

Note to the Management Board

Concept paper on the review of EFSA's Policy on independence and scientific decision making process

At its meeting held on 16 March 2016, this Board discussed a conceptual approach to the review of EFSA's Policy on independence and scientific decision making process it had adopted in December 2011.

The concept paper accompanying this note crystallises this approach and presents the main lines according to which the Authority intends reviewing the Policy.

The Board is invited to discuss the proposals outlined in annex to the concept paper. In line with the engagement and transparency principles EFSA is committed to, the proposals resulting from the discussion are envisaged to be put out for consultation later this year.

EFSA will then take stock of the input received and submit to this Board a draft reviewed Policy on independence, ideally by December 2016.

Table of Contents

I. Introduction – EFSA’s Independence	3
II. The implementation of the 2011 Policy.....	4
III. Independence at EFSA in 2016	8
IV. How to get there.....	9
V. Next steps.....	10
Annex.....	11

Purpose of this document – the review of the 2011 Policy on independence

The purpose of this paper is to discuss the review of the European Food Safety Authority's Policy on Independence and Scientific Decision Making Processes.¹

This paper outlines achievements of the current Policy and implementing rules,² analyses outstanding challenges and drivers for change, and provides a framework and methodology to further enhance the accountability, traceability, and engagement with the public of the Policy currently in force.

I. Introduction – EFSA's Independence

Due to historical reasons behind its establishment,³ EFSA's governance and setup is acknowledged in the EU institutional setting for the importance it attaches to its independence, and to that of the individuals supporting its operations.⁴

Independence at EFSA is a concept that could be described as consisting of three dimensions: one is deriving from its legal dimension; a scientific one is connected to the way the Authority's scientific decision making processes produce EFSA's outputs; and a third one is linked to the importance that the agency is perceived as independent.

EFSA is required by law to deliver independent scientific advice, scientific and technical support to the European Commission, European Parliament and EU Member States, and to communicate independently on it.⁵ Further, the members of its Scientific Committee, Scientific Panels and Working Groups, the members of its Management Board and of the Advisory Forum and its Executive Director are required to make a public declaration of interest and to sign a commitment to act independently in the public interest or of external influence, respectively.⁶

The delivery of independent advice, support and risk communication presupposes far reaching obligations so as to ensure that the individuals

¹ EFSA mb 15 12 11 – Policy on independence and scientific decision making process – ADOPTED.

² Decision of the Executive Director on Declarations of Interest of 31 July 2014, EFSA/LRA/DEC/02/2014.

³ See e.g. European Commission, *White Paper on Food Safety* COM (1999) 719 final of 12 January 2000.

⁴ See e.g. the composition of EFSA's Management Board, Scientific Committee and Scientific Panels *vis-à-vis* corresponding bodies, belonging to the European Medicines Agency and European Chemicals Agency.

⁵ Article 22 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 31, 1.2.2002, p. 1–24, as last amended.

⁶ Article 37 of Regulation (EC) No 178/2002, *supra*.

contributing to EFSA's scientific processes and outputs deliver correct, up to date, and objective scientific reflections; that the underlying dataset used are accurate and complying with applicable standards; and that the methodologies relied upon are comprehensive, transparent, shared and allow for reproducible outcomes.

To fulfil its mandate and create trust into the Union food safety system, it is also important that the Authority is perceived by the stakeholders and the general public to be independent of external interests and pressure. It is therefore fundamental that the Authority makes its system of managing interests and avoiding conflicts of interests fully transparent to allow society to check perceptions against the factual functioning of the system. Since 2004, the Authority has been investing regularly to review compliance with these requirements and to live up to the societal expectations linked to them.⁷

Today the state of play of EFSA's approach to independence is described by EFSA's 2011 Policy on Independence and its Rules on Declarations of Interest adopted in 2014.⁸

The Policy commits EFSA to review its approach to independence within five years of its adoption.

II. The implementation of the 2011 Policy

From the adoption of the Policy until 2014, EFSA prioritised the implementation of commitments related to individual independence.

The system in force to prevent conflicts of interest among EFSA's scientific experts, Management Board and Advisory Forum members and the Authority's staff, requires individuals supporting EFSA's operations to declare in detail any activity falling under EFSA's remit. The system mainly relies on trust and on the individuals' ability to reflect all relevant interests in their declarations of interest.

