distinction between Food Safety Organisations (FSOs) and non-Food Safety Organisations (non-FSOs). This (non-) FSO classification directly impacts the eligibility of a scientific expert to work for EFSA or restrict his/her involvement in the activities of the Scientific Committee, Panel or Working Group (e.g. exclusion from applying for a Chair or Vice Chair position).

The assessment of the DoIs is performed in regards to three elements: the potentially competing interest is scrutinised against the nature of task(s) to be performed by the

[9] The ADoI is used to decide on the person's general eligibility with respect to the relevant activity within EFSA.

[10] The SDoI and ODoI are used to identify whether the member of EFSA's Scientific Committee, Scientific Panel, Working Group or external expert who is already member of the concerned group should abstain from the discussion of a specific item on the agenda or from participating to a specific meeting of that entity.

expert, the mandate of the specific group, as well as the expert's role and function. The European Parliament and the NGO community have repeatedly recommended to the Agency to perform the screening of interests against the remit of EFSA's mandate[11]. On the basis of the results of the screening, appropriate actions – which may vary from case to case given the specific interests and situation of the individual expert – are adopted.

The current rules impose no generalised 'cooling-off' period for any activity exercised in the past in the private sector. For specific cases, e.g. past employment in the private sector within the past two years, a cooling-off period is applicable. However, a generalised two-years cooling-off period on all material interests related to companies it regulates has been one of the recurrent requests of the European Parliament to the Agency[12]. In 2016, the Executive Director of EFSA committed publicly to the European Parliament to implement such approach in its response to the discharge procedure for financial year 2014.

The current approach of the DoI rules also do not make any distinction regarding the risk profile of the scientific expert (i.e. risk-based approach).

To mitigate the risks of the lack of available scientific or highly specialised expertise (due to the strict independence requirements) the current 2014 DoI rules provide for two options: the concept of a 'hearing expert' (Article 11) and waivers (see Article 16). Hearing experts are individuals with a specific expertise or relevant knowledge, who can be invited to give a presentation or provide information during meetings of a Scientific Committee, Panel or Working Group, but however are excluded from the drafting and adoption of scientific outputs. Waivers can be granted to scientific experts, for which competing interests have been identified, but have an expertise which is considered essential for the decision-making process and for which no suitable alternative expert is available. Waivers may be issued only at WG level and not for WGs dealing with "regulated products", the rationale being that areas more prone to the insurgence of potential CoIs due to their interest for industry should be excluded from this additional degree of flexibility.

As the potential reputational risk linked to a Conflict of Interest might not suffice to ensure compliance, the 2014 DoI Rules provide for two procedures to secure a high level of compliance of the scientific experts with the rules, and – as a side effect – increase the accuracy and quality of information submitted in the DoIs. The 'compliance and veracity check' (Article 14) assesses on a limited set of selected experts the compliance with information and procedural requirements as well as the veracity of the information provided on declarable interests. Subsequently, the identification of a CoI resulting from the omission of a declarable interest, revealed by the compliance and veracity check, initiates a Breach of Rules or Trust procedure (Article 15). The BoT procedure may also be initiated as a result of "whistle-blowing"[13] complaints submitted to EFSA (i.e. serious

[11] European Parliament decision of 29 April 2015 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2013 (2014/2108(DEC)).

[12] European Parliament decision of 28 April 2016 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2014 (2015/2176(DEC)).

[13] The Deloitte "High level analysis and input paper regarding future orientations regarding the EFSA DoI policy and its Implementing Rules" (2014) recommended to EFSA to put in place an institutionalised "whistle-blower"

irregularities discovered in the course of or in connection with independence policy procedures which are reported to EFSA) as well as a proactive investigation from EFSA beyond the regular compliance and veracity checks.

2014 DoI rules and procedures applicable to Agency staff

As EFSA staff is involved in the scientific decision-making process at different levels, in particular by providing support to the activities and work of the Scientific Committee, Panels and Working Groups, the 2014 DoI Rules also establish a comprehensive system to secure the independence of EFSA's staff. However, the current rules do not take account of differences in varying risk levels/risk profiles (e.g. staff in scientific functions are more exposed to potential CoIs). EFSA staff has to proactively declare competing interests and comply with independence requirements set out in the EU's Staff Regulations, EFSA's DoI Rules and EFSA's Code of Good Administrative Behaviour. The 2014 DoI Rules commit EFSA staff to:

- Declare interests during the selection and recruitment procedure;
- After having commenced working with EFSA, submit annually and regularly update ADoIs;
- Declare any negotiation with prospective employer(s) (EFSA may impose restrictions in case a potential CoI has been identified);
- Notify EFSA within two years of the end of the contractual relationship any professional activity to be undertaken.

For transparency reasons, EFSA makes the ADoIs of Agency staff in managerial positions available online. Moreover, EFSA communicates in its Annual Activity Reports on the cases of staff leaving the Agency for the private sector in which restrictions have been adopted. EFSA's Annual Activity Reports also include statistics on its DoI system management, i.e. number of DoIs processed, CoIs prevented as well as resources invested in this activity. However, in its current practice, EFSA does not publish information about senior officials who have left the Agency, as requested by the European Parliament[14].

Similar to the cooling-off period for EFSA's scientific experts, the European Parliament and the NGO community suggested to the Agency to adopt a "revolving door[15] policy" [16], clarifying the rules by which the Agency manages the employment of staff having a potential CoI given their previous work in the agri-food industry (e.g. restrict the employment or refrain from the appointment of staff) or impose conditions after the departure of staff to functions in the private or regulatory sector in the agri-food sector.

process. The Report on the Implementation of EFSA's Anti-Fraud Strategy, presented to the Management Board in December 2016, indicates the adoption of implementing rules on whistle-blowing in the course of 2017.

[14] European Parliament decision of 28 April 2016 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2014 (2015/2176(DEC)).

[15] The movement of key personnel between the public and private sector is known as the "revolving door" phenomenon. (See definition according to § 81, European Court of Auditors' Special Report No 15/2012 'Management of conflict of interest in selected EU Agencies')

[16] European Parliament decision of 28 April 2016.

Moreover, the 2014 DoI Rules recognise the importance of training of Agency staff to secure a high level of compliance, for the effectiveness of the system (Article 25) and to establish an advisory function for independence related issues. Basic trainings and information sessions are provided to Agency staff.

2014 DoI rules and procedures applicable to EFSA's governance bodies

Although the members of EFSA's governance bodies are not directly involved in the scientific decision-making process, EFSA's independence policy and 2014 DoI rules define independence requirements for the members of EFSA's Management Board and the Executive Director. In addition to the exercise of signing a declaration on commitment and confidentiality, the members are required to submit annually an ADoI. Similar to the DoI policy for EFSA's scientific experts, ODoIs are a constitutional part of the MB meetings and recorded in the meeting minutes, which are published online.

In contrast to the notification requirement applicable to Agency staff and management leaving EFSA, members of the MB are not required to inform the Agency of any professional activity taken up within the two years after the end of their mandate.

2014 DoI rules and procedures applicable to experts appointed by Member States

In line with the principle of subsidiarity, the DoIs of experts involved in EFSA's work that are appointed under the exclusive responsibility by Member States, are exempted from screening by EFSA.

While members of the EFSA's Advisory Forum have to complete an ADoI by law, members of peer review groups in the area of pesticides risk assessment, are invited to complete and submit – for transparency reasons only – an annual DoI. No legal requirement to submit an ADoI is actually contemplated in the 2014 DoI rules. EFSA takes note of DoIs submitted by Member States representatives, and no screening or validation is performed on them. In contrast, external experts participating in these groups, appointed by the Agency, have to comply with all EFSA's DoI rules applicable to scientific experts, i.e. submit an ADoI and declare their interests in form of SDoIs and ODoIs.[17] Hence, EFSA performs a full-fledged screening and validation of DoIs submitted by external experts participating in peer review meetings.

The table below summarises the current DoI system for the different target groups.

[17] EFSA: Decision of the Executive Director of the European Food Safety Authority concerning pesticides risk assessment peer review, 18.09.2015, see Article 8.

Table 2: Overview of types of DoIs and rules for the different target groups

Level	Target group	DoI	Screening
Scientific experts[18]	*Scientific Committee* *Scientific Panels* *Working Groups* *Other external experts*	• ADoI • SDoI • ODoI • Declaration on commitment and confidentiality	Full and systematic screening of all declared interests against EFSA's rules on DoIs
	Peer review meeting	• ADoIs *(facultative for Member States representatives)* • SDoIs *(only external experts)*	Screening required for external experts not representing Member States For Member States representatives no screening required
	Networks	• ADoI *(facultative)*	No screening needed
	Hearing experts	• ADoI before meeting *(facultative)*	No screening needed
	Observers	• No DoI required	Not applicable
EFSA governance bodies and EFSA staff[19]	*Management Board*	• ADoI • Declaration on commitment and confidentiality	Screening required, assessment provided by the Executive Director and Decision taken by the Management Board
	Executive Director	• ADoI • Declaration on commitment and confidentiality	Screening required and performed by the Management Board
	Advisory Forum	• ADoI • Declaration on commitment and confidentiality	No screening needed
	Staff	• ADoI • Negotiation with prospective employers	Responsible officer
Tenderers[20]	*Tenderers participating to EFSA procurement procedures*	• Institutional DoI in cases of outsourcing of sensitive scientific matters	Screening required and performed by The Head of Unit and by the evaluation committee. Decision lies with Authorising Officer
	Tenderers and participants to grant awarding procedures	• Individual DoI in cases of outsourcing of sensitive scientific matters	Screening performed by the Head of Unit and by the evaluation committee. Decision lies with Authorising Officer

Source: Deloitte

[18] Article 8-16, *supra*.
[19] Article 17-20 of the Decision of the Executive Director of the European Food Safety Authority on Declarations of Interest.
[20] Article 20-23 of the Decision of the Executive Director of the European Food Safety Authority on Declarations of Interest.

Operational support to the implementation of EFSA's independence policy

One of the **major changes** to the assessment of the DoIs of scientific experts during the period 2014-2017 was introduced at organisational level in the set-up of the DoI screening process.

In reply to the request of the European Parliament, EFSA has **centralised** the validation of the DoIs submitted by scientific experts, introducing a new layer of independence in the DoI assessment itself. Positive effects are expected in terms of consistency of the assessment and levels of compliance rates. The shift from the validation performed by the competent scientific units (i.e. in charge of providing the secretariat to the Panels and Working Groups) to staff not involved in the scientific work, i.e. the Legal and Assurance Services Unit (at the time of the signature of the contract for this project – now Legal and Assurance Services Unit (LA)), has been completed recently in 2016. While the pre-assessment of ADoIs and SDoIs continues to be performed by scientific staff – requiring scientific knowledge and the substance of the work/role to be performed by an expert – the final assessment and validation of ADoIs are carried out by the Legal and Assurance Services Unit. The LA is moreover responsible for the coordination of the compliance and veracity checks, involving the Heads of EFSA's scientific departments. The Unit is also coordinating the Committee of Conflicts of Interest meetings as well as the development of SOPs (Standard Operating Procedures) and WINs (Work Instructions). Finally, the LA Unit ensures the delivery of awareness raising sessions.

It further has to be noted that EFSA's DoI processes are facilitated by an **IT tool** which is at the disposal of Agency staff and scientific experts. The DoI tool has been aligned with the 2014 regulatory changes. Due to recurrent technical issues, EFSA is currently in the process of deploying a new version of the engine workflow of the DoI tool to improve efficiency and sustainability. Further efforts are expected to be made in the medium term on finding additional support to optimise the administrative burden for Agency staff and scientific experts alike.

3.3 Main challenges to the implementation of EFSA's independence policy

The Agency cannot improve the system without taking into consideration the structural limits from its political, financial and scientific context. The main challenges which EFSA is currently facing in regards to its independence policy are:

- **(Cost-) effective management of resources:** the Agency's current competing interest management system is resource intense, although efficiency improvements are expected in the medium term from the centralisation of the DoI validation. While facing budgetary constraints, additional resources will be required for further strengthening of the system;

- **Scientific excellence:** the Agency has to find the right balance between a high level of independence and the availability of expertise needed to deliver its opinions. The 2014 DoI Rules are restricting the pool of eligible experts and the adoption of even stricter rules might challenge the sustainability of the Panels' system;
- **Alignment with EFSA's organisational strategy:** in March 2016, EFSA adopted its Strategy 2020, which confirms EFSA's independence as one of the main corporate values and a continuing priority to accomplish the mission of the Agency in line with societal and institutional expectations. It moreover announces a streamlined management of competing interests and a revised independence policy.

Against this background, the Agency has explored various ways to secure its **reputation** as an independent Agency and to address a number of complaints and criticisms towards the Agency expressed by the European Parliament and NGOs. During the 2014-2016 period, EFSA has capitalised on transparency and stakeholder engagement to showcase its independence.

EFSA has taken initiatives to increase **transparency** on its activities as well as the work and functioning of its scientific and governance bodies, i.e. the Scientific Committee and Panels and the Management Board. In this context, EFSA has set up the 'Open EFSA' initiative and the 'TERA' (Transparency and Engagement in Risk Assessment) project[21].

One of EFSA's key transparency instruments is its website via which it makes information available allowing stakeholders and the public to get insight into its work. The Agency thereby facilitates public scrutiny of its processes and scientific outputs by its interested parties. EFSA actively uses its website to publish different types of documents on its independence policy system, e.g.:

- Declarations of Interest and CVs;
- Agendas and minutes of meetings of the Scientific Committee and Panels, including ODoIs;
- Opinions (including minority opinions) and reports;
- Risk assessment methodologies and working procedures;
- Rules of Procedure of the Agency's bodies.

In conjunction with its transparency policy, EFSA has reflected on new ways of **interacting with its stakeholders**, which has led to the adoption of a new approach to stakeholder

[21] EFSA launched its "Open EFSA" initiative in 2014 with the main objective of improving transparency and public access to risk assessment processes and to data. A discussion paper "Transformation to an Open EFSA" was drafted and a public consultation organised soliciting feedback of various stakeholders on the proposed approach and initiatives. In 2015, "Open EFSA" was replaced by the "Transparency and Engagement in Risk Assessment" project, combined with the adoption of an implementation plan. The plan outlines initiatives and actions planned by EFSA until 2019, in view of enhancing opportunities for stakeholder involvement in its work (e.g. open meetings of EFSA's scientific panels) as well as public scrutiny of EFSA's scientific risk assessment processes and workflows (e.g. better access to and availability of data on risk assessment processes; publication of full biographies of EFSA's scientific experts).

engagement in 2016[22]. Furthermore, the 'MATRIX'[23] project has been set up by EFSA to improve efficiency and transparency in the interactions with applicants in the area of regulated product applications.

Finally, EFSA has initiated a project to enhance the **transparency of its scientific assessments** by developing a new methodological framework for evidence-based risk assessment processes, i.e. the 'PROMETHEUS' project (Promoting Methods for Evidence Use in Science)[24].

[22] EFSA: Stakeholder Engagement Approach (2016).

[23] EFSA: Programming Document (2017-2019), p. 16.

[24] EFSA: Consolidated Annual Activity Report (2015), p. 6.

4 Evaluation of EFSA's Independence Policy and Scientific Decision-making and Rules on DoI

This chapter includes the analysis of the main evaluation questions. These insights are drawn based on a comprehensive analysis of different information sources, in particular desk research, interviews and an online survey.

4.1 Contribution to EFSA's reputation

Introduction

In this section, we present our analysis on the following research question:

"*To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 contributed to EFSA's reputation?*"

The aspect of reputation can be seen from different angles, on the one hand from the viewpoint of different stakeholders, both internal (EFSA staff) and external (experts, NGOs, industry representatives, Members of the European Parliament, etc.). On the other hand, the reputation of EFSA can be linked to different aspects of EFSA's core activities such as: scientific research, application handling, communication and creating awareness, etc. In our assessment, we look onto EFSA's reputation from a holistic point of view.

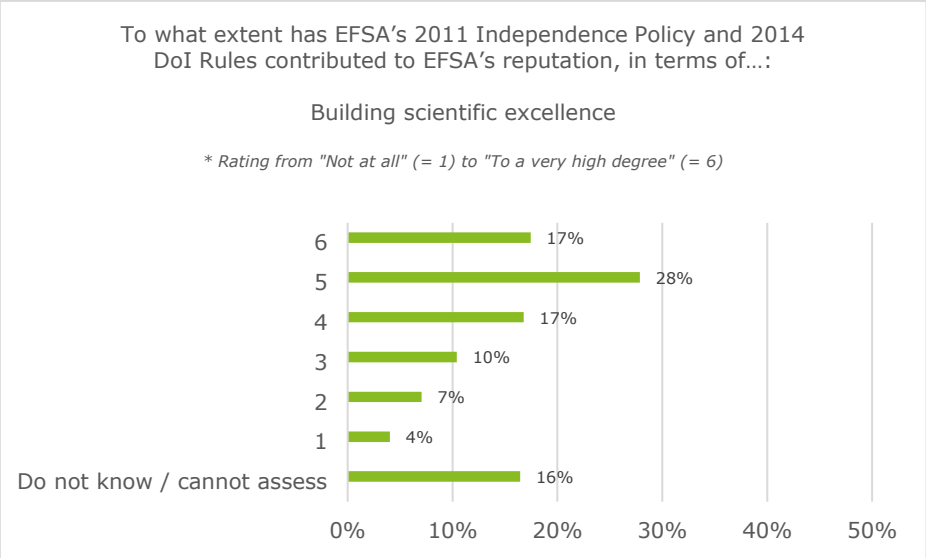
Main analysis

Since the foundation of EFSA, the organisation has received criticisms on its independence, mostly by a vocal group of non-governmental organisations (NGOs) and consumer associations which has been confirmed during interviews and is moreover illustrated by a number of open letters addressed to the Agency and articles published by NGOs and consumer associations on conflict of interest cases at EFSA (see Annex D). Furthermore, EFSA's independence has been challenged by very active number of members of the European Parliament represented in the ENVI and BUDG Committees, for which interviews as well as the EP's conclusions on EFSA's independence in the Annual Discharge Reports provide evidence.

By contrast, the organisation is perceived by interviewed Commission officials and EFSA's scientific experts as a professional institution, developing sound scientific expertise in the field of food safety and consumer protection while remaining independent and transparent.

The results of Deloitte's expert survey revealed that more than 60% of EFSA's surveyed scientific experts consider that EFSA's 2011 Independence Policy and 2014 DoI Rules have contributed to the organisation's reputation for building scientific excellence (see graph below).

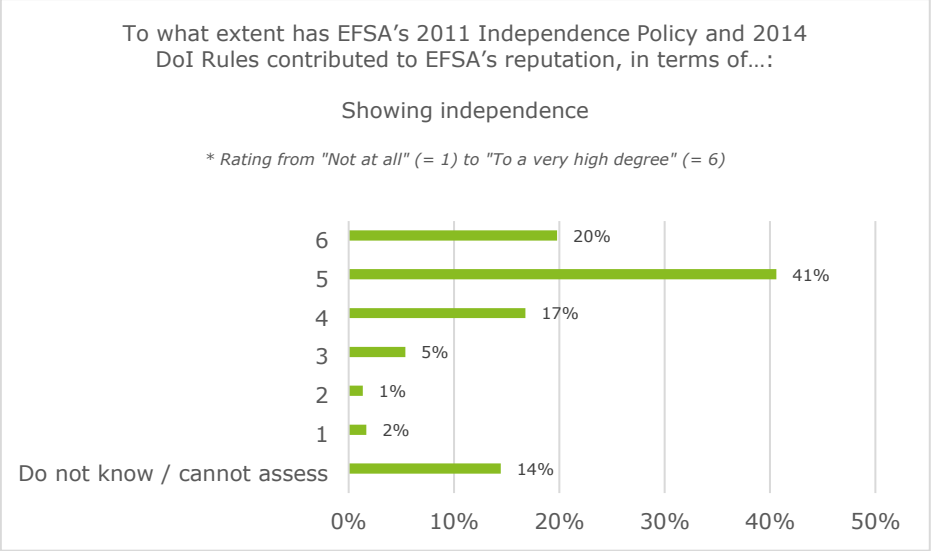
Figure 3: Contribution of EFSA's Independence Policy and DoI rules to EFSA's reputation, in terms of building scientific excellence



Source: Deloitte Expert Survey (2017)

Moreover, the online survey shows similar results on the topic of EFSA's reputation regarding independence. A majority of respondents perceive that EFSA's 2011 Independence Policy and the 2014 DoI Rules have largely contributed to protecting EFSA's image as an independent organisation.

Figure 4: Contribution of EFSA's Independence Policy and DoI rules to EFSA's reputation, in terms of showing independence



Source: Deloitte Expert Survey (2017)

Interviewed EFSA staff and management describe the reputation of its organisation as sound and indicate that EFSA has installed the required safeguards (i.e. the Independency Policy and Implementing Rules on DoI) to protect its independence. Indeed, when comparing EFSA's system in place with OECD guidelines[25] and European guidelines[26] on conflict of interest management, EFSA has been able to comply with these standards to a large extent[27]. Still, a majority of interviewees believe that EFSA will remain systematically criticised today and in the future by specific interest groups as long as EFSA evaluates sensitive topics such as GMOs, pesticides, etc.

Strengthening reputation via transparency and openness

One key aspect of strengthening the organisation's reputation is remaining vigilant to adhering to EFSA's core principles of transparency and openness, as was especially raised during interviews with NGOs and a representative of an MEP.

Several academic sources (also from non-food safety areas) investigated for this evaluation indicate that transparency is key in the independence debate:

- "A key argument in favour of transparency declarations is that even if they cannot capture all sources of bias, they are considerably better than not capturing any"[28];

[25] OECD (2003): Managing Conflict of Interest in the Public Service

[26] Inter-institutional Working Group on EU decentralised agencies (2013): Guidelines on the prevention and management of conflict of interest in EU decentralised agencies.

[27] Deloitte (2014): Input document to inspire the debate between EFSA and its stakeholders regarding the future of the EFSA DoI policy and its Implementing Rules.

[28] Addiction Journal (2014): McCarthyism, conflict of interest and Addiction's new transparency declaration procedures (p. 109)

- "Disclosure is generally considered preferable to non-disclosure, because it makes explicit and transparent details that are important to the interpretation, credibility and value of the information presented"[29];
- "Although some reformers seek to manage or eliminate conflicts of interest in specific domains, the most common policy response to conflicts of interest is to disclose them"(…) "Supporters of disclosure argue that transparency (…) protects the public by reducing information gaps between conflicted advisors and recipients of their advice"[30].

In this context, EFSA has made clear efforts in disclosing more information to the general public by for example webcasting specific meetings (e.g. Management Board meetings), sharing minutes of the meetings of the Panels and Working Groups on their website, etc. Another example of EFSA's transparency practice is EFSA's Register of Question database[31] via which the Agency makes publicly available requests for opinion submitted by the European Commission, the European Parliament or the Member States, as well as related information and reports on the status of assessment of the individual request.

Also on the topic of strengthening its transparency, is the level of involving key stakeholders, such as for example the 'Open EFSA' initiative, which was launched mid-2014. Aiming for a more direct engagement with external stakeholders and the public on food safety related topics, EFSA has been rolling out several transparency and risk assessment actions (TERA project)[32]. Full implementation is planned by end of 2019. In addition, EFSA has made considerable investments in setting up permanent and targeted stakeholder platforms[33], enabling interested parties to share valuable insights on the topic of Independence, Transparency and Openness.

