

High level analysis and input paper regarding future orientations regarding the EFSA DoI policy and its Implementing Rules

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Support of the review of the Implementing Rules of the 2012 DoI policy
Specific Contract 16 under Framework contract
“Organisational Evolution Support”



Table of Contents

Preface	5
1. Executive summary	6
2. Context and objectives of the study.....	9
2.1. Context	9
2.2. Objectives of the study	10
3. Methodology	11
4. Overview of the current state of play regarding independence	14
5. Analysis	16
5.1. Assessment of the completeness of the 2012 independence Implementing Rules	16
5.1.1. Analysis of the topics and categories addressed in the 2012 Implementing Rules	16
5.1.2. Conclusions	22
5.2. Clarity and transparency of the 2012 independence Implementing Rules	23
5.2.1. Analysis of the Conflict of Interest definition	23
5.2.2. Procedures related to the Declarations of Interests (Dols)	24
5.2.3. Clarity and transparency of online information	28
5.2.4. Assessment of the transparency of EFSA's independence policy	31
5.2.5. Level of awareness raising regarding the 2012 independence Implementing Rules	32
5.2.6. Conclusions	34
5.3. Assessment of the effectiveness of the measures for the detection of Conflicts of Interest .	36
5.3.1. Analysis of the effectiveness of the measures	36
5.3.2. Assessment of the improvements made by EFSA regarding its independence policy	40
5.3.3. Conclusions	42
5.4. Assessment of the effectiveness of the mechanisms in place for ensuring expert and staff compliance.....	44
5.4.1. EFSA's independence governance structure	44
5.4.2. Assessment of the effectiveness of the independence procedures	49
5.4.3. Assessment of the effectiveness of independence trainings.....	52
5.4.4. Conclusions	52
6. Conclusions and recommendations	54
ANNEXES.....	61
ANNEX I - Analytical framework.....	61
ANNEX II - EFSA follow up on recommendations.....	69
ANNEX III – Risk based approach: possible implementation process.....	76

List of Tables

Table 1: Step-by-step approach used for this study	11
Table 2: EU guidelines on management of Cols	16
Table 3: OECD guidelines on management of Cols	17
Table 4: Comparison of the consequences of a Col between EFSA, ANSES, EMA and FDA	25
Table 5: Summary table on EFSA Dols and the consequences of Cols	25
Table 6: Sophistication scale of websites for users	29
Table 7: EFSA transparency on independence compared to the EU guidelines	31
Table 8: Key performance indicators on the EFSA Dol screening	36
Table 9: Results of the implementation of the independence policy in 2011, 2012 and 2013	37
Table 10: Veracity and compliance checks outcomes	39
Table 11: EFSA's governance structure related to Dols	45

List of Figures

Figure 1: The EFSA 2011 Independence Policy and 2012 Dol Implementing Rules	10
Figure 2: Current state of play of the EFSA independence landscape	14
Figure 3: Long term strategy: going from centralisation to outsourcing of the Dol implementation	57
Figure 4: Scatter chart - Portfolio of recommendations	60

List of abbreviations used

ADoI	Annual Declaration of Interest
ANSES	Agency for Food, Environmental and Occupational
CCI	Committee on Conflict of Interest
CoI	Conflict of Interest
DoI	Declaration of Interest
EFSA	European Food Safety Authority
EMA	European Medicines Agency
FDA	Food and Drug Administration (USA)
FSO	Food Safety Organisation
IR	Implementing Rules
KPI	Key Performance Indicator
ODoI	Oral Declaration of Interest
SDoI	Specific Declaration of Interest
WHO	World Health Organisation

Preface

The purpose of this document is to inspire EFSA's reflections on possible improvements to and future orientations for the independence policy of EFSA.

The intention of this study report was not to audit the EFSA Policy on independence and scientific decision-making processes nor the Implementing Rules on Declarations of interests (DoI).

The opinions and ideas put forward in the report are based upon a research on the current Independence systems conducted within a 6 weeks timeframe. Therefore, the analysis has been kept at a high level and the benchmarking conducted was rather topical and therefore very limited.

When relevant in order to complement our analysis, benchmark organisations have been selected to compare EFSA with. These organisations have been selected for their good practices regarding their independence system and similarities with EFSA. The main objective of these benchmarking efforts was to identify possible further improvements to EFSA's current practices. The benchmarking exercise consisted of analysing documents available on the corporate websites of three selected organisations.

Also in terms of scope, this report focuses mainly on the 2012 Implementing Rules on DoIs, although this document only partly implements the EFSA independence policy. Moreover, in the analysis, the main focus is put on the experts' DoIs, as the experts are by far the largest target group and the group that is most 'at risk' in terms of independence, as they are working on the scientific decision making.

The reader will find in this document a number of recommendations that could be considered for implementation by EFSA in the months and years to come. These will need to be assessed, prioritized and decided upon by EFSA.

1. Executive summary

In recent years, there have been some independence incidents at EFSA causing a greater awareness and attention for independence in general and Conflicts of Interest in particular.

In 2011 and 2012, EFSA respectively adopted a Policy on independence and scientific decision-making processes of the EFSA and Implementing Rules on Declarations of interests (DoI). The objective of this specific set of rules is to ensure the independence of EFSA's scientific decision-making by identifying in a transparent manner all relevant interests and by preventing the occurrence of Conflicts of Interests.

Today, EFSA's Legal and Regulatory Affairs unit has been asked to analyse the 2012 Implementing Rules on DoIs on the basis of the findings of an ex post assessment thereof. This report provides general considerations on whether the independence system of EFSA is deemed to be balanced when comparing the measures in place with the risks and the benefits peculiar to EFSA and identifies possible improvements and amendments to the Implementing Rules on Declarations of Interests.

The main issues / questions that are addressed in this report are the following:

1. Are all relevant elements for the detection and mitigation of possible conflicts covered in the independence Implementation Rules?
2. Are the current elements for detection and mitigation of possible conflicts clearly and transparently described in the independence Implementation Rules?
3. Are the measures effective to detect and mitigate Conflicts of Interests and do they effectively address Breaches of trust?
4. Are the mechanisms effective to ensure expert compliance and EFSA staff compliance with the rules?

In terms of the scope of the study, this report focuses mainly on the 2012 Implementing Rules on DoIs.

The conclusions and recommendations for the four evaluation questions can be summarised as follows:

1. Are all relevant elements for the detection and mitigation of possible conflicts covered in the independence Implementation Rules?

The EFSA 2012 Implementing Rules can be considered as complete and cover the different topics required by the OECD and EU guidelines. However, some additional topics (transparency, trainings and awareness raising, periodical review of the independence policy) could be included in order to enhance the document.

The 2012 Implementing Rules group all the information related to DoIs and Conflicts of Interest in one complete document. This is a clear strong point as compared to other organisations.

2. Are the current elements for detection and mitigation of possible conflicts clearly and transparently described in the independence Implementation Rules?

The 2012 Implementing Rules are in general clear. The new definition of Conflicts of Interest complies with the OECD and EU guidelines. The different categories of interests are clear and the definitions are well developed. However, EFSA could include in the DoI documents concrete examples and a definition of the categories.

The consequences of Conflicts of Interest for experts are clear and comprehensively detailed in articles 10, 11 and 12 of the Implementing Rules. However, this is not always the case for the other EFSA target groups. For instance, Article 19 (for observers) and Article 25 (for employees and consultants) could be reviewed and further clarified.

EFSA has advanced procedures concerning the management of Conflicts of Interest. Nevertheless, the compliance and veracity procedure is not completely and clearly defined in the Implementing Rules. Additional information concerning this process is available in the Annual Activity Reports and on demand a quarterly internal report can be requested. Yet, having all information centralised in the Implementing Rules would be beneficial. Finally, the very limited random selection of experts could be reviewed and replaced by a risk based approach.

ESFA is very transparent in its online information provision related to independence, yet there is still some room for improvement as the information provided is hidden in various sections of the website.

Also for the trainings on independence EFSA is providing, there are still some improvement points. EFSA could consider to put in place a more elaborated, detailed and frequent independence training package, both for its staff members and the experts EFSA is working with, tailored for specific target groups (e.g. following an expert risk profile; following the subject matter an expert is involved in; for experts who had omissions, etc.).

EFSA has developed different initiatives regarding transparency. In general the organisation tends to be very open and transparent with its information provision to external stakeholders. Moreover, EFSA is constantly looking for improvements of its transparency policy and listens to its stakeholders in order to propose new transparency initiatives that live up to the stakeholders' expectations.

Finally, EFSA could increase its initiatives regarding the awareness raising on independence. Specifically, there is a need to formalise and improve the communication and trainings about this topic.

3. Are the measures effective to detect and mitigate Conflicts of Interests and do they effectively address Breaches of trust?

The EFSA measures related to Conflicts of Interest are relatively effective. It is apparent that the screening of Dols is compliant with the EFSA 2012 IR and performed prior to the meetings in close to 100% of the cases. This high percentage of pre-screening prevents potential Conflicts of Interest. Indeed, the compliance and veracity checks support those findings. The compliance checks revealed that the majority of experts were evaluated correctly with regards to EFSA's policy on independence. However, a high amount of omissions detected during the investigation reveal a lack of understanding by the experts of the necessity to have accurate and up-to-date information on their Dols and CVs. Although these omissions did not lead to Conflicts of Interest, it is important to put additional measures in place in order to reduce this number (more than half of the experts checked had at least one omission in their ADol). This could be done by strengthening the trainings and by improving the communication on independence.

EFSA has implemented the majority of the suggestions received from stakeholders. EFSA constantly improves its measures and policy in regards to independence and Conflicts of Interest. However, there is still a clear need for EFSA to increase / improve communication with civil society. Indeed, the different complaints received are often based on a misunderstanding of the screening process. EFSA assesses Conflicts of Interest based on

objective, pre-defined criteria. Interests are assessed by EFSA in relation to (1) the role played by the expert, (2) the work that the expert is required to carry out and (3) the mandate of the group. However, EFSA cannot exclude or accept experts only based on common criteria as each specific situation needs to be assessed on the basis of its particular peculiarities. In order to legitimate the process, EFSA should be constantly transparent about it and on-board external stakeholders in the process. Lastly, the post-employment measure represented an important point in this respect and appropriate measures have been taken to mitigate this problem.

4. Are the mechanisms effective to ensure expert compliance and EFSA staff compliance with the rules?

Regarding the governance structure, the screening of Dols of Management Board members by the Management Board might create a perception of subjectivity. EFSA could consider creating an external body responsible for checking potential Conflicts of Interest of the Management Board members.

EFSA could also consider to replace the Committee on Conflicts of Interest by a centralised team that would be in charge of the management of the Cols and the procedures related to independence such as the screening of the Dols of experts, staff and the Management Board members. This team could at first be internally managed. Later on, when the processes are fully in place, EFSA could even decide to outsource the screening of the Dols to an independent external body. It goes without saying that outsourcing the screening of Dols and the management of Cols to an independent body would require further analysis (e.g. on topics such as accountability, etc.) and the development of a 'business case'.

Throughout our analysis of the main independence procedures, it became apparent that EFSA is putting a strict control on the experts. The three Dols requested and their screening represent a real administrative burden for the experts and for EFSA staff. EFSA could consider reviewing its independence strategy towards a strategy based on trust, openness and transparency instead of trying to control everything. The principle of the responsibility to keep Dols up to date could to be embedded in the Declaration of Commitment.

Finally, the independence monitoring system could be reviewed and a risk based approach could be installed instead of the current random selection of experts for the compliance and veracity checks.

On top of these specific conclusions and recommendations, the following, more general conclusions and recommendations were formulated:

- EFSA should increase the predictability of its processes and could consider to get certified to ISO's management system standards;
- EFSA will need to strike the right balance between sharing sufficient information to increase trust and transparency ('open data'), without having to share everything;
- With respect to relationships with the industry, EFSA could install more dialogue with the industry, rather than trying to reduce this. If the dialogue is put in place in all transparency, this should not pose a problem;

2. Context and objectives of the study

2.1. Context

In recent years, there have been some independence incidents at EFSA causing a greater awareness and attention for independence in general and Conflicts of Interest in particular.

As a result, EFSA has put forward as a key strategic objective in its Multiannual Plan 2014-2016¹ 'trust' as a crucial element to EFSA's work for citizens. Many initiatives have already been taken in relation to transparency, openness, independence and communication and EFSA is dedicated to continue to strengthen these key pillars of the trust principle in collaboration with its stakeholders.

In 2011 and 2012, EFSA respectively adopted a Policy on independence and scientific decision-making processes of the EFSA² and Implementing Rules on Declarations of interests (DoI)³. The objective of this specific set of rules is to ensure the independence of EFSA's scientific decision-making by identifying in a transparent manner all relevant interests and by preventing the occurrence of Conflicts of Interests.

An effective DoI screening system contributes to build trust in EFSA's work. The current system of Declarations of Interests and subsequent screening requires to be regularly monitored to ensure that it is an effective tool for the prevention of potential Conflicts of Interests.

In October 2012, the Court of Auditors published a report on the Management of Conflicts of Interest in selected EU agencies and in December 2013, as part of its Roadmap for the implementation of the Common approach on EU decentralised agencies, the Commission published its Guidelines on the prevention and management of Conflicts of Interest in EU decentralised agencies. According to the Court of Auditors report, EFSA's policies and rules on Declarations of Interests can be seen as a good practice.

This notwithstanding, as EFSA regularly takes steps to review and improve the efficiency and proportionality of its activities, and in line with the recommendation of the Commission to perform a risk assessment on the severity of the risk of Conflicts of Interest occurring in the context of the operations of each agency, it is appropriate to evaluate whether the measures currently in place are adequate in view of the risks they address. This assessment should be combined with a stock taking exercise considering the suggestions, findings and conclusions of EFSA's institutional stakeholders and other interested parties.

EFSA's Legal and Regulatory Affairs unit is asked to analyse the 2012 Implementing Rules on DoI on the basis of the findings of an ex post assessment thereof and of the suggestions

¹ EFSA, "Programming Document of the European Food Safety Authority 2014-2016, incorporating Annual Management Plan 2014 and Multiannual Plan 2014-2016", December 2013

² EFSA, "Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority", December 2011.

³ EFSA, "Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests", February 2012.

made by stakeholders at a dedicated event in Brussels in early June 2014 and to prepare a report to the attention of the Executive Director.

2.2. Objectives of the study

This report analyses the 2012 Implementing Rules on Dols on the basis of the findings of an ex post assessment thereof.

It provides more general considerations on whether the independence system of EFSA is deemed to be balanced when comparing the measures in place with the risks and the benefits peculiar to EFSA and identifies possible improvements and amendments to the Implementing Rules on Declarations of Interests.

The main issues / questions that are addressed in this report are the following:

- Are all relevant elements for the detection and mitigation of possible conflicts covered in the independence Implementation Rules?
- Are the current elements for detection and mitigation of possible conflicts clearly and transparently described in the independence Implementation Rules?
- Are the measures effective to detect and mitigate Conflicts of Interests and do they effectively address Breaches of trust?
- Are the mechanisms effective to ensure expert compliance and EFSA staff compliance with the rules?

In terms of the scope of the study, this report focuses mainly on the 2012 Implementing Rules on Dols, although this document only partly implements the EFSA independence policy. In the figure below, this is depicted more clearly.

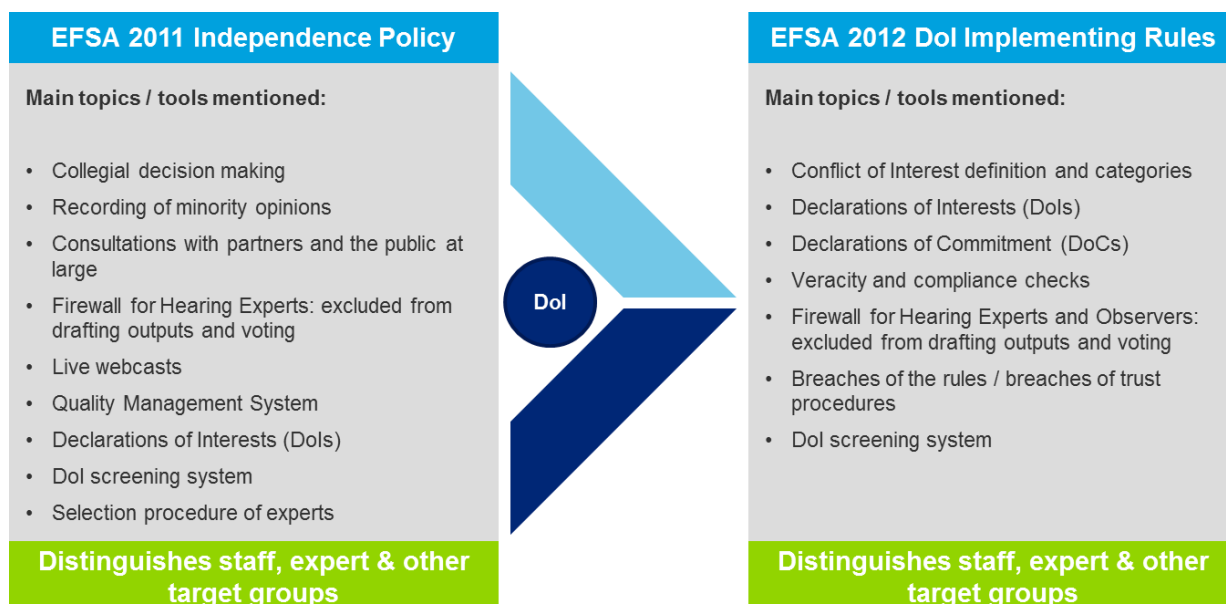


Figure 1: The EFSA 2011 Independence Policy and 2012 Dol Implementing Rules

Moreover, in the analysis, the main focus is put on the experts' Dols, as the experts are by far the largest target group and the group that is most 'at risk' in terms of independence, as they are working on the scientific decision making.