The rules prevent the occurrence of conflicts of interest by a systematic and detailed evaluation on whether activities (interests) performed by the expert over the last five years and activities the expert is supposed to perform for EFSA (for a certain scientific task in a certain role) overlap and, based on that evaluation, by applying measures that prevent to put the expert in a conflictual situation.⁹ This allows interested parties to scrutinise whether declarations of

⁷ See e.g. EFSA mb 16.12.04 - Guidance on declarations of interests and EFSA mb doc. 10.03.2004 – 5 EFSA code of conduct on declarations of interests. An initial set of rules was adopted in 2007, refined in 2009 and replaced by a more recent one in 2012. Currently, EFSA operates a set of rules adopted in 2014, which represents a leaner version of the ones previously in force

⁸ See e.g. mb 15 03 12 – Decision of the Management Board of the European Food Safety Authority concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups.

⁹ Mainly outlined in Article 8 of the Decision of the Executive Director on Declarations of Interest of 31 July 2014, above.

interest were screened by EFSA in compliance with its rules, and empower the concerned individual to know in advance of engaging in another activity whether this is likely to impact on his or her involvement at EFSA. The potential impact on the reputation of the concerned individuals, as well as the risk of dismissal from EFSA's activities, is relied upon as mitigation to incomplete, or false, declaration of interest. The implementation of the screening operations is performed via a proprietary IT tool developed in 2008 and regularly adjusted in line with regulatory changes.

EFSA efforts in ensuring the independence of scientific expertise has been acknowledged by the European Court of Auditors and is described as "relatively effective" for conflicts of interest prevention.¹⁰ A constantly decreasing trend (Table 1) in the incidence of breach of trust cases and conflicts of interest prevented has been observed.

Year	DoIs Screened (ADoI+SDoI)	Potential CoI prevented (ADoIs+SDoIs)	Ratio	Meeting agenda items	Breach of trust cases	Staff members leaving EFSA
2011	8526	356	4.2%	39,500	2	Total : 25 Private sector : 3 Restrictions : 1
2012	6869	272	4%	36,609	1	Total : 28 Private sector : 4 Restrictions : 0
2013	6191	247	4%	36,501	0	Total : 29 Private sector : 4 Restrictions : 3
2014	6962	145	2.1%	34,456	0	Total : 20 Private sector : 2 Restrictions : 2
2015	7607	96	1.3%	32,200	0	Total: 28 Private sector: 5 Restrictions: 2

Table 1

In terms of monitoring compliance, twice a year, EFSA performs *ex post* compliance and veracity checks on a sample of assessed declarations of interest. The results are published in EFSA's Annual Reports. The results (Table 2) highlight an improving picture in terms of the experts' ability to declare all relevant interests in their declarations of interest, with no substantial changes in terms of compliance.

¹⁰ Deloitte, Input document to inspire the debate between EFSA and its stakeholders regarding the future of the EFSA DoI policy and its Implementing Rules May 2014, p. 7.

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

Table 2

The implementation of the current rules has required substantial investments, implying a considerable burden for the concerned experts subject to the rules. Human resources deployment peaked in 2016 in connection with the phasing-in of the enhanced screening capacity of the centralisation of declarations of interest validation. This measure was meant to address the request of the European Parliament to assign the DoI validation to specialised staff not involved in the scientific departments (Table 3).

Competing interest implementation activities		
Full Time Equivalents		
Year	Tasks	FTEs
2014	<ul style="list-style-type: none"> ▪ Screening of DoIs ▪ Compliance & veracity checks ▪ FSO classification ▪ Independence Policy & implementing rules review 	3
2015	<ul style="list-style-type: none"> ▪ Screening of DoIs ▪ Compliance & veracity checks ▪ FSO classification ▪ Independence Policy & implementing rules review 	2.9
2016	<ul style="list-style-type: none"> ▪ Centralised validation of DoIs ; decentralised assessment ▪ Compliance & veracity checks ▪ FSO classification ▪ Independence Policy & implementing rules review 	3.9*

Table 3 * estimate

Figures below (Tables 4 and 5) show the investment (human and financial resources) over the years in the software supporting the screening operations.

