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# Evaluation of the EFSA independence policy: analysis and recommendation of the Management Board sub-group on independence



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# EVALUATION OF THE EFSA INDEPENDENCE POLICY

## ANALYSIS AND RECOMMENDATION OF THE MANAGEMENT BOARD SUB-GROUP ON INDEPENDENCE

### Background

Article 6 of EFSA's Independence Policy<sup>1</sup> foresees that the Policy be subject to an ex-post evaluation not later than five years after its entry into force. Following a procurement procedure, EFSA commissioned the ex-post evaluation to 'Economisti Associati Srl' in March 2023.

The evaluation had two dimensions:

- **retrospective**, i.e.: to collect, systematise and report evidence on the effectiveness, efficiency and impact of the Policy and its coherence with the pertinent legal and strategic framework;
- **forward-looking**, i.e.: to evaluate the extent to which the Policy remains relevant and fit for purpose in the light of emerging needs and challenges.

The Management Board created its sub-group on independence on 21 June 2023, assigning to it, the task of providing the Management Board with advice in steering the review of EFSA's independence regulatory framework. Specifically, based on the evaluation report to be delivered by the contractor, the sub-group was tasked with providing the Management Board with advice on whether the Policy on Independence needs to be updated.

The Management Board appointed as members of the sub-group Pamela Byrne (Chair - Ireland), Claire Bury (European Commission), Floriana Cimmarusti (Consumers Organisations), Hrönn Jörundsdóttir (Iceland), Astrid Thors (European Parliament), Marie-Luise Trebes (Germany) and Ana Viloría (The Netherlands).

### The ex-post evaluation report

The work carried out by the contractor involved the collection, processing and analysis of information gathered through the following steps and the delivery of the ex-post evaluation report. The steps were:

- Stakeholder consultation  
Namely: EFSA Management Board members; EFSA Advisory Forum members; Focal Points network; members of the EFSA Scientific Committee, Panels and Working Groups; representatives of the Member States competent organisations (i.e.: Art 36 organisations); EFSA Stakeholder Forum's and Stakeholder Bureau's members; EFSA staff.

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<sup>1</sup> EFSA's Policy on Independence: available on EFSA's website at the link <https://www.efsa.europa.eu/en/corporate/pub/policyonindependence>



Two consultation tools were used:

- a. In-depth interviews with representatives of the stakeholder categories mentioned above (37 interviews were carried out).
- b. Questionnaire-based survey addressing the entire population of the above-mentioned stakeholder categories (a total of 256 responses were received)<sup>2</sup>.

- Desk research

This workstream involved the review of the EFSA Policy and implementing documents, as well as a review of the EU legal framework of reference. Additionally, desk work covered EU supervisory institutions reports and case-law (e.g.: European Parliament's budget discharge resolutions, European Ombudsman's decisions and recommendations, and European Court of Auditor's reports) and scientific literature.

- Benchmarking exercise

The benchmarking exercise consisted of a comparative analysis of independence policy and measures in force in EU and Member State organisations that are similar to EFSA in terms of type of mandate and operational activities. Five comparators were selected: the European Centre for Disease Prevention and Control (ECDC), European Chemicals Agency (ECHA), European Medicines Agency (EMA), Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES, France), and Agence fédérale pour la sécurité de la chaîne alimentaire (AFSCA, Belgium).

The ex-post evaluation report was provided to the sub-group on independence for review on 23 October 2023.

### **The outcome of the ex-post evaluation report**

Overall, the ex-post evaluation report concludes that EFSA has a robust system in place that ensures a satisfactory level of independence and the management of conflicts of interests. The report outlines that the Policy is coherent and in line with the objectives and values set out in EFSA's corporate strategy as well as the requirements laid down in the legal framework. Furthermore, the report highlights that there is widespread recognition of EFSA recent improvements in relation to how it strives to ensure independence. Evidence of positive reputational impact is found in EU supervisory bodies' reports<sup>3</sup>, as well as in feedback from scientific community and stakeholders<sup>4</sup>. According to the report, minor issues mainly regarding the clarity and the consistency of specific provisions or implementing measures do not represent substantial and/or urgent threats to the functioning and achievement of the Policy's objective.

The report includes a list of 21 recommendations, which set out possible improvements to the EFSA independence regulatory framework. The report highlights that further reflection on the

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<sup>2</sup> For detailed information on the number of interviews carried out and on the number of responses received from each stakeholder category, see table 3.2 "Participants in stakeholder consultation" at page 18 of the final report on the "Ex-post evaluation of the Policy on Independence of the European Food Safety Authority adopted by EFSA Management Board on 21/06/2017"

<sup>3</sup> European Parliament discharge resolutions, European Ombudsman decisions and recommendations, European Court of Auditor reports, ruling and opinions of the Court of Justice of the European Union, studies and reports commissioned by the European Parliament.

<sup>4</sup> For detailed information, see section "4.2 Effectiveness" at page 25-27 of the final report on the "Ex-post evaluation of the Policy on Independence of the European Food Safety Authority adopted by EFSA Management Board on 21/06/2017"



feasibility and coherence of the suggested recommendations is required prior to their consideration for implementation.