3. Methodology

Step-by-step approach:

The study was executed in three phases including several steps. This step-by-step approach allowed to efficiently address the analysis of the 2012 Implementing Rules. This approach and the steps followed are presented in the table below.

Table 1: Step-by-step approach used for this study

Phase	Step	Main objective
1. Preparation phase	1.1 Kick off meeting	Reach a common understanding about the scope, objectives and expectations regarding the project
	1.2 Desk research	Get acquainted with the subject matter
	1.3 Prepare Analytical Framework and template for the Final Report	Define high level and detailed study questions
	1.4 Validation of the Analytical Framework and the template for the Final Report	Discussion and validation of the Analytical Framework
2. Data analysis phase	2.1 Analysis of available documentation	Analysis of the documentation found during the desk research
	2.2 Interview with EFSA staff	Completion of the analysis via conference calls with EFSA staff
	2.3 Working session with EFSA representatives	Discussion on the preliminary findings
3. Reporting phase	3.1 Prepare draft Final Report	Development of a draft Final Report providing short and long term actions
	3.2 Validation of the draft Final Report	Review and comments from EFSA on the draft Final Report before formal submission

Analytical Framework:

The basis for the research conducted for this study was the development of an Analytical Framework (see annex I). The use of a structured Analytical Framework allows the

evaluation team to conduct robust, logical, and solid evaluation work and to elaborate conclusions and recommendations based on the evaluation findings.

The Analytical Framework allows the evaluators to:

- assess the evaluation questions;
- map and organise all the evaluation questions to be answered;
- identify the judgment criteria and indicators to be collected;
- identify the sources of information;
- build a common vision on the work to be performed;
- structure the tasks to be performed, the findings and the final report.

This framework is comprised of the main topics to be addressed and the evaluation questions linked to these sections. Based on the Analytical Framework, this report is divided into four main topics. In each section, different aspects of EFSA's 2012 independence Implementing Rules are evaluated:

- Section 1 assesses the completeness of the Implementing Rules;
- Section 2 focuses on the clarity and the transparency of the Implementing Rules;
- Section 3 assesses the effectiveness of the applicable measures regarding Conflicts of Interests;
- Section 4 analyses the current mechanisms for ensuring expert and staff compliance.

Each of those four sections have been divided into sub-sections in order to adequately and comprehensively address all relevant subjects. The methodologies used throughout the analysis depend on the issues addressed and are listed in Annex I.

Benchmarking:

When relevant in order to complement our analysis, benchmark organisations have been selected to compare EFSA with. These organisations have been selected for their good practices regarding their independence system and similarities with EFSA. The main objective of these benchmarking efforts is to identify possible further improvements to EFSA's current practices.

Different criteria were used for the selection of organisations used in the benchmarking:

- The governance structure and the presence of a management board;
- The presence of external experts, that assist the organisation in science-based decision making;
- International recognition for having a good independence policy;
- The recognition for good practices in term of independence;
- The openness of procedures and the level of transparency;
- Data availability;
- Type of organisation.

The final selection was:

- 1 European national food safety authority: the Agency for Food, Environmental & Occupational Health Safety (ANSES) in France;
- 1 non-European food safety authority: the Food and Drug Administration (FDA) in the USA;
- 1 European non-food safety authority: the European Medicines Agency (EMA).

These three organisations represent the principal organisations we have benchmarked EFSA with. Additionally, for selected evaluation questions additional good practices from other organisations have also been looked into.

The benchmarking exercise consisted of analysing documents available on the corporate websites of the selected organisations. We have limited our benchmark to three organisations.

4. Overview of the current state of play regarding independence

The EFSA independence policy is very much linked to the three key priorities of EFSA as set out in the 2014-2016 multiannual plan⁴:

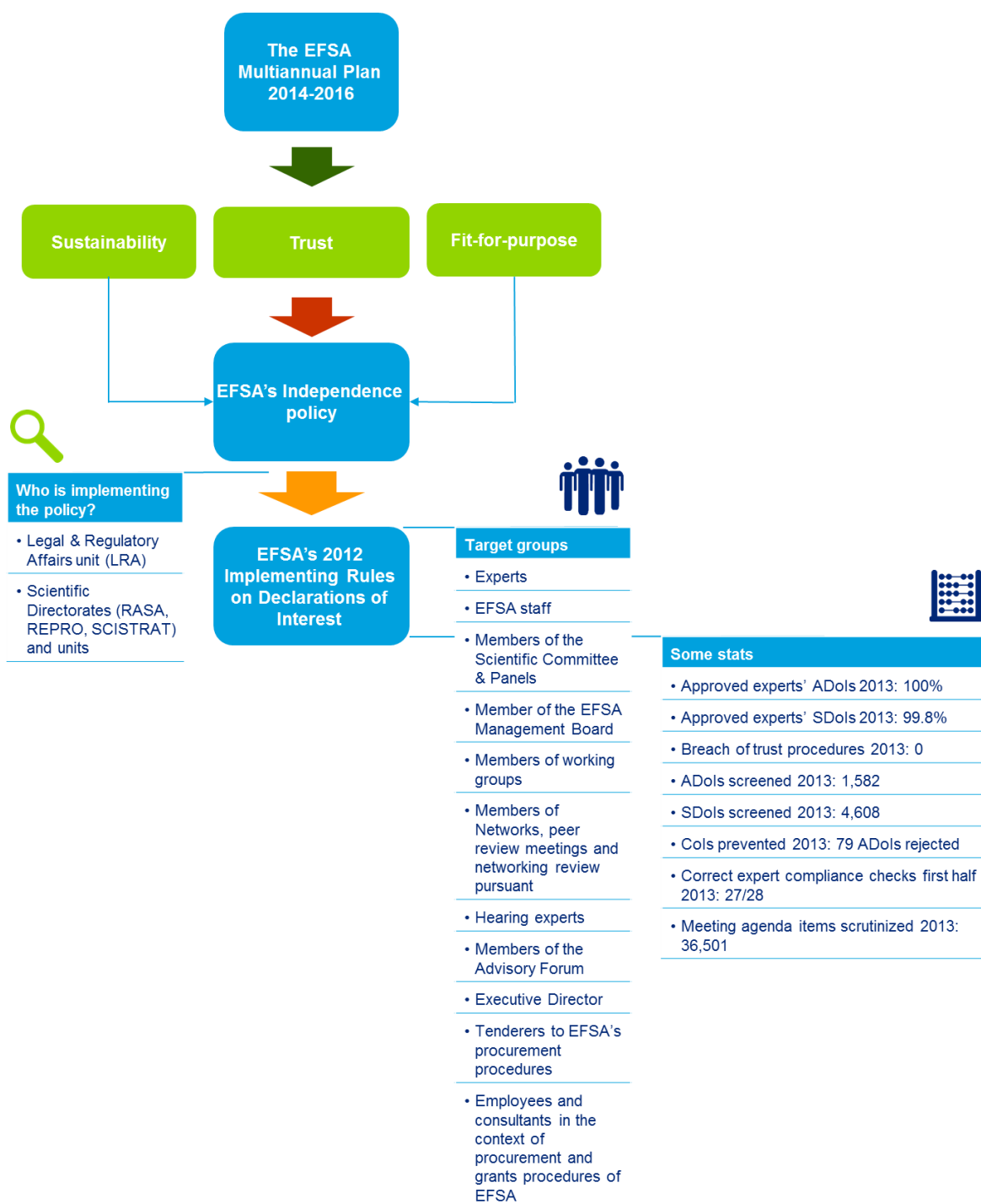


Figure 2: Current state of play of the EFSA independence landscape

⁴ EFSA, "Programming Document of the European Food Safety Authority 2014-2016, incorporating Annual Management Plan 2014 and Multiannual Plan 2014-2016", December 2013

The implementation of EFSA's independence policy is outlined in the Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests⁵ (hereafter referred to as the 'Implementing Rules'), which is the key focus area of this study.

EFSA has put in place a set of internal mechanisms and working processes to safeguard the independence of its scientific work and that of its Scientific Committee and Panels.

The different target groups, as listed here above, that are working with or for EFSA, need to declare their interests. For instance, all experts of the Scientific Committee, Scientific Panels and Working Groups are required to sign a Declaration of Commitment, including a commitment to act independently, and to provide an annual Declaration of Interests (ADoI) for each EFSA group of which they are a member. EFSA monitors and reviews the ADols of experts. In full transparency, all ADols as well as the mandates for each Panel and Working Group are published on the EFSA corporate website.

Experts are also required to declare in advance their specific interests for each agenda point of a meeting in writing, through a Specific Declaration of Interest (SDoI), and any additional interests orally at the beginning of the meeting. Minutes of the meetings are published which show how the policy on declarations has been implemented. For example, they will indicate when an expert declared a particular interest and if that led to his/her withdrawing from the meeting for a particular item.

Having an interest does not necessarily imply that there is a Conflict of Interest. EFSA screens the information provided by an expert in the DoI and assesses whether a declared interest constitutes a conflict. The responsibility for ensuring that DoIs are complete and truthful lies entirely with the person submitting the declaration. Depending on the outcome of the assessment of the DoI, EFSA makes a decision on whether or not the person is allowed to participate in EFSA's scientific work and in what role. In addition to this screening, EFSA reviews on a regular basis a small sample of the Annual Declarations of Interest (ADols) to check compliance and veracity.

Also EFSA staff members need to act with independence and integrity and need to avoid Conflicts of Interest. EFSA requires all its professional staff to fill out an annual Declaration of Interests. These ADols are screened and those of EFSA's Management Team are published on the EFSA website. EFSA ensures that staff members are not assigned to projects where potential Conflicts of Interest may arise.

Staff members who leave EFSA are required to inform the Authority with respect to future employment, within two years after leaving, so that EFSA can consider whether that may lead to a Conflict of Interest.

The implementation of the independence policy is driven by the Legal & Regulatory Affairs unit (LRA), and executed by the different Scientific Directorates / Units.

⁵ EFSA, "Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests", February 2012.

5. Analysis

5.1. Assessment of the completeness of the 2012 independence Implementing Rules

In the paragraphs below, an assessment is made of the completeness of the EFSA 2012 independence Implementing Rules. These sections do not attempt to give a complete overview of all topics related to independence, but focus on the most important topics and categories.

5.1.1. Analysis of the topics and categories addressed in the 2012 Implementing Rules

We have based our analysis of the completeness of the EFSA 2012 independence Implementation Rules on the EU and OECD guidelines on the subject matter. The two tables below compare these guidelines with EFSA's practices in order to detect any incompleteness.

Table 2: EU guidelines on management of Cols

	EU guidelines	EFSA	Implemented
Conflict of Interest definition	A Conflict of Interest generally refers to a situation where the impartiality and objectivity of a decision, opinion or recommendation of an Agency is or might be perceived as being compromised by a personal interest held or entrusted to a given individual.	Conflict of Interest (Col) means a situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with EFSA.	✓
	Interest may be financial or non-financial.	EFSA categories foresee financial and non-financial interests.	✓
Policy framework	Dols should cover current and past interests.	ADols and SDols offer the possibility to declare current and past interests.	✓
	Dols should at least include the following information: <ul style="list-style-type: none">- past activities- current activities- above a certain min. threshold, any direct financial interests or grant or other funding- any other relevant interests- spouse's / partner's / dependent family members' current activity and financial interests that might entail a risk of Conflict of Interest.	The 2012 IR include all the categories required.	✓

EU guidelines		EFSA	Implemented
	The person concerned should be responsible for their own declarations.	Article 2 of the 2012 IR stipulates that the responsibility for completing accurately the DoI lies with the person completing it.	✓
	The policy should determine which checks are needed on the information provided.	Screening procedures are present in the 2012 IR.	✓
	The policy should determine how training and awareness-raising is organised in order to understand that the rules are well understood.	The policy does not present the trainings proposed and the awareness-raising initiatives in place.	X
	Establish the actions to be taken as a result of the screening.	The consequences of potential Cols are included in the 2012 IR.	✓
	Breach of Trust and remedial actions in case of Breach of Trust.	Breach of Trust procedures and remedial actions are present in the 2012 IR	✓

(Sources: EU guidelines on management of Col and EFSA 2012 IR)

Table 3: OECD guidelines on management of Cols

OECD guidelines		EFSA	Comparison
Definition: conflict of interest	A “Conflict of Interest” involves a conflict between the public duty and private interests of a public official, in which the public official has private capacity interests which could improperly influence the performance of their official duties and responsibilities.	Conflict of Interest (Col) means a situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person’s function in the context of his or her cooperation with EFSA.	✓
	Interest can be current or past	ADols and SDols offer the possibility to declare current and past interests.	✓
	Private interests are not limited to financial or pecuniary interests	Article 1 of the 2012 IR foresees financial and non-financial interests.	✓
	The negotiation of future employment by a public official prior to leaving public office is widely	Article 23 of the IR foresees the declaration of any	✓

	OECD guidelines	EFSA	Comparison
	regarded as a Conflict of Interest situation.	negotiation with potential employer(s).	
Policy framework	Provide clear and realistic description of situations leading to Col.	Article 1 of the 2012 IR develops nine categories of interests, however, only few examples are given.	±
	Identification of unacceptable Col situations.	Consequences Articles	✓
	Ensure that the Col policy is supported by organisational strategies and practices to help with identifying the variety of Col situations.	2012 Implementing Rules detail the management of Cols. Yet, the training material is not well advanced.	±
	Awareness that assists compliance and anticipation of at-risk areas for prevention.	The policy does not present the trainings proposed and the awareness-raising initiatives in place.	X
	Appropriate disclosure of adequate information, and effective management of conflicts.	Screening of Cols is present in the 2012 IR.	✓
	Partnerships with other stakeholders (contractors, etc.).	The 2012 IR are applicable to bodies and agencies participating in EFSA's meetings, as well as contractors, grant beneficiaries and their employees.	✓
	Redevelopment and adjustment of policy and procedures as necessary to meet evolving situations.	No periodical review is included in the policy.	✓

Legend

✓ : Yes

X : No

+/- : More or Less

N/A : Not Applicable

(Sources: OECD guidelines on management of Col and EFSA 2012 IR)

After our analysis of the guidelines we have divided the sections of the EFSA 2012 IR into main topics detailed further here below.

Conflict of Interest definition and categories:

The definition of Conflict of Interest⁶ adopted by EFSA in its 2012 independence Implementing Rules⁷ was compared with the OECD⁸ and EU guidelines⁹ on Conflicts of Interest. We assessed the definition as comprehensive. The interests are detailed into nine categories that are further defined in section 1 of the 2012 independence Implementing Rules. The ADol and the SDol forms are attached to the Implementing Rules. The different categories of interests are presented in the ADol in table format, in which the interests have to be filled in (period, organisation's information and subject matter).

Article 1 defines all the stakeholders to whom the 2012 Implementing Rules apply: members of Scientific Committee, Scientific Panels, working groups, members of the Networks, peer review meetings and networking meetings pursuant, hearing experts, observers, Management Board members, Advisory Forum, the Executive Director, other EFSA staff, staff of other EU institutions, bodies and agencies participating in EFSA's meetings, as well as contractors, grant beneficiaries and their respective employees. The different categories of scientific experts are mentioned, however a short definition of the categories of scientific experts could be a nice to have in annex of the Implementing Rules. Instead, EFSA refers to the document "Decision of the Executive Director Concerning the Selection of Members of the Scientific Committee, Scientific Panels and External Experts to Assist EFA with its scientific work".

In comparison with benchmark organisations FDA, EMA and ANSES, the definition of Conflict of Interest is comprehensive and well explained. The interests are divided into categories that are mutually exclusive and collectively exhaustive.

Declarations of Interest (Dols):

The stakeholders mentioned in Article 1 are requested to declare interest at different points in time. Additionally Management Board members, Advisory Forum members and the Executive Director have to complete a Declaration of Commitment (annex II of the IR). The rules are particularly strict regarding the scientific experts who have to declare any interest at three different points in time:

- annually with the Annual Declaration of Interest (ADol);
- prior to a meeting with the Specific Declaration of Interest and based on the meeting agenda items (SDol);
- at the beginning of a meeting with the Oral Declaration of Interest considering the final agenda of the meeting (ODol).

⁶ "Conflict of Interest meaning a situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with EFSA"

⁷ EFSA, "Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests", February 2012.

⁸ OECD, "Managing Conflict of Interest in the Public Service: OECD guidelines and country experiences", June 2003.