DoI tool: development and maintenance BUDGET			
Year	Development	Maintenance	Total
2011	€ 601,000.00	€ 90,150.00	€ 691,150.00
2012	€ 500,000.00	€ 75,000.00	€ 575,000.00
2013	€ 300,000.00	€ 45,000.00	€ 345,000.00
2014	€ 185,000.00	€ 27,750.00	€ 212,750.00
2015	€ 8,500.00	€ 1,500.00	€ 10,000.00
Total	€ 1,594,500.00	€ 239,400.00	€ 1,833,900.00

Table 4

DoI tool: development and maintenance Full Time Equivalents			
	Development	Maintenance	Total
2011	1.2	0.2	1.4
2012	1.0	0.2	1.2
2013	0.8	0.1	0.9
2014	0.3	0.1	0.4
2015	0.2	0.1	0.3
Total	3.5	0.7	4.2

Table 5

Financial and human resources¹¹ taken together (Tables 3, 4 and 5) deliver an average in the range of 750k EURO invested every year by EFSA to ensure its independence.

7,231 declarations of interest are being screened on average every year by the Authority. EFSA's experts are asked to submit an Annual Declaration of Interest per scientific group they contribute to, and a Specific Declaration of Interest per meeting they attend, in addition to updates each time a new interest emerges, or an already declared one is modified.

From a qualitative perspective, it is noted that whilst the measures adopted by EFSA are comparable to those adopted by other Union institutions¹², the European Parliament continues to encourage the Authority to further strengthen its approach to individual independence.¹³

¹¹ Assuming an FTE corresponds on average to 100,000 EURO.

¹² The European Centre for Communicable Diseases still lacks a comparable regulatory framework. The rules in place at the European Chemicals Agency do not encompass screening criteria for the assessment of the interests. The European Medicines Agency and the Scientific Committees of the European Commission adopt policies and rules comparable to those in place at EFSA since 2011/2012.

¹³ E.g. European Parliament's decisions on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial years 2010 – 2014.

In its decisions, the Parliament asked EFSA to put in place for its experts a two year cooling off period on all material interests related to the "companies it regulates";¹⁴ that no appointment to an EFSA vacancy should be made until a potential conflict has been resolved on the basis of clear, transparent and verifiable criteria;¹⁵ that EFSA publishes information about senior officials who have left the service and a list of conflicts of interest on an annual basis;¹⁶ that the Authority performs the screening of the interests with respect to its entire mandate rather than with reference to the mandate of the relevant scientific group;¹⁷ that it ensures that experts employed by university and research institutes declare all relevant direct interests held by their employers;¹⁸ that it does not apply a double standards conflict of interest policy towards experts from "food safety organisations";¹⁹ it called upon the Authority to adopt a revolving door policy;²⁰ and finally requested that experts should declare amount of financial interests.²¹

The European Parliament is not alone in seeking further enhancements²², with stakeholders regularly voicing their concerns on these matters.²³

III. Independence at EFSA in 2016

The internal regulatory framework in which the Authority's scientific processes take place also evolved compared to the situation in place in 2011. As of 2013, first with the conference on Transparency²⁴ and later with the publication of the discussion paper on "Transformation to an Open EFSA", EFSA has recognised the importance of allowing external parties to scrutinise its scientific activities. The

¹⁴ European Parliament decision of 28 April 2016 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2014 (2015/2176(DEC)); European Parliament decision of 29 April 2015 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2013 (2014/2108(DEC)); and European Parliament decision of 3 April 2014 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2012 (C7-0298/2013 – 2013/2220(DEC)); and the European Parliament decision of 17 April 2013 on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2011 (C7-0258/2012 – 2012/2196(DEC)).

¹⁵ European Parliament decision of 28 April 2016, *supra*.

¹⁶ European Parliament decision of 28 April 2016, *supra*.

¹⁷ European Parliament decision of 28 April 2016, and European Parliament decision of 29 April 2015, *supra*.

¹⁸ European Parliament decision of 28 April 2016, and European Parliament decision of 29 April 2015, *supra*.

¹⁹ European Parliament decision of 28 April 2016, European Parliament decision of 29 April 2015 and European Parliament decision of 3 April 2014, *supra*.

²⁰ European Parliament decision of 29 April 2015, European Parliament decision of 17 April 2013 *supra*.