### **Meetings of the sub-group on independence**

The sub-group met three times (on 18 September, 3 and 24 November 2023) with the objective of analysing the EFSA independence regulatory framework and discussing the conclusions and recommendations of the evaluation report.

### **Advice of the sub-group to the Management Board**

The sub-group considers that:

1. the majority of the recommendations set out in the evaluation report identify valuable improvements to the current independence framework;
2. there are a couple of recommendations that require further analysis regarding their efficacy and effectiveness; and
3. there are concerns in respect of some of the recommendations regarding the benefit and positive impact they would have on the existing policy.

Therefore, the sub-group advises the Management Board to review the policy:

1. to take account of those recommendations which will improve the policy and strengthens its ability to ensure independence;
2. to carry out further analysis of the recommendations related to efficiency and effectiveness; and
3. to not proceed with those recommendations for which the benefits and positive impacts are unclear and unlikely to deliver greater independence.

The following section provides a more detailed analysis and the rationale justifying the above advice.

From a procedural point of view the sub-group clustered the recommendations in groups for ease of progressing the discussions. However, the sub-group recognises that during a review of the Policy, planned in 2024, should the Management Board agree to the advice, any additional reflection raised by the Management Board, including all recommendations of the external report, may be triggered by the Management Board members.

### **Sub-group analysis of the recommendations in the evaluation report**

As a result of the work of the sub-group, the twenty-one recommendations (R#) in the evaluation report are clustered in three groups:

- A. Recommendations that are suggested to be part of the reflections on the Independence Policy review, as they provide an improvement to the current Independence framework,
- B. Recommendations that are suggested to be part of the independence Policy review subject to additional analysis before implementation,
- C. Recommendations that raise doubts regarding their benefit and impact in upgrading EFSA's independence framework.

#### **A. Recommendations to be part of the review**

The sub-group suggests making reflections regarding the implementation of fourteen recommendations part of the Policy review by means of reviewing the corresponding provisions in the Independence Policy and in its implementing rules. Some of these recommendations suggest communication activities aimed at enhancing the knowledge and comprehension of the



EFSA independence regulatory framework. Some other recommendations focus on enhancing clarity and effectiveness of the current rules. Finally, four recommendations are dedicated to adjust the independence rules in case of scientific cooperation with member states and service providers, proposals that were particularly well received during the discussions among the sub-group members in view of the enhanced effectiveness and appropriateness of the framework proposed.

- R#1** *Maintain and enhance proactive dialogue on independence-related matter with all relevant counterparts, especially on critical dossiers.*
- R#2** *Consider actions to enhance awareness and visibility of the Policy among target groups.*
- R#3** *Consider communication actions addressing the general public.*
- R#8** *Clarify how EFSA can detect conflicts of interests (CoI) in members of the Advisory Forum/Networks and – if relevant – strengthen whistleblowing policy and the like.*
- R#10** *Consider revising the 'self-rule' mechanism for CoI management within the Management Board.*
- R#11** *The deterring effect of ex post checks can be enhanced, extending checks to online sources (e.g. via external contractors).*
- R#13** *Make larger use of IT tools, to enhance efficiency and to gather granular information on efforts and bottlenecks associated to specific independence-related activities.*
- R#14** *Consider operational-level refinements of Declarations of Interests (DoI) screening process, e.g. to reduce – where feasible – the need for discretionary judgment from senior officer.*
- R#15** *Find appropriate instruments to foster more uniform criteria for designation of Art. 36 organisations across Member States<sup>5</sup>.*
- R#16** *Apply to grantees performing critical tasks the same CoI rules of working group members.*
- R#17** *For non-critical outsourced tasks, consider rely on grantee/ contractor declaration, while applying accurate checks on a sample basis and a sanction regime effective in deterring omissions.*
- R#18** *Consider involving Member States (e.g. via Focal Points) in ensuring national organisations' compliance with EFSA rules and the application of sanctions.*
- R#19** *Explain why Hearing Expert's DoI are not screened; Clarify criteria and modality for granting waiver; Clarify the rules applied to DoI screening in case of Art. 36 organisations.*
- R#21** *Publish DoI from Art. 36 grantees; Consider publishing CVs from key staff and Management Board members; Consider publish decisions regarding former staff engaging in occupational activities.*

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<sup>5</sup> The sub-group recommends EFSA to closely liaise with the European Commission for the follow up on this recommendation, in particular with regard to the possible review of the [Commission Regulation \(EC\) No 2230/2004 of 23 December 2004 laying down detailed rules for the implementation of European Parliament and Council Regulation \(EC\) no 178/2002 with regard to the network of organisations operating in the fields within the European Food Safety's mission.](#)



## B. Recommendations deserving additional analysis

The sub-group considers that additional elements shall be explored before concluding on the efficacy and effectiveness of two recommendations. Benchmarking and additional analysis would be required at Policy drafting stage in order to reach conclusions on whether the proposed recommendations are to be implemented and to what extent.