⁹ EU, "Guidelines on the prevention and management of Conflicts of Interest in EU decentralised agencies", December 2013.

The interests to be declared, are the ones mentioned in the nine categories developed in the Article 1:

- Economic interest;
- Member of a managing body or equivalent structure;
- Member of a scientific advisory body;
- Employment;
- Ad hoc or occasional consultancy;
- Research funding;
- Intellectual property;
- Other memberships or affiliations;
- Other relevant interest.

In accordance with the EU guidelines on Conflicts of Interest, the EFSA Dols collect all the relevant information such as past activities, current activities, direct financial interests, interest of close family members and any other relevant interests.

Article 2 of the EFSA Implementing Rules clearly specifies the individual responsibility of the experts and staff members to declare their interests for a retrospective period of five years.

The consequences of Conflicts of Interest for the experts are described in Article 10 and 11 of the 2012 independence Implementing Rules. These consequences depend on the categories of interest, and the period of the activity. A summary table can be found in the annexes.

Following the decision of the European Ombudsman on the complaint 775/2010/ANA¹⁰, EFSA has included in its 2012 Implementing Rules a paragraph under Article 23 ‘Dol of other EFSA staff’ tackling the potential risks related to post-employment of EFSA staff. It is stated that “...EFSA staff shall declare also any negotiation with prospective employer(s) having a vested interest in EFSA or in its activities.” Nevertheless, the employee does not have the possibility to directly notify a future employment in its Dol. Indeed, in the Dol, the Conflicts of Interest to be declared in the employment category can only refer to past or current periods and not to future periods. EFSA staff members currently need to declare future employment by selecting “current” in the Dol and by adding a comment about the future character of the employment.

Compliance and veracity checks:

The screening of the Dols is performed following strict criteria in accordance with the interest categories.

Nevertheless, the Dols compliance checking procedure is not completely expressed in the Implementing Rules but only briefly mentioned in Article 14. EFSA could insert a more

¹⁰ European Ombudsman, “*Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA against the European Food Safety Authority (EFSA)*”, May 2013.

elaborated topic on the checking procedure (e.g. the step-by-step procedure) as EMA did in its code of conduct¹¹.

Breach of Trust:

In case the omission of information from an expert implies a Breach of Rules, this can lead to a Breach of Trust. In such a case, Article 15 of the Implementing Rules specifies the appropriate actions to be followed. As recommended in the EU guidelines¹², EFSA has foreseen to perform a review of the Scientifics outputs that the expert in question was involved in, and to undertake appropriate remedial actions if it appears that the scientific decisions have been influenced.

The Breach of Trust procedures for EFSA staff members are not detailed in the IR, yet they can be found in the EU Staff Regulation.

Trainings and awareness raising:

When comparing the EFSA 2012 IR with the OECD and EU guidelines, it appears that no topics related to trainings and awareness raising were included in the 2012 IR. We recommend EFSA to develop a section on the different trainings in place related to independence and the initiatives that EFSA has developed in order to increase awareness.

Transparency:

EFSA briefly mentions the transparency principle in its introduction to the independence Implementing Rules. In contrary, EMA¹³ and ANSES¹⁴ consecrate a separate paragraph on developing transparency initiatives. This topic is not required for the completeness of the Implementing Rules but might be interesting to thoroughly address at EFSA as well.

EFSA has promoted transparency in its Policy on independence through different initiatives, such as the transparency in its decision-making processes, transparency in the selection of experts and staff, the collegial decision making, etc. EFSA is transparent with its information on independence processes. However, it could be an added value for the reader's understanding to express the main transparency initiatives related to independence (also presented on the EFSA corporate website) directly in the Implementing Rules.

¹¹ EMA, "Breach of Trust procedure on Conflicts of Interests for Scientific Committees' Members and Experts", April 2012.

¹² EU, "Guidelines on the prevention and management of Conflicts of Interest in EU decentralised agencies", December 2013.

¹³ EMA, "The European Medicines Agency Code of Conduct", May 2013.

¹⁴ ANSES, "Code of ethical standards for expert appraisal by the French agency for food, environmental and occupational health & safety", November 2012.

Periodical Review:

The EU and the OECD guidelines recommend a periodical review of the Conflict of Interest policy. EFSA states in its Independence policy¹⁵ it will conduct such a review within four years following its adoption. However, no regular review of the Implementing Rules is foreseen in the 2012 Implementing Rules.

5.1.2. Conclusions

The EFSA 2012 Implementing Rules can be considered as complete and cover the different topics required by the OECD and EU guidelines. Some additional topics (transparency, trainings and awareness raising, periodical review of the independence policy) could be included in order to enhance the document, yet EFSA's Implementing Rules are robust.

In comparison with EMA, only the topic on transparency is missing in the EFSA Implementing Rules. However, EFSA already mentions transparency in its independence policy and has additional documents devoted to the topic.

The 2012 Implementing Rules group all the information related to Dols and Conflicts of Interest in one complete document. This is a clear strong point as compared to other organisations. For instance, EMA has two different documents related to its policy for handling Conflicts of Interest.

Some recommendations could be drawn from the analysis here above, all of which possible to be realised in the short term:

Short term recommendations
Add a table with a short definition of the categories of scientific experts in the annexes of the Implementing Rules.
Add the possibility to elaborate on future employment in the DoI.
Add a paragraph on trainings and awareness raising in the Implementing Rules.
Add a more detailed procedure description concerning the compliance and veracity checks of Dols in the Implementing Rules.
Make explicit reference to EFSA's transparency initiatives in the Implementing Rules.
Include the periodical review of the Implementing Rules.

¹⁵ EFSA, "Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority", December 2011.

5.2. Clarity and transparency of the 2012 independence Implementing Rules

In the paragraphs below, an assessment is made of the clarity and the transparency of the EFSA 2012 independence Implementing Rules. The analysis covers the main topics of the Implementing Rules and is based on benchmarking with similar organisations, on the EU and OECD guidelines on Conflicts of Interest and on our own judgement.

5.2.1. Analysis of the Conflict of Interest definition

The analysis of the definition of Conflict of Interest in Article 1 of the 2012 Implementing Rules has been performed based on a benchmarking exercise with EMA, FDA and ANSES as well as the EU and OECD guidelines on Conflicts of Interest. Additionally, for this particular topic, EFSA has also been compared to WHO. Indeed, WHO has been recognised as a good practice regarding its definition of Conflict of Interest in an earlier benchmarking exercise¹⁶.

EFSA's definition of Conflict of Interest¹⁷ is clear and has been changed in the 2012 Implementing Rules in line with the OECD guidelines. In comparison with the four benchmark organisations, EFSA provides a clear and comprehensive definition. However, WHO goes further by including "...any interest that may affect, or may reasonably be perceived to affect, the expert's objectivity and independence"¹⁸.

EFSA has divided the interests into nine different categories. These categories are complete and cover a wide range of interests. EFSA does not restrict interest to financial interest such as FDA or to direct or indirect interest such as EMA. EFSA covers every possible interest that might result in a Conflict of Interest. Indeed, intellectual interests and other potential interests that might compromise the expert's independence are also taken into consideration. The different categories are explained in detail and some concrete examples are given where necessary. For instance, when talking about self-employment the example of consultancy is given. Nevertheless, ANSES provides more concrete examples for the different categories.¹⁹ EFSA could consider to also give concrete examples on the DoIs for the different categories. Moreover, the definition of 'research funding' could be better elaborated.

In order to facilitate the task of the experts while completing either their ADol or SDol, EFSA could include a short definition and concrete examples under each category. For instance, in this respect WHO has a good practice: rather than putting a table with all the categories, it asks questions related to the categories. If the expert has replied 'yes' to one of the questions, then he has to explain his 'yes response' by giving additional information.²⁰

¹⁶ Milieu Ltd, "Comparison between the tools ensuring EFSA's independence scientific advice and the instruments in used by organisations similar to EFSA", January 2011.

¹⁷ "Conflict of Interest meaning a situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with EFSA"

¹⁸ WHO, "Declaration of interest for WHO experts", June 2010.

¹⁹ ANSES, "Déclaration publique d'intérêt: notice explicative".

²⁰ WHO, "Declaration of interest for WHO experts", June 2010.

In the annexes of ANSES's Implementing Rules on the Declaration of Interests²¹ an explicative document has been inserted concerning the online completion of CVs and Dols. This step-by-step explanation could be a nice to have for EFSA in its annexes. Additionally, contact information in case of problems / questions could also be mentioned on EFSA's DoI document and Implementing Rules.

Finally, EFSA does not clearly state which interests of the staff/expert's close family members are allowed and the restrictions to be applied as pointed out by European Parliament in its 2010 discharge.

5.2.2. Procedures related to the Declarations of Interests (Dols)

In the paragraphs below, an assessment is made on the clarity of a selection of three main procedures of the EFSA 2012 Implementing Rules: Management of Conflict of Interests, compliance and veracity checks and Breach of Trust procedures. In this paragraph, only the main procedures related to the Declarations of Interests are evaluated based on own judgment, the recommendations made by the Court of Auditors and the 2011 EFSA benchmarking study.

Management of Conflict of Interests:

EFSA has different procedures regarding the identification and the handling of potential Conflicts of Interest for the scientific experts and EFSA staff members (see table 5). The general procedure is based on a screening of the Dols completed by the individuals. The analysis of the definition of the consequences of Conflicts of Interest has been performed based on a benchmarking exercise with EMA, FDA and ANSES.

EFSA has a comprehensive framework for handling Conflicts of Interest as already pointed out by the European Court of Auditors. The consequences of Conflicts of Interest for the Scientific Committee, Scientific Panels and Working Groups are explained in Article 10 (for the ADol), Article 11 (for the SDol) and Article 12 (for the ODol) of EFSA's Implementing Rules on independence. Additionally, summary tables are present in annex IV and V of EFSA's Implementing Rules regarding articles 10 and 11.

The criteria to determine the consequences of a Conflict of Interest are based on the type of interest. Moreover, EFSA, in its screening of the ADol, distinguishes between "experts having an interest related to Food Safety Organisations (FSOs)" and "experts having interests related to other organisations"²². The criteria are quite detailed, however the tables presented in annex IV and V of the Implementing Rules are really helpful for the understanding and the clarity of the consequences applied to the experts. The definition of an FSO could however be improved.

In comparison with ANSES, EMA and FDA, concerning the actions applied on experts, EFSA provides clearer definitions of consequences on a Col. Only EMA provides levels of intensity of Cols and the consequences. FDA provides detailed consequences but the descriptions are not really clear. Finally, ANSES does not provide reference to actions.

²¹ ANSES, "Déclaration publique d'intérêt: notice explicative".

²² EFSA, "Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests", February 2012.

Moreover, ANSES does not provide information on the levels of intensity of Cols nor on the consequences applied to the different roles.

The table below compares the consequences of a Col for experts for the four benchmarked organisations. This table indicates that only EFSA and EMA provide detailed and clear consequences regarding the experts' Cols.

Table 4: Comparison of the consequences of a Col between EFSA, ANSES, EMA and FDA

Consequences of a Col for the experts				
	EFSA	ANSES	EMA	FDA
Provide consequences	✓	X	✓	✓
Provide description of consequences	✓	X	✓	✓
Clarity of the consequences	+	N/A	+	-

Legend

✓ : Yes X : No +/- : More or Less N/A : Not Applicable

For the other target groups, the actions that need to be taken related to independence are less clear. Indeed different types of stakeholders need to complete different types of Dols. A recapitulative table might be necessary (see example below) in order to clarify what each type of stakeholder needs to declare and what the consequences of Cols are for them.

Table 5: Summary table on EFSA Dols and the consequences of Cols

Target group	Declarations to make	Consequences
Scientific Committee, Scientific Panels, Working Group	Declaration of Commitment ADoI SDoI ODoI	Article 10 Article 11 Article 12
Members of Networks, peer review meetings and networking review pursuant	Declaration of Commitment ADoI ODoI	Article 10 Article 12
Hearing experts	Declaration of Commitment ADoI	The ADoI is requested for an informational purpose, the declaration is not screened and no remedial actions are foreseen.
Observers	/*	/*
Members of the Management Board	Declaration of Commitment ADoI	Article 20

Target group	Declarations to make	Consequences
Members of the Advisory Forum	Declaration of Commitment ADoI ODoI	Article 10 Article 12
Executive Director	Declaration of Commitment ADoI	Article 11a of the staff Regulations
Other EFSA staff	ADoI	Article 10 Article 23
Tenderers to EFSA's procurement procedures	Institutional Declaration of Interest (annex VI of EFSA's Implementing Rules)	Article 25
Employees and consultants in the context of procurement and grants procedures of EFSA	Individual Declaration of Interest	Article 11
* As observers do not play any role in the decision making process, no declarations are requested from them.		

We recommend EFSA to clarify the Article 19 (for observers) and the Article 25 (for employees and consultants) of the Implementing Rules. Indeed, these two articles do not clearly indicate which DoI needs to be completed nor the screening and consequences resulting from a Col.

Compliance and veracity checks:

The procedure regarding the compliance and veracity checks of a sample of Dols is not clearly explained in the 2012 Implementing Rules. However, more information can be found in EFSA's 2012 Annual Activity Report²³ and in internal reports²⁴ that are not available online but can be made available upon request. It would be interesting to have directly in the EFSA 2012 Implementing Rules the complete checking procedure as already mentioned in section 5.1.1.

The process of the compliance and veracity checks consists of the screening of the Dols of a very limited selection of 15 randomly selected experts (out of on average 3,000 experts) which is conducted twice every year. The selection excludes Network and Advisory Forum experts, hearing experts and observers as they do not play any role in the decision making process.

Two checks are performed on the Dols by the Committee on Conflict of Interest (CCI). For the compliance check, the Dols are evaluated to check to what extent they are in accordance with EFSA's policy on Independence. For the veracity check, the ADols of the selected experts are checked against their CVs, which limits the merits of the control as the CVs are drafted by the experts themselves. Additionally, every expert is asked to confirm the accuracy of the information provided in their ADols. If inconsistencies are

²³ EFSA, "Annual Activity Report of the European Food Safety Authority for 2012",

²⁴ EFSA, "Report on the compliance and veracity checks of Dols of experts of EFSA's Scientific Committee, Scientific Panels and Working Groups in the first quarter of 2013", Augustus 2013.

EFSA, "Report on the compliance and veracity checks of Dols of experts of EFSA's Scientific Committee, Scientific Panels and Working Groups in the second quarter of 2013", October 2013.

detected the experts have to clarify those incoherencies and if necessary to update their Dols.

Regarding the random selection of experts, it might be interesting to select the experts on the basis of a risk based approach (see section 5.4.2 for more details). Using such an approach, experts with a higher probability to have a Conflict of Interest will also be ranked higher on the list of experts to be selected for a compliance and veracity check. Ideally, a more thorough internet research on the experts in question would be conducted during these checks. However, as this is a very labour intensive task, EFSA will need to investigate further to what extent this is feasible and to what extent this task would be proportionate as compared to the benefits it might bring.

Also, from a legal point of view, EFSA would need to investigate how it will be able to assure that all experts that are being scrutinised through internet research will be treated equally (e.g. internet searches often generate different results depending on the browsing history of the researcher; searches on scientists with a commonly used name will generate much more irrelevant results; etc.). A sound procedure and methodology would need to be put in place.

Breach of Trust procedures:

In the 2012 report of the European Court of Auditors, it was mentioned that EFSA should develop clear, transparent and consistent Breach of Trust policies and procedures for the entire agency²⁵.

There are defined and implemented Breach of Trust procedures for all experts (in the 2012 Implementing Rules), for staff members (stipulated in the Staff Regulation) and for Management Board members (rules and procedures of the Management Board of EFSA).

The process regarding Breaches of Trust for the members of the Scientific Committee, Scientific Panels and Working Groups is detailed in Article 15 of the 2012 Implementing Rules. The procedures and consequences are clearly expressed and EFSA established a possible “review of the scientific outputs adopted by the scientific body(ies) to which that expert has contributed”²⁶. On several occasions in the past years, audits have taken place of the scientific outputs by EFSA’s Internal Audit Capacity.

The process regarding Breaches of Trust for the staff members is presented in the Staff Regulation’s articles 16, 17, 19²⁷ and is comprehensively detailed.

The process regarding Breaches of Trust for the Management Board members is explained in Article 15 of the rules of procedures of the Management Board of EFSA²⁸. Moreover, Article 20 of the 2012 Implementing Rules details clearly the procedure followed when an update of a Dol is received.

Although EFSA has procedures in place for the different roles involved in EFSA’s work, the Breach of Trust procedures are not really developed. Compared to EMA that has a detailed step-by-step Breach of Trust procedure on Conflicts of Interest²⁹ for the Management

²⁵ European Court of Auditors, “*Management of Conflict of Interest in selected EU agencies*”, 2012.

²⁶ EFSA, “*Decision of the Executive Director implementing EFSA’s Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests*”, February 2012.

²⁷ European Commission, “*Staff regulation of Officials of the European Communities*”, May 2004.

²⁸ EFSA, “*Rules of procedure of the Management Board of the European Food Safety Authority*”, June 2013.

²⁹ EMA, “*European Medicines Agency breach of trust procedure on conflicts of interests for scientific committee members and experts*”, April 2012.