²¹ European Parliament decision of 29 April 2015 and European Parliament decision of 3 April 2014, *supra*.

²² See the Decision of the European Ombudsman closing the inquiry into complaint 346/2013/SID against the European Food Safety Authority ('EFSA'), 28 January 2015.

²³ See e.g. Testbiotech's open letter on alleged conflicts of interest at EFSA: available online at <http://www.testbiotech.org/en/node/1587>.

²⁴ See <http://www.efsa.europa.eu/en/events/event/131003>.

project on Transparency and Engagement in Risk Assessment (TERA)²⁵ implements the measures stemming from the Open EFSA paper and the subsequent public consultation. The final goal is to increase the ability of external parties to scrutinise, if not reproduce, EFSA's scientific decision making processes. It means individual Declarations of Interest are not the only means the public has of verifying the independence of the Authority's outputs.

In March 2016, EFSA also adopted its Strategy 2020,²⁶ setting out the Authority's strategic objectives for the next five years. Independence remains a top priority for EFSA, with the aspirations of EFSA's 2011 Policy still relevant and confirmed.

This means in 2016 the review of the Authority's approach to individual independence of 2011 is informed by a) the experience gained in the implementation of EFSA's Policy and DoI rules, b) the qualitative feedback received from political institutions and interested parties and c) the alignment with the vision, values and objectives of the 2020 Strategy aiming at increased transparency, impartiality, reproducibility levels and cost effectiveness²⁷ both in the scientific and administrative decision-making processes of the Authority.

IV. How to get there

The outcome of the exercise takes the form of the preliminary proposals described in the annex to this Paper. In these proposals, which should be intended without prejudice to further operational thinking, EFSA deliberately chose to depart from the concept that concerned individuals and experts should not have intellectual bias. The Authority acknowledges that the assessment of potential intellectual conflicts by definition has to rely on assumptions about the extent of an intellectual bias and therefore weakens transparent and reproducible decision making. Instead, in the proposals put forward in annex, EFSA opts for verifying the existence of potential conflicts of interest on the basis of the presence of an economic or financial gain of some sort.

The proposals also comprise commitments made by EFSA in Q4 2015 with reference to putting in place cooling off periods for its experts (proposal 3) and implementing a centralised handling of declarations of interest (proposal 1),²⁸ aspects found liable to bring the approach to individual independence developed

²⁵ See e.g. Update on the project 'Transparency and Engagement in Risk Assessment' provided to EFSA's Management Board at its December 2015 session, and available online at <http://www.efsa.europa.eu/sites/default/files/mb151203-d2.pdf>.

²⁶ EFSA strategy 2020. *Trusted Science for safer food. Protecting consumers' health with independent scientific advice on the food chain, adopted by EFSA's Management Board on 15 March 2016 and available at http://www.efsa.europa.eu/sites/default/files/corporate_publications/files/strategy2020.pdf.*

²⁷ EFSA strategy 2020, *supra*, at 19.

²⁸ Letter of EFSA's Executive Director Mr Bernhard Url to Mr Vaughan, Vice President of the Committee on Budgetary Control of the European Parliament of 14 October 2015 (EFSA ref. 14778909).

in 2011 in line with commitments of increasing transparency (proposal 2), cost effectiveness (proposal 1) and reproducibility (proposals 1 and 2);²⁹ or measures addressing explicit demands from the European Parliament (proposals 1, 3, 4 and 5).

V. Next steps

Following the debate amongst the Management Board EFSA will consult the public on the proposals endorsed. EFSA will then review the comments received by the public and submit to the Board a draft Policy on Independence as a result of this process.

²⁹ Deloitte Belgium, Input document to inspire the debate between EFSA and its stakeholders regarding the future of the EFSA DoI policy and its Implementing Rules, May 2014, Support of the review of the Implementing Rules of the 2012 DoI policy Specific Contract 16 under Framework contract "Organisational Evolution Support".