[29] PLoS Medicine Editors (2012): Does Conflict of Interest Disclosure Worsen Bias (p. 1)

[30] Cain et al. (2011): When Sunlight Fails to Disinfect: Understanding the Perverse Effects of Disclosing Conflicts of Interest

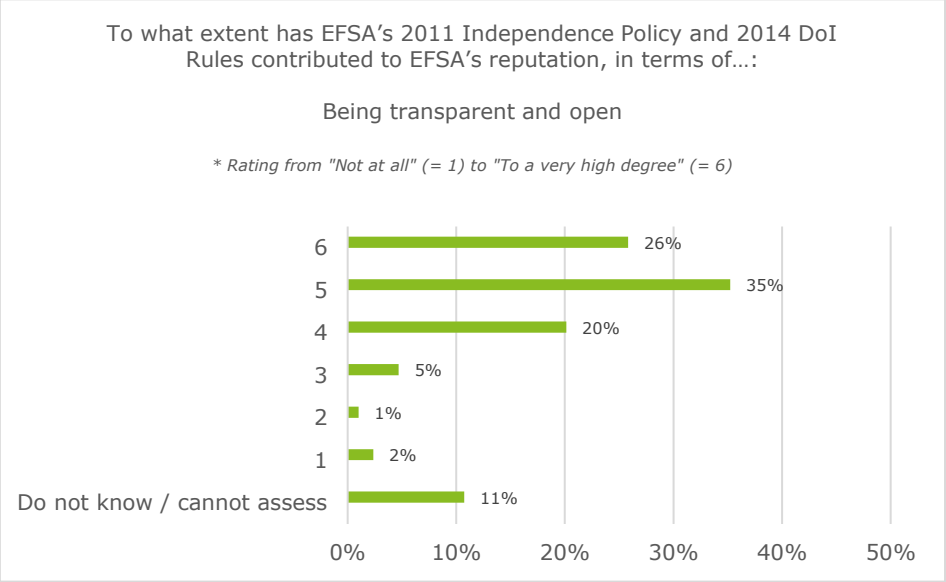
[31] http://registerofquestions.efsa.europa.eu/roqFrontend/ListOfQuestionsNoLogin?0&panel=ALL

[32] 69th Management Board Meeting: Board adopts new stakeholder approach, takes stock of progress on transparency, discusses independence policy enhancement: https://www.efsa.europa.eu/en/events/event/160615

[33] EFSA – EFSA Stakeholder Engagement Approach (2016)

Surveyed on the topic of transparency and openness, EFSA's scientific experts confirmed by majority that EFSA's 2011 Independence Policy and 2014 DoI Rules contributed at a high degree in promoting EFSA's reputation as a transparent and open institution.

Figure 5: Contribution of EFSA's Independence Policy and DoI rules to EFSA's reputation, in terms of being transparent and open



Source: Deloitte Expert Survey (2017)

A risk to reputational loss

As mentioned previously, the independence of EFSA's scientific experts and of the scientific decision-making process is called into question by some external stakeholders. No clear evidence could be provided on why the reputation of EFSA would have diminished, besides possibly not being responsive enough in specific dossiers (e.g. ECJ Case C-615/13 P), which adds to a negative perception of the organisation's reputation. The results of the evaluator's screening of coverage in EU online media regarding independence issues at EFSA suggest that EFSA critical articles are often signed by a small but vocal group of NGOs and consumer associations, with some negative reporting on conflict of interest issues in traditional media, especially in the context of glyphosate debates (see Annex D). This is particularly the case during the review period 2014-2016.

Moreover, two complaints[34][35] to the European Ombudsman have been raised on EFSA's conflict of interest management in the period 2014-2016. For both cases, the EO has opened an inquiry. In parallel, two cases investigated by the European Ombudsman since

[34] European Ombudsman inquiry into complaint 747/2016/ANA against EFSA: "EFSA's handling of the review of the Threshold of Toxicological Concern (TTC)", (Date of case opening: 29 August 2016)

[35] European Ombudsman inquiry into complaint 176/2015/JF against EFSA: "Handling of a set of questions concerning an application for authorisation of a genetically-modified ('GM') maize", (Date of case opening: 5 May 2015).

2011[36] and 2013[37] have been closed with a critical remark. We refer to Annex D for more details on the allegations against EFSA as well as the recommendations addressed by the European Ombudsman to EFSA.

EFSA is fully aware of the reputation challenges it faces, as became apparent in the 2014 risk management workshop with the EFSA Management Team[38], where a loss of reputation was identified as a significant risk: "EFSA becoming a questioned, frequently challenged reference at large, hence defeating its role as authority". Consequently, a risk action plan was set up. However, one year later (2015), this risk was still defined[39] as significant.

4.2 Contribution to a high level of food safety and consumer protection

Introduction

In this section, we present our analysis on the following research question:

"To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 contributed to a high level of food safety and consumer protection?"

Contributing to ensuring a high level of food safety by delivering trusted regulatory science is the core mission of EFSA. As such, it is imperative that all horizontal and vertical activities contribute to this mission. The Independence Policy plays an important role in that regard. In our analysis, we focus on two key elements: the scientific decision making process, and the potential risk of the current system in safeguarding a high level of food safety and consumer protection.

Main analysis

During the reference period 2014-2016, EFSA is regarded by the majority of interviewed stakeholders as an institution providing high quality scientific advice and is moreover recognised as a leading institution in the area of food safety. EFSA has adopted an impartial scientific approach to risk assessment, with a high scrutiny level, effectively avoiding 'regulatory capture' by industry. Although it is indisputable that EFSA is regularly

[36] Decision of the European Ombudsman closing the inquiry into complaint 2522/2011/(VIK)CK against EFSA: "Alleged failure to guarantee the independence of the TTC working group and related claim" (Date of case closure: 27 March 2014).

[37] Decision of the European Ombudsman closing the inquiry into complaint 346/2013/SID against EFSA: "Alleged failure to address the Conflict of Interest issues raised in respect of certain members of the Working Group on Genetically Modified Insects and the related claim", (Date of case closure: 30 January 2015).

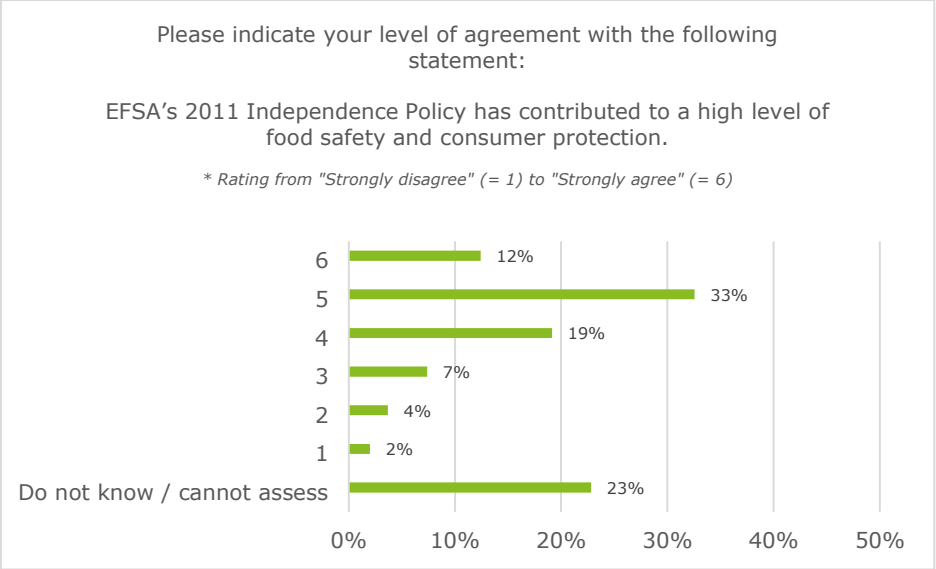
[38] EFSA – EFSA Programming document 2015-2017 (2014), p. 51.

[39] EFSA – EFSA Programming document 2016 – 2018 (2015)

put under the spotlight and is criticised in high profile cases arising media attention (see Annex D), the number of incidents is limited. In this respect, EFSA could improve its communication and showcase the soundness of its scientific outputs, for instance by reporting on the number of inconclusive or negative opinions adopted by its Scientific Panels, e.g. by providing statistics on this on the EFSA website.

From the perspective of scientific experts, as is visible in the graph below, a significant group of surveyed scientific experts attribute a positive contribution to EFSA's 2011 Independence Policy in promoting a high level of food safety and consumer protection. However, a noticeable number of survey respondents cannot assess the statement, which suggests that the Agency could improve its communication on the contribution of the current independence policy system to a high level of food safety and consumer protection and explain more explicitly the direct causal link.

Figure 6: Contribution of EFSA's Independence Policy to a high level of food safety and consumer protection



Source: Deloitte Expert Survey (2017)

Growing ability in preventing potential Conflicts of Interests

The independence system in place allowed EFSA to increasingly prevent potential Conflicts of Interests over the past years, resulting in not a single Breach of Trust case since 2013, as can be noted in the table below. Several elements play a role in the decrease in prevented Conflict of Interests:

- a steady improvement of the quality of submitted DoIs;
- the adoption of effective risk mitigation measures, such as leading experts to resign from conflictual activities.

Table 3: Number of potential CoIs prevented and Breach of Trust cases

	2014	2015	2016
Potential CoIs prevented (ADoIs+SDoIs)	145	96	107
Breach of Trust cases	0	0	0

Source: EFSA, Concept paper on the review of EFSA's Policy on independence and scientific decision making process, 2016, p. 5

Procedural independence safeguards in EFSA's scientific decision-making process

EFSA's scientific decision making process encapsulates the core in protecting food safety and consumers within Europe. Different procedural elements have been put into place by the 2011 policy and the 2014 DoI Rules to safeguard high independence such as:

- independence is one of the exclusion criteria during the selection and appointment procedure of members for the Agency's Scientific Committee, Panels and Working Groups;
- general principle of exclusion of scientific experts from the assessment or review of their own work (Article 3h of EFSA's 2014 DoI Rules);
- in case of a Breach of Rules, a review of the scientific outputs to which the expert in question has contributed is performed by the Internal Audit Capability (Article 15 (5) of EFSA's 2014 DoI Rules);
- Rules of Procedures[40] are in place for the Scientific Committee, the Scientific Panels and their Working Groups, ensuring coherence in their way of working, preventing biased scientific outputs;
- a consensus-oriented, collegial decision making is the driver in the development and adoption of scientific outputs in the Agency's Scientific Committee, Panels and Working Groups which limits the risk of one biased view dominating a scientific output. Different viewpoints are published in the final scientific outputs (including minority opinions).

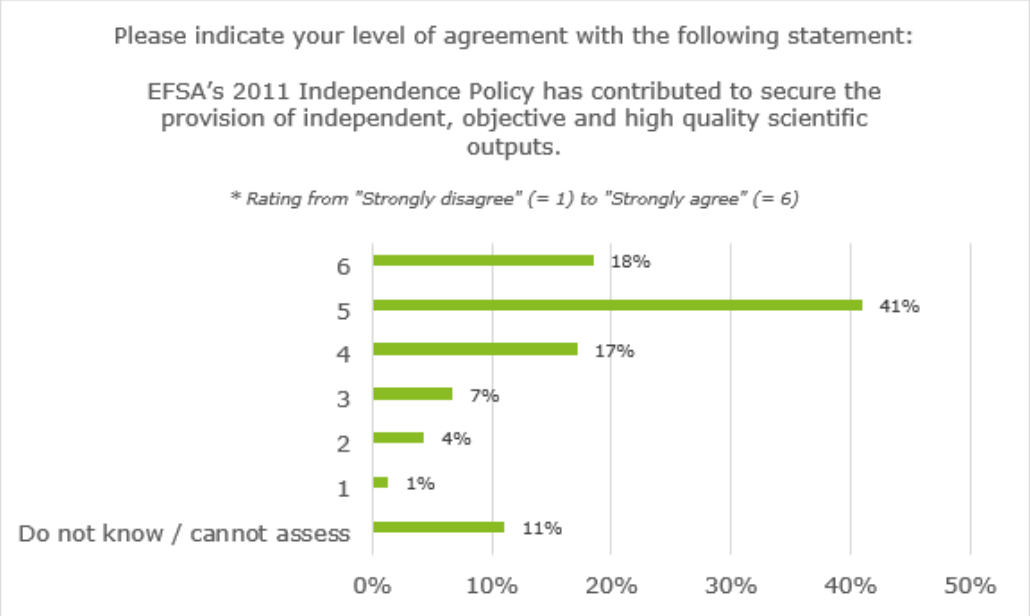
Asked to comment on the independence of the Agency's scientific decision making process, interviewed EFSA staff and management from different organisational departments expressed a positive contribution of EFSA's Independence Policy and Scientific Decision-making and Rules on DoI to EFSA's core mission, enabling high food safety and consumer protection[41]. The system in place facilitates EFSA to construct robust, objective scientific opinions by identifying potential Conflicts of Interest at an early stage.

[40] http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/paneloperation.pdf

[41] EFSA (2011): Technical Report of EFSA – Outcome of the public consultation on the Draft Policy on Independence and Scientific Decision-Making Processes

EFSA's surveyed scientific experts share a similar view: more than 59% of respondents highly agree with the statement that EFSA's 2011 Independence Policy has contributed to a secure provision of independent, objective and high quality scientific outputs.

Figure 7: Contribution to EFSA's Independence Policy to independent, objective and high quality scientific outputs



Source: Deloitte Expert Survey (2017)

Potential risks to safeguarding a high level of food safety and consumer protection

Yet, the current system does imply potential risks related to the availability of scientific resources. Several interviewed EFSA staff members raised the concern that a continuation or even strengthening (in terms of level of rigidity of rules) of the current system can potentially diminish the number of available scientific experts in the future. Interviewees pointed to the fact that a number of EFSA's Scientific Panels are made up of more experienced experts whilst it seems that younger experts are more difficult to attract. This situation can risk putting pressure on the expert panel system EFSA is relying upon by law to contribute maintaining a high level of food safety and consumer protection.

4.3 Provided value for money to ensure the policy's implementation

Introduction

In this section, we present our analysis on the following research question:

"To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 provided value for the money the Authority invested to ensure the policy's implementation?"

The aspect 'value for money' can be interpreted in different ways. In terms of clarity, the study team judged value for money on three main aspects:

- The system in place is considered by stakeholders to deliver the expected results;
- The costs of the system are considered to be proportionate compared to the outputs produced;
- The Agency has taken actions to improve the overall cost-effectiveness of the system.

Main analysis

Human resources

In terms of **staff** assigned to the management of EFSA's Independence Policy System, the number of Full Time Equivalents (FTE) has remained rather stable in the period 2014 – 2016, as can be seen in the table below. The tasks of staff working on independence related processes prior to the centralised validation of DoIs by the LA Unit and the decentralised assessment by the Scientific Departments include:

- Screening of DoIs;
- Compliance & veracity checks;
- FSO classification;
- Independence Policy & implementing rules review;
- Trainings.

Table 4: Evolution of staff resources allocated to the management of the independence policy

	2014	2015	2016	2017
Staff working on independence processes in EFSA's Departments/Units (FTE)	Not available	1.75[42]	1.01[43]	1.23[44]
Staff working on independence processes in EFSA's LA Unit (FTE)	Not available	0.41	1.54	1.91
Total number of staff working on independence processes (FTE)	3	2.16	2.55	3.14
Share of FTEs in LA Unit/total number of FTEs working on independence processes (%)	N/A	18.9	60,4	60,82

Source: EFSA (Legal and Assurance Services Unit)

Cost of the Independence system

For the calculation of the costs of the current system, the costs for IT operations, staff managing the independence process, as well as specific costs for the management of the independence system have been taken into account. For the period 2014-2017, EFSA invested on average € 558,526 per year in the system.

An increasing trend is noticeable (2015 – 2016) in absolute numbers, which can be mainly explained by substantial IT investments but also higher HR costs, which is illustrated by the figure below.

[42] FTE breakdown per EFSA Unit/Department (2015): ALPHA (0.00); RASA (0.00); AMU (0.00); AFSCO (0.02); PTT/ITS (0.02); FIP (0.02); DATA (0.02); PRAS (0.03); FEED (0.09); RESU (0.09); NUTRI (0.12); REPRO (0.13); GMO (0.15); RESU (0.16); SCER (0.17); BIOCONTAM (0.18); SCISTRAT (0.64).

[43] FTE breakdown per EFSA Unit/Department (2016): RESU (0.001); AMU (0.002); EXREL (0.01); AFSCO (0.02); PTT (0.02); REPRO (0.024); FEED (0.024); RASA (0.041); ED (0.06); NUTRI (0.07); BIOCONTAM (0.073); GMO (0.10); PRAS (0.11); FIP (0.125); SCER (0.142); ALPHA (0.19).

[44] FTE breakdown per EFSA Unit/Department (2017): DATA (0.02); RASA (0.03); ED (0.03); FEED (0.05); PRAS (0.05); COMMS (0.07); REPRO (0.08); NUTRI (0.10); PTT (0.11); GMO (0.15); FIP (0.15); SCER (0.15); BIOCONTAM (0.24).

Figure 8: Costs for the operation and management of EFSA's current independence policy system (2014-2017)

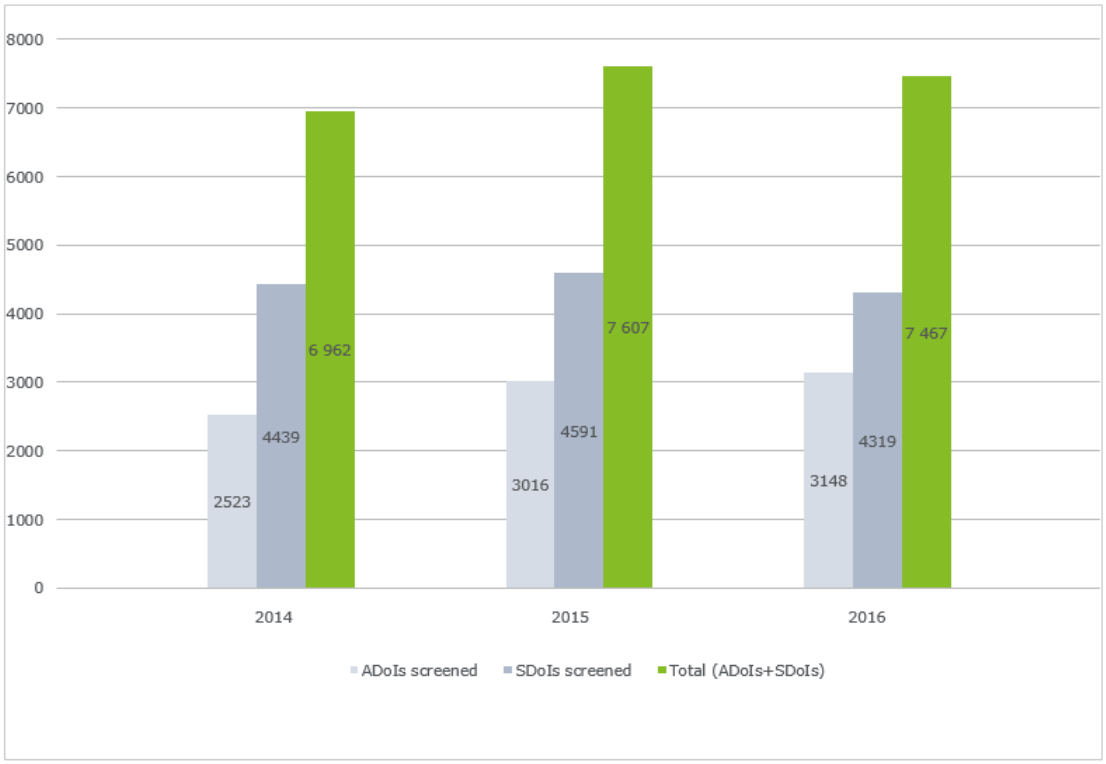
Sources: EFSA Annual Activity Reports (2014-2015), EFSA Annual Budgets (2016-2017), EFSA LA Unit

As mentioned in the previous chapter, an IT tool is used to automate part of the DoI management process. As indicated in the table above, the cost of the tool has decreased significantly compared to 2014. This trend is to be expected given that the maturity of the tool increases over time, which leads to a lower need for new developments or extensive maintenance of the tool. However, given the disadvantages of the current tool (slow, unstable, etc.), it has been decided within EFSA to commence with the development of a new tool, which explains the sudden budget surge in 2016 and budgeted for 2017.

Stable level of outputs compared to resources

In the context of stable financial resources available for the management of its independence policy system, decreasing IT costs and a stable number of FTEs, EFSA has been able to reach a steady set of outputs, as illustrated by the number of screened ADoIs and SDoIs in the figure below.

Figure 9: Outputs of the DoI assessment



Source: EFSA Annual Activity Reports (2014-2015)/EFSA LA Unit

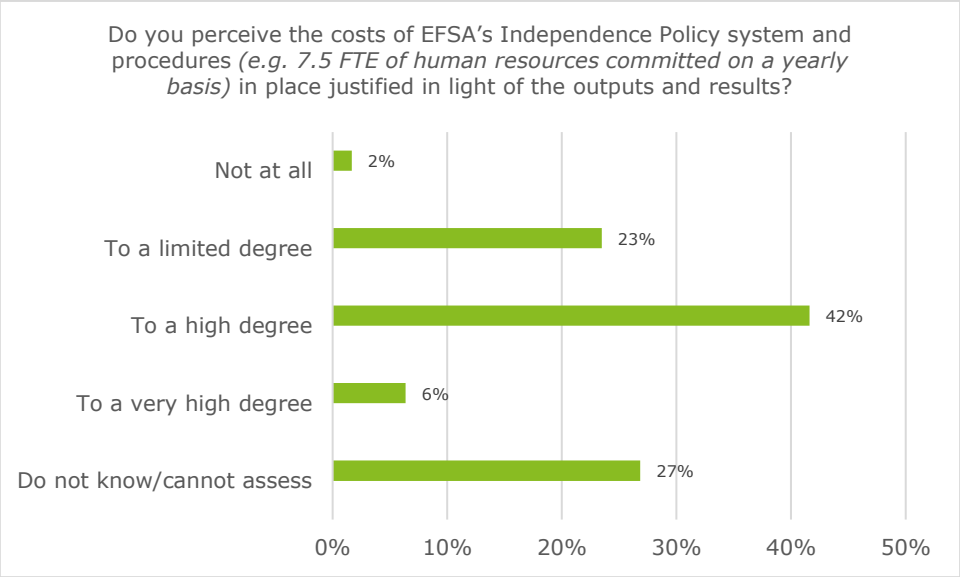
When looking at the period 2014-2016, EFSA has been able to increase its DoI management outputs (DoIs screened) by 7%.

Perceived as costly but required

From a qualitative perspective, several interviewees (both internal [EFSA staff and management] and external [EU Commission and Parliament representatives]) perceive the system as being relatively expensive. However, the costs need to be put into the perspective of EFSA's political environment. EFSA is facing constant pressure to mitigate any potential risk for Conflicts of Interest, and to remain vigilant to the expectations of the outside world in terms of openness, transparency and rigidity.

In general, the responses of surveyed scientific experts on the cost-effectiveness of the current system converge with the view of EFSA staff and management, as illustrated by the figure below. Nearly half of all respondents believe to either a high or very high degree that the cost of EFSA's Independence Policy system and procedures is justified, while close to a quarter (23%) of the respondents also agree yet to a lesser extent. Interestingly, just over a quarter (27%) of respondents claim not to have insight into this topic and therefore cannot assess this question, which might indicate EFSA could communicate more openly on the resource-intensity of the current system in particular to raise awareness about the financial implications of the system, in particular in light of the sustainability debate.

Figure 10: Cost-effectiveness of EFSA's independence policy system and procedures



Source: Deloitte Expert Survey (2017)

4.4 Relevance, effectiveness, efficiency and proportionality of the Policy on independence, scientific decision making process and DoI procedure

Introduction

In this section, we present our analysis on the following research question:

"To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 2014 relevant, effective, efficient and proportionate to the policy objective of ensuring compliance with the Independence requirements laid down in Regulation (EC) No 178/2002?"

This evaluation question looks into the core working methods, procedures, processes, organisational frameworks and tools in place to support a rigid Independence Policy system. We approach this question both from a quantitative and qualitative perspective, taking into account different sources of information.

Main analysis

Relevance of the current independence policy system

From a legal point of view, the Independence policy plays a vital relevant role for EFSA. In its Founding Regulation (EC) No 178/2002 the notion of Independence and consequently the need for a supporting system is explicitly defined (art 37)[45]. To the question whether the Independency Policy remains relevant from an operational point of view, several sources indicate this is indeed the case. The system has allowed EFSA to install a rigid approach in maintaining an objective and independent risk assessment process when developing scientific outputs. All relevant stakeholders (EFSA staff, EU Commission representatives, EU Parliament representative, NGO, industry representative) confirmed during interviews, there is still a need to maintain the system, for different reasons such as:

- the rising trend of public - private partnerships, including Horizon 2020 incentives, contributing to the perception of greater risk of Conflicts of Interest among scientific experts;
- complaints or cases concerning transparency or independence raised with the European Ombudsman or the European Court of Justice, which reaffirm the need for a rigid independence policy system (see Annex D).