Board members and the Scientific Committees' members and experts, EFSA could further develop its information concerning the procedures and the difference between a Breach of Rules and a Breach of Trust should be better explained to the public at large.

EFSA has been criticised in the past for not publishing the outcomes of the Breach of Trust procedures. This is due to European legislation that does not allow for the publication of personal data. This restriction is clearly explained in Article 27 of the 2012 Implementing Rules.

5.2.3. Clarity and transparency of online information

A brief review was made of the EFSA website, to assess the online availability of documents, related to independence, and the accessibility and usability of information provided.

As a consequence of the EFSA policy on transparency and openness, a large number of documents are made available online in general. In January 2013, EFSA launched an initiative designed to facilitate access to data and enhance transparency in risk assessment. The transparency initiative is in line with EFSA's Science Strategy for 2012-2016³⁰ which highlights the importance of the Authority's role in making data accessible to interested parties. EFSA is currently developing a new policy on transparency, to be finalised in 2014.

The EFSA website is seen as the organisation's most important communication tool. The importance of the website has increased in recent years, with visits reaching 4.4 million in 2012, representing an increase of 27% compared to 2011³¹.

Specifically related to EFSA's independence, a number of documents are to be found on EFSA's website (e.g. the agenda, minutes and broadcasts of Management Board meetings, decisions of the Management Board, Dols of experts and Management Board members, opinions and reports of the Scientific Committee, Panels and Working Groups, procedures and guidelines, policy documents, etc.).

Under the 'Who we are' section, a dedicated webpage is offered on the Dols, listing the categories of interests to be declared, offering the submitted ADols of the EFSA experts, and pointing at who needs to complete a Dol.

Also, the 2012 Implementing Rules are offered on this page, alongside the 2012 Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests and EFSA's policy document on Independence and Scientific Decision-Making Processes.

Given the ongoing criticism on EFSA's independence, even more transparency and improved online communication would be beneficial, e.g. on screening procedures, decisions on Conflicts of Interest, etc., in order to mitigate further the criticisms from the external stakeholders.

EMA, "European Medicines Agency breach of trust procedure on conflicts of interest for Management Board members", June 2012.

³⁰ EFSA, "Science Strategy of the European Food Safety Authority 2012- 2016"

³¹ EFSA, "Annual Activity Report for the European Food Safety Authority for 2012", 2013.

From a more general perspective, increasing the openness and transparency on EFSA's scientific activities on the website even more would meet stakeholders' high expectations related to this. It needs to be noted that EFSA has already made great progress in this area over the past years by publishing its scientific opinions and other documents on the website. Moreover, a number of online tools have been installed such as online videos, FAQs, the EFSA Journal, newsletters, webcasting, news alerts, the use of social media, etc. Specifically on the topic of independence, the online publication of the Declarations of Interest is also proof of EFSA's efforts in this area.

For the availability aspect, the existence of documents and their 'findability' were assessed, apart from an assessment of the sophistication of the website and the user friendliness of navigation.

The information provided on the website can seem diffused, hidden in various sections of the website (e.g. the DoI forms cannot be immediately found / downloaded on the Declarations of Interests (Dols) page, but can be found as an annex to the Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests).

'Independence' can be found as a topic under the 'Topics A-Z' pages, but for instance 'Declarations of Interests' cannot. Surprisingly, clicking this topic does not redirect the leader to the 'Declarations of Interests' page, but to the 'Independence' page which is not offered as such on the homepage of the website.

The navigation on the website can therefore be assessed as rather complex.

Overall, the 'findability' of documents, the sophistication of the website and the user friendliness of the navigation can still be improved. The current situation puts unnecessary administrative burden on users of the website. However, thanks to the fact that e.g. Dols can be submitted via an online tool that is made available on the EFSA corporate website, DoI forms can be pre-filled with previously submitted information and there is a notification of the validation, the sophistication of the website can be assessed as at level 3 on a scale of five, with some of functionalities of level 4 and 5 already in place, following the website sophistication scale as summarised in the table below.

Table 6: Sophistication scale of websites for users

Sophistication Scale of Websites for Users	
Level 1.	Basic information provision to user; passive website where information can be read.
Level 2.	One-way interaction for users to fill in information; downloadable forms on the website.
Level 3.	Two-way interaction (electronic forms that allow two way information exchange, meaning information can be uploaded into the system as well).
Level 4.	'Full' electronic case handling (e.g. follow-up the status of your files yourself).

Sophistication Scale of Websites for Users

Level 5.	Personalisation: pro-active and automatic handling (e.g. pre-filled forms, deadlines, alarms, etc.).
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EFSA is currently procuring a study on their website strategy, user needs and site objectives, with a view on a fundamental redesign of the website, which should result in the mitigation of this suboptimal situation.

The clarity and transparency of the online information can be assessed as sufficient. For instance, the EFSA risk assessments are clearly explained on the website by showing a video explaining the main processes related to EFSA's independence.

However, the EFSA communication on independence could as well benefit from adapting the language to the different target groups that are interested in this kind of information.

The following recommendations could be drawn from our analysis:

In the short term, EFSA could use its website to raise awareness about independence issues and capitalise on the upcoming website redesign.

Possible long term actions:

- EFSA could review its website in general, and the webpages related to independence in view of further administrative simplification for the EFSA experts. The fact that EFSA uses intelligent electronic DoI forms, that reuse already submitted information (personal details, earlier declared interests, etc.) in order to ease the administrative tasks of the experts has been a major improvement in this respect. However, further efforts could be done in this area, e.g. by putting in place key levers such as e.g. the use of eSignature, eID and eDocumentation and to install a 'one-stop-shop' webpage on independence on the EFSA website that clusters all information, templates, etc. around the topic. By doing so, EFSA would evolve towards a true 'level 5' website;
- EFSA could also develop more user-oriented webpages, offering user-centric services to the different stakeholder profiles that visit the EFSA website to learn more about the EFSA independence policy (e.g. via different pathways for different users, providing different information for different users, etc.);
- EFSA could conduct regular benchmarking with other, similar organisations such as ANSES, EMA, FDA, etc. on how these organisations communicate on independence issues on the web, to monitor progress, to stimulate mutual learning, and to promote excellence.

5.2.4. Assessment of the transparency of EFSA's independence policy

As can be derived from the overview table below, EFSA respects the EU guidelines³² on transparency related to independence.

Table 7: EFSA transparency on independence compared to the EU guidelines

EU guidelines on transparency	EFSA	Implemented?
Agencies should publish on their websites their policies and rules for the management or prevention of Cols.	EFSA publishes its policies and rules for the management of Cols. EFSA publishes all its procedures related to the development of scientific outputs.	✓
The names of the board members and external experts should be published in the website.	EFSA publishes all names of the Management Board members, the staff and the experts on its website. EFSA publishes the CVs of the Authority's Executive Director, Senior management and panel experts on its website.	✓
Minutes of meetings should also be published on the website along with the list of participants and Dols.	EFSA publishes all scientific outputs including its scientific opinions as well as the agendas and minutes of the meetings and other important documents on its website. EFSA publishes the Dols of all members and external experts on its website. EFSA publishes in the minutes the discussions regarding the outcomes of the Dol screenings. EFSA broadcasts Management Board meetings online.	✓
A special section on the implementation of the Col policy could be included in the Annual Activity Report.	EFSA has a section dedicated to the implementation of Independence Policy and Implementing Rules in its Annual Activity Report.	✓

³² EU, "Guidelines on the prevention and management of Conflicts of Interest in EU decentralized agencies", December 2013.

When benchmarking EFSA to similar organisations on the topic of transparency, in general all the organisations benchmarked consider transparency as very important and are constantly looking for improvements in this area. The scientific meetings decisions of the three benchmarked organisations are always available on the internet together with the Dols.

In comparison with the benchmark organisations, EFSA has a robust transparency policy and is constantly improving it. As a matter of fact, EFSA is currently reviewing its policy.

The commitment of EFSA to improve the transparency of the agency can be noted in the different initiatives launched over the past years:

- In 2012, a pilot initiative was launched to open up the meetings of the Scientific Committee and the Scientific Panel. EFSA confirmed its willingness to continue this initiative in the future.
- In January 2013, EFSA launched an initiative designed to facilitate access to data and enhance transparency in risk assessment. This initiative was based on recommendations made by stakeholders in an external evaluation in 2012.
- In 2013, a conference with stakeholders was organised to discuss how transparency regarding the risk assessment process could be enhanced.
- Furthermore, EFSA takes into account stakeholder's points of view through the Stakeholder Consultative Platform and the annual Stakeholder Conference.

Accomplishing transparency does not mean EFSA should share all its data. For instance, personal data needs to be processed in accordance with Regulation (EC) n° 45/2001 of the European Parliament and of the Council on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data.

We recommend EFSA to continue the improvement of its transparency policy, it is indeed a good way to strengthen the public trust. EFSA should further communicate and explain to external stakeholders its independence processes. By clarifying the independence processes, EFSA could consider to reduce the current administrative burden imposed to the experts (related to the Dols processes).

5.2.5. Level of awareness raising regarding the 2012 independence Implementing Rules

EFSA installed different measures for its staff members and experts in order to increase the awareness on independence. These measures are detailed here below:

For staff members:

- Mandatory training on Ethics & Integrity for all staff members including EFSA's Management Board;
- Mandatory training on the new policy and rules for all EFSA staff involved in their implementation;
- Internal guide on ethics and integrity;
- Appointment of an ethic advisor in 2011. The ethics advisor advises staff members and other actors of the Authority's bodies on subjects related to ethics,

independence and Conflict of Interests. For instance, if a staff member has a doubt about a private activity that might result in a Conflict of Interest he can directly be advised by the ethic advisor.

For experts:

- Mandatory on-boarding trainings on Ethics, Integrity and Conduct (covering the issue of conflict of interest);
- Functional mailbox: in case of doubts, experts can directly post their questions on the mailbox;
- Welcome pack with the internal rules and information about EFSA.

Also here some recommendations can be made.

For the experts, the measures in place could be completed by putting in place a policy on gifts, invitations, etc.

But also on training, more efforts can be done. EFSA considers training its staff and the experts as important for raising awareness on the topic of independence. The adoption of a Learning and Training Policy shows that EFSA is taking the development of its staff and experts seriously.

Although the independence trainings seem quite short and concise, they capture the most relevant elements of the independence topic. For instance, the training on the 2012 Implementing Rules explains the DoI processes, the key principles of the screening exercise, and some key concepts. The on-boarding training offered to EFSA experts is very basic and should be further elaborated.

In terms of recommendations, it is clear that EFSA could increase and improve its communication with the experts through the improvement of its training portfolio in this area extensively. Experts should receive a thorough on-boarding training when starting to work with EFSA, and then have regular online trainings on updates, frequently asked questions, etc. Concerning the EFSA staff members, we recommend to increase the communication on independence with the creation of a dedicated intranet page on independence.

In the short term, EFSA could consider to put in place a more elaborated, detailed and frequent independence training package, both for its staff members and the experts EFSA is working with, tailored for specific target groups (e.g. following an expert risk profile; following the subject matter an expert is involved in; for experts who had omissions, etc.).

Trainings in general, and the on-boarding training in particular could be more elaborate, and detailed. Also, the training frequency and repetition could be augmented and from a content perspective, trainings could cover e.g. case studies, live exercises on filling in DoIs, discussing past complaints, discussing “grey” areas such as private-sector sponsorship, public-private partnerships, interchange of personnel between sectors, NGO relations, and party-political activity by individuals, etc. In terms of repetition of trainings, enhancements could entail e.g. linking new training waves to the renewal rate of experts (every three years approx. one third of the experts enters the expert pool).

In the longer term, EFSA could consider to put in place online trainings for both experts and EFSA staff, resulting in a short mandatory test.

Also communicating in all transparency on the training possibilities / necessities for both target groups would not only ensure a lower level of possible non-compliance, but would also showcase to the external world and stakeholders that EFSA is taking the issue of independence serious and puts all measures in place to mitigate potential Conflicts of Interest and Breaches of Trust.

5.2.6. Conclusions

The 2012 Implementing Rules are in general clear. The new definition of Conflicts of Interest complies with the OECD and EU guidelines. The different categories of interests are clear and the definitions are well developed. However, EFSA could include in the DoI documents concrete examples and a definition of the categories.

The consequences of Conflicts of Interest for experts are clear and comprehensively detailed in articles 10, 11 and 12 of the Implementing Rules. However, this is not always the case for the other EFSA target groups. For instance, Article 19 (for observers) and Article 25 (for employees and consultants) could be reviewed and further clarified.

EFSA has advanced procedures concerning the management of Conflicts of Interest. Nevertheless, the veracity and compliance procedure is not completely and clearly defined in the Implementing Rules. Additional information concerning this process is available in the Annual Activity Reports and on demand a quarterly internal report can be requested. Yet, having all information centralised in the Implementing Rules would be beneficial. Finally, the very limited random selection of experts could be reviewed and replaced by a risk based approach.

EFSA is very transparent in its online information provision, yet there is still some room for improvement as the information provided is hidden in various sections of the website. Overall, the sophistication of the website can be assessed as at level three on a scale of five, as the EFSA website does not yet fully cover all elements to be assessed as a full level 4 website.

Also for the trainings on independence EFSA is providing, there are still some improvement points (see recommendations below).

EFSA has developed different initiatives regarding transparency. In general the organisation tends to be very open and transparent with its information provision to external stakeholders. Moreover, EFSA is constantly looking for improvements of its transparency policy and listens to its stakeholders in order to propose new transparency initiatives that live up to the stakeholders' expectations.

Finally, EFSA could increase its initiatives regarding the awareness raising on independence. Specifically, there is a need to formalise and improve the communication and trainings about this topic.

Short term recommendations
Add in the Dols a definition and a concrete example under each category of interests.
Add contact information in case of questions in the Implementing Rules and in the Dol documents.
Add in the annexes of the Implementing Rules a step-by-step explanation regarding the Dol submission for experts.
Clarify which interests of the staff/expert's close family members can lead to a Col.
Draft summary tables concerning the Dols required and the consequences that apply to the different stakeholders.
Clarify articles 19 and 25 of the Implementing Rules regarding the Dol and the consequences applied to the respective stakeholders.
Develop step by step Breach of Trust procedures for the different target groups.
Make better use of the EFSA website to raise awareness about independence.
Put in place a policy on gifts, invitations, etc. for experts.
Build a true independence training portfolio, with eye for training frequency and repetition.

Long term recommendations
Increase EFSA's transparency initiatives.
Increase and improve the communication around independence.
Develop mandatory online independence trainings (incl. certification) and a dedicated communication track on training possibilities and necessities in this area.

5.3. Assessment of the effectiveness of the measures for the detection of Conflicts of Interest

In the paragraphs below, a high level assessment is made of the effectiveness of the measures for the detection and mitigation of Conflicts of Interest. The first part will focus on the analysis of the outputs and the second part will analyse the improvements implemented based on the recommendations made by external stakeholders.

5.3.1. Analysis of the effectiveness of the measures

In this section, outputs related to the detection of Conflicts of Interest are being analysed. The data used for the analysis are derived from the EFSA Annual Activity Reports and internal reports on compliance and veracity checks. It should be taken into account that the new Implementing Rules only entered into force on 1 July 2012. Therefore, it is somewhat premature to fully assess the effectiveness of those new rules at this point in time.

The screening of the Dols can be assessed as effective judging from the numbers shown below. Realisation rates are close to 100%.

Table 8: Key performance indicators on the EFSA Dol screening

Indicator	Target 2011/2012	Achieved 2011	Achieved 2012	Achieved 2013	Evolution 2011-2013
Proportion of experts with approved annual Dol before invitation to first meeting of new working group	100%	97.47%	99.6%	100%	↗
Proportion of experts with approved specific Dol prior to meeting	100%	99%	99.8%	99.8%	↗

(Sources: EFSA Annual Activity Report 2011³³, 2012³⁴ and 2013)

Numbers regarding the implementation of the EFSA independence policy are given in the table below. The proportion of potential Cols prevented in regards to the Dols screened is approximately the same in 2011, 2012 and 2013. As previously mentioned, the percentage of screened Dols is close to 100%, therefore EFSA effectively detected potential Cols prior to meetings and Breach of Trust procedures have only been required in very exceptional cases (2 occurrences in 2011, 1 in 2012 and none in 2013). For the Breach of Trust procedures, audits have taken place of the scientific outputs by EFSA's Internal Audit Capacity.

³³ EFSA, "Annual Activity Report for the European Food Safety Authority for 2011", 2012.

³⁴ EFSA, "Annual Activity Report for the European Food Safety Authority for 2012", 2013.

Table 9: Results of the implementation of the independence policy in 2011, 2012 and 2013

Year	Dols Screened	Potential Cols prevented	Proportion potential Cols prevented / Dols Screened	Breach of Trust procedures	Staff members leaving EFSA
2011	8,526	356	4.2%	2	Total: 25 Private sector: 3** Restrictions: 1
2012	6,869	272	3.9%	1*	Total: 28 Private sector: 4*** Restrictions: 0
2013	6,190	247	4%	0	Total: 29 Private sector: 4**** Restrictions: 3*****

* The Breach of Trust procedure involved an expert for whom EFSA became aware of a potential Conflict of Interest. On investigation, the expert confirmed an omission in the Declaration of Interest and EFSA has opened a Breach of Trust procedure. The expert was not considered in the Panel renewal exercise in 2012.