Annex

Proposals enhancing EFSA's approach to Independence

Table of contents

- Proposal 1 – Risk based approach for individual independence
- Proposal 2 – Publication of EFSA's validation process for declarations of interest
- Proposal 3 – "Cooling off" periods for members of EFSA's Scientific Committee, Scientific Panels and Working Groups
- Proposal 4 - Enhanced reputation management stemming from Management Board turnover
- Proposal 5 - Public repository of outside activities of EFSA staff and of activities undertaken after termination of employment with EFSA

Proposal 1 **Risk based approach to individual independence**

Addressing

Impartiality, Cost Effectiveness and reproducibility with respect to independence of EFSA experts and staff

Current situation/issues

EFSA has in place a thorough set of rules for the identification and prevention of potential conflicts of interest (CoI). This approach encompasses all kinds of activities, and screening criteria apply to the declared activities irrespective of whether the concerned individual derives some kind of financial gain from them.

While this is ideal in abstract terms, it also implies a heavy administrative burden on the experts subject to declaring requirements and raises intrinsic challenges when it comes to transparent and reproducible decision making when seeking to identify intellectual bias.

EFSA's current rules leave a certain level of discretion on the way core scientific activities, such as authoring or participation to conferences and workshops should be considered in terms of CoI prevention. This is not ideal, since EFSA's partners and interested parties should be in a position to identify *ex ante* all allowed or non-allowed activities.

Currently EFSA applies an inclusive approach for experts with activities concerning "Food Safety Organisations", that is organisations operating within EFSA's remit pursuing public interest objectives and funded for more than 50% of their budget by public entities. This notwithstanding, it still considers certain activities incompatible with chairmanship or attendance at its scientific meetings. This situation stands in contrast to the public interest objective pursued by both the Authority and the FSOs and to EFSA's strategic objective of enhancing cooperation with Member States' authorities and international organisations.³⁰

Further, EFSA currently has blanket rules applicable to all its scientific activities with no differentiation based on the actual risk level that a potential CoI actually emerges. Both the European Court of Auditors and the European Data Protection Supervisor have advised Union agencies to set up CoI rules in line with a proportionate and risk based approach.

³⁰ EFSA 2020 Strategy, *supra*, at 17.

Finally, EFSA's current rules on declarations of interest prescribe a screening of the DoI of the candidates chosen to be appointed to a given vacant position as EFSA staff with the aim of avoiding conflicts of interest.

Description

The proposal consists of the adoption of a leaner, more proportionate and risk based version of the rules currently in force for the prevention of CoIs.

a. HOW WOULD THE CURRENT SYSTEM BE CHANGED

a.i. Transparency of declared interests: individuals subject to the DoI requirement would not anymore be allowed to ask the confidential treatment of interests, or details, set out in their declarations.

a.ii. Focus on economic interests: conflicts of interest would be limited to situations where an economic gain by the concerned person or his or her close family members is identified. Economic gains would include also contribution in kind and would not be limited to actual financial transactions. Transparent thresholds for the relevance would be applied so as to exclude benefits where the gain is so low not to represent a concern in terms of individual independence. This focus would be applicable to all activities, irrespective of their nature. However, regardless of financial interests, experts or staff would continue not to be allowed to review their own work.

a.iii. Food Safety Organisations: due to the common public health objectives shared by EFSA and its fellow institutional partners, conflicts of interest would not be identified with regard to activities performed by the concerned individuals to the benefit of international, EU, national, regional or local authorities performing research, risk assessment or risk management functions. Situations of conflict of interests would be identified only with respect to risk assessments and ongoing in parallel on the same subject matter.

a.iv. Core scientific activities: the rules would clarify that core scientific activities, ranging from authoring of publications and papers, to research activities, with the exception of exclusively privately funded research, activities in scientific journals and participation, organisation or speaking at conferences, seminars, workshops open to the public do not result in a conflict of interest, insofar as no cash flow or other economic benefit beyond a certain threshold is identified. This, irrespective of the private or public nature, or identity, of the legal or natural person benefiting from the activity in question.

a.v. Specific Declarations of Interest: to make EFSA's approach cost effective, leaner and more risk proportionate, the recourse to Specific Declarations of Interest would be limited to EFSA's Scientific Panels, Working groups or other groups dealing with regulated products, organisms, claims or substances.