The findings of the screening of EU online media, i.e. negative reporting on EFSA's independence (e.g. glyphosate debate) and on in individual conflict of interest cases (e.g. selection of experts for the GMO Panel) provide further evidence in this respect (see Annex D).

Higher exposure of specific domains

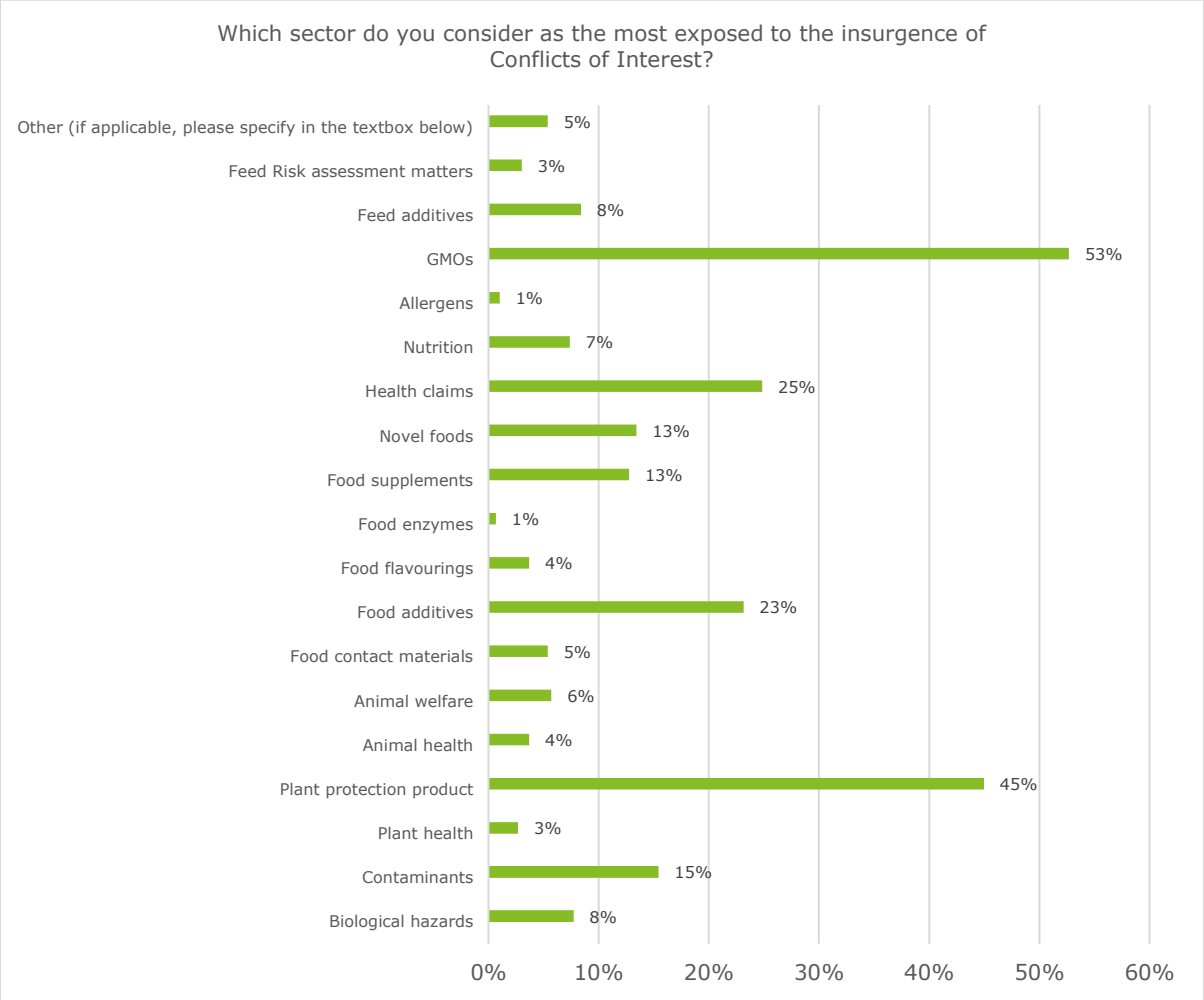
In addition the relevance of the current system can also be seen in light of the needs which are addressed by the current system, i.e. preventing and mitigating the risk of the occurrence of conflicts of interest and thereby securing independent and objective scientific decision-making processes. Maintaining the current system is justified given the risk of the insurgence of conflicts of interest inherent in the current system (e.g. reliance on external scientific experts for the work of the Scientific Panels and Committees). However, the actual degree of exposure to potential conflict of interest varies with the specific sector or area in which EFSA and its scientific bodies perform their risk assessment.

As the results of Deloitte's expert survey suggest (see figure below), some sectors incur a considerably higher exposure to industry influence than other sectors. With regards to the sectors thought to be most exposed to the risk of a potential Conflict of Interest, three of them account for more responses than the remaining sixteen combined. These are: GMOs (22%), Plant Protection Products (19%) and Health Claims (10%). Also worth noting is that several sectors are considered to have extremely low to very low exposure to risk,

[45] Regulation (EC) No 178/2002 of the European Parliament and of The Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety.

with twelve of these sectors accounting for just over 20% of the total vote, while none of them accounted for more than 5% individually (note that up to three responses could be selected). Given these insights, a risk based approach to independence remains an option to consider.

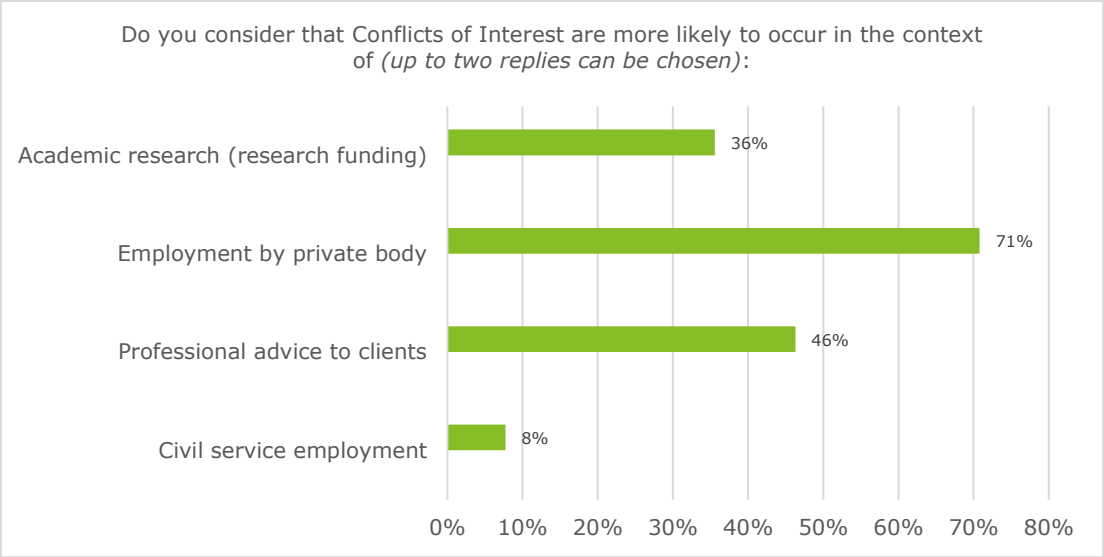
Figure 11: Sectors most exposed to the insurgence of CoI



Source: Deloitte Expert Survey (2017)

Employment by a private body is the context in which respondents view a Conflict of Interest as most likely to occur, and by a significant margin. The top three answers account for more than 95% of responses, while employment in Civil Service came in last with less than 5% (note that up to three responses could be selected).

Figure 12: Contexts most exposed to the occurrence of CoI



Source: Deloitte Expert Survey (2017)

In order to maintain the relevance of the policy in place, EFSA has taken up the approach of continuous improvement as well as a rigorous implementation of its policies and rules[46] for quite some time. It should be noted however that the aspect of continuous improvement can be strengthened further. By comparison, EMA performs a yearly review of its Independence Policy and Implementing Rules, enabling a faster response to any issues which might hinder the relevance of the policies and rules in place (see Chapter 5 on the comparative analysis of competing interest management systems of similar organisations).

Effectiveness of the current independence policy system

DoI system

Specific adaptations to EFSA's DoI Rules in 2014 have further increased the effectiveness of the system, allowing it to increase its level of rigidity and the overall reputation of the system in place. As was expressed in recent (social) media, the following updates were well received by the NGO community[47]:

- EFSA staff now have to file a Declaration of Interest (DoI), and submit to a pre- and post-employment screening to prevent cases of revolving doors;
- Regular consultancy is considered as employment;
- Clearer definition of what constitutes a 'Food Safety Organisation';
- Tighter rules on procurement.

However, although some incremental changes were well received by key external stakeholders (e.g. NGO's, industry representatives), EFSA is being criticised for missing

[46] EFSA Report to the European Parliament on the Implementation of its Independence Policy 2007 – 2012 (2012)

[47] https://corporateeurope.org/efsa/2014/11/efsas-credibility-loopholes

the opportunity for more radical changes, as was expressed by a number of NGOs (see Annex D), such as:

- Extending the scope of interpretation regarding the assessment of the interests of experts, applying for Panel membership, by not only assessing the declarable interests against the specific mandate of the Panel or Working Group, but against the Agency's entire remit;
- Making more systematically use of the concept of 'hearing expert';
- Introducing cooling-off periods for all material interests related to companies it regulates;
- Requiring experts to disclose financial interests, i.e. remuneration for their activities.

While the proposal of a more systematic use of the concept of 'hearing expert' raises questions on its implementation in practice, the use of cooling-off periods as well as the disclosure of financial interests are currently discussed as priority topics by the Management Board's Working Group on the Independence Policy Review[48].

The effectiveness of the Policy builds upon EFSA's proactive utilisation of the 'triple protection' approach (ADoI, SDoI, ODoI), already in place since 2007. The declared interests are assessed by EFSA in relation to the mandate of the group (Panel or Working Group) as well as the role of the expert (e.g. Chair, Panel Member, Rapporteur, etc.)[49].

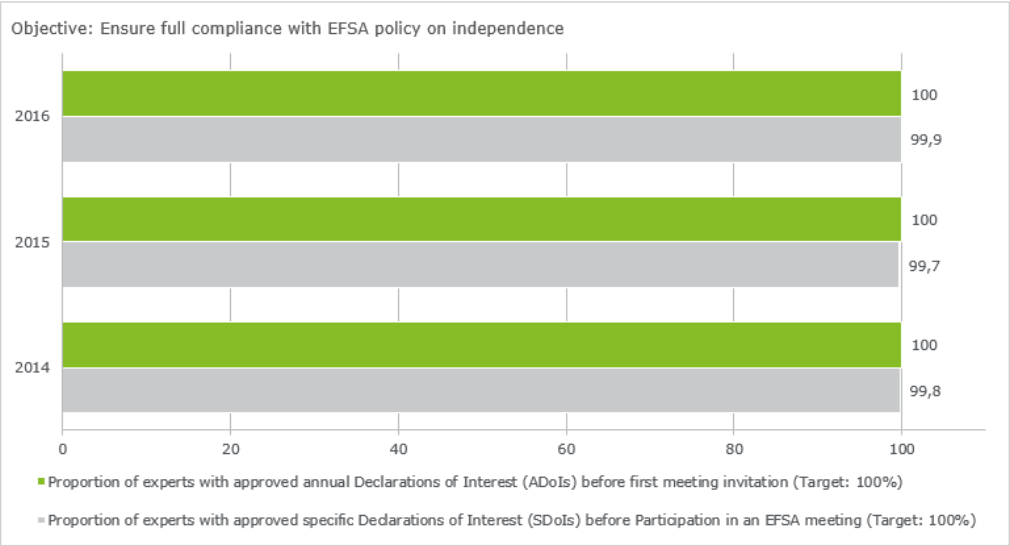
It needs to be noted that there is a risk of duplication linked to the deployment of both SDoIs and ODoIs to tackle CoIs causing unnecessary administrative burden for experts and EFSA staff working on the independence processes.

From a quantitative point of view, the Independence Policy system is effective in reaching its core objectives. When looking at the level of compliance with the Independence Policy, EFSA has obtained an almost complete compliance rating in the past three years, both in terms of number of experts with approved ADoIs before a first meeting invitation as well as the number of experts with an approved SDoI before participating in an EFSA meeting.

[48] EFSA concept paper on the review of EFSA's Policy on independence and scientific decision making process, 15.06.2016

[49] EFSA Report to the European Parliament on the Implementation of its Independence Policy 2007 – 2012 (2012)

Figure 13: Compliance rate with DoI Rules



Source: EFSA Annual Activity Reports (2014-2015)

Similar proof for an effective system in place is visible in the different outputs delivered in context of rigid control and monitoring mechanisms (screening, mitigation actions, BoT procedures, etc.) (see table below). A stable trend is recognised when comparing yearly outputs in the period 2014 – 2016. Lastly, no Breach of Trust procedure has been initiated since 2014, showcasing the system in place is perceived by the concerned experts as effective in tracking and pursuing omissions and breaches leading to potential Conflicts of Interest.

Table 5: EFSA independence policy related statistics

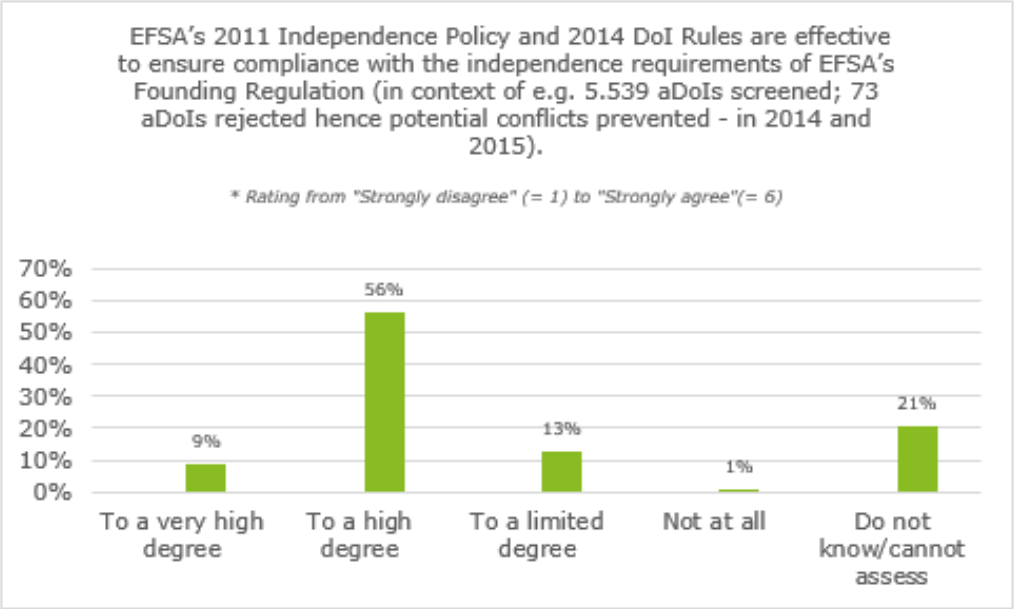
Objective	Indicator	2014	2015	2016
Ensure full compliance with EFSA policy on independence	DoIs screened	4439 SDoIs 2523 ADoIs	4591 SDoIs 3016 ADoIs	4319 SDoIs 3148 ADoIs
	Meeting agenda items scrutinised	34,456	32,200	29,080
	Potential conflicts prevented	SDoIs: 92 agenda items 53 ADoIs rejected	SDoIs: 76 agenda items 20 ADoIs rejected	SDoIs: 99 agenda items 8 ADoIs rejected
	BoT procedures	0	0	0

Source: EFSA Annual Activity Reports (2014-2015)

Also experts perceive the system in place as quite effective, as became apparent in the online survey.

Overall, respondents agree that the Independence Policy and 2014 DoI Rules are effective. More than 65% believe these to be highly or very highly effective. Just over 20% of respondents claim not to have insight into this topic and therefore cannot assess this question, while only 1% (3 respondents in total) claim that they are not at all effective in ensuring compliance and independence requirements.

Figure 14: Effectiveness of EFSA's Independence Policy system in ensuring compliance



Source: Deloitte Expert Survey (2017)

Compliance and veracity checks

The effectiveness of EFSA's Independence Policy is also reflected in the results of the yearly set of compliance and veracity checks performed by the LA Unit. Twice a year, a sample of 15 randomly selected experts is checked for compliance and accuracy. Even though some issues were identified during this process (as is depicted in the table below), not a single Conflict of Interest was identified due to severe compliance and/or veracity findings. Yet, the question can be raised if a larger sample can be taken in the yearly checks, as was mentioned by a NGO representative during interviews. However, EFSA staff and management share the view that the current sample size is proportionate compared to the number of cases of BoT and CoIs detected. Also the findings resulting so far from these exercises appear to support this consideration.

Table 6: Results of EFSA's compliance and veracity checks (2014-2016)

Period	Experts selected	Compliance findings	Veracity findings	CoIs identified
Q1 2013	13	0	7	0
Q4 2013	15	1	6	0
Q1 2014	15	1	4	0
Q4 2014	14	1	6	0
Q1 2015	15	1	5	0
Q4 2015	15	2	3	0
Q1 2016	15	1	1	1
Q4 2016	15	0	3	0

Source: EFSA, Concept paper on the review of EFSA's Policy on independence and scientific decision making process, 2016, p. 6

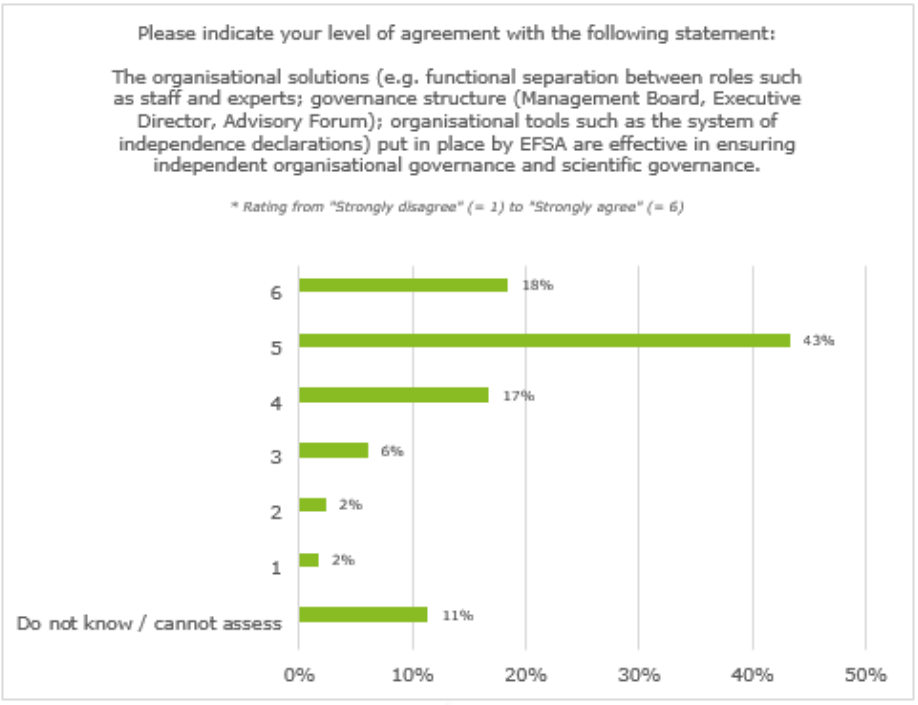
Organisational governance

Another major element of EFSA's independence policy consists in its specific organisational set-up and governance structure, supporting EFSA's independent operation in the public interest. As outlined in EFSA's independence policy, a number of safeguards are built into the Agency's organisational governance, e.g.:

- Clear separation of roles and responsibilities between the Agency's bodies as well as Agency staff providing support to the operation of the Agency's bodies;
- Specific composition of the Management Board (i.e. the Management Board is not composed of one representative per Member State as in the case of EMA or ECHA), but of 14 individual experts selected for their competence and expertise, acting independently in their personal capacity and in the public interest (see Article 25 (1) of EFSA's Founding Regulation);
- Independence requirements related to the selection and recruitment process of external scientific experts (e.g. open call for expression of interest, open and transparent selection procedure by an EFSA internal team, external review of selection procedure);
- Inclusion of independence requirements in the Rules of Procedure and Codes of Conduct of the Agency's bodies;
- The decision-making of the Agency's bodies follows consensus/majority rules (e.g. the final decision is taken by the collegial body; no individual member can impose a single view-point);

Surveyed scientific experts perceive the current organisational solutions and procedures (as depicted above), established by the Agency to ensure an independent governance, as effective. More specifically, respondents were overall in agreement (18% very strong agreement; 43% high agreement) that EFSA's organisational solutions and tools are effective in ensuring independence related to both organisation and scientific governance. 1 out of 10 respondents is not able to assess whether the system in place is effective in ensuring independent organisational governance and scientific governance.

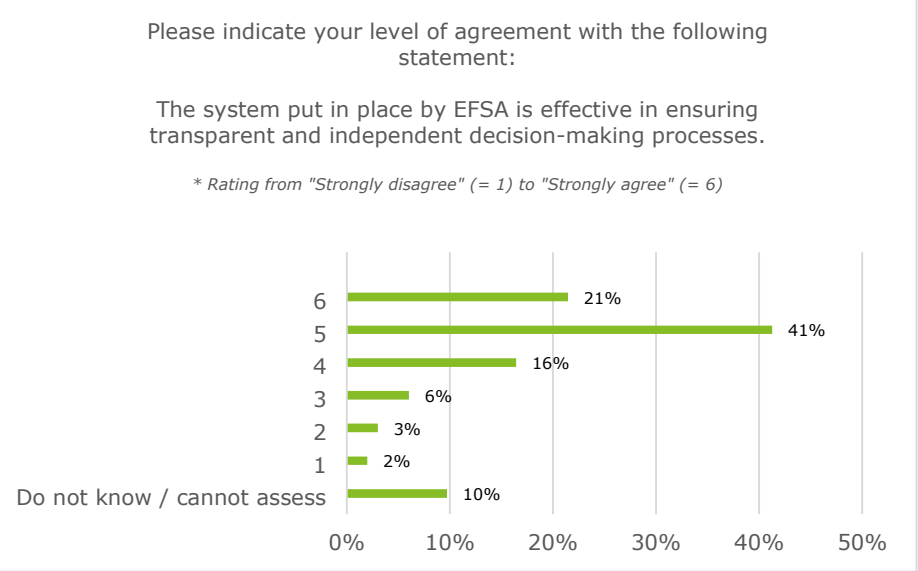
Figure 15: Effectiveness of EFSA's organisational solutions and tools in ensuring independent organisational and scientific governance



Source: Deloitte Expert Survey (2017)

Similarly, a majority of surveyed scientific experts indicates EFSA's system as effective in ensuring transparent and independent decision-making processes (21% very strongly, 41% highly, 16% to some extent). Only a small minority expresses a different view-point, and 11% among the survey respondents are not able to answer the question.