** One to the textiles sector, one to the public health sector and one to the private sector in the area of nanotechnologies (for which EFSA applied restrictions).

*** Two to the chemical/pharmaceutical sector, one to a humanitarian non-profit organisation, and one self-employed in the mechanical components sector.

**** One to an unrelated industry and three to the chemical/pharmaceutical sector.

***** (i) refraining from contacting EFSA staff to gain access to non-public documents and/or information; (ii) preventing the individual from becoming the acting reference contact point between EFSA and clients of the new employer; (iii) refraining from contacting or seeking information from EFSA staff outside the formal communication channels; (iv) reminding the individuals of their obligations under Staff Regulations, in particular Articles 16, 17(2) and 19 thereof; (v) requesting the individuals to inform EFSA of future activities of their new employer related to the food sector; and any changes in position within the company or occupational activities.

(Sources: EFSA Annual Activity Report 2011³⁵, 2012³⁶, and draft 2013³⁷)

³⁵ EFSA, "Annual Activity Report for the European Food Safety Authority for 2011", 2012.

³⁶ EFSA, "Annual Activity Report for the European Food Safety Authority for 2012", 2013.

³⁷ EFSA, "Draft Annual Activity Report for the European Food Safety Authority for 2013", 2014.

The table below focuses on the compliance and veracity checking system. This process was launched at the beginning of 2013. The purpose of this process consists of performing compliance and veracity checks on Dols of 15 randomly selected experts out of approximately 3,000 experts. The sample size is very low compared to the total number of experts, indeed only 0.5% of experts are checked. However, due to the heavy workload that represents the checking procedure, EFSA is currently not planning to increase the sample. We recommend therefore EFSA to select the experts in a more strategic way (see chapter 5.4.2. on risk based approach). In doing so, EFSA could mitigate the disadvantage of the very small sample size by selecting the experts at risk instead of randomly selecting the experts. Moreover, the sample size for these checks could increase if EFSA would not pursue other independence procedures any longer (see further), so that more staff could be made available for this task.

The compliance check on two samples of experts in 2013 (Q1 & Q2) indicated that only one expert out of 28 did not have a correctly evaluated Dol (represents 3.5% of the sample). Indeed, the Implementing Rules require SDols to be evaluated prior to a meeting. It appeared during the check that one expert had his SDol evaluated after the meeting. Therefore he participated to the meeting without having received a prior approval. However, it needs to be noted that the total percentage of SDols scrutinised prior to meetings is very high (99.8% in 2012, see table 6). Moreover, in this specific case, no interests relative to the meeting agenda items were detected in the post-investigation. This default in the system was due to a human error. In all the other cases the Dols were timely evaluated and managed in order to exclude any potential Conflict of Interest. The weak points related to this evaluation system are the high workload for EFSA staff related to it and the fact that the checks are only based on information declared by the experts.

The veracity check revealed however a large number of minor omissions from the experts, none of which were linked to industry activity. More than half of the experts had at least one omission in their Dols. EFSA considers that “those omissions were due to the experts’ misunderstanding of the rules and the importance of providing an up-to-date information in their ADols”³⁸. Even though none of these omissions raised a Conflict of Interest and all Dols were immediately updated by the experts involved, this clearly proves the need for stronger training and communication efforts about independence and the importance of accurate information on the SDols. We refer to section 5.2.5. for more insights on this point.

³⁸ EFSA, “Report on the compliance and veracity checks of Dols of experts of EFSA’s Scientific Committee, Scientific Panels and Working Groups in the first quarter of 2013”, Augustus 2013.

EFSA, “Report on the compliance and veracity checks of Dols of experts of EFSA’s Scientific Committee, Scientific Panels and Working Groups in the second quarter of 2013”, October 2013.

Table 10: Compliance and veracity checks outcomes

Period:	Experts selected:	Compliance : <i>experts not evaluated correctly according to EFSA's policy on independence</i>	Veracity: <i>Expert's Dols not in line with EFSA's policy on independence</i>	Cols identified:
First quarter 2013	13*	0/13	7**/13	0
Second quarter 2013	15*	1/15	6***/15	0
Total	28*	1/28	13/28	0
<p>* 30 experts were selected out of approximately 3,000 experts (represents 0.5%). For the first quarter one observer and one hearing expert were selected. Therefore, the compliance and veracity checks were performed on a sample of 13 experts. According to EFSA's sampling methodology, only experts who participated in at least one Scientific Committee or Panel or Working Group meeting in the review period are subject to be included in the sample. Experts who do not participate in the EFSA scientific opinions are excluded from the sample: experts participating in Network or Advisory Forum meetings, as well as hearing experts and observers.</p> <p>** On seven experts, 13 minor omissions were identified in the ADols checked:</p> <ul style="list-style-type: none"> - 4 related to participation in EU or public projects; - 2 to affiliation in other professional organisations; - 4 to employment (2 of them concerning wrong date quotation); - 1 to participation in a management body; - 1 to participation in a scientific advisory body; - 1 to occasional consultancy in the past. <p>*** On six experts, 18 minor omissions were identified in the ADols checked.</p> <ul style="list-style-type: none"> - 7 related to participation in scientific advisory bodies (2 of them concerning wrong date quotation); - 1 related to ad hoc consultancy to a public risk assessment authority; - 3 related to membership in editorial boards of scientific journals; - 4 related to affiliation in other professional organisations. 				

(Sources: Report on compliance and veracity checks first³⁹ and second quarter⁴⁰ 2013)

³⁹ EFSA, "Report on the compliance and veracity checks of Dols of experts of EFSA's Scientific Committee, Scientific Panels and Working Groups in the first quarter of 2013", Augustus 2013.

⁴⁰ EFSA, "Report on the compliance and veracity checks of Dols of experts of EFSA's Scientific Committee, Scientific Panels and Working Groups in the second quarter of 2013", October 2013.

In conclusion, the measures in place to prevent Conflicts of Interest can be considered as effective, taking into account the current EFSA checking system and its weak points already flagged earlier. The majority of the Dols are screened on time and potential Conflicts of Interest are in general immediately detected. Only few Breach of Trust procedures have been initiated.

Analysing the recent compliance and veracity checks procedure (started in 2013), the Dols appear to be evaluated adequately and in accordance to the EFSA Implementing Rules. However, the veracity checks revealed an important amount of minor omissions on the expert's Dols. This calls for more adequate trainings and the improvement of communication on independence (see section 5.2.5.). Moreover, the veracity checks are only based on a very small sample of randomly selected experts (only 0.5% of the total number of experts). In order to minimise the negative effect of this small sample size, we recommend EFSA to implement a risk based approach for the selection of experts and to investigate which actions related to independence could be reduced in order to free up time to do more veracity checks.

5.3.2. Assessment of the improvements made by EFSA regarding its independence policy

In this section, the improvements made by EFSA following different recommendations received from different stakeholders have been assessed. A comprehensive table in annex III presents the main recommendations. This table is based on suggestions made in the 2010 benchmarking report⁴¹, the 2010, 2011 and draft 2012 European Parliament Discharge on EFSA and the response from EFSA⁴², the decision of the European Ombudsman on complaints 775/2010/ANA⁴³ and 0662/2012/ANA⁴⁴, and the European Court of Auditors report⁴⁵.

The main topics that result from the overall analysis table are presented here below.

Stakeholder involvement:

EFSA has received the recommendation, following a 2011 benchmarking study, to increase stakeholder involvement. In the 2011 discharge document, EFSA has received the suggestion to start a structured dialogue with civil society on matters related to Conflicts of Interest. As previously mentioned, EFSA has further improved transparency by creating a Stakeholder Consultative Platform and by recently opening the meetings of the Scientific Committee and Panels to observers. The initiative is still ongoing, and EFSA's recent initiatives to further promote an open dialogue with non-governmental organisations are aligned with this approach.

⁴¹ Milieu Ltd, "Comparison between the tools ensuring EFSA's independence scientific advice and the instruments in used by organisations similar to EFSA", January 2011.

⁴² EFSA, "Follow up of actions suggested in 2010 Discharge on Conflicts of Interest".

⁴³ European Ombudsman, "Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA against the European Food Safety Authority (EFSA)", May 2013.

⁴⁴ European Ombudsman, "Decision of the European Ombudsman closing his inquiry into complaint 622/2012/ANA against the European Food Safety Authority (EFSA)", December 2013.

⁴⁵ European Court of Auditors, "Management of Conflict of Interest in selected EU agencies", 2012.

We recommend EFSA to further increase its dialogue with external stakeholders. EFSA should engage in an ongoing and direct communication with external stakeholders (e.g. industry, NGOs, etc.). It should on-board the stakeholders through these processes and discuss issues on their online stakeholder platform instead of just responding to issues / complaints when they arise. This continuous dialogue would improve the understanding of the stakeholders on EFSA's work and procedures. It also appears that even if EFSA replies to complaints and takes remedial actions it does not properly acknowledge its error and does not apologise for it, as mentioned in the decision of the European Ombudsman on complaints 775/2010/ANA and 0662/2012/ANA. The recognition of error is important in order to strengthen dialogue and trust with civil society.

Vis-à-vis the European Parliament, EFSA could communicate more clearly the resource effort that is linked to the independence policy in order to trigger a dialogue on how this taxpayer's money is most effectively spent.

Additionally, EFSA could consider to put in place a more 'institutionalised' whistle-blower process, both internally and externally. By putting in place such a system, stakeholders can be included in the reviewing process. They can raise the flag with EFSA on possible issues, and the Executive Director can then decide if action needs to be taken to further investigate. However, EFSA will need to ensure that the experts can still work freely on their scientific tasks.

Conflict of Interest management:

EFSA received different complaints regarding the definition of Conflict of Interest and the screening of Dols procedure. EFSA has taken those complaints and recommendations into account in its 2012 Implementing Rules. Indeed, the definition has been reviewed and specific criteria have been defined for the screening of Dols. However EFSA did not yet clarify which interests of the staff/expert's close family members are allowed and the restrictions to be applied in its independence policy as mentioned in the 2010 discharge document from the European Parliament. EFSA should therefore continue to improve its Implementing Rules. Through our analysis we have found different improvements to be made (see sections 5.1. and 5.2.). EFSA should also constantly review the recommendations made by external stakeholders.

Finally, the European Parliament, in its draft on the 2012 discharge document, calls upon EFSA to come up with a simplified procedure with less 'case-by-case' assessment of possible Conflicts of Interest. EFSA did not yet reply to this comment. Yet, after our discussion with EFSA staff members on this, it appears that EFSA would have some difficulties to implement the suggestion. Indeed, it would be difficult for EFSA to further categorise and formalise the screening of Dols. It needs to be noted that EFSA assesses Conflicts of Interest based on objective, pre-defined criteria. Interests are assessed by EFSA in relation to (1) the role played by the expert, (2) the work that the expert is required to carry out and (3) the mandate of the group. In its 2012 Implementing Rules EFSA has excluded persons employed by industry to become members of EFSA's Scientific Committee, Scientific Panels and working groups. However, EFSA cannot exclude or accept experts only based on common criteria as each specific situation needs to be assessed on the basis of its particular peculiarities. Indeed, if EFSA wants to work in collaboration with highly skilled experts it has to cope with the fact that those experts would

have prior experiences and interests. Therefore, in order to be able to work with those experts, EFSA has developed a DoI system that screens and avoids potential Conflicts of Interest and ensures independence. In order to reduce the complaints⁴⁶ about its procedure regarding the management of CoI, EFSA should further improve its transparency through the process and improve its dialogue with external stakeholders.

Post-employment:

The problem of post-employment and cooling-off period have been mentioned several times (by the European Ombudsman on complaint 0775/2010/ANA⁴⁷, by the European Court of Auditors and in the 2010 Discharge). The complaints regarding this problem have been taken seriously by EFSA. Indeed, EFSA has established a new policy in regards to it. EFSA staff members have to inform EFSA of any negotiation with prospective employers and of any change in circumstances linked to their position within two years (cooling-off period) after leaving EFSA. Based on this information, the Executive Director can approve or forbid the activity. Moreover, during these two years restrictions can be imposed on former staff members (as detailed in table 9 of section 5.3.1).

EFSA has also included in the Annual Activity Reports information on the sectors in which employees leaving the Authority will be starting to work. EFSA has also inserted information in its 2013 draft Annual Activity Report regarding the restrictions imposed on staff members leaving to a related sector (textiles sector, public health sector, nanotechnologies sector, chemical/pharmaceutical sector, etc.). This information indicates the willingness of EFSA to work in all transparency and to respond to stakeholders' concerns related to the subject (e.g. the 775/2010/ANA complaint).

In conclusion, the table presented in Annex III demonstrates that EFSA takes into consideration the remarks received from the different stakeholders. Most of the recommendations have been implemented or their implementation is ongoing. EFSA also provides detailed responses to the suggested actions received by stakeholders. However, EFSA should further involve external stakeholders throughout its processes and start a direct and ongoing dialogue with them. This action has already been suggested by the European Parliament and this could reduce the number of complaints from the stakeholders that do not always understand the screening procedures of DoIs, and sometimes fail to understand that the EFSA experts are bound to have some interests, but that these interests not necessarily imply Conflicts of Interest. Finally, the improvements made on the post-employment policy also need to be noted.

5.3.3. Conclusions

The first part of this section demonstrated the relative effectiveness of EFSA measures related to Conflicts of Interest. It is apparent that the screening of DoIs is compliant with the EFSA 2012 IR and performed prior to the meetings in close to 100% of the cases. This high percentage of pre-screening prevents potential Conflicts of Interest. Indeed, the veracity and compliance checks support those findings. The compliance checks revealed that the majority of experts were evaluated correctly with regards to EFSA's policy on independence.

⁴⁶ Reference to the different letters of complaints from external stakeholders on potential Conflict of Interests.

⁴⁷ European Ombudsman, "*Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA against the European Food Safety Authority (EFSA)*", May 2013.

However, a high amount of omissions detected during the investigation reveal a lack of understanding by the experts of the necessity to have accurate and up-to-date information on their Dols. Although these omissions did not lead to Conflicts of Interest, it is important to put additional measures in place in order to reduce this number (more than half of the experts checked had at least one omission in their ADol). This could be done by strengthening the trainings and by improving the communication on independence.

The second part of this section focused on the improvements made by EFSA in regards to the recommendations received. The table presented in Annex III reveals that EFSA implemented the majority of the suggestions received from stakeholders. EFSA constantly improves its measures and policy in regards to independence and Conflicts of Interest. However, this table also reveals the needs to increase communication with civil society. Indeed, the different complaints received are often based on a misunderstanding of the screening process. EFSA assesses Conflicts of Interest based on objective, pre-defined criteria. Interests are assessed by EFSA in relation to (1) the role played by the expert, (2) the work that the expert is required to carry out and (3) the mandate of the group. However, EFSA cannot exclude or accept experts only based on common criteria as each specific situation needs to be assessed on the basis of its particular peculiarities. In order to legitimate the process, EFSA should be constantly transparent about it and on-board external stakeholders in the process. Lastly, the post-employment measure represented an important point in this respect and appropriate measures have been taken to mitigate this problem.

Short term recommendations
Increase direct and ongoing dialogue with external stakeholders.
Put in place a more ‘institutionalised’ whistle-blower process, both internally and externally in the reviewing process.

5.4. Assessment of the effectiveness of the mechanisms in place for ensuring expert and staff compliance

In the paragraphs below, an assessment is made of the effectiveness of the mechanisms in place in order to ensure the independence throughout the EFSA decision making process. The section is divided into 3 parts. Firstly, the governance structure is being analysed; secondly, the main procedures related to independence are studied; and finally the suitability of the independence trainings is addressed.

5.4.1. EFSA's independence governance structure

The following paragraphs analyse to what extent the EFSA governance structure is fit-for-purpose as regards to independence. The governance structure needs to assure / support the independence of EFSA throughout the different decision making processes. Different roles intervene in EFSA's governance structure. These roles, their appointment, their responsibilities in the organisation and the applicable procedures related to CoIs are detailed in the table below.