**R#6** *Explicit reference to national interests/ political pressure in the Policy.*

**R#20** *Clarify and address apparent inconsistencies in the approach to the calculation of the percentage of relevant private research funding.*

- ❖ **R#6** The evaluation report highlights that “*objective screening criteria*” aimed at preventing the possible undue influence of national interests and political pressure on EFSA’s operations “*seem poorly applicable*”.

Overall, R#6 is considered to be already implemented by the Independence Policy to a large extent since, in compliance with the provisions in the General Food Law, it preserves the segregation of risk management functions from the risk assessment and risk communication ones. This is flanked by the obligation of the Member States to refrain from providing the experts with any instruction incompatible with the independence of EFSA and detailed in Article 28(5d) of the General Food Law.

More in-depth reflections addressing aspects of cooperation between EFSA and the Member States should be carried out, in particular in the context of scientific partnerships with the organisations included in the Art. 36 list.

- ❖ **R#20** highlights the need to improve communication on the application of the 25% threshold of private funds in research activities, which the sub-group endorses.

The sub-group acknowledges that national and EU research programmes actively encourage and promote public-private partnership in the research and development areas and that, consequently, most of EFSA’s experts are engaged in research activities co-funded by public and private funds. The sub-group also acknowledges that the Transparency Regulation reinforces the requirement that EFSA’s scientists be active in the research field and appreciates that more stringent rules in the research area may result in a restriction of its pool of experts.

Further analysis of EFSA’s approach in considering contributions of private nature as always supporting the public interests pursued by the (co-)contributions of public nature is suggested. The sub-group recommends benchmarking EFSA’s approach with those applied by other EU agencies.

## C. Recommendations where the sub-group expresses doubts as to their benefit and impact on EFSA’s independence framework

**R#4** *Maintain the current principle of screening interests against the specific mandate involved but consider extending ‘unconditional restrictions’ to additional typologies of interest.*

**R#5** *To cope with possible shortage of expertise, consider modulating measures in relation to the risk involved, i.e.: sensitivity of the subject matter and/or expert’s role, facilitating contributions from occasional experts, who are not working group members and do not hold interests subject to ‘unconditional restrictions’.*



- R#7** *Develop criteria for 'revolving doors' rules for staff, consider expanding to Panel and Scientific Committee members the information obligations applied to Management Board members, and improve enforcement.*
- R#9** *Consider DoI requirements for all Member States experts involved in drafting pesticides risk assessments, and not only those who attend to Peer Review meeting.*
- R#12** *Consider re-focussing the allocation of resources, modulating efforts and rules with risk level, e.g.: with greater reliance on declarant's assessment for 'low risk' situations and more resources allocated to critical situations.*

- ❖ **R# 5 & 12:** The two recommendations are combined since they propose re-modulating the so called 'risk-based approach' introduced by the Independence Policy in 2017.

The risk-based approach consists in screening the interests declared against the remit of the relevant scientific group to which the expert is invited to take part, applying an 'in-or-out' decision model.

R# 5 and 12 are intrinsically linked to the ex-ante definition of concepts such as 'sensitivity' of EFSA's mandates and/or 'high risks of conflicts'. These concepts are subject to a large degree to changing perceptions in the socio-political sphere, imply political/economic qualification outside of EFSA's remit and entail considerable margins of discretion at detriment of more objective approaches.

- ❖ **R#4** suggests the extension of "unconditional restrictions' to other categories of interests". The R# is to a large degree already implemented in the current Policy. The Policy, in fact, requires that any time conflicting interests (other than financial investment or employment in food/feed industry) impact more than 25% on the annual earning of the declaring person, they shall be considered as employment, hence falling into the unconditional restriction regime.
- ❖ **R#7** suggests preventing cases of so called "revolving doors" by applying on scientific experts provisions similar to those applied on EFSA staff members.

The existing independence framework already responds to a large extent to the exigencies depicted in R#7, since EFSA's Independence Policy introduced in 2017 the cooling off period of two years after the end of conflicting interests. In case of late declaration or omission of the conflicting interest, in addition, the expert is subject to enforcement measures including the possible prohibition to participate in further EFSA activities for a period up to 10 years.

The application of measures analogous to those applied to staff members on grounds of the EU Staff Regulations is potentially legally disproportionate for the reasons that scientific experts are not subject to an employment contractual engagement with EFSA and, therefore, they are not subject to the Staff Regulations.

- ❖ **R#9** suggests considering the extension of EFSA's DoI requirements to all experts taking part in the preparation of a draft pesticide risk assessment on behalf of the Rapporteur Member States.

EFSA's Independence Policy already foresees the obligation for representatives of Member States in EFSA peer-review meetings to submit a DoI, which EFSA assesses in application of its independence rules.





Extending the application of the EFSA independence rules to the stages of the pesticide peer-review procedure which are under the responsibility of the Rapporteur Member State may be considered disproportionate by the Member States.

### **EFSA Management Board decision**

Based on the outcome of the ex-post evaluation report and in view of the advice from the sub-group, the Management Board is kindly invited to decide on whether to open the EFSA Independence Policy to review in line with the above advice.