Figure 16: Transparent and independent decision-making processes



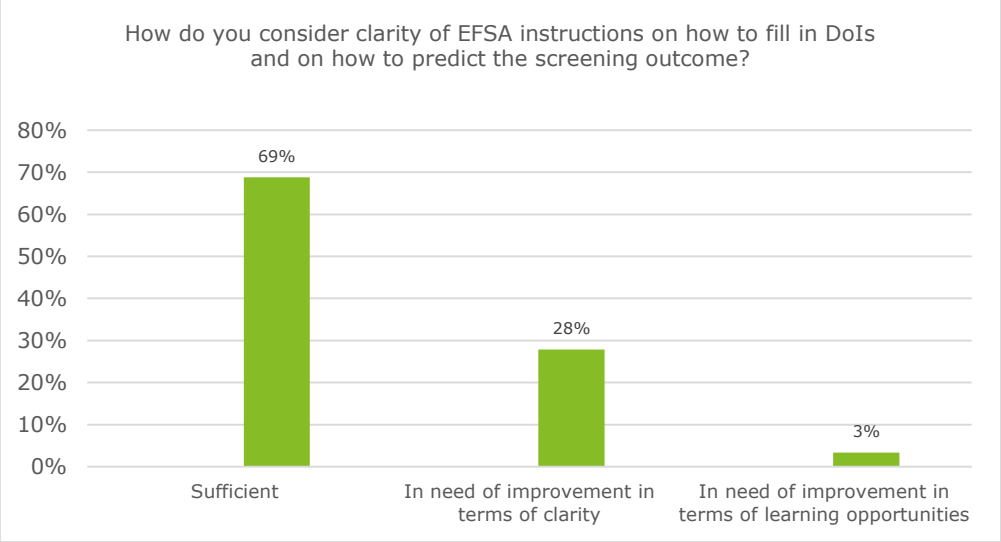
Source: Deloitte Expert Survey (2017)

Training and awareness-raising

The higher levels of compliance can also be explained by a better understanding/more awareness among scientific experts and Agency staff of EFSA's Independence Policy and DoI Rules. EFSA organises trainings and information sessions on a regular basis, both for EFSA staff and experts. Based on feedback received during interviews as well as inputs via the online survey (see subsection below), these awareness-raising activities were perceived as effective in achieving this main goal. This is expressed in a higher maturity among experts and staff when discharging their DoI obligations (better awareness on when to submit DoIs, how to fill in the forms, better quality of DoIs, etc.). as well as is reflected in the decrease of ADoIs rejected.

As regards the clarity of the DoI screening process, the evaluator's assessment has been informed by views of EFSA's scientific experts, asked in Deloitte's expert survey to comment on the clarity and communication provided by EFSA during the process. While the clarity of instructions on how to fill in DoIs and predict screening outcomes was perceived as being sufficient by nearly 70% of respondents, improvements are perceived as necessary by over 30% of respondents, largely related in terms of clarity (28%) as opposed to learning opportunities (3%).

Figure 17: Clarity of DoI Rules and EFSA's screening process



Source: Deloitte Expert Survey (2017)

As is visible in the table below, a limited number of trainings, information sessions/ awareness raising activities are being performed on a yearly basis. During interviews (especially raised by EFSA staff), it was acknowledged that more effort can be taken in raising awareness and understanding of the Agency's independence policy and DoI Rules,

yet in an efficient manner by for example developing an eLearning tool instead of organising multiple live-class trainings.

Table 7: Number of trainings, awareness-raising activities and communications on EFSA's independence policy

	2014	2015	2016	2017
Number of trainings organised for EFSA staff	1	1	2	2 (planned)
Number of trainings organised for EFSA's experts	1	2	1	1 (planned)
Number of information sessions/awareness-raising activities (for EFSA staff/experts)	1	1	2	1 (planned)

Source: EFSA (Legal and Assurance Service Unit)

Efficiency of the current independence policy system

To assess the level of efficiency of a specific system or process, a suitable technique is to search for examples of 'lean' principles, such as: timeliness, no duplication, no over processing, limited iteration, etc. When assessing these domains, it can be stated that a sufficient level of efficiency is in place within EFSA, yet with potential further efficiency gains in the short- to midterm.

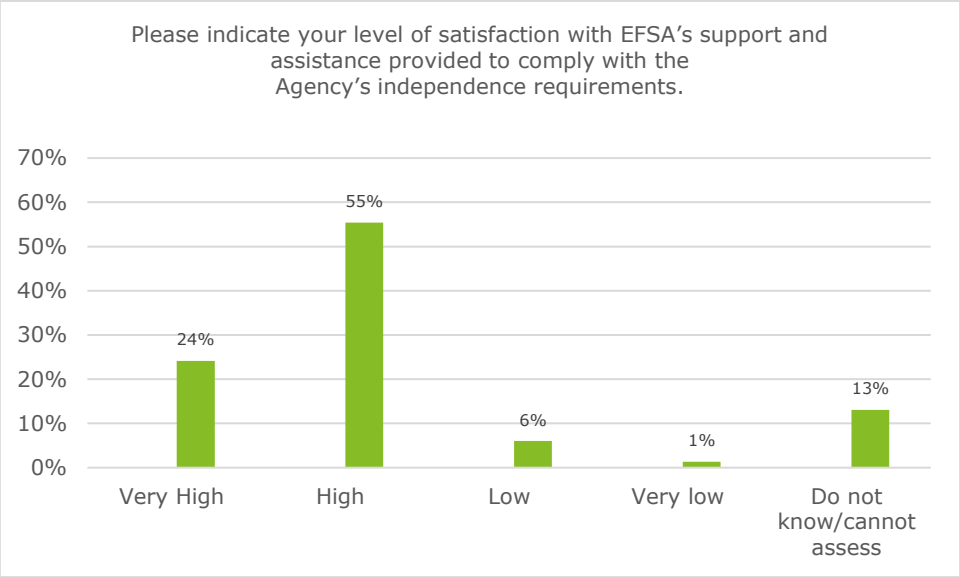
Centralisation of the DoI assessment system

A crucial factor is the recent shift (completed mid 2016) to a partial centralised management of DoIs. This shift is considered by the majority of interviewed stakeholders as a significant step in reaching a high level of efficiency. The advantages of this centralised approach are manifold:

- harmonised, standardised way of working in DoI management/screening;
- consistent level of quality in regards to submitted DoIs;
- alignment in the interpretation and application of Independence Policy and Implementing Rules;
- better support to the Scientific Units - replies to questions are often provided within one day;
- processing the classification of new organisations in a timely manner;
- targeted approach in creating more awareness and clarity within and outside EFSA on its Independence Policy;
- DoI validations are separated from the decentralised (scientific) units, enabling an additional degree of objectivity in the implementation of the Independent Policy applied.

Satisfaction regarding EFSA's support and assistance provided to comply with their independence requirements is very high, with nearly 80% expressing a high or very high rate of satisfaction. At the other end of the spectrum, we find just over 7% of respondents expressing low (6%) or very low (1%) satisfaction rates.

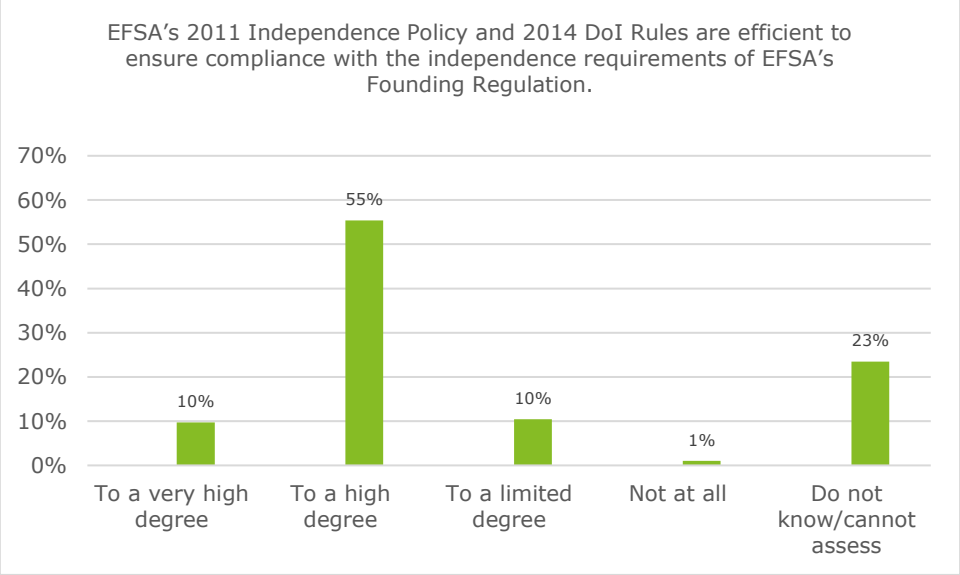
Figure 18: EFSA's support and assistance to compliance with independence requirements



Source: Deloitte Expert Survey (2017)

A majority of respondents – almost 65% – also recognise the efficiency of the Agency's Independence Policy and 2014 DoI Rules towards ensuring compliance with independence requirements. Yet, 23% of respondents do not know or cannot make a proper assessment, – more than double those who see limited or no value (11%).

Figure 19: Efficiency of EFSA's 2011 Independence Policy and 2014 DoI Rules



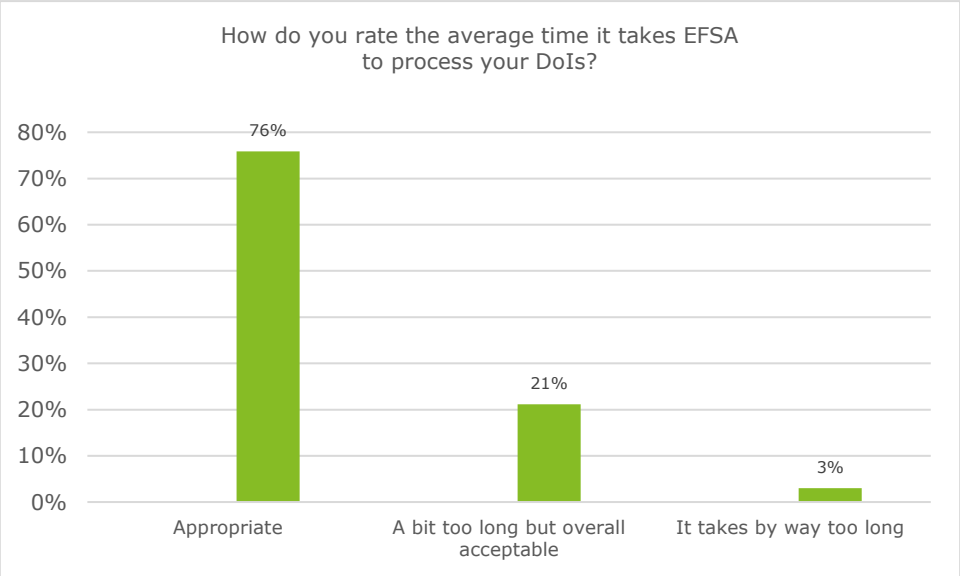
Source: Deloitte Expert Survey (2017)

Performance management

From a quantitative point of view, a similar viewpoint can be obtained. EFSA has been able to reach full compliance with its Independence Policy KPIs (e.g. number of DoIs screened and validated; number of veracity checks performed). Moreover, the LA Unit is able to comply with its internal KPI on timeliness (performing a DoI validation within 48 hours from the receipt of an ADoI).

Surveyed on the efficiency of the DoI assessment, respondents came to a clear consensus with 76% finding that EFSA's processing time of DoIs is appropriate, 21% finds it a bit too long but acceptable, with only 3% who would like to see a faster process.

Figure 20: Time for processing DoIs



Source: Deloitte Expert Survey (2017)

Efficiency improvement opportunities

However, regardless of the overall agreement among stakeholders that the current Independence Policy system is indeed efficient in reaching its core objectives, a number of improvement points in the current system have been identified by Agency staff and management involved in managing independence processes as well as by the surveyed scientific experts:

- The DoI IT tool is perceived as out-dated (not user-friendly, slow and not stable). This has been acknowledged by EFSA and the transition to a new workflow engine in the short term and to a new IT system in the medium term has been launched;
- Experts perceive the process as burdensome, given the diverse sets of DoIs they need to submit (ADoI, SDoI, ODoI) and the extent of information obligations;
- Due to a limited availability of specific scientific knowledge within the LA Unit, iterations are sometimes required with the decentralised Units during the DoI screenings and validations. As was expressed during interviews with EFSA staff,

these exchanges are very constructive although some iterations between LA and Science Units take time in order to align;

- No risk based approach is applied when screening DoIs as well as performing compliance and veracity checks, meaning the same process (and as such time and resources) is applied across all types of experts, Units, Scientific Panels, Committees and topics[50];
- A risk of duplication and non optimal use of resources is identified in the deployment of both SDoIs and ODoIs to tackle CoIs at the individual item or meeting level. A reconsideration of the same approach applied to across all sectors could be considered appropriate;
- As became apparent during our review of NGO view-points and online media coverage on EFSA's independence policy system, the overall response time and direct communication of EFSA can be improved, especially when confronted with reputational hazards.[51] [52]

Proportionality of the current independence policy system

Since the foundation of EFSA, the organisation has gradually adapted its policies to include ever stricter rules and transparent procedures, resulting in the system currently in place to, among other reasons, mitigate the continuous pressure from external stakeholders. The question can be raised whether this high maturity is an absolute requirement to uphold independence among EFSA staff and external experts.

In comparison with other independence management systems (we refer to the Chapter 5 on the comparative analysis of competing interest management systems for more detail), EFSA maintains a very elaborate and comprehensive system, for example by:

- Requesting both Annual, Specific and Oral Declarations of Interest from experts;
- Performing annual compliance and veracity checks;
- Implementing a Breach of Trust procedure;
- Operating an advisory committee;
- Operating an internal review procedure; and

[50] With the exception of hearing experts and member states representatives, which are not assessed or validated, as well as only one SDoI is asked to one mandate working group

[51] "EFSA was also very late in acknowledging that conflicts of interest is an issue that needs to be addressed. Addressing conflicts of interest too until 2012 -eight years after the start of EFSA and after intervention by the European Parliament. In the end a policy was adapted. Direct ILSI-ties were not allowed anymore as well as being a full industry consultant. Still many industry-linked people are part of the EFSA panels and the EFSA policy needs to be improved to realise more independent panels". (http://www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20A%20Poisonous%20injection.pdf, p. 30)

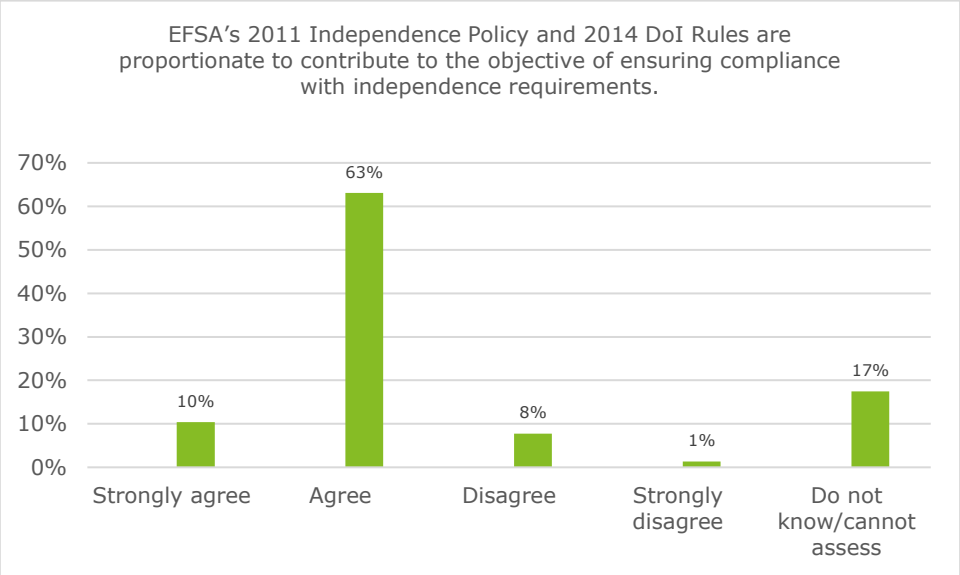
[52] Appointment of new communications director: "Not only is this a questionable choice from an operational point of view (this appointment puts this person in a very difficult position as her background will undermine her credibility with the media and civil society for months), but the very rules applicable to the case would normally question EFSA's director's decision."(https://corporateeurope.org/efsa/2016/03/efsa-appoints-food-industry-lobbyist-communications-director-and-refuses-disclose-why)

- Ensuring transparency and openness by live broadcasting specific Panels discussions as well as sharing all DoIs, CVs and risk assessment methodologies via its website.

Besides the wide-ranging system installed, EFSA applies other safeguards in upholding independence, such as the individual level of trust and integrity of experts, strong peer review in the Scientific Panels and the reputational risks/impact for experts inherent to CoIs. Nevertheless, for specific interest groups (specifically NGOs), as long as experts work on a voluntary basis and uphold a financial connection with other organisations, the current system needs to be kept in place, or even further strengthened.

The current system translates in a considerable number of resources (both centralised and decentralised) deployed on the independence processes, a significant workload (e.g. CoI management outputs) and administrative burden for staff and experts (e.g. managing ADoI, ODoI, SDoI). Still, interviewed EFSA staff and management consider the current system as proportionate in relation to the main outputs of the system. This perception is shared by a majority of surveyed scientific experts, as shown in the figure below: over 70% of survey respondents confirm the proportionality of the current system, while 17% either do not know or consider themselves unable to make a proper assessment.

Figure 21: Proportionality of EFSA's 2011 Independence Policy and 2014 DoI Rules



Source: Deloitte Expert Survey (2017)

4.5 Sustainability of the Policy on independence, scientific decision making process and DoI procedure

Introduction

In this section, we present our analysis on the following research question:

"To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 sustainable against the evolving political and financial perspectives?"

Assessing the sustainability of a system or procedure in place implies two key elements:

- To what extent are the resources invested in the system sufficient in order to maintain an efficient and effective Independence Policy?
- Does the Independence system and its Rules on scientific Decision-making and DoI imply the required impact, in context of its core objectives and political and financial reality?

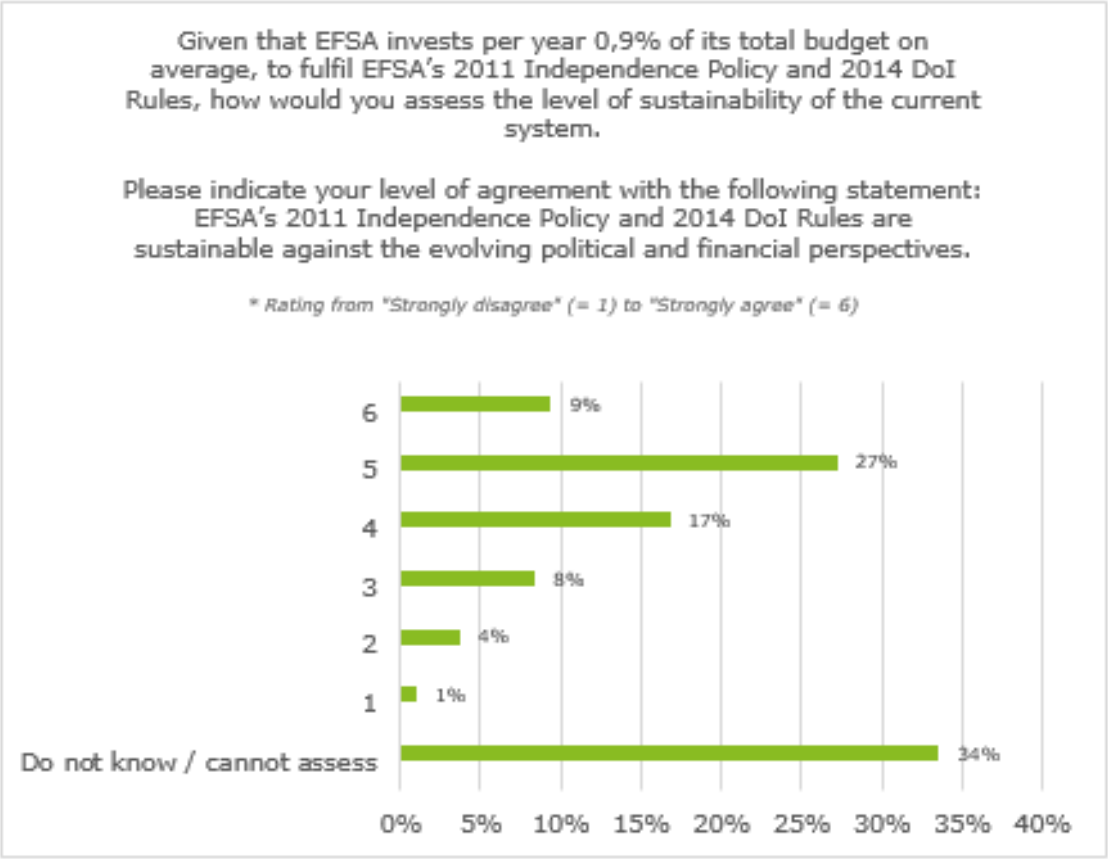
Main analysis

When asking the question whether the current system is sustainable in its operation and consequently desired impact, there is no unilateral answer.

On the one hand, looking at the operational framework which supports the Independence policy, there are indications that the current system is stable and can be maintained in the present budgetary reality.

The results of the expert survey regarding the sustainability of the current system does not provide a clear and conclusive answer. One-third of respondents find themselves in a position where either they do not know or consider themselves unable to make a proper assessment. Next, a significant group agreed with the sustainability of EFSA's Independence Policy and DoI Rules (9% very strongly agree, 27% highly agree), whilst only a small number of respondents clearly disqualifies the current system as not sustainable against the evolving financial and political perspectives (1% very strongly disagree, 4% highly disagree).

Figure 22: Sustainability of the current system against the evolving political and financial perspectives



Source: Deloitte Expert Survey (2017)

However, there are indications that the capacity for future 'continuous improvement' is limited. As was revealed during interviews with EFSA staff, the current workload is manageable. However, additional resources would be required if significant changes, which entail additional workload, would be made to the Independency Policy / DoI system.

On the other hand, doubt is raised whether the strict nature of the Independence rules is sufficiently sustainable. The perception exists, both among EFSA staff as well as external stakeholders (NGO, industry associations and representatives of the European Parliament) that a continuous increase of restrictions (e.g. longer cooling off periods, specified financial thresholds, etc.) for experts, might make it increasingly difficult to find suitable candidates for the Scientific Panels. Although today EFSA is still able to man its Scientific Panels, this perceived complexity is reflected in a new trend that can be noticed by the use of the concepts of 'granting waivers' and 'hearing experts'. As defined in Article 11 of the Rules on the Declarations of Interest (2014): "hearing experts are individuals possessing particular and relevant knowledge, who are invited by EFSA to share the information [...] on a single occasion or in a limited numbers of instances". Hearing experts do not participate in the deliberations or drafting of scientific outputs. This is different to the concept of waivers. In some rare cases, an identified external expert has a potential CoI, yet if the expertise he or she holds is crucial, and no suitable alternative expert can be

identified, this expert can be granted a waiver. Such experts are allowed to take part in the discussions and in the drafting of scientific outputs (Article 16), yet some limitations (e.g. not be allowed to act as chairman, vice-chairman or rapporteur, etc.) are applied[53].

As can be seen in the tables below, in recent years, an upward trend in the use of both concepts is visible, which means that EFSA uses scientific expertise in a more transparent manner, by appointing members devoid of potential CoIs to its Scientific Committee, Scientific Panels and Working Groups.

Table 8: Number of granted waivers

EFSA Unit	2014	2015	2016
SCER (Scientific Committee and Emerging Risks Unit)	1	1	2
BIOCONTAM (Biological Hazards and Contaminants Unit)	1	0	3
Total number of granted waivers	**2**	**1**	**5**

Source: EFSA (Legal and Assurance Services Unit)

Table 9: Number of hearing experts

EFSA Unit	2014	2015	2016
ALPHA (Animal and Plant Health Unit)	23	107	106
AMU (Assessment and methodological support Unit)	-	21	7
BIOCONTAM (Biological Hazards and Contaminants Unit)	5	19	44
SCER (Scientific Committee and Emerging Risks Unit)	7	65	45
FIP (Food Ingredients and Packaging Unit)	31	27	21
GMO (Genetically Modified Organisms Unit)	23	41	47
FEED (Feed Unit)	11	3	22
PRAS (Pesticides Unit)	7	21	20
DATA (Evidence Management Unit)	15	5	6
NUTRI (Nutrition Unit)	0	1	9
Total number of hearing experts	**122**	**311**	**327**

Source: EFSA (Legal and Assurance Services Unit)

To address this evolution, interviewees suggested to clarify the framework for the use of both concepts. One solution (as was raised by comparable Agencies during interviews) is to further standardise or clarify the hearing expert procedure as well as implications for the scientific risk assessment process.