a.vi. Candidates to EFSA vacant positions: pursuant to Article 11 of the EU Staff Regulations, EFSA is required to perform a screening of declarations of interests filed by candidates to vacant positions as staff members before appointing them. Subject to the Commission's scrutiny under Article 110 EU Staff Regulations, EFSA would develop clearer, more transparent and verifiable criteria for the assessment and validation of declarations of interests submitted by candidates. Depending on the seniority level of the position at stake, these would consider incompatible with recruitment by EFSA all candidates having: a direct financial interest in the sector impacted by EFSA's scientific operations beyond a certain threshold; an ongoing managerial responsibility of any kind, or an ongoing professional or gainful activity of any kind in the "food, feed, animal rearing, horticulture" industry.

b. WHAT THE IMPACT OF THE CHANGES WOULD BE

b.i. Transparency of declared interests: all details of declared interests would be transparently available online, with no exception whatsoever. Experts would not be in a position to ask for the confidential processing of their interests.

b.ii. Focus on economic interests: conflicts of interest would be identified, only to the extent that a financial gain or economic transaction of some kind is declared by the concerned person. For instance, if an expert declares an ongoing advice *pro bono* to a not for profit association established by, and paid for, food industry, and no coverage or reimbursement of expenses, or fee of any kind is received by him, EFSA would not identify a conflict of interest. On the contrary, if the same activity implies a direct coverage or reimbursement of expenses, and/or fee, beyond a given threshold (to be set), it would lead to the identification of a conflict of interest, with the impossibility for the expert to participate to the relevant scientific activity at EFSA.

b.iii. Food Safety Organisations: this measure would exclude that any activity performed by an expert to the benefit of a public international, EU, national, regional or local authority performing research, risk assessment or risk management functions is considered a CoI. For instance, being a head of unit or senior manager with the national research institute of an EU Member State responsible for the research programmes on the same topic on which he or she cooperates with EFSA would imply no restrictions at the Authority. Instead, a conflict of interest would be identified the moment when the same person becomes involved in the context of his or her professional activity in an actual risk assessment on the same topic on which he or she works on at EFSA. The consequence is that he or she will be excluded until the parallel activity goes on, and, as it is the case also now, later he or she will not be allowed to review at EFSA his or her own work.

b.iv. Core scientific activities: Public or private/public joint research initiatives, educational activities or attendance and participation to conferences, workshops, seminars or public events, membership in learned societies and activities in scientific journals would not represent a CoI. For instance, this would imply that the fact an expert coordinates or speaks at a conference organised or financed by food industry does not amount to a CoI, and would imply no restrictions at the Authority.

b.v. Specific Declarations of Interest: SDoIs would be deployed in relation to meetings where regulated products, substances, organisms or claims are discussed. They would not be required in EFSA's scientific groups where topics of a general nature and not addressing these regulated products etc. are discussed. For instance, SDoIs would be required on the Working Group dealing with health claims application, and not in the Working Group responsible for Hazard Analysis approaches for certain retail establishments in view of the application of their food safety management systems.

b.vi. Candidates to EFSA vacant positions: before applying, candidates would have the possibility of understanding which interests would be allowed, and which ones would be most likely be considered not compatible for a given position. The application of these criteria, for instance, would mean that before being recruited, a candidate to an officer's position would have to sell shares owned in a company involved in the production of foodstuffs, or that he or she would have to resign from the position of management board member in a company involved in animal rearing.

Rationale

This proposal would streamline the activity of identification and prevention of conflict of interest, reducing the risk of misunderstanding, better managing concerned individuals' and stakeholder's expectations, while also improving in terms of communication with

the general public due to simpler less discretionary rules.

This proposal would also address explicit demands from the European Parliament for leaner and clearer rules.

Proposal 2 Publication of EFSA's validation process of Declarations of Interest

Addressing

Transparency, reproducibility and impartiality with respect to independence of experts

Current situation/issues

Scientific Experts' declarations of interest are currently available on the web, while the evaluation of their interests performed on a systematic basis by EFSA is not made publicly available.

In several instances, the description of the interests does not allow the reader to understand why EFSA concluded that no CoI was identified, or to see that CoI preventing measures were adopted by EFSA.

As a consequence, the reader might believe that EFSA did not take any action, while the opposite is most likely true.

Description

EFSA would be making proactively available on its website the validation process of each Annual Declarations of Interest with respect to each involvement of the expert, together with the measures taken to prevent or mitigate a CoI, if any, and the reasoning followed by EFSA's assessors.

Rationale

EFSA would show the full extent of the scrutiny exercised on its experts' interests. An external reader might still disagree with EFSA's positions, but EFSA would be seen as caring and compliant with its rules.