Table 11: EFSA's governance structure related to Dols

Role	Appointment	Responsibilities	Procedures related to Col	Improvement points
Management Board members	Appointed by the European Council in consultation with the European Parliament	<p>Provide strategic direction and adopt strategic documents (e.g. rules, budget, etc.).</p> <p>Appoint the Executive Director and Scientific Committee and Panel members.</p>	<p>Draft a Declaration of Commitment and an ADol.</p> <p>Screen and discuss the ADols submitted by each member.</p> <p>When an update is made to a Dol from any member, the Board discusses and screens the updated ADol and decides on the actions to be taken. If a Col is identified, the Board may ask a replacement of the concerned member (decision is collegial and should be on a two-third majority).</p> <p>Screen the ADol of the Executive Director.</p>	Create an independent body in charge of the Dol screening.
Executive Director	Appointed by the Management Board	Implement the strategic documents adopted by the Board and manage the daily operation of the Authority.	<p>Draft a Declaration of Commitment and an ADol.</p> <p>Inform the Management Board of any change in his or her interests.</p> <p>Screen the ADols and ODols of the Advisory Forum members and liaise with the national competent authority in case of a potential Col.</p>	<p>Replace the ADol by a Dol that would be updated voluntary by the Executive Director when needed.</p> <p>Creation of a centralised team for the screening of Dols.</p>

Role	Appointment	Responsibilities	Procedures related to Col	Improvement points
Advisory Forum members	One representative designated by each EU Member State + Iceland and Norway	Advise the Executive Director regarding cooperation and networking with Member State authorities.	Draft a Declaration of Commitment, an ADol and ODols. Members shall inform the Advisory Forum of any change in their interests and update their ADol.	Replace the ADol by a Dol that would be updated voluntary by the members when needed. Creation of a centralised team for the screening of Dols.
Scientific Panels and Scientific Committee members	Appointed by the Board	Adopt scientific opinions.	Draft an ADol, SDols and ODols.	Replace the ADol by a Dol that would be updated voluntary by the member when needed. Remove the obligation to complete an SDols. Creation of a centralised team for the screening of Dols.
EFSA staff members	Hired on the basis of a fixed term contract following a transparent procedure and bound by the Staff Regulation adopted by the Council.	Provide scientific and technical advice and secretarial support to the Scientific Committee and Scientific Panels.	Draft an ADol as part of the recruitment procedure and declare any negotiation with prospective employer(s) having a vested interest in EFSA or in its activities. The responsible line manager screens the ADols of EFSA staff members. Screen Dols of the Scientific Panels and Scientific Committee members.	Replace the ADol by a Dol that would be updated voluntary by the staff member when needed. Creation of a centralised team for the screening of Dols.

Role	Appointment	Responsibilities	Procedures related to Col	Improvement points
Committee on Conflict of interests (CCI)	Composed of three Science Directors and the Head of Legal and Regulatory Affairs	<p>Review decisions on interests subject to possible complaints or questioning.</p> <p>Advise the Executive Director on Conflict of Interest issues.</p> <p>Perform the compliance check of the selected experts' Dols.</p>	N/A	

(Sources: EFSA 2012 IR, EFSA policy on Independence)

Overall, the governance structure of EFSA can be assessed as fit-for-purpose for ensuring independence.

However, there are some improvement points that can be noted.

The Management Board is responsible for the screening of the Dols of its own members. Indeed, the Management Board is responsible for defining if an interest of a member might cause a potential Conflict of Interest. The members are therefore party and judge at the same time. We recommend EFSA to use an external body that would be responsible for the screening of the Dols of the Management Board. Nevertheless, this external body should have a sound scientific knowledge in order to properly judge the potentiality of Conflict of Interest. The European Commission's DG SANCO could be an option in this respect.

In comparison, ANSES and EMA have similar governance structures. Similar committees such as the EFSA Committee on Conflicts of Interest are also present at ANSES and EMA. EMA has the Committee for Ethical Standards and Prevention of Conflicts of Interests that is comprised of six members that are fully independent from the agency (appointed by Ministerial Orders). However, following interviews with EMA and EFSA it appears that these committees do not have an adequate role. EMA is even planning to abolish the Committee for Ethical Standards and Prevention of Conflicts of Interests as they is now a centralised service taking care of all the checks in order to increase consistency. Moreover, through our analysis it became apparent that EFSA does not have a centralised independence team. Currently, it is the responsibility of the Heads of all the Units supporting the Scientific Committee or the different Scientific Panels or Working Groups to screen the ADols of the respective experts, which causes different interpretations of the rules. Furthermore, scientific officers often interact frequently with experts which might cause a perception of subjectivity that could be avoided if the independence procedures are centralised. That being said, in the end it is the Director that does the final validation. A centralisation of the work on independence would also reduce the workload of the Heads of Units and Directors that are now heavily involved in the process. It needs to be noted that centralising the independence function is not a new concept at EFSA. An attempt in that respect has been made already in 2011, however, with few resources.

Therefore, we recommend EFSA to replace the Committee on Conflicts of Interest by a non-operationally involved, centralised team that would be in charge of the management of the Cols and the procedures related to independence such as the screening of the Dols of experts, staff and the Management Board members. This team could at first be internally managed. Later on, when the processes are fully in place, EFSA could even decide to outsource the screening of the Dols to an independent external body. It goes without saying that outsourcing the screening of Dols and the management of Cols to an independent body would require further analysis (e.g. on topics such as accountability, etc.) and the development of a 'business case'.

5.4.2. Assessment of the effectiveness of the independence procedures

The paragraphs below analyse the procedures related to Conflicts of Interest and the monitoring system put in place. EFSA has established a range of procedures in order to safeguard its core values of independence, scientific excellence, transparency and openness in order to build trust in its work.

Procedures on Conflict of Interest:

EFSA assures independence throughout its decision making process by using at different points in time Declarations of Interest. As previously explained, the different roles in the EFSA governance structure, depending on their responsibilities, have to complete Dols. In total EFSA has three different types of Dols: ADols, SDols and ODols. The members that have the most influence on EFSA scientific opinions (the scientific experts) are more strictly controlled and are requested at several times to declare their interests. It should also be pointed out that EFSA could reconsider the Dol obligations of the Network and Advisory Forum experts, hearing experts and observers. Although there is a different kind of control system in place for these stakeholders, also they have somewhat heavy Dol obligations that might not be in proportion with the risk they carry. Of course, for transparency reasons it is good to have also their Dols available in all transparency, but EFSA could investigate how it could reduce the administrative burden for those stakeholders, for instance by using a risk based approach (see section 5.4.2 for more details).

EMA and ANSES have a more simplified system. ANSES only requires its experts to fill in the Public Declaration of Interest at the time they take office. The Declaration is then only updated at the initiative of the person concerned on the occasion of any event likely to give rise to changes in its content. It needs to be noted that experts working with ANSES can be prosecuted by Criminal Law in case they are not compliant with the ANSES rules on independence. This is not an option at EU level. EMA has only the ADol to be filled in, moreover no screening of the veracity of the information is done by EMA. EMA only checks if the declaration has been completed correctly.

We recommend EFSA to follow the example of ANSES and EMA and to further responsabilise the experts. Indeed, the current procedure is burdensome for the experts that have to declare interests at three points of time (as was confirmed by the 2011 EFSA Scientific Expert Satisfaction Survey report⁴⁸). Instead of imposing a strict control on the experts, EFSA should trust the experts and involve them more in the detection of Conflicts of Interest. The experts would no longer be required to complete SDols for each separate meeting, but they would need to raise the flag if they consider themselves to be in a Conflict of Interest, prior to a meeting. Furthermore, ADols only need to be updated if the expert sees the need to do so. The reduction of ADols and SDols would be greatly beneficial to the reduction of the cost and time spent by EFSA on the screening of Dols. This workload could be reallocated to other (independence) tasks that add more value. Thus, the new independence strategy would be based on trust towards the experts (and the principle of the responsibility to keep Dols up to date would need to be embedded in the Declaration of Commitment) and more transparency towards the stakeholders.

⁴⁸ Technical report submitted to EFSA - EFSA Scientific Expert Satisfaction Survey, 2011

Moreover, EFSA has put in place different initiatives that promote the independence of its scientific opinions:

- Experts cannot review their own work;
- Collegial decision making: the final opinions are adopted by consensus or by a majority decision. Therefore, one single expert only has a limited influence on the final decision, and the final decision does not represent the point of view of a single expert;
- If experts disagree with the opinions adopted by the majority, their 'minority' opinions are also published as part of the scientific outputs. In this way, EFSA takes into account all point of views in its outputs;
- EFSA has made a significant investment in the development of an electronic DoI tool in order to facilitate the implementation, monitoring and enforcement of the DoI screening system.

EFSA should concentrate its strategy on improving its transparency and better communicate with the external stakeholders, even more than is the case currently. Indeed, it is essential to explain to the external stakeholders that experienced scientific experts are bound to have some interests, but that these interests do not always materialise into a Conflict of Interest. A more formal communication with the experts would also be beneficial, thus increasing the experts' awareness about the importance of constantly having an up-to-date ADol. In doing so, EFSA would reduce the number of minor omissions detected during the veracity and compliance checks.

Moreover, EFSA should also increase the predictability of its processes and could consider to obtain an ISO certification for its management system.

Many organisations become registered to ISO 9001 in order to showcase to their stakeholders that they deliver upon the expectations. For example Boeing is using the standard to assure that their suppliers (hardware, software or service) have a management system for quality that will supply products and services to their requirements. Also non-profit organisations start to implement ISO standards (e.g. EASA).

An ISO 9001 certificate will provide maximum benefit to the organisation if it approaches ISO 9001 implementation in a practical way. This will ensure that the quality management systems that are adopted, work to improve the business and are not just a set of procedures that employees will find hard to manage. By adopting an approach that starts out to implement more efficient working practices and focuses on the business objectives of the organisation, a system can be achieved that will help and support staff, and improve stakeholder satisfaction.

Basic Requirements

ISO 9001 requires organisations to have a quality manual which includes the documented procedures or references to them. The manual must include a description of the sequence and interaction of the processes that make up the quality management system. In addition, the scope of the system has to be clearly defined.

Some of the **benefits** that an ISO certification could bring to EFSA:

- Sets out areas of responsibility across the organisation;
- Communicates a positive message to staff and external stakeholders;
- Increases transparency regarding the processes;
Highlights deficiencies, risks and proposes mitigation actions;
- Provides continuous assessment and improvement;
- Fewer complaints from external stakeholders;
- Etc.

The key benefit to the external stakeholders is that an ISO certification demonstrates EFSA's commitment to independence and quality procedures of work, by means of an independent audit.

Disadvantages could be the elevation of bureaucracy and lack of flexibility, which are inherent parts of the ISO standards, together with a significant workload to set up the system.

Monitoring system:

EFSA has established recently a compliance and veracity check process. In section 5.2.3, this process is explained in detail. It consists of reviewing twice every year the Dols of 15 experts that are selected randomly. However, to enhance the efficiency of EFSA's procedure to check the veracity of their experts' independence declarations, we recommend to evolve towards a more risk based procedure. By doing so, EFSA would subscribe to a general trend towards risk based auditing that is observed in the internal audit practice. In a risk-based approach, the priorities of the internal audit plan are determined based on a risk analysis. This approach holds the following advantages:

- A more efficient use of resources: the identification of high and low risk areas or activities allows a shift in resource allocation from the low risk to high risk activities;
- An increased effectiveness of the checks: the checks lead to a higher assurance that the organisation's most important risks are under control, because the areas or activities holding the highest risks will be controlled more frequently.

Risk based internal auditing is fully in line with the International Standards for the Professional Practice of Internal Auditing defined by the Institute of Internal Auditors. The 'Standard 2010 – Planning' defines a risk based control planning approach as the best practice.

A risk based approach in the context of checking the veracity of the experts' independence declarations aims at:

- *Assessing the risk of an independence breach for each expert.* This assessment is based on predefined risk criteria and results in a risk score for each expert;
- *Assigning experts to predefined 'risk categories'* (e.g. high – medium – low), based on the expert's risk score;

- *Performing veracity checks*, where the audit scope (full scope / large sample / limited sample), the level of detail and the timing (ex ante / ex post) of the check depend on the risk category to which an expert belongs.

But a risk based approach could also be implemented in other areas of the independence processes: it could be linked to the training (e.g. give more training to high risk profiles), or to the initial selection of the experts (as in EMA), etc.

An example on how a risk based approach for checking the veracity of the EFSA experts' independence declarations could be implemented is presented as a step-by-step approach in Annex III.

5.4.3. Assessment of the effectiveness of independence trainings

In this section, a high level analysis is made of the effectiveness of the independence trainings given at EFSA.

EFSA installed different measures for its staff members (mandatory trainings on Ethics & Integrity, on the new policy and rules, etc.) and experts (mandatory on-boarding trainings, welcome pack, functional mailbox, etc.) in order to increase the awareness on independence.

Overall, these trainings seem quite basic, although they cover the most important points, and can therefore be subject to improvements.

We refer to section 5.2.5 for more details on how the EFSA independence training curriculum could be enhanced (e.g. more elaborated training packs, increase the training frequency and repetition, online trainings, mandatory certifications, etc.).

An interesting indicator for EFSA to follow could be the correlation between the number of people trained vs. the de- / increase in the quality of the Declarations of Interest, or the number of Breaches of Trust / number of omissions, etc. For the time being, as the new Implementing Rules have only been installed in 2012, there is not yet enough data available to make a sound analysis at this point in time.

When comparing EFSA with similar organisations, it proved to be difficult to assess the level of training maturity of other organisations, as little or no information on trainings could be found on the corporate websites.

5.4.4. Conclusions

In conclusion, different recommendations can be considered in order to further increase the effectiveness of EFSA mechanisms related independence. Regarding the governance structure, the screening of Dols of Management Board members by the Management Board might create a perception of subjectivity. EFSA could consider creating an external body responsible for checking potential Conflicts of Interest of the Management Board members.

EFSA could also consider to replace the Committee on Conflicts of Interest by a centralised team that would be in charge of the management of the Cols and the procedures related

to independence such as the screening of the Dols of experts, staff and the Management Board members. This team could at first be internally managed. Later on, when the processes are fully in place, EFSA could even decide to outsource the screening of the Dols to an independent external body. It goes without saying that outsourcing the screening of Dols and the management of ColS to an independent body would require further analysis (e.g. on topics such as accountability, etc.) and the development of a ‘business case’.

Throughout our analysis of the main independence procedures, it became apparent that EFSA is putting a strict control on the experts. The three Dols requested and their screening represent a real administrative burden for the experts and for EFSA staff. EFSA could consider reviewing its independence strategy towards a strategy based on trust, openness and transparency instead of trying to control everything.

Finally, the independence monitoring system could be reviewed and a risk based approach could be installed instead of the current random selection of experts for the compliance and veracity checks.

Long term recommendations
Review the strategy toward a less strict control of the experts.
Define a risk based approach for the selection of experts in the compliance and veracity checks procedure.
Creation of an external body responsible for the screening of Dols of the Management Board members.
Increase the predictability of the independence processes and get certified to ISO's management system standards.
Creation of a centralised independence unit.
Add the principle of the responsibility to keep Dols up to date in the Declaration of Commitment.
Full outsourcing of the Dol implementation.

6. Conclusions and recommendations

In terms of **completeness** of the EFSA independence rules, the 2012 Implementing Rules can be considered as complete and cover the different topics required by the OECD and EU guidelines. Some additional topics (e.g. transparency) could be included in order to enhance the document, yet EFSA's Implementing Rules are robust. The 2012 Implementing Rules group all the information related to Dols and Conflict of Interest in one complete document. This is a clear strong point as compared to other organisations.

The 2012 Implementing Rules are in general **clear**. The new definition of Conflicts of Interest complies with the OECD and EU guidelines. The different categories of interests are clear and the definitions are well developed. However, EFSA could also consider to include in the Dol documents concrete examples and a definition of the categories.

The **consequences** of Conflicts of Interest for experts are clear and comprehensively detailed in articles 10, 11 and 12 of the Implementing Rules. However, this is not always the case for the other EFSA stakeholders. For instance, article 19 (for observers) and article 25 (for employees and consultants) could be reviewed and further clarified.

EFSA has advanced **procedures** concerning the management of Conflicts of Interest. Nevertheless, the procedure on the veracity and compliance checks is not completely and clearly defined in the Implementing Rules. This information can be found elsewhere, but having all information centralised in the Implementing Rules would be beneficial.

Moreover, EFSA should also **increase the predictability of its processes** and could consider to get certified to **ISO's management system standards**.

Also, EFSA could consider to **centralise the entire independence process**, in order to avoid a decentralised interpretation of the independence policy and rules. Scientific officers often interact frequently with experts which might cause for a perception of subjectivity that could be avoided if the independence procedures are centralised.

In terms of the clarity and transparency of the information regarding independence provided online, EFSA is very transparent in its information provision, but for the findability of information, there is still some room for improvement. Overall, the **sophistication of the website can be assessed as medium**.

In terms of **transparency**, EFSA tends to be very open and transparent with its information provision to external stakeholders. Moreover, EFSA is constantly looking for improvements of its transparency policy and listens to its stakeholders in order to propose new transparency initiatives that live up to the stakeholders' expectations.

One of the key priorities of EFSA, as stipulated in the 2014-2016 multiannual plan, is to install **trust** in its scientific advice as a central pillar of its work for European citizens. In this respect, EFSA has launched in 2013 an initiative on transparency, with the aim of i.e. open various science meetings to observers, increase **transparency** on EFSA working processes and allow access to scientific data used in the EFSA risk assessments.

EFSA will however need to strike the right balance between sharing sufficient information to increase trust and transparency (**'open data'**), without having to share everything.

Also for the **trainings** on independence EFSA is providing, there are still some improvement points. EFSA could consider to put in place a more elaborated, detailed and frequent independence training package, both for its staff members and the experts EFSA is working with, tailored for specific target groups (e.g. following an expert risk profile; following the subject matter an expert is involved in; for experts who had omissions, etc.). In terms of **awareness raising** on independence, more could be done. Specifically, there is a need to formalise and improve the communication and trainings about this topic.