Another, more radical solution (raised by NGOs), is to revise the current financial model applied at EFSA. Today, experts are providing their expertise on a voluntary basis, while EFSA only covers expenses and provides a small fee to compensate their contribution. One proposal, mainly advocated by external stakeholders, is to allow EFSA to recruit their own experts and build scientific risk assessment capacity in-house. However, the organisation does not have the necessary financial resources to achieve this in the short term, and major legislative changes would be required to make this option simply conceivable.

[53] No waivers are granted to experts involved in activities related to the evaluation of applications related to regulated products, claims, organisms, processes or substances. In addition, experts with a waiver are not allowed to be chairman, vice-chairman or rapporteur of EFSA's scientific groups.

5 Comparative analysis of competing interest management systems

This chapter includes a high level comparative analysis of the competing interest policies and procedures established by similar organisations to EFSA with regard to scientific experts and scientific decision-making process. The European Chemicals Agency (ECHA) and the European Medicines Agency (EMA) have been selected for the comparison of a number of elements of EFSA's current independence policy (see explanations and criteria for the selection in the methodology section of this report).

The focus of the analysis is set on determining the level of rigidity of EFSA's independence policy and procedures as compared to other organisations and to identify good practices which could be explored by EFSA to optimise its current system. The approach is topical, i.e. parallels are only drawn on topics and the current systems of EMA and ECHA are not fully described.

Information on EMA's and ECHA's competing interest management systems has been obtained from the Agencies' websites, including policies, procedures and reports (see Annex D for the full list of documentation consulted). In addition, interviews with both Agencies allowed to capture views on the effectiveness of EMA's and ECHA's current systems, to clarify differences between the systems, to identify shortcomings and good practices. Given the limited access to information related to the Conflict of Interest management in DG SANTE's Scientific Committees (i.e. SCCS, SCHEER), a complete and comprehensive comparison with these Committees could not be undertaken by the evaluator. Consequently, the analysis presented below is exclusively making reference to ECHA and EMA.

As the features of EFSA's system were described and explained in the previous sections, the evaluator restricts the following analysis to explanations of the similarities or differences between the systems under comparison.

Unique to EFSA

The comparative analysis shows that EFSA has established a very comprehensive system of independence policy and procedures. The following features cannot be found in the systems of comparable organisations or are only partially existent:

- EFSA has opted for the **centralisation** of the DoI assessment thereby increasing the consistency of the DoI assessment as well as the objectivity/independence of those performing the DoI assessment. In **ECHA** and **EMA** the DoI screening process

is performed in a decentralised way. In the case of ECHA, the units and departments providing the Secretariat to the Scientific Committees and Working Groups perform the **screening** of the annual DoIs while the chair of the Committees and Working Groups is responsible for the evaluation of specific declarations (i.e. oral Declarations of Interest). In **ECHA**, only the **provision of legal advice** for Conflict of Interest cases is provided at a centralised level, including the Legal Affairs Unit, the Data Protection Officer in the Executive Office as well as a Conflict of Interest Advisory Committee (CoIAC). Similar to ECHA, **EMA's** scientific departments, providing the Secretariat to its Scientific Committees and Working Parties, carry out the DoI screening. In addition, **EMA** has established a virtual Declaration of Interests Assessment Group (DIAG) comprising EMA staff to consider cases where a declared interest falls under a higher risk category and to recommend appropriate actions to be taken for experts classified at risk level three. Only the **coordination of specific aspects** of **EMA**'s competing interest management system is centralised within the Committees and Inspections Department. The Experts and Declarations of Interests Management team is responsible for the maintenance of the EMA's Experts database and coordinates the implementation of the policy on the handling of competing interests within the Agency.

- EFSA has established a **system of waivers** (Article 16, 2014 DoI Rules) to which its Working Groups have recourse in case an expert for whom a CoI has been identified is essential for the output of the risk assessment process, and no suitable alternative expert is available. The conditions to which the granting of waivers are subject are specified in EFSA's DoI Rules (2014). A similar system of waivers has not been formalized / is not documented by **EMA** or **ECHA** (no reference can be found in the respective policies on competing interest management).
- EFSA has adopted a set of **performance indicators** (KPIs)[54] on the management of its independence policies and procedures and reports on the results in its Annual Activity Reports. Moreover, interviews revealed that EFSA has a well-established system in monitoring and documenting the implementation of its DoI Rules (e.g. reporting on number of screened DoIs, etc.). No evidence could be found on similar KPIs in ECHA and EMA.

Similar procedures and practices in place at ECHA and EMA

- Similar to EFSA's concept of **'hearing expert'**, **EMA** and **ECHA** have installed the status of 'expert witness' for experts and members of the Scientific Committees/Working Groups for which an evident competing interest has been identified: as in the case of EFSA, the expert can be invited to participate in the meeting as 'expert witness'. However, the role of the 'expert witness' is limited to

[54] Two key performance indicators on the compliance with EFSA's independence policy have been adopted: Proportion of experts with approved annual declarations of interest before first meeting invitation: (1) Proportion of experts with approved annual declarations of interest before first meeting invitation; (2) Proportion of experts with approved specific declarations of interest before Participation in an EFSA meeting.

testify and to give specialist advice on a specific issue by providing information and replying to any questions; the expert witness is excluded from participating in the scientific decision-making process. EFSA's DoI Rules specify that the recourse to hearing experts shall be recorded in the minutes of the meetings, as well as in the ensuing scientific output on which the expert has been consulted.

- **'Revolving door' policy**: according to Article 16 of the EU Staff Regulations, staff members leaving the Agency have to notify any professional activity they are considering to take up within the two years after their departure to **EMA**, **EFSA** and **ECHA**. Restrictions may be imposed on the staff members by the Agencies to mitigate any potential Conflict of Interest. EFSA has established the practice to report in its Annual Activity Report on the number of applications for authorisation as well as the number of cases, in which restrictions have been adopted. Similarly, **EMA** provides statistics on staff leaving the Agency since 2015 and gives examples for cases in which restrictions were applied in its Annual Report on Independence. On the top of this, EMA has published online annual reports for the period from 2012 to 2015 on staff engaging in an occupational activity within two years of leaving the service. At the example of EMA, EFSA could consider to be more specific about the restrictions applied in the cases for which a potential CoI has been identified. In none of the Agencies a specific revolving door policy has been adopted. Moreover it has to be noted that in the case of all three Agencies, post-employment duties only apply to staff members, but not to members of the Management Board.
- EFSA has established in 2013 a system of **compliance and veracity checks** that are performed twice a year on a limited sample of DoIs submitted by experts. The compliance check assesses the compliance with the DoI Rules and related procedures. The veracity checks consist of the assessment of the veracity of information provided in the DoIs compared to the expert's biography, combined with an (online) research on the expert in question. While **ECHA** only performs compliance checks during the annual update of DoIs (i.e. assessing whether the DoIs have been correctly and completely filled in), **EMA** has adopted a system similar to EFSA's compliance checks. Since 2012, **EMA** performs *ex ante* and *ex post* controls on the DoIs submitted by scientific experts. The ex post controls include a check of the current DoI against the CV and the previous DoI, as well as a check of the documented evaluation of the DoIs and a check of the documented implementation of restrictions at meetings. *Ex post* controls are also performed with regard to DoI screening of EMA staff. For instance, in 2015, an *ex post* control was performed in 2015 on the assessment of Conflicts of Interests of EMA Product Leads (EPLs) in the Scientific and Regulatory Management Department within the Human Medicines Evaluation Division[55]. In both cases, EMA uses a risk analysis approach for the selection of the expert DoIs on which *ex post* controls are performed. Similar to ECHA, since 2015, EMA reports on the outcome of its *ex ante* and *ex post* controls. As confirmed during interviews with ECHA and EMA, veracity checks – as performed by EFSA – are not established practice in both Agencies.

[55] EMA: 2015 Annual report on independence, p. 12.

- Similar to the efforts of **EMA** and **ECHA**, EFSA has taken initiatives to **promote transparency on its work and provide insight into its internal functioning**, in particular on independence relevant aspects. For instance, EFSA makes online available audio recordings of the Management Board meetings, as well as the agenda, presentations, documents and minutes online available. Moreover, the CVs and ADoIs of the Management Board members are published on the Agency's website; ODoIs are recorded in the minutes of the meeting. EFSA is committed to open plenary sessions to the public: stakeholders can register and participate as observers to the meetings that are announced in advance on the Agency's website[56]. Moreover, for 2017 the Agency started to webstream live open meetings of its Scientific Panels to facilitate access to as well as public scrutiny of its scientific decision-making.
- **Transparency and openness of the work of the Scientific Committees**: EFSA, **EMA** and **ECHA** have established the practice to publish online the CVs and ADoIs of members of the Scientific Committees as well as agendas, minutes and technical reports of the meetings of the Scientific Committees and Panels. In the case of EFSA, the minutes of the Scientific Panels and Working Groups report on the outcome of the screening of ADoIs and SDoIs by EFSA, as well as the actions taken to mitigate potential CoIs. The minutes also take note of ODoIs and the decision of the Chair of the Scientific Committee/Panel to restrict the involvement of a scientific expert for whom a CoI has been identified. In the case of all three Agencies, the final scientific outputs (e.g. decisions, opinions and guidance documents) of the Committees are published online. Moreover, minority opinions are recorded in the final opinions.
- **IT support to DoI processes**: EFSA has recently invested in the improvement of its DoI tool to allow for a more efficient operation of the process and to make the completion of DoI more user-friendly for the scientific experts. As confirmed during interviews, technical difficulties with the IT tool supporting the DoI screening and, subsequently, a perceived high administrative burden are challenges common to EFSA and **EMA**. The system put in place by **ECHA** for the DoI screening of scientific experts is very basic and manually operated.
- In addition, EFSA operates an online **Declaration of Interest (DoI) database**[57] allowing the search of DoIs per expert, subject area and entity. **EMA** gives access to its expert database via its website: apart from the experts' DoIs and CVs, the interest level of the expert is indicated.
- EFSA **reports annually on the implementation of its independence policy** in a specific Chapter incorporated in its Annual Activity Reports. While **ECHA** does not publish any statistics related to its independence policy, **EMA** has established since 2015 the practice to publish a specialised annual report providing information on the state of implementation of various elements of its independence policy[58].

[56] https://www.efsa.europa.eu/en/stakeholders/observers

[57] https://ess.efsa.europa.eu/doi/doiweb/doisearch/panel/AFSCO/wg/28

[58] EMA: 2015 Annual report on independence, 16 September 2016.

Similarly, EFSA could – in addition to its Annual Activity Report – consider publishing a special report on the implementation of its independence policy.

Good practices in EMA and ECHA to be explored by EFSA

The comparison with EMA and ECHA revealed a number of good practices:

- Since 2015, **EMA** performs an **annual independence policy review** of which results are presented in an annual report.
- **EMA** uses a **risk-based approach** in the screening of DoIs of scientific experts. EMA has defined three interest categories (i.e. direct interests, indirect interests and no interests) to which different sets of rules are applicable. The experts with no interest are exempt from the DoI screening process and no restrictions apply.
- **EMA** has adopted **different policies on the handling of competing interests per target group** (i.e. Management Board members, Scientific Committees' members and experts) that highlight the principles of the policy (e.g. transparency and efficiency of the process), clarify interest categories and applicable rules as well as restrictions and the practical operation of the policy. The policies also include a DoI assessment matrix with a clear and simple structure.
- **Pre-screening of DoIs:** In the case of **EMA**, experts are required to submit Initial Declarations of Interest (IDoI) to the Agency during the selection process and prior to their appointment. Thereby EMA ensures that only experts with approved DoIs are accepted in the Agency's expert database and may be invited to meetings.
- **Cooling-off period**: EFSA applies a five year cooling-off period for certain interests, which is in line with the temporal scope for consideration applied by **ECHA** and the Commission's Scientific Committees. Only recently, **EMA** has reduced the cooling-off period applicable to the majority of declarable interests from initially five years to three years (only in exceptional cases a three year period applies), considering this temporal scope more proportionate to maintain the right balance between availability of scientific expertise and effective conflict of interest management. For financial interests, no cooling-off period is applied as only current interests are taken into consideration.
- The **Breach of Trust procedure** is detailed by **EMA** for the members of its Scientific Committees and experts[59] as well as for the members of its Management Board[60]. While EFSA's 2014 recast of the DoI Rules have brought more clarity on the BoT procedure, taking EMA's example as inspiration, EFSA could consider to be more precise in outlining the different procedural steps.
- In terms of **training and awareness-raising of Agency staff on conflicts of interest**, **ECHA** makes extensive use of its Intranet to provide information on its

[59] European Medicines Agency breach of trust procedure on declarations of interests for scientific committees' members and experts, EMA/154320/2012, Rev. 1, 24 April 2015.

[60] For more information on the 2015 revision of EMA's Breach of Trust procedure: http://www.ema.europa.eu/ema/index.jsp?curl=pages/news_and_events/news/2016/01/news_detail_002456.jsp&mid=WC0b01ac058004d5c1

independence policy as well as virtual practical exercises on independence and conflict of interest scenarios. In addition, trainings to staff are provided in the format of e-Learnings.

- **Streamlined DoI portfolio**: EFSA's special DoIs consist of oral declarations of interest (ODoIs) and specific declarations of interest (SDoI), which is perceived in the case of Working Groups with only one mandate duplicative. Instead of having two different sets of special declarations, EFSA could align with **ECHA**'s practice. In fact, prior to a meeting of a Committee, the experts' ADoIs are screened against the agenda items to be discussed. No specific declaration in written form has to be submitted to the Chair specifically on the agenda items. The ODoIs requested at the beginning of each meeting provide the opportunity to the expert to make any specific declarations, which will be assessed by the Chair and the appropriate restrictions are decided instantly. This approach would represent a shift to an increased trust-based approach vis-à-vis the scientific experts and their responsibility to declare any relevant specific interests during the meeting with less control exercised by EFSA. This approach might only be limited to one-mandate Working Groups, but could represent an opportunity for increased efficiency (given the resource intensity on the side of EFSA and the perceived administrative burden on the side of the experts of the SDoI process).
- **Facilitated public scrutiny and transparency on the outcome of DoI evaluations:** The minutes of **EMA**'s Scientific Committees include a table indicating the role of the participant in the meeting, the outcome of the DoI evaluation in relation to the meeting as well as restrictions applicable to specific agenda items[61].
- **Notification of potential future DoIs in the case of scientific experts**: **EMA**'s policy for handling competing interests stipulates the obligation for scientific experts (i.e. a scientific committee/working party/SAG/ad hoc expert group member) to notify to EFSA their intention to be engaged (either solicited or not) in occupational activities with a pharmaceutical company (such as employment) during the term of the mandate (irrespective if an employment contract with a company has been signed or not). EMA will fully restrict the member from further involvement in the Agency's activities from the date of notification. Thereby any potential CoI is to be mitigated in relation to a future employment exercised by the expert.[62]
- In view of **improving transparency on the working of its Scientific Committees and ensuring on-time availability of information** (e.g. agenda, minutes and reports), **EMA** has established the practice of indicating by when the information will be online available.

While the comparison with independence policy systems established by similar organisations suggests that EFSA has a very elaborate and extensive system in place,

[61] See as example: EMA, Committee for medicinal products for human use (CHMP), Minutes of the meeting on 07-10 November 2016, p. 43: http://www.ema.europa.eu/docs/en_GB/document_library/Minutes/2017/01/WC500219563.pdf

[62] European Medicines Agency policy on the handling of competing interests of scientific committees' members and experts, EMA/626261/2014, Rev. 1, 6 October 2016, p. 8.

EFSA could further investigate to what extent good practices of EMA and ECHA could be transposed in EFSA's specific operational framework and, subsequently, contribute to improved effectiveness, efficiency and transparency of the current system.

6 Conclusions and recommendations

This chapter highlights the main conclusions and recommendations in context of a future review of EFSA's Independence Policy. The conclusions and recommendations have been listed according to the different evaluation questions addressed in chapter 5.

Q.1: Contribution of the current independence policy system to EFSA's reputation

Conclusions

- EFSA has been subject to (external) criticism, but also praise on how the organisation applies the principle of independence within its daily business as well as manages potential Conflicts of Interest.
- EFSA has continuously shown efforts, via several projects and initiatives (e.g. TERA project, Open EFSA, Stakeholder platforms) in strengthening the organisation's reputation.
- Only a limited number of complaints, in the domain of independence, have been raised in the period 2014 – 2016.
- More than 60% of the online survey respondents state that EFSA's 2011 Independence Policy and the 2014 DoI Rules have largely contributed to EFSA's reputation.
- However, a reputational risk remains, as was confirmed by the Management Team during its annual risk management exercise.
- EFSA will remain scrutinised by specific interest groups as long as the Authority evaluates the safety of regulated products in sensitive sectors such as GMOs and pesticides.
- In certain dossiers, EFSA could have shown more swift and reactive communication efforts in response to criticisms regarding independence policy issues.

Recommendations

For addressing some of the remaining challenges, EFSA could:

- Follow-up and assess the mitigating actions defined in the Risk plan whether these are successful in diminishing the risk of losing reputation.
- Continue the efforts made in terms of communication and transparency via the existing platforms and initiatives.
- Promote a more holistic approach to independence by not only creating transparency on individual independence, but also on other aspects, such as the applied methodology for risk assessment, collegial decision-making, governance, etc.

- Strengthen responsiveness to outspoken criticisms by more pro-active communication on conflict-sensitive topics, and by a more proactive approach in replying to (formal) complaints.
- Expand the use of web-streaming meetings of Panels.
- Finalise the assessment on option of outsourcing (at least the central part) of the CoI assessment process, and thus potentially elevating the level of perceived neutrality and independence.

Q.2: Contribution of the current independence policy system to a high level of food safety and consumer protection

Conclusions

- The DoI system in place allowed EFSA to prevent potential Conflicts of Interest over the past years, resulting in not a single Breach of Trust case since 2013.
- The current independence policy system provides additional safeguards to ensure the independence of the scientific assessment and thereby contributes to a high level of food safety and consumer protection.
- However, continuing or increasing the rigidity of the independence system could diminish the number of available scientific experts in the future which might negatively impact food safety and consumer protection.

Recommendations

For addressing some of the remaining challenges, EFSA could:

- Consider carefully any possible future elevation of the rigidity of the Independence rules and policy, given the potential risk of a lack of experts available.
- The Agency could improve its communication on the contribution of the current independence policy system to a high level of food safety and consumer protection and explain more explicitly the direct causal link between these.
- To better sell its image as impartial assessor, EFSA could also improve its communication on the number of inconclusive or negative opinions, e.g. by providing statistics on this on the EFSA website.

Q.3: Provided value for money of the current independence policy system

Conclusions

- EFSA has been able to increase its DoI management outputs over the last three years, within a context of stable financial resources and number of FTEs.
- The current Independence system is perceived as relatively expensive by both internal and external stakeholders.

- Yet the costs of the system are defensible compared to the outputs obtained, especially given EFSA's unique political environment, with a constant pressure to mitigate any potential risk for Conflicts of Interest and the growing expectations of external stakeholders in more openness, transparency and rigidity.
- A majority of experts expressed in the online survey that the costs of the system are justified in light of the outputs and results delivered by the system.

Recommendations

For addressing some of the remaining challenges, EFSA could:

- Conduct a study to estimate the potential cost when facing reputational damage in case of serious independence issues, in comparison to the value for money of the system in place, the results of which can be used in budget discussions at Management Board level and with the budgetary authority.
- Investigate the possibility of increasing the number of yearly compliance & veracity checks, perhaps on a risk-based approach.
- Investigate the option of installing a centralised / shared DoI screening and/or compliance and veracity check, together with other EU Agencies.
- Move towards an Independence system based on Data Analytics and Artificial intelligence, especially in context of the DoI assessment.

Q.4: Relevance, effectiveness, efficiency and proportionality of the current independence policy system

Conclusions

- Overall, EFSA's Independence policy and its implementing system is perceived as highly relevant by both internal and external stakeholders in order to maintain impartiality and independence when developing scientific outputs.
- The Independence Policy is effective in reaching its core objectives, which is expressed in a high compliance rating, significant number of control and monitoring outputs delivered as well as no Breaches of Trust since 2013.
- Since 2014, incremental changes have been made by EFSA to increase the effectiveness of the system, yet the NGO community hoped for more radical changes.
- The recent shift to a partial centralised screening of DoIs is considered by the majority of interviewed stakeholders as a significant step forward in Conflict of Interest management. Overall, EFSA has been able to set-up a system with a sufficient level of efficiency.
- The LA Unit, responsible for coordinating Conflict of Interest management and implementation of the Independence Policy, is able to manage the current workload, expressed in a high compliance with (internal) KPIs.
- Nevertheless, potential efficiency gains in the short- to midterm are applicable, ranging from process optimisation with less iterations, over IT improvements, to quicker communication.

- Both EFSA staff and experts consider the current system as proportionate in relation to the main outputs of the system, given the challenging external environment EFSA is confronted with.
- Overall, respondents to the online survey agree with these findings.

Recommendations

For addressing some of the remaining challenges, EFSA could:

- Strengthen training & awareness-raising efforts among EFSA staff & scientific experts by looking into other ways of communicating Independence Policy rules and procedures (e.g. eLearning, interactive trainings) as well as clearer, shorter and more targeted information.
- Improve the DoI assessment process as well as reduce administrative burden for experts by more effective and user-friendly IT tools.
- Identify possible administrative burden reduction for experts and staff (e.g. pre-filling of SDoI; remove the SDoI in the three-level system; etc.).
- Improve the response time and direct (pro-active) communication, especially when confronted with reputational hazards.
- Given the heightened exposure of some areas of work (e.g. GMOs, Health claims, Plant protection products), a risk-based approach for the rules or procedures to be applied to DoIs submitted by experts in these sectors remains an option to consider. A full-fledged scrutiny could be reserved to the most sensitive sectors, whereas the scrutiny for medium or low risk sectors could be more limited.

Q.5: Sustainability of the current independence policy system

Conclusions

- Given the current budgetary reality, the operational framework supporting the Independence policy can be maintained.
- EFSA might be limited in the near future for upholding its 'continuous improvement of the Independence Policy/system' approach, given the available level of resources and increase in tasks for the LA Unit.
- A potential increase of the strictness of the rules applied, might hinder the sustainability of EFSA, in providing adequate scientific outputs, as less experts become available.
- No clear view was expressed by experts in the online survey in terms of the level of sustainability of the system.

Recommendations

For addressing some of the remaining challenges, EFSA could uphold a phase of stability in terms of the rigidity of rules & high-level process, in order to obtain a reasonable level

of available experts as well as to allow experts and staff to further improve their awareness of the policies in place.

Comparative analysis of competing interest management systems of similar organisations

Conclusions

- Compared to similar organisations at EU Agency level, EFSA has set-up a particularly comprehensive, sophisticated and resource-intense independence policy system.
- While a number of elements are unique to EFSA's current organisational solutions and procedures (e.g. centralisation of the DoI screening, system of waivers, veracity check as part of the compliance and veracity check procedure), the comparison reveals that EFSA's system converges on a number of parameters with practices in similar EU Agencies, i.e. ECHA and EMA.
- Looking at independence policy systems of similar EU Agencies, a set of elements and good practices has been identified which are currently not in place at EFSA but could potentially be implemented by the Authority.

Recommendations

The evaluator recommends to EFSA to **further investigate** to what extent good practices of EMA and ECHA could be transposed into EFSA's specific operational and legal framework and, subsequently, contribute to improved effectiveness, efficiency and transparency of its current system. EFSA could consider to:

- Differentiate risk profiles of experts according to the category of their interests and apply a risk-based approach to the DoI screening at the example of EMA;
- Use, similar to EMA, a risk analysis approach for the selection of the expert DoIs on which compliance checks are performed;
- Publish annually - in addition to its Annual Activity Report - a special report on the implementation of its independence policy;
- Adopt specific BoT procedures for the different target groups;
- Introduce the obligation for scientific experts to notify to the Authority potential future CoIs such as required by EMA to its scientific experts;
- Streamline its DoI portfolio with only one type of specific Declarations of Interest (i.e. ODoIs) similar to ECHA;
- Facilitate public scrutiny of CoI assessment by including – as in EMA's case – a table in the meeting minutes of EFSA's Scientific Committees / Panels that clearly indicates the role of the participant in the meeting, the outcome of the DoI evaluation in relation to the meeting as well as restrictions applicable to specific agenda items.