Proposal 3 "Cooling off" periods for members of EFSA's Scientific Committee, Scientific Panels and Working Groups

Addressing

Impartiality, cost effectiveness and reproducibility with respect to independence of EFSA experts

Current situation/issues

EFSA has in place a thorough set of rules for the identification and prevention of potential conflicts of interest. This approach includes targeted cooling off periods for employment and occasional consultancy activities of its experts.

The European Parliament keeps reiterating its demand for a two-year cooling-off period on all material interests related to the companies EFSA "regulates".

Description

The proposal consists of the adoption of systematic two-years cooling-off periods for experts sitting in EFSA's Scientific Committee, Scientific Panels and their Working

Groups.

The cooling off periods would be applied to experts who declare past activities implying a managerial or advisory role, or otherwise professional involvement for, or with, legal entities pursuing private or commercial interests and whose operations or interests are impacted on by EFSA's operations. This would capture all companies, associations and not for profit organisations likely to gain from influencing EFSA's scientific decision making processes.

The cooling-off periods would not be applicable to the same activities if carried out with universities, research institutes, learned societies, scientific journals and comparable entities. These cooling-off periods would not be directly applicable to selection procedures for EFSA vacant positions mentioned under proposal n. 1 above, due to the different legal framework applicable to them.

The application of this measure would mean, for instance, that an expert having ceased in January 2016 an advisory role to a company involved in horticulture would not be in a position to join the EFSA Scientific Panel on Plant Health until January 2018.

Rationale

This proposal would streamline the activity of identification and prevention of conflict of interest, reducing the risk of misunderstanding, better managing stakeholder's expectations, while also scoring better in terms of communication with the general public due to simpler messages.

This proposal would also address explicit demands from the European Parliament to put in place such cooling-off periods.

Proposal 4 **Enhanced reputation management** **stemming from** **Management Board turnover**

Addressing

Transparency and impartiality with respect to independence of methods

Current situation/issues

EFSA's founding regulation does not require monitoring of activities undertaken by the former members of its Board after they terminate their mandate with the Authority.

EFSA has been exposed to criticism from stakeholders, who have advocated for some time the establishment of measures aimed at avoiding the involvement of former Board members in commercial, or industry funded, entities that have an interest in EFSA's scientific activities.

Description

EFSA would be developing a voluntary scheme aimed at establishing a process comparable to that outlined in Article 16 of the Staff Regulations for its former employees, implying a notification requirement for all former Board members wishing to engage in an occupational or professional activity in the two years after the end of their term. The process and applicable rules would have to be fine-tuned to be proportionate to the different legal nature and situation of Board members.

Rationale

The adoption of a clear and proportionate scheme avoiding the involvement of former Board members in certain activities perceived as incompatible with their mandate at EFSA is expected to increase trust in the independence of EFSA's Board.

Proposal 5
Public repository of outside activities of EFSA staff and of activities
undertaken after termination of employment with EFSA

Addressing

Transparency and impartiality with respect to independence of EFSA staff

Current situation/issues

Under the EU Staff Regulations, staff employed by EFSA are required to obtain *ex ante* permission from EFSA before engaging in an external activity. No transparency requirement is currently established under the EU Staff Regulation for the disclosure of data linked to these "outside activities".

Former EFSA staff are required under the Staff Regulations to notify EFSA in advance of taking up a professional activity within two years of leaving the Authority. In this context, if necessary and proportionate, EFSA may adopt limiting measures. However, transparency requirements are imposed only on senior officials on a position of Director or equivalent. In EFSA, this applies only to the Executive Director.

Overall, the framework in place does not contribute to enhancing an accurate perception of the efforts EFSA makes to ensure that its staff abstain from activities that could be detrimental to their impartiality or the independence of the agency, if not to its reputation.

Description

With the support of the European Personal Data Protection Supervisor, EFSA would explore ways of increasing the transparency levels applied to the activities performed by officers in key positions, or who used to cover these posts.

Rationale

The publication of this repository would increase the transparency and scrutiny ability of third parties on outside activities authorised by EFSA and on gainful activities undertaken by former staff. This is expected to increase trust in EFSA's staff independence and credibility and make EFSA's efforts in this respect more evident.