It is apparent that the **screening of Dols** is performed prior to the meetings in close to 100% of the cases. The compliance checks revealed that the majority of experts were evaluated correctly with regards to EFSA's policy on independence. However, a high amount of omissions detected during the investigation reveal a lack of understanding by the experts of the necessity to have accurate and up-to-date information in their Dols, their CV and in the EFSA expert database. Although these omissions did not lead to Conflicts of Interest, it is important to put additional measures in place in order to reduce this number (more than half of the experts checked had at least one omission in their ADol). This could be done by strengthening the trainings and by improving the communication on independence.

EFSA has implemented the majority of the suggestions received from stakeholders. EFSA constantly improves its measures and policy in regards to independence and Conflicts of Interest. However, there is still a need to **increase the communication with civil society**. Indeed, the different complaints received are often based on a misunderstanding of the screening process. A Dol screening process based on objective, pre-defined criteria, but with an eye for each specific situation is necessary and in order to legitimate the process, EFSA should be constantly transparent about it and on-board external stakeholders in the process. Lastly, the post-employment measure represented an important point in this respect and appropriate measures have been taken to mitigate this problem.

The independence mechanisms that EFSA has put in place can be assessed as relatively **effective**. Also its independence **governance structure** is robust, although the screening of the Dols of the Management Board members by the Management Board itself might create a perception of subjectivity. EFSA could consider to create an external body responsible for checking potential Conflicts of Interest of the Management Board members.

Throughout our analysis of the main independence procedures, it became apparent that EFSA is putting a strict control on the experts. The three Dols requested and their screening represent a real administrative burden for the experts and for EFSA staff. EFSA could consider to review its independence strategy towards a strategy based on trust, openness and transparency instead of trying to control everything. The principle of the **responsibility** to keep Dols up to date could to be embedded in the Declaration of Commitment.

The independence monitoring system could be reviewed and a **risk based approach** could be installed instead of the current random selection of experts for the compliance and veracity checks, which will prevent EFSA from checking every single data point related

to independence. Moreover, EFSA could consider to only go back 2 years in time to check interests. This risk based approach could also be implemented in other independence areas such as e.g. training (give more training to at-risk target groups) or the selection of experts.

EFSA should put in place a **balanced system of pro-active measures** (e.g. a risk-based approach) **vs. reactive measures**. It should be made clear (also to the external stakeholders) that the possibility of error can never be totally excluded, but EFSA should at all times have an open communication on Conflicts of Interest and Breaches of Trust. Also with respect to relationships with the industry, EFSA could – like the EMA – install **more dialogue with the industry**, rather than trying to reduce this. If the dialogue is put in place in all transparency, this should not pose a problem.

In short, EFSA has put in place an independence process which can be considered as very thorough, comprehensive and extensive. For instance, experts need to declare their interests very often in different declarations. **Rethinking the entire process**, and reducing the amount of paperwork, would reduce the administrative burden both for EFSA staff and scientific experts. On the contrary, an extensive independence process creates the perception that there is something to hide. The better option is to put in place a system based on trust, which still ensures the same level of independence, but lies the responsibility more with the experts.

Finally, EFSA could consider **to outsource (parts of the activities related to) the screening of Dols and the management of Cols** to an independent body. In order to move towards this optimal scenario, we recommend EFSA to have a transitional stage where the Dol implementation would be first centralised inside EFSA before being outsourced to an independent body.

These two scenarios are further detailed below in Figure 2.

Figure 3: Long term strategy: going from centralisation to outsourcing of the Dol implementation

Key orientations: gradually transitioning between 2 scenarios

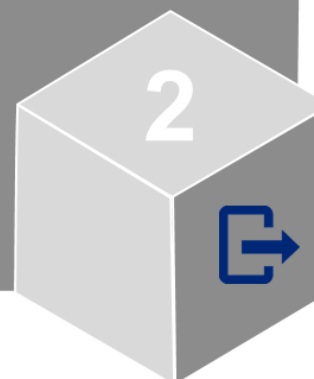
Centralisation of the Dol implementation in a Quality, Risk and Reputation function

- Transitional scenario
- For controlling and optimisation of the Dol process
- Benefits: increased harmonisation and significant efficiency gains (resources that can be redeployed to increase the sample of the compliance and veracity check)



Full outsourcing to an independent body

- To mitigate the inherent conflict in the current system (perception that EFSA has nothing to gain with identifying more potential conflicts)
- The EFSA Quality, Risk and Reputation function manages the service, but does not deal with the execution
- Will guarantee higher trust in the work of EFSA and will allow EFSA to further enhance its trusted relationships with its experts



Optimal conditions for both scenarios:

- Full transparency on risk assessment processes ('open data')*
- ISO certified processes
- One Dol per expert (trust and responsabilise them to keep the Dol up to date)
- Risk based approach for the compliance and veracity checks, based upon expert risk profiles
- Tackle the need for having subject matter expertise to do Dol screening

(*) in line with the strategic objectives of the RASA Directorate (RASA roadmap)

The transitioning strategy mentioned here above will of course need to be investigated and developed further. Further analysis (e.g. on topics such as accountability, etc.) will need to be done, a business case will need to be developed and the transition between the two scenarios can be implemented gradually over time.

The tables below present the full list of short term and long term recommendations. In Figure 3, our recommendations are mapped on a scatter chart based on two criteria (1) their complexity of implementation and (2) their impact on trust, sustainability and fit-for-purpose.

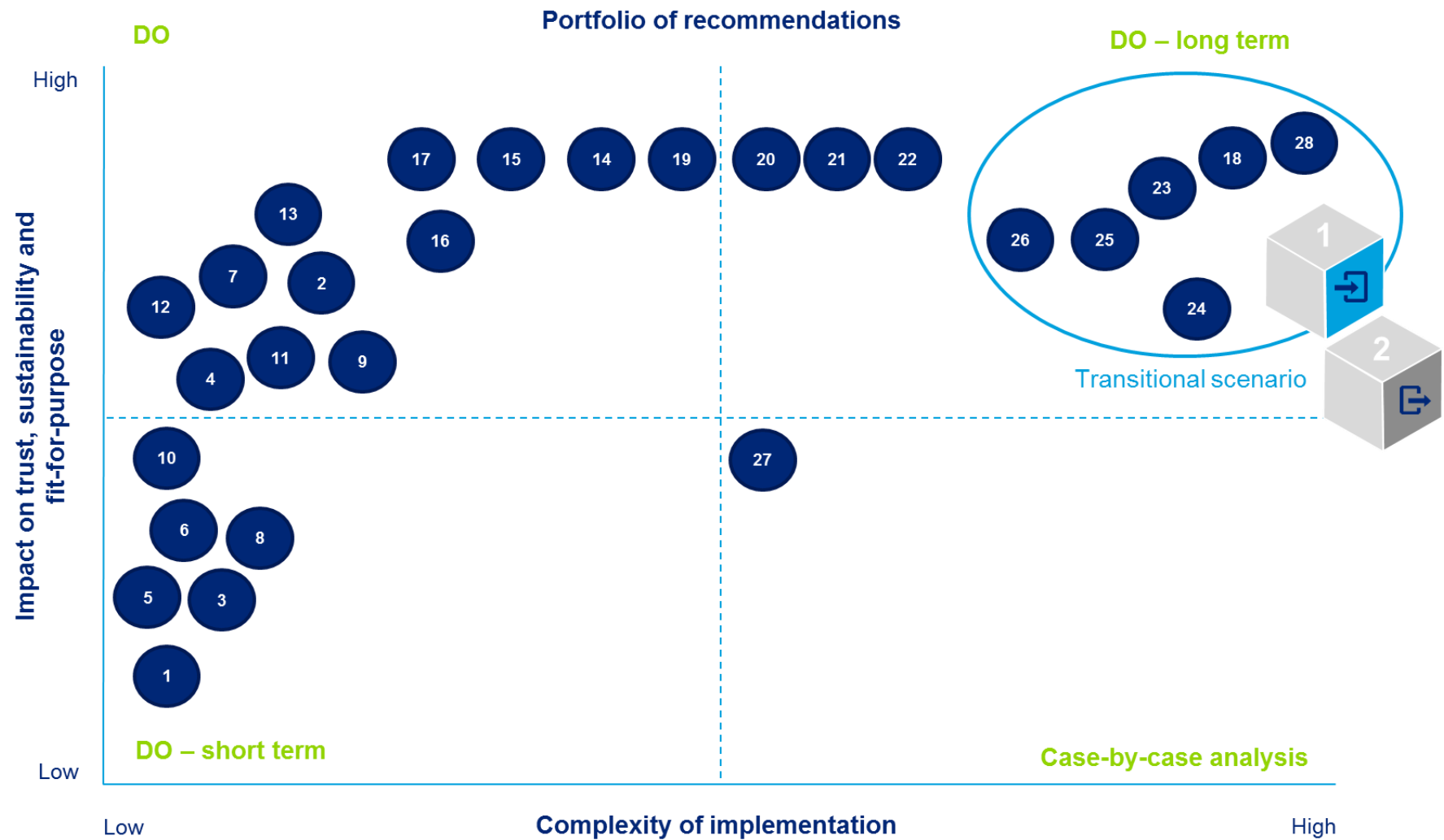
Short term recommendations	
1.	Add a table with a short definition of the categories of scientific experts in the annexes of the Implementing Rules.
2.	Add the possibility to elaborate on future employment in the DoI.
3.	Add a paragraph on trainings and awareness raising in the Implementing Rules.
4.	Add a more detailed procedure description concerning the compliance and veracity checks of Dols in the Implementing Rules.
5.	Make explicit reference to EFSA's transparency initiatives in the Implementing Rules.
6.	Include the periodical review of the Implementing Rules.
7.	Add in the Dols a definition and a concrete example under each category of interests.
8.	Clarify which interests of the staff/expert's close family members can lead to a Col.
9.	Develop step by step Breach of Trust procedures for the different target groups.
10.	Add contact information in case of questions in the Implementing Rules and in the Dol documents.
11.	Add in the annexes of the Implementing Rules a step-by-step explanation regarding the Dol submission for experts.
12.	Draft summary tables concerning the Dols and the consequences that apply to the different stakeholders.
13.	Clarify articles 19 and 25 of the Implementing Rules regarding the Dol and the consequences applied to the respective stakeholders.
14.	Make better use of the EFSA website to raise awareness about independence.
15.	Build a true independence training portfolio, with eye for training frequency and repetition.
16.	Put in place a policy on gifts, invitations, etc. for experts.
17.	Increase direct and ongoing dialogue with external stakeholders.

Short term recommendations	
18.	Put in place a more 'institutionalised' whistle-blower process, both internally and externally in the reviewing process.

Long term recommendations	
19.	Define a risk based approach for the selection of experts in the compliance and veracity checks procedure.
20.	Increase EFSA's transparency initiatives.
21.	Increase and improve the communication around independence.
22.	Develop online independence trainings and a dedicated communication track on training possibilities and necessities in this area.
23.	Review the strategy toward a less strict control of the experts.
24.	Creation of an external body responsible for the screening of Dols of the Management Board members.
25.	Increase the predictability of the independence processes and get certified to ISO's management system standards.
26.	Creation of a centralised independence unit.
27.	Add the principle of the responsibility to keep Dols up to date in the Declaration of Commitment.
28.	Full outsourcing of the Dol implementation.

Obviously, all these recommendations should undergo a thorough risk and impact assessment before implementation, in order to assess the benefits and drawbacks and to test the recommendations against the proportionality principle.

Figure 4: Scatter chart - Portfolio of recommendations



ANNEXES

ANNEX I - Analytical framework

Are all relevant elements for the detection and mitigation of possible conflicts covered in the independence implementation rules?				
Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
1.1. Are there missing topics compared to other organisations?	<ul style="list-style-type: none"> ▪ Overview of the different topics present in the EFSA 2012 IR of the DoI policy ▪ Analysis of the topics present in other organisations ▪ Gap analysis 	<ul style="list-style-type: none"> ▪ Benchmark with maximum 3 other organisations (to be decided based on best practices found) ▪ Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) 	<ul style="list-style-type: none"> ▪ Desk research ▪ Benchmarking 	<ul style="list-style-type: none"> ▪ Benchmarking results will depend on the availability of data within the short project time frame
1.2. Are there missing topics compared to OECD and EU guidelines on Conflict of Interest?	<ul style="list-style-type: none"> ▪ Overview of the different topics present in the EFSA 2012 IR of the DoI policy ▪ Analysis of the generic guidelines ▪ Gap analysis 	<ul style="list-style-type: none"> ▪ OECD guidelines on Conflict of Interest ▪ EU guidelines on Conflict of Interest ▪ Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) 	<ul style="list-style-type: none"> ▪ Desk research 	
1.3. Are there missing topics based on the comments received by stakeholders (if any)?	<ul style="list-style-type: none"> ▪ Overview of the different topics present in the EFSA 2012 IR of the DoI policy ▪ Review of the stakeholder feedback on the EFSA 2012 IR 	<ul style="list-style-type: none"> ▪ Stakeholder feedback received by EFSA ▪ Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) 	<ul style="list-style-type: none"> ▪ Desk research ▪ Stakeholder feedback analysis 	<ul style="list-style-type: none"> ▪ Feedbacks might refer to previous implementation rules

Are the current elements for detection and mitigation of possible conflicts clearly and transparently described in the independence implementation rules?				
Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
2.1. Are the definition and the different types of categories of Conflict of Interest clear? Are the definition and the different types of categories comprehensive or are there missing elements?	<ul style="list-style-type: none"> ▪ Analysis of the definition and the different types of categories of EFSA Conflict of Interest ▪ Analysis of the definition and different types of categories of Conflict of Interest from other organisations or from generic guidelines ▪ Gap analysis 	<ul style="list-style-type: none"> ▪ Benchmarking with best practice definition (WHO), types of categories (EMA) ▪ OECD and EU guidelines ▪ Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) ▪ Stakeholder feedback received by EFSA 	<ul style="list-style-type: none"> ▪ Desk research ▪ Benchmarking ▪ Own judgement 	<ul style="list-style-type: none"> ▪ Benchmarking results will depend on the availability of data within the short project time frame ▪ Feedbacks might refer to previous implementation rules
2.2. Are the consequences of Conflicts of Interest clear?	<ul style="list-style-type: none"> ▪ Overview of the consequences of Conflicts of Interest at EFSA ▪ Analysis of the generic guidelines on managing Conflict of Interest ▪ Analysis consequences of Conflicts of Interest of other organisations 	<ul style="list-style-type: none"> ▪ Benchmarking with a maximum of 3 organizations (to be decided based on best practices found) ▪ OECD and EU guidelines ▪ Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) ▪ Stakeholder feedback received by EFSA 	<ul style="list-style-type: none"> ▪ Desk research ▪ Benchmarking ▪ Own judgement 	<ul style="list-style-type: none"> ▪ Benchmarking results will depend on the availability of data within the short project time frame ▪ Feedbacks might refer to previous implementation rules
2.3. Are the procedures clear?	<ul style="list-style-type: none"> ▪ Overview and analysis of the main procedures related to Conflicts of Interest 	<ul style="list-style-type: none"> ▪ EFSA main procedures on Conflicts of Interest ▪ EFSA policy on independence 	<ul style="list-style-type: none"> ▪ Own judgement ▪ Desk research 	<ul style="list-style-type: none"> ▪ Feedbacks might refer to previous implementation rules

Are the current elements for detection and mitigation of possible conflicts clearly and transparently described in the independence implementation rules?				
Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
		<ul style="list-style-type: none"> ▪ Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) ▪ EFSA Decision of the executive director concerning the selection of members of the scientific committee, scientific panels and external experts to assist EFSA with its scientific work ▪ European court of auditors: Management of Conflict of Interest in selected EU agencies ▪ Benchmarking of EFSA's Independence 		<ul style="list-style-type: none"> ▪ Court of auditor report might be outdated ▪ Benchmarking report might be outdated
2.4. Is the information provided online easy to find and to use?	<ul style="list-style-type: none"> ▪ Overview of the documents available on EFSA website ▪ Analysis of accessibility and usability of data 	<ul style="list-style-type: none"> ▪ EFSA website 	<ul style="list-style-type: none"> ▪ Internet research ▪ Own judgement 	
2.5. Are there compulsory trainings? How are the trainings given (online video)?	<ul style="list-style-type: none"> ▪ Overview of the trainings materials ▪ Analysis of the trainings quality based on its accessibility, 	<ul style="list-style-type: none"> ▪ Trainings materials ▪ Expert survey ▪ EFSA staff input ▪ EFSA staff satisfaction survey 	<ul style="list-style-type: none"> ▪ Desk research ▪ Interviews with EFSA scientific officers and EFSA staff in EXO, LRA and Comms (if needed) ▪ Own judgement 	<ul style="list-style-type: none"> ▪ The expert survey comments might be outdated

Are the current elements for detection and mitigation of possible conflicts clearly and transparently described in the independence implementation rules?				
Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
	comprehensiveness and channels used			
2.6. What is the level of transparency compared to other organisations?	<ul style="list-style-type: none"> ▪ Overview of EFSA publicly available information ▪ Overview of EFSA undisclosed information ▪ Analysis of the EFSA initiatives on transparency ▪ EFSA openness compared to other organisations 	<ul style="list-style-type: none"> ▪ Benchmarking with maximum 3 organizations (to be decided based on best practices found) ▪ EFSA multi-annual and communication plan 2014 – 2016 ▪ European court of auditors: Management of Conflict of Interest in selected EU agencies ▪ EFSA website ▪ E&Y : EFSA Evaluation report 2012 	<ul style="list-style-type: none"> ▪ Desk research ▪ Benchmarking ▪ Internet research ▪ Own judgement 	<ul style="list-style-type: none"> ▪ Court of auditor report might be outdated ▪ Benchmarking results will depend on the availability of data within the short project time frame
2.7. Are the 2012 implementing rules embedded in the EFSA culture? What is the level of awareness raising on the subject?	<ul style="list-style-type: none"> ▪ Assessment of the culture at EFSA and the awareness raising on the new implementation rules (02/2012) 	<ul style="list-style-type: none"> ▪ EFSA independence policy ▪ EFSA website ▪ EFSA intranet ▪ Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) 	<ul style="list-style-type: none"> ▪ Own judgement ▪ Desk research ▪ Internet research ▪ Intranet research ▪ Interviews with EFSA scientific officers and EFSA staff in EXO, LRA and Comms (if needed) 	

Are the measures effective to detect and mitigate conflicts of interests and do they effectively address breach of trusts?				
Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
3.1. Based on the quantitative Data received from EFSA, what are the conclusions of the effectiveness of the measures?	<ul style="list-style-type: none"> ▪ Analysis of main KPIs ▪ Analysis of statistics (#Col, #BoT) 	<ul style="list-style-type: none"> ▪ EFSA quantitative Data 	<ul style="list-style-type: none"> ▪ Desk research 	
3.2. Is there a continuous improvement of the independence system?	<ul style="list-style-type: none"> ▪ Overview of the recommendations ▪ Overview of the improvements made 	<ul style="list-style-type: none"> ▪ EFSA report to the European Parliament on the implementation of its independence policy 2007-2012 ▪ Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA against EFSA ▪ Decision of the European Ombudsman closing his inquiry into complaint 622/2012/ANA against EFSA ▪ European court of auditors: Management of Conflict of Interest in selected EU agencies 	<ul style="list-style-type: none"> ▪ Desk research ▪ Workshop/Interviews with EFSA scientific officers and EFSA staff in EXO, LRA and Comms (if needed) 	<ul style="list-style-type: none"> ▪ The recommendations and criticisms might be based on the previous independence policy

Are the measures effective to detect and mitigate conflicts of interests and do they effectively address breach of trusts?

Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
		<ul style="list-style-type: none"> EFSA: Benchmarking of EFSA's Independence 2010/2011/2012 discharge on Conflict of Interest 		

Are the mechanisms effective to ensure expert compliance and EFSA staff compliance with the rules?

Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
4.1. Is the governance, organisation structure related to independence appropriate (fit-for-purpose)?	<ul style="list-style-type: none"> Overview of EFSA governance structure related to independence 	<ul style="list-style-type: none"> EFSA website EFSA organisation structure EFSA independence policy Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) EFSA Decision of the executive director concerning the selection of members of the scientific committee, scientific panels and external experts to assist EFSA with its scientific work 	<ul style="list-style-type: none"> Own judgment Desk research Benchmarking 	<ul style="list-style-type: none"> Benchmarking results will depend on the availability of data within the short project time frame

Are the mechanisms effective to ensure expert compliance and EFSA staff compliance with the rules?				
Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
		<ul style="list-style-type: none"> ▪ Benchmark with maximum 3 organisations (to be decided based on best practice) ▪ E&Y : EFSA Evaluation report 2012 		
4.2. Are the main procedures appropriate (fit-for-purpose)?	<ul style="list-style-type: none"> ▪ High level analysis of the main procedures related to Conflict of Interest (declaration of Interest, preventive actions, remedial actions) 	<ul style="list-style-type: none"> ▪ High level benchmarking with maximum 3 organisations (to be defined based on best practice) ▪ Implementing EFSA's Policy on Independence and Scientific Decision Making (02/2012) ▪ EFSA Decision of the executive director concerning the selection of members of the scientific committee, scientific panels and external experts to assist EFSA with its scientific work ▪ Report on the compliance and veracity checks of Dols of experts of EFSA's Scientific Committee, 	<ul style="list-style-type: none"> ▪ Own judgement ▪ Desk research ▪ Benchmarking 	<ul style="list-style-type: none"> ▪ Benchmarking results will depend on the availability of data within the short project time frame

Are the mechanisms effective to ensure expert compliance and EFSA staff compliance with the rules?				
Detailed evaluation questions	Evaluation criteria/indicators	Main sources	Methods & techniques	Attention points/ risks
		Scientific Panels and Working Groups in 2013 <ul style="list-style-type: none"> ▪ Draft report on the discharge in respect of the implementation of the budget of the EFSA for the financial year 2012 ▪ E&Y : EFSA Evaluation report 2012 		
4.3. Are the trainings appropriate (fit-for-purpose)?	<ul style="list-style-type: none"> ▪ High level analysis of the effectiveness of the trainings material (mandatory or not, certification or not, number of trainings followed, number of people trained vs increase in declaration of Interest quality) 	<ul style="list-style-type: none"> ▪ Trainings material ▪ Expert survey ▪ Staff satisfaction survey ▪ High level benchmark with maximum 3 organisations (to be decided based on best practice) 	<ul style="list-style-type: none"> ▪ Own judgement ▪ Desk research ▪ Benchmark 	<ul style="list-style-type: none"> ▪ Expert survey comments might be outdated ▪ Benchmarking results will depend on the availability of data within the short project time frame
4.4. Is the monitoring system appropriate (fit-for-purpose)?	<ul style="list-style-type: none"> ▪ High level analysis of EFSA monitoring system (compliance and veracity check) 	<ul style="list-style-type: none"> ▪ Quantitative data received from EFSA ▪ Report on compliance and veracity checks ▪ High level benchmark with maximum 3 organisations (to be decided based on best practice) 	<ul style="list-style-type: none"> ▪ Own judgement ▪ Desk research ▪ Benchmark ▪ Workshop/Interviews with EFSA scientific officers and EFSA staff in EXO, LRA and Comms (if needed) 	<ul style="list-style-type: none"> ▪ Benchmarking results will depend on the availability of data within the short project time frame

ANNEX II - EFSA follow up on recommendations

Source	Recommendations	Status
Milieu Ltd, Benchmarking of EFSA's Independence⁴⁹	More comprehensive definition of Conflict of Interest.	Implemented: EFSA's new definition on Conflict of Interest is compatible with OECD guidelines.
	Special dedicated committees to advice on issues related to Conflict of Interest.	Implemented: EFSA has appointed an Ethics advisor and created a Committee on Conflict of Interest.
	Shortening of the retrospective period (5 years period).	Not Implemented
	Increased opportunities for stakeholder involvement.	Implemented: Creation of the Stakeholder Consultative Platform and the opening of meetings of the Scientific Committee and Panels to observers.
Milieu Ltd, Benchmarking of & Follow up of actions suggested in 2010 Discharge on Conflicts of Interest⁵⁰	Increase the number of in-house experts/scientists.	Ongoing: EFSA aims to increase the proportion of its scientific staff from 60% to 70%. (EFSA Science Strategy 2012-2016).

⁴⁹ Milieu Ltd, "Comparison between the tools ensuring EFSA's independence scientific advice and the instruments in used by organisations similar to EFSA", January 2011.

⁵⁰ EFSA, "Follow up of actions suggested in 2010 Discharge on Conflicts of Interest".

Source	Recommendations	Status
Complaint 0662/2012/ANA ⁵¹	The screening of DOIs should be more rigorous.	Implemented: The 2012 Implementing Rules provide strict criteria for the screening of Dols.
Complaint 0662/2012/ANA & Complaint 0775/2010/ANA ⁵²	When an error is made, in addition to taking remedial action to correct it, it would be appropriate to acknowledge this error and to apologise for it.	Not implemented
Complaint 0775/2010/ANA & European court of Auditors: Management of Conflict of Interest in selected EU agencies ⁵³	EFSA should address the post-employment issues.	Implemented: Staff have to inform their employer of negotiation with prospective employers and of any change in circumstances linked to their post within 2 years after leaving service. The staff members are imposed some restrictions in regards of a new job in industry of related sectors.
Complaint 0775/2010/ANA	Amendment of the Annex 1 (Annual DoI in order to have the possibility to insert future employment and not only past and current employment).	Not implemented

⁵¹ European Ombudsman, “Decision of the European Ombudsman closing his inquiry into complaint 622/2012/ANA against the European Food Safety Authority (EFSA)”, December 2013.

⁵² European Ombudsman, “Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA against the European Food Safety Authority (EFSA)”, May 2013.

⁵³ European Court of Auditors, “Management of Conflict of Interest in selected EU agencies”, 2012.

Source	Recommendations	Status
European court of Auditors: Management of Conflict of Interest in selected EU agencies	Candidates should be screened for Conflict of Interest before their appointment.	Implemented: The screening of prior to appointment is already in place for EFSA staff and experts. Regarding the Management Board members and the Advisory Forum members, the screening is done after their appointment respectively by the Council and by Member States.
	EFSA should establish clear and objective criteria for the assessment of DoI.	Implemented: The 2012 Implementing Rules clearly defines the criteria for the screening of DoI.
	EFSA should have gifts and invitations policies and procedures that cover the entire agency.	Implemented: EFSA has for many years applied the framework provided by the European Commission on ethic and integrity and has adopted a specific policy in July 2012.
	EFSA should develop clear, transparent and consistent breach of trust policies and procedures that cover the entire Agency.	Implemented: As previously detailed EFSA has defined breach of trust procedures for the experts, the staff members and the Management Board members.
	EFSA should fully disclose interests declared during meeting and in the context of scientific decision-making process.	Implemented: The ADol and the discussion regarding the outcomes of the Dols screening (in the minutes) are available on EFSA website.

Source	Recommendations	Status
	EFSA should have comprehensive and compulsory training on Conflict of Interest.	Implemented: Mandatory training on Conflict of Interest and on Ethics & Integrity for EFSA staff member since 2010. Mandatory training on Ethics & Integrity for the new experts.
Follow up of actions suggested in 2010 Discharge on Conflicts of Interest	Creation of an independent scientific standards committee, whose task is to develop standards of best practice and ensure they are followed at all times.	Implemented: The scientific committee guarantees that the main aspects of EFSA's scientific activities are consistent.
	Publish the names of the experts, the way they voted and the reasoning behind the vote when this is given.	Implemented: All EFSA's outputs are published on its website (including name of the experts) + minority opinions are systematically recorded.
	EFSA Management Board itself should adopt a code of conduct that includes a stop on revolving doors (e.g. case of Diana Banati).	Implemented: In 2011, The Management Board adopted a Code of Conduct tackling this problem.
	The election of the chairperson of the Management Board should be public.	Implemented
	Update the current independence policy by clarifying which interests of the staff/Expert's close family members are allowed and the restrictions to be applied.	Ongoing: This will be considered in the next review of the policy on independence.

Source	Recommendations	Status
	Publish the outcomes of the breach of trust procedures, including the outcomes of the integrity of the scientific review.	Ongoing: The publication of the breach of trust procedures should consider the restriction of data protection.
	An in-house expert/scientist must abandon every link with the industry.	Implemented
	Reinforce and broaden the mandate of the current Committee on Conflict of Interest (CCI), possibly in collaboration with the European Commission and EMA, with a similar mandate to the ANSES Committee for Ethical Standards and Prevention of Conflict of Interest:	Ongoing: This will be considered in the next review of the policy on Implementing Rules.
	Publish bi-annual reports on the implementation of the Agency Conflict of Interest policy and on the progress of any investigation.	implemented: As from its 2011 Annual Activity Report, EFSA includes a dedicated section on its independence.
	Extend Conflict of Interest training to experts and make it mandatory.	Ongoing: EFSA already have mandatory training for new comers on Ethics and Integrity. However, an improvement of trainings should be foreseen.
Follow up of actions suggested in 2010 Discharge on Conflicts of Interest & Draft on 2012 discharge: European	EFSA makes a strong difference between Food Safety Organisations (FSOs) and non- FSOs.	Not implemented
	The list of FSOs should be scrutinised and revised by excluding organisations which received more than 50% of their funding from sources other than public sources.	Not implemented

Source	Recommendations	Status
Food Safety Authority⁵⁴		
2011 discharge : European Food Safety Authority⁵⁵	Publish the CV and Declaration of interest of the in-house experts/scientists.	Not Implemented: CV of Authority's Executive Director, Senior management and panel experts are now available on EFSA website. However, considering EU Regulation on personal data protection, the Authority does not envisage to make the CV of its in-house experts available on its website.
	Management Board should hold open ballots when electing its chair and Vice chairs.	Not implemented: The Management Board agreed to hold the election of its Chair and Vice-Chairs in public session but rejected the idea of open ballots. EFSA is bound by the decisions of its Management Board which is its governing body.
	Calls on the authority to start a structured dialogue with civil society on matters relating to Conflicts of Interest and to invite those organisations concerned to openly discuss matters of common interest.	Ongoing: EFSA increased its interaction with society stakeholders by holding open consultations via the EFSA website, face-to-face meetings, information sessions. The authority recent initiatives to further promote an open dialogue with non-governmental organisations is aligned with this approach
	Strongly suggest a cooling off period for staff moving to a similar post in related sector.	Implemented: Staff have to inform their employer of negotiation with prospective employers and of any change in

⁵⁴ European Parliament, "Draft discharge 2012: European Food Safety Authority", January 2014.

⁵⁵ European Parliament: "2011 discharge: European Food Safety Agency", 2013.

Source	Recommendations	Status
		circumstances linked to their post within 2 years after leaving service. The Executive Director may approve, conditionally approve or forbid the activity. Moreover restrictive measures during the cooling-off period are foreseen.
Draft on 2012 discharge: European Food Safety Authority	Calls on the Authority to come up with a simplified procedure with less case by case assessment of possible Conflict of Interest.	Not implemented

ANNEX III – Risk based approach: possible implementation process

Step 1: Defining risk criteria

The first step consists of defining which criteria will need to be taken into account when assessing the risk of an independence breach for each individual expert. Possible criteria are:

- Number of years active as expert;
- Number of interests reported;
- Previous non-compliance;
- Previous employment;
- Number of expert meetings participated in;
- Number of scientific publications of the expert;
- Number of complaints received related to the expert;
- Topic(s) the expert is involved in ('Regulated Products' / 'hot topics' / high visibility, 'big tickets', etc.);
- Etc.

These criteria need to be further investigated in order to come to a relevant list that is fit-for-purpose.

Step 2: Developing a risk scoring model

Once the evaluation criteria are defined, EFSA will need to develop a risk evaluation scale for each risk criterion. This scale allows a consistent and an objective assessment of all experts against the risk criteria that are selected.

The table below shows a possible evaluation scale for some of the suggested criteria. These scales are suggestions, it is key that EFSA adapts them to their own specific situation.

Risk level				
Risk criterion	1	2	3	4
Number of years active as expert	> 5 years	3-5 years	1-2 years	< 1 year
Number of interests reported	0	1-3	4-10	> 10
Previous non-compliance	0	1-2	3-5	> 5
Etc.				

The application of the risk scale results in a table for each expert, stating the risk level of the expert on the different risk criteria.

Expert X	
Risk criterion	Risk level
Number of years active as expert	3
Number of interests reported	3
Previous non-compliance	1
Etc.	

In a next step, these criteria need to be aggregated into one summarising risk score per expert. There are different possibilities to aggregate the risk levels into a risk score:

- average risk level;
- weighted average risk levels;
- percentile (e.g. 50%, 60%, 75%).

The table below shows the results of calculating an expert's risk score, based on a weighted average:

Expert X		
Risk criterion	Weight	Risk level
Number of years active as expert	0,3	3
Number of interests reported	0,2	3
Previous non-compliance	0,5	1
Risk score expert	2	

Step 3: Defining risk categories and their implications

In the final stage of the methodology development process, EFSA will need to develop 'risk categories'. This means that EFSA will need to decide:

- How many categories to be used (e.g. high risk – medium risk – low risk, or more detail);
- Which are the preferred thresholds to use to assign an expert to a risk category, based on the expert's risk score. The decision on the thresholds reflects EFSA's risk appetite: a low willingness to take risks will result in lower thresholds.

Once the risk categories are defined, EFSA will need to develop a strategy for veracity checking for each defined risk category. This strategy is the result of a trade-off between the costs of the control process and the benefits. The costs of the control process are determined by the scope of the checks (all experts / a large sample / a limited sample) and the level of detail of the checks. The benefit of the control process is the assurance that a

risk is under control. The more important the risk, the higher the potential benefit of the checks.

These considerations imply that for the category of 'high risk' experts, a larger (or full) sample of experts will be subject to veracity checks and the checks will be more detailed than for the 'low risk' category. It is also likely that for the experts belonging to the high risk category, EFSA prefers to focus on ex ante, preventive veracity checks, whereas for the low risk categories, the approach is more focused on ex post, detective veracity checks.