Moreover, EFSA could consider **intensifying its cooperation** with similar EU Agencies, to combine resources and to set-up shared support functions for the management of its independence policy system. This could include the following elements:

- Set-up of a centralised / shared (externalised) body for the assessment of DoIs of the members of the Management Board and expert panels;
- Joint development of an IT tool for the DoI screening;
- Design of a standard training portfolio (including video, webinars and/or eLearnings);
- Sharing of communication tools and awareness-raising best practices on independence policy.

Annex A – Acronyms and abbreviations

This annex provides a list of acronyms and abbreviations.

ADoI	Annual Declaration of Interest
BoR	Breach of Rules
BoT	Breach of Trust
BUDG	European Parliament Committee on Budgets
CoI	Conflict of Interest
CV	Curriculum vitae
DG SANTE	European Commission, Directorate-General Health and Food Safety
DoI	Declaration of Interest
EC	European Commission
ECA	European Court of Auditors
ECHA	European Chemicals Agency
ECJ	European Court of Justice
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENVI	European Parliament Committee on Environment, Public Health and Food Safety
EO	European Ombudsman
EP	European Parliament
EU	European Union
FSO	Food Safety Organisation
FTE	Fulltime staff equivalent
HoU	Head of Unit
ICCG	DG SANTE, Inter-Committee Coordination Group

KPI	Key Performance Indicator
LA	EFSA Legal and Assurance Services
LRA	EFSA Legal and Regulatory Affairs
MB	EFSA Management Board
MS	Member State
NGO	Non-Governmental Organisations
ODoI	Oral Declaration of Interest
OECD	Organisation for Economic Cooperation and Development
PROMETHEUS	EFSA Promoting Methods for Evidence Use in Science project
SC	EFSA Scientific Committee
SCCS	DG SANTE, Scientific Committee on Consumer Safety
SCHEER	DG SANTE, Scientific Committee on Health, Environmental and Emerging Risks
SDoI	Specific Declaration of Interest
SOP	Standard Operating Procedure
TERA	EFSA Transparency and Engagement in Risk Assessment project
ToR	Terms of Reference
WG	Working Group
WIN	Work Instruction

Annex B – Detailed work plan

This annex contains the detailed work plan and description of the phases at activity level as validated in the Inception Report[63].

Phase 1: Inception

The Inception phase focuses on defining the methodological approach and structuring the project implementation. This phase consists of six activities, namely:

- **Activity 1.1:** Kick-off Meeting;
- **Activity 1.2:** Preliminary Desk Research;
- **Activity 1.3:** Refine Methodological Approach;
- **Activity 1.4:** Draft Inception Report;
- **Activity 1.5:** Interim Meeting 1 and finalisation of the Inception Report.

Activity 1.1: Kick-off Meeting (KoM)

A Kick-off Meeting between EFSA and Deloitte has been organised via conference call on 21 December.

The purpose of the meeting was to present and discuss the exact approach and methodology as well as the practical planning of the study, including the sequencing and timing of the different activities during the assignment. In particular, the following topics have been discussed and validated:

- list of interviewees identified to take part in (strategic) interviews;
- set-up of the web-based survey, including respondent profile, questionnaire, timeline, survey tool;
- list of relevant sources of information and data to be analysed by the study team;
- proposed comparative analysis of good practices in similar organisations, and define the scope and pre-selection of relevant organisations.
- draft reference letter introducing the study team in order to facilitate interactions with the various stakeholders.

A follow-up meeting between the EFSA project Steering Group and the Deloitte evaluation team will be organised at EFSA premises in Parma, Italy, end of January.

[63] Please note that the original timeline has been updated to include one additional week between the delivery of the Final Inception Report and the delivery of the Draft Comprehensive Report, to accommodate a later starting point of the project.

Activity 1.2: Preliminary desk research

Desk research starts already in the Inception phase and will include all information publically available on EFSA's website on the Agency's governance and organisation, its independence policy, Conflict of Interest management, approach to transparency and stakeholder management. Preliminary desk research allows the study team to form an inventory of available data sources and organise them according to type, relevance, quality and appropriateness to the assignment at hand.

Additional sources, in cooperation with the EFSA project team will be added to the inventory of data sources. The reference of identified sources is provided in Annex C.

Activity 1.3: Refine the Methodological Approach

The outcomes of the Kick-off Meeting and the findings from the initial desk research have been used to further refine the initial proposed methodology.

This involves two main steps: further elaboration of the **Intervention Logic** (of the Agency's Independence Policy) and the further elaboration and validation of the **Analytical Framework**. Subsequently, the work plan and data collection tools (e.g. the survey questionnaire, the interview guides) have been updated / drafted. The Steering Group will be asked to validate the consultation tools before they are used for the survey and interviews.

Activity 1.4: Draft Inception Report

The outcomes of the Kick-off Meeting, as well as findings from the initial desk research have been used to further refine our proposed methodology. This has been included in the draft Inception Report, provided to the Agency at least **three working days** in advance of Interim Meeting 1.

The draft Inception Report will contain the detailed Intervention Logic and Analytical Framework.

The draft Inception Report is the first deliverable of the study. It describes:

- Organisation of the work (including a detailed and complete work plan);
- Fully developed methodology for the evaluation;
- Approach to the implementation of the methodology;
- Various sources of information and data;
- Data collection methods and tools (e.g. interview guide, survey questionnaire).

As stated in the ToR, the Inception Report, to be submitted by the **09/01/2017**, consists of max. 15 pages, excluding annexes and will be submitted in English in MS-Word format with any relevant supporting charts in MS-Excel.

Activity 1.5: Interim Meeting 1 and finalisation of the Inception Report

The Interim Meeting 1 (teleconference) will take place **five weeks** after the entry into force of the specific contract. During this meeting, we will present the Inception report and

discuss it with EFSA. A short PowerPoint presentation of the draft report will be prepared by the Study team to facilitate the meeting.

Before the meeting the study team will seek pre-validation of the proposed templates for the interview guides and (survey) questionnaires.

As stated in the ToR, the meeting also provides the opportunity to draw to any technical or administrative difficulties encountered in the implementation of the project with discussion and resolution. We will prepare minutes of this meeting that will be shared with EFSA at the latest 1 week after the meeting for the purpose of validation.

In case of comments, the study team will modify the Inception report as required (or respond as appropriate).

Phase 2: Data collection

Phase 2 will consist of the collection of data. We have divided this phase into six activities, namely:

- **Activity 2.1:** Desk Research;
- **Activity 2.2:** Interviews;
- **Activity 2.3:** Web-based survey;
- **Activity 2.4:** Preliminary analysis incl. good practices in similar organisations;
- **Activity 2.5:** Draft Comprehensive and Summary Reports;
- **Activity 2.6:** Interim Meeting 2.

Activity 2.1: Desk research

Desk research will be a continuous activity during all phases of the study. During the consultation of stakeholders, more sources of information will be discovered that need to be analysed and included in the final analysis, if relevant.

The study team will scrutinise all documentation related to EFSA's independence policy and Rules on Declarations of Interest, including previous assessments and external literature.

In addition, the evaluation team will make use of statistical and monitoring data received upon request by EFSA as well as statistical data from other available sources. These data sources will most importantly include EFSA's own performance monitoring data, as well as statistical data sources of a more general purpose for contextual or supportive analysis.

Depending on the publically availability of data, possible data sets are:

- EFSA survey of staff and stakeholders on independence related topics (if available);
- Number of Declarations of Interest submitted;
- KPIs and monitoring reports on compliance with EFSA's independence policy; number of DoIs submitted, results of veracity and compliance checks, number of CoIs, etc.
- Etc.

During the desk research, the appropriate data sets will be further detailed and requested to EFSA in a timely manner within the agreed upon project timelines.

As part of the desk research, the evaluation team will also conduct a limited web screening of media (e.g. online news sites; social media) to investigate the reputational issues EFSA has been facing over the review period. By searching the web, via commonly used search portals, for a number of key words related to EFSA's independence, reputation, CoIs, etc., the evaluation team will be able to make an overall assessment on the impact of CoIs on its reputation.

Activity 2.2: Interviews

The evaluation team will carry out interviews (face-to-face or via tele- or videoconference) after having acquired a comprehensive understanding of the Agency's work and challenges through desk research.

Selection of interviewees

Based on our experience with similar studies, and on initial feedback from the EFSA project team, we have listed potential interview candidates from the following organisations:

- *Members of EFSA staff and management of the EFSA's Science Units and functions;*
- *Members of the European Parliament – ENVI Committee*
- *Officials of the European Commission – DG HEALTH*
- *Agents of ECHA and EMA*
- *Consumer organisations, NGOs, industry associations.*

Interaction with stakeholders

Given the very short time frame of the study, a structured approach to contact the pre-selected stakeholders and to set-up the interviews will be applied, respecting, a proper notification to the involved stakeholders, high quality of communication and follow-up with stakeholders. The study team will establish a follow-up Excel sheet with the selected stakeholders and systematically monitor the status of response to the interview requests.

Design of interviews

All interviews will be conducted in a **semi-structured manner**, i.e. based on an interview guide but with liberty for the flow of conversation and additional matters to be flagged by the interviewee, either face-to-face or over the phone.

An **interview guide** with sub-sets of questionnaires, adaptable to the targeted profiles, is provided in Annex. This interview guide was discussed with EFSA during the Interim Meeting 1.

The focus of the interview will be set according to the role of the interviewee in EFSA's independence policy system, allowing to collect information on the different aspects under the evaluation questions.

Activity 2.3: Web-based survey

In addition to interviews, primary data for the study will be collected from a web-based survey. The aim of the survey exercise will be to reach out to a larger number of stakeholders and to get a broader understanding of how the Agency's independence policy is perceived. Moreover, the survey allows to capture views on the Agency's reputation as an open, independent and transparent organisation, as well as views on the relevance, the effectiveness and the sustainability of the system in place.

The survey will consist predominantly of closed (and direct) questions (to facilitate ratings and comparisons with differentiated sections of the target respondent group) and a very limited number of open questions (to facilitate understanding and interpretation of the responses).

The web-based survey will be targeted towards the following **stakeholder groups**:

- *Experts of EFSA's Scientific Committee and Scientific Panels;*
- *Experts of EFSA's Pesticides Steering Committee;*
- *Representatives of Member States*

The survey will be designed in cooperation with EFSA, the final version is provided in Annex. **EUSurvey** will be used as the survey tool. Given the short time-frame of the study, the web-based survey will be **open** for responses during **10 days** (deadline was put on 27 January 2017).

Special attention will be given to the confidential manner of handling the input received from stakeholders. More specific, contact details will be disposed after the survey and results will be handled and reported in anonymised form.

Survey respondents will have the opportunity to contact the study team for any questions or support requests. We will facilitate and assist their further participation, thereby ensuring a successful completion of the survey.

Activity 2.4: Preliminary analysis incl. good practices in similar organisations

To complement the analysis, a limited number of organisations with a similar mandate (i.e. scientific decision-making EU Agencies) will be looked at to compare EFSA's Independence Policy and DoI system with good practices implemented by similar EU bodies.

For the selection of the organisations, the following **criteria** were used:

- Governance structure and presence of Scientific Committees composed of external experts;
- Recognition at EU level for having a good independence policy;
- Recognition for good practices in terms of independence;
- the level of transparency;
- Data availability;
- Type of organisation (i.e. EU Agency or institution).

Two organisations at EU level with a similar scientific decision making mandate and a well-functioning Conflict of Interest management system have been identified: the **European Medicines Agency (EMA)**, **European Chemicals Agency (ECHA) and European Commission Scientific Committees (Scientific Committee on Consumer Safety; Scientific Committee on Health, Environmental and Emerging Risks; Inter-Committee Coordination Group)**. The main objective of this high-level analysis is to identify improvement potentials to EFSA's current system in place. The analysis will be fully based on desk research, utilising publically available data sources on the Agency's websites, such as the description of policies, procedures and working practices, as well as strategic plans, (multi-)annual work programmes and activity reports (which may include KPIs on compliance with independence policy and DoI rules).

The findings will substantiate the analysis of specific evaluation questions and give input for suggestions to improve the Agency's independence policy.

Activity 2.5: Draft Comprehensive and Summary Reports

The ToR specify that the **Draft Comprehensive Report**, consisting of max. 50 pages, excluding annexes, should include:

- Substantiated description of the evaluation;
- Overview of the evaluation process;
- Preliminary analysis.

The **Draft Summary Report**, consisting of max. 20 pages, should contain a draft executive summary, providing a synthesis of first analysis, conclusions and recommendations.

The deadline for submission of the Draft Comprehensive Report and the Draft Summary Report has been set for the **06/02/2017**. Both reports will be submitted in English and in MS-Word format, including any supporting charts in MS-Excel.

Activity 2.6: Interim Meeting 2

The Interim Meeting 2 (teleconference) will take place **seven weeks** after the entry into force of the specific contract.

During this meeting, the study team presents and discusses with EFSA the Draft Comprehensive and Summary Reports, which will be submitted to EFSA **3 working days** in advance of the meeting. The meeting also provides the opportunity to draw to any technical or administrative difficulties encountered in the implementation of the project with discussion and resolution.

Minutes of this meeting will be prepared by the team and shared with the Steering Group at latest 1 week after the meeting for validation.

Phase 3: Analysis, Judgement & Reporting

Analysis, judgement and reporting occurs at different times throughout the project. Phase 3 constitutes the final phase of the project during which the critical information is further triangulated, validated and analysed and the final analysis produced. This phase consists of the following activities:

- **Activity 3.1:** Data triangulation and validation;
- **Activity 3.2:** Data analysis;
- **Activity 3.3:** Teleconference 1;
- **Activity 3.4:** Draft Final Comprehensive and Summary Reports;
- **Activity 3.5:** Final Meeting and Finalisation.

Activity 3.1: Data triangulation and validation

Once all data collection activities of Phase 2 are concluded, the study team will triangulate the data collected through different methods. Data triangulation involves using multiple sources of information in order to increase the validity of the evidence, by confirming results through the comparison of findings from different sources.

Moreover, the triangulation technique is used to verify the reliability of the sources and to test the quality, the accuracy and relevance of the data; to aggregate quantitative and qualitative data-sets and to ensure the overall coherence of the analysis; as well as to identify data gaps and contradictory findings, for which clarification is needed.

Rather than focusing on one data source, which could lead to a biased conclusion, the evaluator will challenge findings from one data sources with (ideally different) other data sources. This will allow the evaluator to formulate a neutral, objective opinion and answer to the question. It will furthermore deepen the evaluator's understanding of the issues and maximise confidence in the findings.

The objective assessment of the data will be assured by the use of the Analytical Framework and the predefined evaluation criteria.

Activity 3.2: Data analysis

Subsequently to the triangulation and validation, the collected data will be analysed for the purpose of drawing conclusions and of answering the evaluation questions. This analysis will be documented in the draft final reports.

The Analytical Framework and predefined judgement criteria will guide the analysis and ensure an objective, transparent and well-balanced assessment.

The study team will moreover provide transparency and clarity on its analysis by the following actions:

- Clearly indicating the different information sources and methods used;
- Explaining the elements on which conclusions and recommendations are built;
- Indicating data gaps;
- Qualifying assumptions; and

- Providing supporting tables with relevant quantitative and qualitative data-sets in the Annexes to the report.

Activity 3.3: Teleconference 1

As stipulated in the ToR, a teleconference will take place **nine weeks** after the entry into force of the specific contract. The purpose of the teleconference is to discuss the status of progress of the project and draw to any technical or administrative difficulties encountered in the implementation of the project with discussion and resolution.

The study team will prepare minutes of this meeting that will be shared with the Steering Group at latest 1 week after the teleconference for the purpose of validation.

Activity 3.4: Draft Final Comprehensive and Summary Reports

The Draft Final Comprehensive and Summary Reports will be presented during the Final Meeting with the Steering Group, which is supposed to take place **12 weeks** after the entry into force of the specific contract.

The **Draft Final Comprehensive Report** will include all findings and conclusions addressing the purpose and specific objectives of the ex post evaluation in line with the structure agreed with EFSA.

As part of the Final Comprehensive Report, the study team will include supporting documentation for a stakeholder meeting where the report and findings will be presented (see "specific tasks" on p. 4 of the ToR). The methodological approach, the practicalities as well as the role of Deloitte as facilitator can be discussed with EFSA during the Final Meeting.

The **Draft Final Summary Report** will contain an executive summary, providing a synthesis of the analysis, conclusions and recommendations, as well as all other elements requested by EFSA.

Activity 3.5: Final Meeting and Finalisation of the Comprehensive and Summary Reports

The Final Meeting (teleconference) will take place **12 weeks** after the entry into force of the specific contract.

During this meeting, the study team will present the Draft Final Comprehensive and Summary Reports and discuss it with the Steering Group.

A short PowerPoint presentation will be prepared to illustrate findings and to support the discussions.

As specified in the ToR, the Steering Group may provide its comments and remarks on both draft reports, which will be addressed to the extent possible by the study team.

The study team will prepare minutes of this meeting that will be shared with the Steering Group at latest 1 week after the meeting for the purpose of validation.

In line with the ToR, the Final Comprehensive Report should comply with the following requirements:

- Reproduce the structure as the Draft Comprehensive Report;
- Include all findings and conclusions addressing the purpose and specific objectives of the ex post evaluation;
- Take on board EFSA's comments and remarks made on the Draft Final Comprehensive Report.

Besides, the Final Comprehensive Report will consist of maximal 50 pages, excluding annexes, while the Final Summary Report will consist of maximal 20 pages. As requested in the ToR, both reports will be submitted in English in MS-Word format with any relevant supporting charts in MS-Excel.

The Final Summary Report should have the same structure as the Draft Final Summary Report and will be reworked by the evaluation team in light of the comments and remarks made on the Draft Final Summary Report.

The ToR set **28/02/2017** as the deadline for submission for the Final Comprehensive Report.

The ToR set **28/03/2017** as the deadline for submission for the Final Summary Report.

Annex C - Analytical Framework and Intervention Logic

6.1 Analytical Framework

The following section includes a detailed overview of the Analytical Framework used for this ex-post evaluation.

The Analytical Framework consists of four consequent levels of analysis. The Analytical Framework will include the **evaluation questions, judgement criteria, indicators**, **main sources and methods**. It will guide our data collection process during the different phases of the project, allowing us to produce conclusions that are evidence-based and objectively verifiable.

The Analytical Framework will constitute a reference point for analysis until the end of the study, to ensure that the objectives of the evaluation are met and every evaluation question is adequately addressed and answered.

During the data collection phase, the quantitative and qualitative data will be checked against the indicators defined in the Analytical Framework to make sure that all of the evaluation issues have been covered. This process of gap analysis is conducted throughout the study, to ensure that all relevant data is available or to engage, if necessary, corrective or mitigation actions.

Please note that the collection of evidence for the proposed indicators depends on the availability of information as well as the comparability of data for the review period 2014-2016. The success of the study team's efforts to collect evidence on the indicators will also rely to a large extent on the cooperation of stakeholders to provide access to relevant data sets and information.

1. To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 contributed to **EFSA's reputation**?

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods[64]
1.1 To what extent has EFSA's reputation in terms of **independence** improved/declined? 1.2 To what extent has EFSA's reputation in terms of **transparency** improved/declined? 1.3 To what extent has EFSA's reputation in terms of **scientific excellence** improved/declined?	• EFSA is perceived as an independent and transparent Agency. • EFSA's Policy on Independence and Scientific Decision-Making Processes and Rules on DoI have contributed to the Agency's reputation as an organisation, providing reliable, objective and high quality scientific and technical advice.	• Perceptions of EFSA's stakeholders on the Agency as an independent, transparent and open organisation and a reference for scientific excellence (i.e. EFSA's corporate values) • Number of complaints against EFSA filed to the European Ombudsman regarding independence issues • Outcome of complaint handling • Views and assessment of the European Parliament on EFSA's independence policy and Conflicts of Interest management system • Negative media coverage (e.g. online press, social media, etc.) • Number of NGO campaigns against EFSA	• Desk research - Academic sources - EFSA Founding Regulation - EFSA Independence Policy and Rules on DoI - Reports and decisions of the European Ombudsman - "Putting it right" reports - Annual Discharge Reports of the European Parliament - Results of EFSA's surveys with external stakeholders - EFSA monitoring data - EFSA Organisational Strategy and Science Strategy - Media publications - Etc. • Interviews - EFSA staff and management - European Commission/European Parliament

[64] This draft version of the Analytical Framework presents the main sources for collecting evidence on the evaluation questions. For a more detailed description of our information sources and methods, as well as the proposed selection of interviewees and survey participants, please refer to Section 4.

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods[64]
		• Perception of the level of independence and transparency of EFSA compared to similar organisations	- EFSA Stakeholder Forum (e.g. consumer organisations, NGOs, industry associations) • Web-based survey • Limited comparative analysis with similar organisations (e.g. EMA/ECHA/EC Scientific Committees)

2. To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 contributed to a **high level of food safety and consumer protection**?

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
2.1 To what extent has EFSA's independence policy secured the provision of independent, objective and high quality scientific outputs? 2.2 To what extent has EFSA's independence policy ensured effective risk communication to the public?	• The high level of food safety and consumer protection could not be adequately ensured without the system provided by the independence policy and Rules on DoI. • Stakeholders perceive the system in place to be conducive to ensuring a high level of food safety and consumer protection. • The system ensures that the public and interested parties	• Number of complaints against EFSA filed to the European Ombudsman regarding independence issues • Outcome of complaint handling • Cases of food safety and consumer protection issues have occurred linked to a CoI (either EFSA scientific staff or members of EFSA bodies) • Number of identified CoI for which mitigation actions have	• Desk research - Academic sources - EFSA Founding Regulation - EFSA Independence Policy and Rules on DoI & related Implementing Rules - Annual Discharge Reports of the European Parliament - Reports and decisions of the European Ombudsman - "Putting it right" reports - EFSA Organisational Strategy and Science Strategy

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
	receive rapid, reliable, objective and comprehensible information on independence related matters.	not been effective, according to stakeholders involved • Number of CoI or BoT which have occurred but have not been reported by the Agency • Perceptions of stakeholders on the positive impact of the current system and procedures in place on the level of food safety and consumer protection • Perceptions of the public on the transparency of the Agency on its CoI management system • Perceptions of stakeholders on the effectiveness of the system to protect EFSA's scientific decision-making processes against external influence	- EFSA Annual Activity Reports - Results of EFSA's surveys with external stakeholders - EFSA monitoring data - EU statistical data - Media publications - EFSA website - Etc. • Interviews - EFSA staff and management - European Commission/European Parliament - EFSA Stakeholder Forum (e.g. consumer organisations, NGOs, industry associations) • Web-based survey

3. To what extent has the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 **provided value for the money** the Authority invested to ensure the policy's implementation?

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
3.1 What are the overall costs of the system in place? 3.2 How effective is the system in place compared to the outputs and results *(see findings under evaluation questions 1-2)*? 3.3 To what extent are the costs proportionate to the outputs and results?	• The system in place is considered by stakeholders to deliver the expected results. • The costs of the system are considered to be proportionate compared to the outputs produced. • The Agency has taken actions to improve the overall cost-effectiveness of the system.	• Evolution of the overall costs compared to the number of outputs produced • Number of resources allocated to the management of the system (FTEs) and organisational units involved in the implementation • Investments in IT systems supporting the implementation of the system • Costs of trainings on independence policy and awareness-raising • Level of satisfaction of EFSA's stakeholders with the outputs of the system in place • Perception of EFSA's stakeholders on the proportionality of the costs • Comparison of the overall costs of the system versus occurrence of independence issues • Benchmarking with resources invested by ECHA and EMA	• Desk research - Academic sources - EFSA Founding Regulation - EFSA Independence Policy and Rules on DoI & related Implementing Rules - Rules of Procedure of EFSA's bodies and scientific-decision making processes - Annual Discharge Reports of the European Parliament - Reports and decisions of the European Ombudsman - "Putting it right" reports - EFSA Organisational Strategy and Science Strategy - EFSA Annual Work Programmes and Multi-Annual Programming Documents - EFSA Annual Activity Reports - Reports of the Internal Audit Capability/Internal Audit Service - Reports of the Quality Manager - Reports of the European Court of Auditors - Results of EFSA's surveys with external stakeholders

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
			- EFSA monitoring and cost data - Etc. • Interviews - EFSA staff and management - European Commission/European Parliament/ECHA/EMA • Web-based survey • Limited comparative analysis with similar organisations (e.g. EMA/ECHA)

4. To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 2014 **relevant, effective, efficient and proportionate** to the policy objective of ensuring compliance with the Independence requirements laid down in Regulation (EC) No 178/2002[65]?

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
4.1 To what extent are the Agency's Independence Policy and the Rules on DoI still **relevant** to contribute to the objective of EFSA's	• Stakeholders consider that there is still a need to maintain the system in place. • Without the system in place compliance with the	• Number of cases of incompliance and independence issues • Number of complaints to the European Ombudsman	• Desk research - Academic sources - EFSA Founding Regulation

[65] In particular Art. 22, 23, 28, 32 and 37 of Regulation (EC) No 178/2002.

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
Founding Regulation to ensure the independence of the Agency's scientific decision-making processes?	independence requirements of EFSA's Founding Regulation could not be adequately ensured. • Stakeholders consider that the risk of external influence and biased scientific decision-making processes continue to exists, requiring the continued operation of the system in place.	• Perceptions of stakeholders on the relevance of the system in place	- EFSA Independence Policy and Rules on DoI & related Implementing Rules - Rules of Procedure of EFSA's bodies and scientific-decision making processes - Annual Discharge Reports of the European Parliament - Reports and decisions of the European Ombudsman - "Putting it right" reports - EFSA Organisational Strategy and Science Strategy - EFSA Annual Work Programmes and Multi-Annual Programming Documents - EFSA Annual Activity Reports - Reports of the Internal Audit Capability/Internal Audit Service - Reports of the Quality Manager - Reports of the European Court of Auditors - Results of EFSA's surveys with external stakeholders - EFSA monitoring data - Etc. • Interviews - EFSA staff and management

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
			- European Commission/European Parliament - EFSA Stakeholder Forum (e.g. consumer organisations, NGOs, industry associations) • Web-based survey
4.2 To what extent are the Agency's Independence Policy and the Rules on DoI **effective** to contribute to the objective of ensuring compliance with the Independence requirements of EFSA's Founding Regulation?	• The system in place effectively ensures compliance with the Independence requirements. • The system in place is effective in detecting and preventing Conflicts of Interests and provides effective mitigation measures. • The system in place establishes effective monitoring and control mechanisms • Stakeholders consider that the system in place provides for transparent, open and independent scientific decision-making processes. • Stakeholders consider that the system in place contributes to the objective of assuring independent,	• Number of reported CoI, BoT or BoR • Number of cases of incompliance • Number of cases in which a CoI, BoT or BoR has not been reported or has not been addressed on time • Results of veracity and compliance checks • Number of complaints to the European Ombudsman • Outcome of complaint handling • Perceptions of stakeholders on the effectiveness of the system in place • Perceptions of stakeholders on the effectiveness of EFSA's communication on the independence system and procedures in place	• Desk research - Academic sources - EFSA Founding Regulation - EFSA Independence Policy and Rules on DoI & related Implementing Rules - Rules of Procedure of EFSA's bodies and scientific-decision making processes - Annual Discharge Reports of the European Parliament - Reports and decisions of the European Ombudsman - "Putting it right" reports - EFSA Organisational Strategy and Science Strategy - EFSA Annual Work Programmes and Multi-Annual Programming Documents - EFSA Annual Activity Reports

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
	reliable, objective and high quality scientific outputs and information. • The system in place contributes to the understanding and awareness of stakeholders about EFSA's Independence requirements.	• Views of EFSA staff and management on the contribution of the system to an organisational culture promoting independence • Number of trainings given on independence	- Reports of the Internal Audit Capability/Internal Audit Service - Reports of the Quality Manager - Reports of the European Court of Auditors - Results of EFSA's surveys with external stakeholders - EFSA monitoring data - Etc. • Interviews - EFSA staff and management - European Commission/European Parliament - EFSA Stakeholder Forum (e.g. consumer organisations, NGOs, industry associations) • Web-based survey • Limited comparative analysis with similar organisations (e.g. EMA/ECHA)
4.3 To what extent are the Agency's Independence Policy and the Rules on DoI **efficient** to contribute to the objective of ensuring	• Stakeholders consider that the system is working efficiently. • Stakeholders consider the level of resources allocated to	• Perceptions of stakeholders on the efficiency of procedures and workflows • On-time delivery of outputs (e.g. screening of DoIs,	• Desk research - Academic sources - EFSA Independence Policy and Rules on DoI & related Implementing Rules

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
compliance with the Independence requirements of EFSA's Founding Regulation?	the operation of the system adequate. • Stakeholders consider that the efficiency of the overall system could be improved. • Stakeholders consider that the organisational solutions enable efficient workflows.	performance of veracity and compliance checks, availability of independence-related documents on the Agency's website, etc.) • Perceptions of stakeholders on the adequacy of organisational solutions (e.g. centralisation, outsourcing) • Perceptions of stakeholders on efficiency improvement potentials (e.g. risk-based approach)	- Rules of Procedure of EFSA's bodies and scientific-decision making processes - Annual Discharge Reports of the European Parliament - EFSA Organisational Strategy and Science Strategy - EFSA Annual Work Programmes and Multi-Annual Programming Documents - EFSA Annual Activity Reports - Reports of the Internal Audit Capability/Internal Audit Service - Reports of the Quality Manager - Reports of the European Court of Auditors - EFSA monitoring data - Etc. • Interviews - EFSA staff and management - European Commission/European Parliament • Web-based survey • Limited comparative analysis with similar organisations (e.g. EMA/ECHA)

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
4.4 To what extent are the Agency's Independence Policy and the Rules on DoI **proportionate** to contribute to the objective of ensuring compliance with the Independence requirements of EFSA's Founding Regulation?	• The system in place is considered by stakeholders as proportionate to ensure compliance with the independence requirements. • The independence requirements could not be implemented with less resource-consuming means.	• Perceptions of stakeholders on the proportionality of the system in place • Comparison with independence management systems in other Agencies • Comparison with rules of procedure of the EC Scientific Committees (SCCS, SCHEER, ICCG) and SAM	• Desk research - Academic sources - EFSA Independence Policy and Rules on DoI & related Implementing Rules - Rules of Procedure of EFSA's bodies and scientific-decision making processes - Annual Discharge Reports of the European Parliament - EFSA Organisational Strategy and Science Strategy - EFSA Annual Work Programmes and Multi-Annual Programming Documents - EFSA Annual Activity Reports - Reports of the Internal Audit Capability/Internal Audit Service - Reports of the Quality Manager - Reports of the European Court of Auditors - Etc. • Interviews - EFSA staff and management - European Commission/European Parliament • Web-based survey

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
			• Limited comparative analysis with similar organisations (e.g. EMA/ECHA)

5. To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 **sustainable** against the evolving political and financial perspectives?

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
5.1 To what extent can the system be maintained in a context of changing resources (e.g. budget or posts) against evolving social or political expectations (e.g. scope and ambitions)? 5.2 To what extent does the system provide the margin for adjustments to the evolving resources or expectations?	• Stakeholders consider that the system in place is sustainable in view of evolving political and financial perspectives. • The operational framework established by the Policy on independence and the DoI rules is sustainable against the evolving political and financial perspectives. • The mechanisms to review the system in place are adequate to ensure sustainability of the system against the evolving political and financial perspectives. • The system in place is considered to be fit-for-purpose against the evolving political and financial perspectives.	• Evolution of Agency budget and availability of resources for the implementation and management of the system in place • Evolution of the maintenance costs of the system • Workload forecasts linked to the system in place • Perceptions of stakeholders on the sustainability of the system and the adaptability of procedures in place against the evolving political and financial perspectives • Composition of the panel system with external experts in context of an evolving level of rigidity on applied rules.	• Desk research - Academic sources - EFSA strategy 2020 - EU 2020 - EFSA Independence Policy and Rules on DoI & related Implementing Rules - Rules of Procedure of EFSA's bodies and scientific-decision making processes - Annual Discharge Reports of the European Parliament - EFSA Organisational Strategy and Science Strategy - EFSA Annual Work Programmes and Multi-Annual Programming Documents - EFSA Annual Activity Reports - Reports of the Internal Audit Capability/Internal Audit Service - Reports of the European Court of Auditors

			- EFSA monitoring data - Etc. • Interviews - EFSA staff and management - European Commission/European Parliament • Web-based survey • Limited comparative analysis with similar organisations (e.g. EMA/ECHA)

As requested per ToR (p. 4), the following question will be part of our analysis. Please note that some elements for this evaluation questions will be interrelated with findings under the previous evaluation questions.

6. To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 compliant with the **proportionality and subsidiarity principles**?

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
6.1 To what extent does the measure go beyond what is necessary to achieve the objectives satisfactorily? 6.2 To what extent is the form of action (choice of instrument) as simple as possible and coherent with satisfactory achievement of the objective and effective enforcement?	• Stakeholders consider that the system in place is proportionate. • Stakeholders are satisfied with the system in place. • Stakeholders consider that the system in place respects the principle of subsidiarity. • Stakeholders consider that compliance with the	• Views of stakeholders on the compliance of the current system with proportionality and subsidiarity principles • Level of satisfaction of stakeholders with the current system • Perceptions of stakeholders on the administrative burden	• Desk research - Academic sources - EFSA Independence Policy and Rules on DoI & related Implementing Rules - Rules of Procedure of EFSA's bodies and scientific-decision making processes

Detailed evaluation questions	Judgement criteria	Indicators	Main sources and methods
6.3 To what extent is the form of action (choice of measure) most appropriate/necessary at EFSA level?	independence requirements could not be effectively ensured without the current intervention of EFSA.	of the current system and potentials for simplification • KPIs on compliance with independence requirements • Comparison with independence management systems in other Agencies • Comparison with rules of procedure of the EC Scientific Committees (SCCS, SCHEER, ICCG) and SAM	- EU and OECD Guidelines on prevention and management of Conflicts of Interest - Annual Discharge Reports of the European Parliament - EFSA Organisational Strategy and Science Strategy - EFSA Annual Work Programmes and Multi-Annual Programming Documents - EFSA Annual Activity Reports - Reports of the Internal Audit Capability/Internal Audit Service - Reports of the European Court of Auditors - EFSA monitoring data - Etc. • Interviews - EFSA staff and management - European Commission/European Parliament • Web-based survey • Limited comparative analysis with similar organisations (e.g. EMA/ECHA)

6.2 Intervention Logic

The Intervention Logic (IL) visualises the operational framework of the Agency's Independence policy as well as the causal links between the different elements of the intervention, i.e. the Agency's Independence Policy, including:

- Needs/Problems
- General Objectives
- Specific Objectives
- Inputs
- Activities
- Outputs
- Results
- Impacts

The Intervention Logic provides a reference point for the assessment of the evaluation criteria[66] presented in the ToR:

- **Effectiveness/Efficacy**: Have the objectives been met and the expected results/outputs been achieved?
- **Efficiency:** What is the relationship between the inputs and the achieved results/outputs?
- **Relevance**: Are the objectives and activities (still) consistent with the needs/problems to be addressed?
- **Sustainability**: Can the system be maintained against an evolving context?
- **Proportionality and Subsidiarity**: Are the costs proportionate compared to the outputs and results achieved? Is the form of action (choice of instrument) most appropriate/necessary at EFSA level?

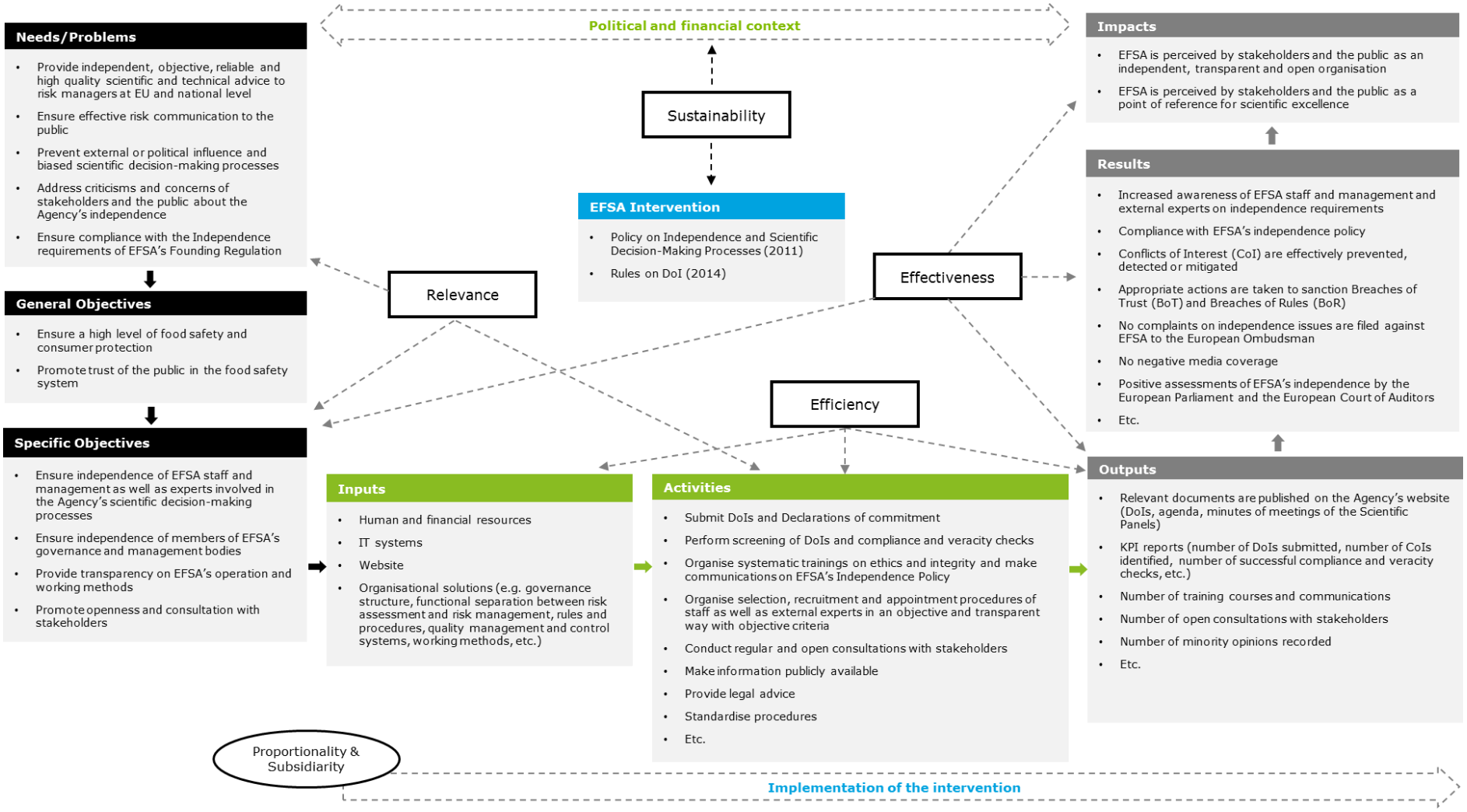
In conjunction with the Analytical Framework, the Intervention Logic will guide the team's analysis during the evaluation.

The Intervention Logic presented in the figure below builds on EFSA's Founding Regulation, EFSA's Policy on Independence and Scientific Decision-Making Processes (2011), EFSA's Rules on DoIs (2014), EFSA's webpages on Independence as well as the Agency's Annual Activity Reports for the period 2014-2015.

The Intervention Logic will be presented to EFSA and further developed by the study team during the inception phase, taking on board EFSA's comments. The strategic interviews will allow the study team to test the IL and clarify causal links. Information and insights collected via desk research will support the completion of the IL.

[66] The Intervention Logic and the definitions of the evaluation criteria have been elaborated in line with the EU's Better Regulation Toolbox (2015), see p. 271-276.

Figure 3 – Intervention Logic of EFSA's Independence Policy and DoI Rules



Annex D – Literature review

This annex contains the list of documentation consulted during the evaluation.

6.3 Legal Documents

- Treaty on the functioning of the European Union (TFEU) (2012): http://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX:12012E/TXT
- EU Charter of Fundamental Rights (2000): http://www.europarl.europa.eu/charter/pdf/text_en.pdf
- EFSA Founding Regulation: Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety: http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2002:031:0001:0024:en:PDF
- EU Staff Regulations: http://eur-lex.europa.eu/legal-content/EN/TXT/PDF/?uri=CELEX:01962R0031-20140501&from=EN

6.4 EFSA Independence Policy & DoI Rules

- EFSA webpage on Independence: https://www.efsa.europa.eu/en/topics/topic/independence
- EFSA Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority (2011): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independencepolicy.pdf
- EFSA Technical Report: Outcome of the public consultation on the draft Policy on Independence and Scientific Decision-Making Processes (2011): http://www.efsa.europa.eu/sites/default/files/scientific_output/files/main_documents/independence.pdf
- Decision of EFSA's Executive Director on Declarations of Interest (31 July 2014): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independencerules2014.pdf
- Decision of EFSA's Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests (21 February 2012): http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/independencerules.pdf

- Decision of EFSA's Executive Director: Derogations concerning recovery orders related to staff missions (2009): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/recoveryorderstaff.pdf
- EFSA Guidelines on Gifts and Hospitality (2012): http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/giftshospitality.pdf
- EFSA Concept Paper of 16 March 2016 on the review of EFSA's Policy on independence and scientific decision making process: http://www.efsa.europa.eu/sites/default/files/160615-d4.pdf
- Decision of EFSA's Executive Director on Declarations of Interest (31 July 2014): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independencerules2014.pdf
- EFSA webpage on Declarations of Interest: https://www.efsa.europa.eu/en/howwework/doi
- EFSA online database of Declarations of Interest: https://ess.efsa.europa.eu/doi/doiweb/doisearch

6.5 EFSA Independence Policy Review – MB WG

- 71st EFSA Management Board meeting: Board adopts multi-annual work programmes and 2017 budget, considers independence policy review and stakeholder engagement (14 December 2016): http://www.efsa.europa.eu/en/events/event/161214-0
- 70th EFSA Management Board meeting: Board elects new chair, endorses independence policy review plan, discusses open data and EFSA Journal migration (5 October 2016): http://www.efsa.europa.eu/en/events/event/161005
- 69th EFSA Management Board Meeting: Board adopts new stakeholder approach, takes stock of progress on transparency, discusses independence policy enhancement (15 June 2016): https://www.efsa.europa.eu/en/events/event/160615
- EFSA: Kick off meeting: WG on Independence of the Management Board (31 Oct 2016)
- EFSA: 2nd meeting MB Working Group on Independence Policy Review (21 Nov 2016)
- EFSA: 3rd meeting MB Working Group on Independence Policy Review (13 Dec 2016)
- EFSA Report (External Relations Unit): Meeting with Industry Associations on the review of EFSA's Independence Policy (23 Nov 2016)
- EFSA Report (External Relations Unit): Meeting with Non-Governmental Organisations on the review of EFSA's Independence Policy (23 Nov 2016)

6.6 EFSA Transparency and Stakeholder Engagement

- EFSA webpage on Transparency: https://www.efsa.europa.eu/en/topics/topic/openefsa
- EFSA's Approach on Public Consultations on Scientific Outputs: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/consultationpolicy.pdf
- Transformation to an "Open EFSA": Preliminary Implementation Plan (27 March 2015): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/openefsapreliminaryimplementationplan150327.pdf
- Discussion Paper - Transformation to an "Open EFSA", Public Consultation (17 July – 15 September 2014): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/openefsadiscussionpaper14.pdf
- Update on the Transparency and Engagement in Risk Assessment (TERA) Project (MB 3 December 2015): http://www.efsa.europa.eu/sites/default/files/mb151203-d2.pdf
- EFSA Stakeholder Engagement Approach (2016): https://www.efsa.europa.eu/sites/default/files/EFSA%20Stakeholder%20engagement%20approach_FINAL.pdf
- EFSA Management Board Decision concerning Implementing Measures of Transparency and Confidentiality Requirements (2005): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/transparencyimplementation.pdf
- EFSA General Principles on Transparency and Confidentiality (2003): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/transparencyprinciples.pdf

6.7 EFSA Governance and Organisation of EFSA Bodies

- Rules of Procedure of the Management Board of the European Food Safety Authority (27 June 2013): http://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/mbrules.pdf
- Decision of the Management Board concern the operation of the Advisory Forum (2016): https://www.efsa.europa.eu/sites/default/files/assets/afoperation.pdf
- Rules of Procedure of the Scientific Committee, the Scientific Panels and their Working Groups (27 June 2013): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/paneloperation.pdf
- Decision of the Executive Director concerning the selection of members of the Scientific Committee, the Scientific Panels and the selection of external experts to

assist EFSA with its scientific work (2016): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/expertselection.pdf

- Decision concerning the establishment and operation of European Networks of scientific organisations operating in the field within the Authority's mission (2010): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/networksoperation.pdf
- Decision of EFSA's Executive Director concerning pesticides risk assessment peer review (18 September 2015): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/eddecisionppr.pdf
- EFSA Code of Good Administrative Behaviour (2003): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/admincode.pdf

6.8 EFSA Strategies, Planning and Reporting

EFSA Strategies

- EFSA Strategy 2020 "Trusted science for safe food" - Protecting consumers' health with independent scientific advice on the food chain: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/strategy2020.pdf
- EFSA Science Strategy 2012-2016: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/scienestrategy12.pdf

EFSA Multi-annual Programming Documents

- EFSA Multi-annual programming document (2016-2018): https://www.efsa.europa.eu/sites/default/files/programmingdocument2016_2018.pdf
- EFSA Multi-annual programming document (2015-2017): http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1517.pdf
- EFSA Multi-annual programming document (2017-2019): https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/amp1719.pdf

EFSA Annual Activity Reports

- EFSA Annual Activity Report 2014: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/ar2014.pdf
- EFSA Annual Activity Report 2015:https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/ar2015.pdf

EFSA Annual Reports of the Quality Manager

- EFSA Annual Report of the Quality Manager (2015): https://www.efsa.europa.eu/en/corporate/pub/qmr15
- EFSA Annual Report of the Quality Manager (2014): http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/qmr14.pdf

6.9 Audits, EO/ECJ cases and external evaluations

European Parliament

- EP Report on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2014 (2015/2176 (DEC)): http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A8-2016-0086+0+DOC+PDF+V0//EN
- EP Report on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2013 (2014/2108 (DEC)): http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//NONSGML+REPORT+A8-2015-0097+0+DOC+PDF+V0//EN
- EFSA Report to the European Parliament on the Implementation of its Independence Policy 2007-2012 (29 June 2012): https://www.efsa.europa.eu/en/about/corporatedocs
- European Parliament, DG IPOL, Policy Department D – Budgetary Affairs, Better avoidance of Conflict of Interest: EU agencies and other bodies moving forward: workshop follow-up, http://bookshop.europa.eu/en/better-avoidance-of-conflict-of-interest-pbBA3213387/

European Court of Auditors

- Special Report on Management of Conflict of Interest in selected EU agencies (2012): http://www.eca.europa.eu/Lists/News/NEWS1210_11/NEWS1210_11_EN.PDF
- Report on the annual accounts of the European Food Safety Authority for the financial year 2013 (16 September 2014): http://www.eca.europa.eu/Lists/ECADocuments/EFSA_2013/EFSA_2013_EN.pdf
- Report on the annual accounts of the European Food Safety Authority for the financial year 2014 (8 September 2015): http://www.eca.europa.eu/Lists/ECADocuments/EFSA_2014/EFSA_2014_EN.pdf

European Ombudsman

- Inquiry into complaint 747/2016/ANA: "EFSA's handling of the review of the Threshold of Toxicological Concern (TTC)" (29 August 2016): https://www.ombudsman.europa.eu/en/cases/caseopened.faces;jsessionid=1934DB0AEEB97C826134BCEB46D17C97
- Inquiry into complaint 176/2015/JF: "EFSA's handling of a set of questions concerning an application for authorisation of a genetically-modified ('GM') maize" (5 May 2015):

https://www.ombudsman.europa.eu/en/cases/case.faces/en/45450/html.bookmark

- Decision of the European Ombudsman closing the inquiry into complaint 346/2013/SID against EFSA: "Alleged failure to address the Conflict of Interest issues raised in respect of certain members of the Working Group on Genetically Modified Insects and the related claim" (30 January 2015): http://www.ombudsman.europa.eu/cases/decision.faces/en/58868/html.bookmark
- Decision of the European Ombudsman closing the inquiry into complaint 2522/2011/(VIK)CK against EFSA: "Alleged failure to guarantee the independence of the TTC working group and related claim" (27 March 2014): http://www.ombudsman.europa.eu/cases/decision.faces/en/53898/html.bookmark
- Decision and draft recommendations of the European Ombudsman closing his inquiry into complaint 775/2010/ANA against EFSA: "Allegation that EFSA failed adequately to address the issue of a potential Conflict of Interest in the move of its former staff member to a biotechnology company and related claims" (23 May 2013): http://www.ombudsman.europa.eu/cases/summary.faces/en/50377/html.bookmark
- EFSA final response to the European Ombudsman (22 March 2012): EFSA's final opinion on the draft recommendations submitted by the European Ombudsman (Complaint 0775/2010/ANA)
- "Putting it right" reports – Follow up report cases http://www.ombudsman.europa.eu/en/cases/followup.faces/en/58401/html.bookmark

European Court of Justice

- Judgement of 16 July 2015, *ClientEarth and PAN Europe v EFSA,* C-615/13 P: http://curia.europa.eu/juris/document/document.jsf?text=&docid=165906&doclang=EN

External evaluators

- Deloitte: Final Report - High level analysis and input paper regarding future orientations regarding the EFSA DoI policy and its Implementing Rules (2014): http://www.efsa.europa.eu/sites/default/files/assets/analysisdoipolicy2014.pdf
- Milieu: Final Report – Comparison between the tools ensuring EFSA's independent scientific advice and the instruments in use by organisations similar to EFSA (2011): https://www.efsa.europa.eu/sites/default/files/assets/mb110317-ax8b.pdf
- Acertis: Independent report on factual findings in connection with the implementation of EFSA policy on DOI in certain Scientific Panels (2011): https://www.efsa.europa.eu/sites/default/files/assets/mb110317-ax8c.pdf

6.10 Comparative Analysis: EU Agencies and European Commission Scientific Committees

European Chemicals Agency (ECHA)

- ECHA webpage and documentation on independence: https://echa.europa.eu/about-us/the-way-we-work/procedures-and-policies/conflicts-of-interest
- Decision of the ECHA Management Board on the prevention and management of potential Conflicts of Interest (2014): https://echa.europa.eu/documents/10162/13608/mb_07_2014_pro_coi_management_en.pdf/c4082b12-5830-4647-abf7-47c4a0879c86
- ECHA Guidance for the prevention of potential Conflicts of Interest in ECHA networks and expert groups (2014): https://echa.europa.eu/documents/10162/13607/ed_decision_39_2014_en.pdf/634e043f-2d9c-4d43-9e8d-423c7d4629eb
- ECHA Guidance for filing in the Declaration of Interest (2014): https://echa.europa.eu/documents/10162/13607/ed_decision_28_2014_en.pdf/44f4ee6a-3203-473d-8159-2f7eb09a14d4

European Medicines Agency (EMA)

- EMA webpage and documentation on Conflicts of Interests: http://www.ema.europa.eu/ema/index.jsp?curl=pages/about_us/document_listing/document_listing_000178.jsp&mid=WC0b01ac0580029338
- EMA policy on the handling of competing interests of scientific committees' members and experts (2016): http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/11/WC500216190.pdf
- EMA policy on the handling of competing interests of Management Board members (2016): http://www.ema.europa.eu/docs/en_GB/document_library/Other/2016/11/WC500216192.pdf
- EMA breach of trust procedure on declarations of interests for scientific committees' members and experts (2015): http://www.ema.europa.eu/docs/en_GB/document_library/Other/2012/04/WC500124976.pdf
- EMA Guidance on the handling of declarations of interests in case of a scientific committee member/other (scientific) forum member's intention to become an employee in a pharmaceutical company (2015): http://www.ema.europa.eu/docs/en_GB/document_library/Regulatory_and_procedural_guideline/2015/05/WC500186536.pdf
- EMA 2015 Annual report on independence, EMA/175527/2016, 16 September 2016
- Annual reports for the period from 2012 to 2015 on staff engaging in an occupational activity within two years of leaving the service (article 16 of the staff regulations) (2016): http://www.ema.europa.eu/docs/en_GB/document_library/Annual_report/2015/05/WC500186565.pdf

European Commission Scientific Committees (SCCS, SCHEER)

- European Commission webpage on SCCS/SCHEER: http://ec.europa.eu/health/scientific_committees/legal_documents_en
- European Commission Decision of 7.8.2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment [C(2015) 5383 final]: http://ec.europa.eu/health/sites/health/files/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf
- Rules of Procedure of the Scientific Committees on Consumer Safety (SCCS) and Health, Environmental and Emerging Risks (SCHEER): https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/rules_procedure_2016_en.pdf
- EU framework for the scientific advice mechanism: Strengthening Evidence Based Policy Making through Scientific Advice - Reviewing existing practice and setting up a European Science Advice Mechanism: https://ec.europa.eu/research/sam/pdf/strengthening_evidence_based_policy_making.pdf
- Register of Commission Expert Groups: http://ec.europa.eu/transparency/regexpert/index.cfm?do=faq.faq&aide=2

6.11 EU/OECD Guidelines on CoI management

- EU Guidelines on the prevention and management of Conflicts of Interest in EU decentralised agencies (10 December 2013): https://europa.eu/european-union/sites/europaeu/files/docs/body/2013-12-10_guidelines_on_conflict_of_interests_en.pdf
- EU Code of Good Administrative Behaviour
- OECD: Managing Conflict of Interest in the Public Service: http://www.oecd.org/gov/ethics/managingconflictofinterestinthepublicservice.htm
- OECD Guidelines and Country Experiences: Managing Conflict of Interest in the Public Service: http://www.oecd.org/governance/ethics/48994419.pdf

6.12 EU Evaluation Methodology

- Better Regulation Guidelines: http://ec.europa.eu/smart-regulation/guidelines/toc_guide_en.htm
- Better Regulation – Toolbox: http://ec.europa.eu/smart-regulation/guidelines/toc_tool_en.htm

6.13 Media coverage and stakeholder viewpoints on EFSA's independence

Online media coverage

Please note that the list below is non-exhaustive and consists of a presents a selection of articles published in EU online media.

- EU Observer: "No conflict of interest at EU food agency, director says" (January 2014): https://euobserver.com/institutional/122804
- EU Business: "Conflicts of interest played down by the European Food Safety Authority (EFSA)" (June 2016): http://www.eubusiness.com/Members/testbiotech/efsa-conflict
- FoodNavigator: "EFSA comes under fire for latest 'revolving door' industry recruitment (January 2016) - http://www.foodnavigator.com/Policy/EFSA-comes-under-fire-for-latest-revolving-door-industry-recruitment
- EU Food Law: "New revolving door scandal hits EFSA" (January 2016) - http://www.eurofoodlaw.com/policy/institutional/new-revolving-door-scandal-hits-efsa--1.htm
- GMWatch: "Flawed risk assessment of Monsanto stacked trait GM soybean leaves public unprotected" (January 2017): http://www.gmwatch.org/news/latest-news/17434-risk-assessment-of-monsanto-stacked-trait-gm-soybean-leaves-public-unprotected
- GM Watch: "New conflicts of interest at the European Food Safety Authority (EFSA)" (March 2016) - http://www.gmwatch.org/news/latest-news/16828-new-conflicts-of-interest-at-the-european-food-safety-authority-efsa
- GM Watch: "EFSA should revise conflicts of interest policy to reflect commercial nature of universities – Ombudsman" (July 2015) - http://www.gmwatch.org/news/latest-news/16278-efsa-should-revise-conflicts-of-interest-policy-to-reflect-commercial-nature-of-universities-ombudsman
- GM Watch: "European Parliament demands stricter regulation of conflicts of interest at EFSA" (April 2014) - http://www.gmwatch.org/news/archive/2014/15375-european-parliament-demands-stricter-regulation-of-conflicts-of-interest-at-efsa
- EU Business: "Conflicts of interest played down by the European Food Safety Authority (EFSA)" (June 2016) - http://www.eubusiness.com/Members/testbiotech/efsa-conflict
- The Guardian: "EU scientists in row over safety of glyphosate weedkiller" (January 2016): https://www.theguardian.com/environment/2016/jan/13/eu-scientists-in-row-over-safety-of-glyphosate-weedkiller
- Deutsche Welle (DW): Independent scientists warn over Monsanto herbicide (December 2015): http://www.dw.com/en/independent-scientists-warn-over-monsanto-herbicide/a-18886833
- The Guardian: "UN/WHO panel in conflict of interest row over glyphosate cancer risk" (May 2016): https://www.theguardian.com/environment/2016/may/17/unwho-panel-in-conflict-of-interest-row-over-glyphosates-cancer-risk

Viewpoints of EFSA's stakeholders

Please note that the list below is non-exhaustive and presents a selection of viewpoints of EFSA's stakeholders available online.

- Corporate Europe Observatory (COE): "A spoonful of sugar – How the food lobby fights sugar regulation in the EU" (July 2016): https://corporateeurope.org/sites/default/files/a_spoonful_of_sugar_final.pdf
- Corporate Europe Observatory: "Conflicts of Interest at the European Food Safety Authority: Enough is enough!" (March 2016):

https://corporateeurope.org/efsa/2016/03/conflicts-interest-european-food-safety-authority-enough-enough

- Corporate Europe Observatory: "EFSA appoints a food industry lobbyist as Communications Director and refuses to disclose why it did" (March 2016): https://corporateeurope.org/efsa/2016/03/efsa-appoints-food-industry-lobbyist-communications-director-and-refuses-disclose-why
- CEO: "EU review of weedkiller glyphosate adds secrecy to controversy" (January 2016): https://corporateeurope.org/food-and-agriculture/2016/01/eu-review-weedkiller-glyphosate-adds-secrecy-controversy
- Corporate Europe Observatory: "EFSA's credibility loopholes: A revised independence policy but the worst problems remain" (November 2014): https://corporateeurope.org/efsa/2014/11/efsas-credibility-loopholes
- Corporate Europe Observatory: "Why EFSA is not (yet?) independent: A background presentation given to EFSA's workshop on its independence policy" (June 2014): https://corporateeurope.org/efsa/2014/06/why-efsa-not-yet-independent
- Test Biotech: "New Conflicts of Interest at the European Food Safety Authority (EFSA)" (March 2016): https://www.testbiotech.org/en/node/1587
- Test Biotech: "Open letter regarding Conflicts of Interest at the European Food Safety Authority (EFSA)" (March 2016): https://www.testbiotech.org/sites/default/files/Testbiotech_Letter%20to%20Bernhard%20Url_March_2016.pdf
- Testbiotech: "Forward to the past - EFSA renews GMO Panel with old acquaintances" (October 2015)": https://www.testbiotech.org/en/node/1273
- PAN Europe: "AOP: The Trojan Horse for industry lobby tools" (December 2016): http://www.pan-europe.info/sites/pan-europe.info/files/public/resources/reports/pan-europe-aop-report-8.8-dec-16.pdf
- PAN Europe: "EFSA's (un-)scientific opinion: glyphosate not a carcinogen" (November 2015) : http://www.pan-europe.info/press-releases/2015/11/efsa%E2%80%99s-un-scientific-opinion-glyphosate-not-carcinogen
- PAN Europe: "A poisonous injection: How industry tries to water down the risk assessment of pesticide mixtures in everyday food": http://www.pan-europe.info/old/Resources/Reports/PANE%20-%202014%20-%20A%20Poisonous%20injection.pdf
- PAN Europe: "Massive industry network uncovered in EFSA and WHO trying to stop the new policy on stricter food standards for pesticide mixtures; first ever example of EU Commission fighting back" (February 2014): http://www.pan-europe.info/press-releases/2014/02/massive-industry-network-uncovered-efsa-and-who-trying-stop-new-policy

Open Letters on independence policy issues at EFSA

- Open Letter to the President of the European Parliament: "European and global research organisations call upon the European Parliament to encourage society to respect independent science advice and to condemn physical attacks on scientists" (11 July 2016): http://www.epsoweb.org/respect-science-advice
- Open Letter to the Management Board of EFSA: "Conflicts of interest at the European Food Safety Authority (EFSA)" (15 June 2016), Authors: Testbiotech/ GeneWatch UK: http://www.testbiotech.org/sites/default/files/An%20Open%20Letter%20to%20EFSA.pdf

- Open Letter to Dr. Bernhard Url, Executive Director European Food Safety Authority (EFSA) "Follow up on incrimination of IOBC-WPRS in open letter [of Testbiotech] addressed to EFSA (15 April 2016), Authors: International Organisation for Biological Control (IOBC-WPRS): https://www.iobc-wprs.org/20160415_Open_Letter_IOBC-WPRS_to_EFSA.pdf
- Open Letter to European Parliament's Budget Control Committee: "Enough is Enough" (March 2016), Authors: Corporate Europe Observatory, Fondation Sciences Citoyennes, GMWatch, Groupe international d'études transdisciplinaires (GIET), Health & Environment Alliance (HEAL), Pesticides Action Network Europe, Testbiotech: https://corporateeurope.org/sites/default/files/attachments/open_letter_to_ep_cont_members_-_cc_european_commission_and_efsa_management_board.pdf
- Open Letter to Dr. Bernhard Url, Executive Director European Food Safety Authority (EFSA): "Conflicts of interest at the European Food Safety Authority (EFSA)" (18 March 2016), Authors: Testbiotech/ GeneWatch UK: http://www.testbiotech.org/sites/default/files/Testbiotech_Letter%20to%20Bernhard%20Url_March_2016.pdf
- EFSA reply to public access to documents request from MEPs (Greens/EFA) of 15 March 2016 (June 2016): https://www.asktheeu.org/fr/request/2691/response/10328/attach/4/EFSA%20Ref.15872910%20PAD%202016%20034%20Reply%20to%20your%20e%20mail%20of%2010%20June%202016.pdf
- Greens/EFA: Follow-up letter to EFSA: Confirmatory application: public access to documents request from MEPs (Greens/EFA) of 15 March 2016 (January 2017): http://www.greens-efa.eu/files/doc/docs/14193ccc97c0680145f126e28979b335.pdf

EFSA multimedia communications on independence

- EFSA online news: "EU Commissioner Andriukaitis: EFSA's scientific advice highly valued in Europe and across the world" (2016): https://www.efsa.europa.eu/en/press/news/160428
- EFSA online news: "Making EFSA scientific opinions more transparent" (2014): https://www.efsa.europa.eu/en/press/news/140923
- EFSA online news: "Independence rules refined, policy review set for 2015" (2014): https://www.efsa.europa.eu/en/press/news/140731a
- "EFSA statement about European Ombudsman decision" (2014): https://www.efsa.europa.eu/en/press/news/140331
- EFSA video: "Independent Scientific Decision Making" (2014): https://www.youtube.com/watch?v=-ryOajLAg1cb

6.14Academic Literature

- "Why Having a (Nonfinancial) Interest Is Not a Conflict of Interest" (Bero/Grundy, December 2016)
- "McCarthyism, conflict of interest and Addiction's new transparency declaration procedures" (Addiction Journal, 2014)
- "Conflicts of Interest: Manipulating Public Health" (Stein/Davis, March 2014)
- "The effect of a conflict of interest disclosure form using closed questions on the number of positive conflicts of interest declared – a controlled study" (Baethge, June 2013)

- "Does Conflict of Interest Disclosure Worsen Bias"? (PLoS Medicine Editors, April 2012)
- "Conflicts of Interest, Institutional Corruption, and Pharma: An Agenda for Reform" (Rodwin, October 2012)
- "Conflict of interest policies and disclosure requirements among European Society of Cardiology national cardiovascular journals" (Alfonso et al., June 2012)
- "How experts are chose to inform public policy: Can the process be improved?" (Rowe et al., January 2012)
- "When Sunlight Fails to Disinfect: Understanding the Perverse Effects of Disclosing Conflicts of Interest" (Cain et al., February 2011)
- "The Vexing Problem of Guidelines and Conflict of Interest: A Potential Solution" (Guyatt et al., May 2010)

Annex E – Interview guide

This annex contains a final version of the interview guide

Interview Guide

General information

Project title:	Ex post Evaluation of the Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority (EFSA) and of its Implementing Rules on Declaration of Interest
Background:	At the request of the European Food Safety Authority (EFSA), Deloitte is carrying out an **independent external ex post evaluation** of EFSA's Policy on Independence and Scientific Decision-making Processes (2011) and the Rules on the Declarations of Interest (2014) and the implementation thereof. This evaluation fulfils the requirement of EFSA's Independence Policy (2011) to review its approach to independence within four years of its adoption (see Article 12). The analysis is framed by the following **evaluation criteria**: • Effectiveness; • Sustainability; • Efficiency; • Relevance; and • Proportionality and subsidiarity. Moreover, the study takes place in the context of the EFSA **"Independence Policy review"**, set up for the review of EFSA's Independence Policy and the alignment of EFSA's Rules on DoI with the new policy to be adopted in 2017. The results of the ex post evaluation will notably contribute to the objectives of the project, with a view to increasing the levels of transparency, engagement, cost effectiveness and efficiency of the system in place. The findings of the study will be consolidated in a Final Evaluation Report and presented to the Agency's Management Board.
Methodological approach:	As part of the study, Deloitte conducts a **series of interviews** with Agency stakeholders impacted by EFSA's Independence Policy and DoI system. The purpose of these interviews is to collect qualitative data on the evaluation questions, to capture different points of view on the overall effectiveness of EFSA's Independence Policy and implementation thereof, to assess the level of satisfaction with the system in place, as well as to identify main challenges and areas of improvement. Interview findings will only be used in our reporting in an aggregated, anonymous manner.

Reference period: 2014-2016

Details of the interview

Name of interviewee:

Name of organisation:

Function:

Contact:

Date:

Location:

Name of interviewer:

Comments:

Interview guide

Reputation

1. To what extent have EFSA's 2011 Independence Policy and 2014 DoI Rules contributed to **EFSA's reputation**?

Do you see any positive/negative trends in stakeholder perceptions on EFSA's during the period 2014-2016:

- Independence;
- Transparency;
- Scientific excellence?

Policy Objectives

2. To what extent have EFSA's 2011 Independence Policy and 2014 DoI Rules contributed to a **high level of food safety and consumer protection**?
   - 2.1 To what extent has EFSA's independence policy secured the provision of independent, objective and high quality scientific outputs?
   - 2.2 To what extent has EFSA's independence policy ensured effective risk communication to the public?

Value for money

3. To what extent have EFSA's 2011 Independence Policy and 2014 DoI Rules **provided value for the money** the Authority invested to ensure the policy's implementation?
   - 3.1 Do you perceive the costs of the system and procedures in place justified in light of the outputs and results?
   - 3.2 Are you aware of any actions been taken by the Agency to improve the cost effectiveness of the system?

Relevant

4. To what extent are EFSA's 2011 Independence Policy and 2014 DoI Rules still **relevant** to contribute to the objective of EFSA's Founding Regulation to ensure the independence of the Agency's scientific decision-making processes?
    - 4.1 Do you consider that EFSA's current system and procedures are still relevant in light of the **problems/risks** related to biased external influence on scientific decision-making processes?
    - 4.2 Could EFSA's independence be ensured without the current system in place?

Effectiveness

5. To what extent are the Agency's Independence Policy and the Rules on DoI **effective** to contribute to the objective of ensuring compliance with the Independence requirements of EFSA's Founding Regulation?
    - 5.1 Do you consider the organisational solutions effective to ensure independent organisational governance and scientific governance?
    - 5.2 Do you consider the system and procedures put in place by EFSA effective in detecting and preventing Conflicts of Interests?
    - 5.3 Do you consider the system and procedures put in place by EFSA effective in ensuring transparent and independent decision-making processes?
    - 5.4 Please indicate the level of awareness of EFSA's independence requirements within the organisation.
    - 5.5 Does EFSA provide an effective communication on its independence policy and requirements?
    - 5.6 Are the trainings/information provided by EFSA on independence requirements adequate/provide added value?
    - 5.7 Can you give any examples for which the current system and procedures did not allow an effective management of Conflict of Interest?
    - 5.8 Please give examples how the system could operate more effectively/how outputs could be improved.

Efficiency

6. To what extent are the Agency's Independence Policy and the Rules on DoI **efficient** to contribute to the objective of ensuring compliance with the Independence requirements of EFSA's Founding Regulation?
    - 6.1 Do you consider that the system in place is working efficiently?
    - 6.2 Do you perceive that the level of resources allocated to the operation of the system is adequate?
    - 6.3 In your opinion, do the organisational solutions to support the operation of EFSA's independence policy (e.g. IT tools) work efficiently?
    - 6.4 Does the current system provide the margin for increased efficiency?
    - 6.5 Please give examples of how the efficiency of the system could be improved (e.g. outsourcing, IT automation).
    - 6.6 Did the Agency take any actions to improve the efficiency of organisational solutions and procedures and to enable more efficient workflows?
    - 6.7 Can you think of any examples of independence policies/CoI systems put in place by other organisations that work more efficiently?

Proportionality

7. To what extent are the Agency's Independence Policy and the Rules on DoI **proportionate** to contribute to the objective of ensuring compliance with the Independence requirements of EFSA's Founding Regulation?
    - 7.1 Do you perceive the current system and procedures as proportionate (e.g. information requirements, frequency of CoI checks, trainings)?

7.2 Do you consider the impact/related workload of the current system and procedures as proportionate?

7.3 Please indicate examples for requirements/actions that you perceive as particularly disproportionate.

7.4 For which elements could the impact/administrative burden of the current system and procedures on EFSA and its stakeholders be reduced?

7.5 Can you think of examples of independence policies/CoI systems put in place by other organisations that you perceive as more proportionate?

Sustainability

8. To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 **sustainable** against the evolving political and financial perspectives?

8.1 To what extent can the system be maintained in a context of changing resources (e.g. budget or posts) against evolving social or political expectations (e.g. scope and ambitions)?

8.2 To what extent does the system provide the margin for adjustments to the evolving resources or expectations?

8.3 Does the current system provide margin for potential cost reductions and/or economies of scale?

Proportionality and subsidiarity

9. To what extent are the 2011 Policy on independence and scientific decision making process and the Decision of the Executive Director on Declarations of Interest of 31 July 2014 compliant with the **proportionality and subsidiarity principles**?

9.1 Does the action need to take place at EFSA level or could the same level of independence be ensured by a decentralised system?

General

- Are you aware of any other policies or systems on competing interest management put in place by similar organisations (e.g. other EU Agencies or national authorities) that you perceive as being more effective/efficient/proportionate/sustainable than EFSA's?
- Do you see any positive effects/improvements since the adoption of the new DoI Rules in 2014 on EFSA's independence? If so, in which respect?
- In which areas do you see the main challenges for an effective Conflict of Interest management?
- Which changes would you suggest to improve the overall performance of the system?
- Which themes should be priority of the 2017 review of EFSA's Independence Policy? Which elements/aspects of EFSA's Independence Policy need to be changed?

Annex F – List of interviewees

This annex contains a list of the interviews conducted per stakeholder category.

Organisation	Department/Unit	Number of interviewees
EFSA	Legal and Assurance Services Unit	4
EFSA	Biological Hazards and Contaminants Unit	1
EFSA	Executive Directorate	1
EFSA	Scientific Committee and Emerging Risks Unit	1
European Commission	DG Health and Food Safety	2
European Medicines Agency (EMA)	Office of the Deputy Executive Director	2
European Chemicals Agency (ECHA)	Executive Office	1
European Parliament	Committee on Environment, Public Health and Food Safety	1
Non-governmental organisations	Not applicable	1
Industry associations	Not applicable	1
Total		**15**