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FRAMEWORK CONTRACT SANTE/2021/OP/0002 CONCERNING THE PROVISION OF SERVICES IN THE AREAS OF EVALUATION, IMPACT ASSESSMENT, MONITORING OF IMPLEMENTATION AND OTHER RELATED SERVICES IN RELATION TO HEALTH AND FOOD POLICIES

Specific Assignment: RC/EFSA/LA/2023/02 - SC01

Ex post evaluation of the Policy on Independence of the European Food Safety Authority adopted by EFSA Management Board on 21/06/2017

EXECUTIVE SUMMARY

submitted by

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1. Purpose and methodology of the Study

➢ PURPOSE OF THE STUDY

The ***purpose*** of the Study was to conduct an ex post evaluation of the Policy on Independence adopted by the European Food Safety Authority (EFSA) Management Board in 2017 (the "Policy"), in accordance with the provision laid down in the Policy itself, which requires such evaluation be implemented not later than five years after its entry into force. The scope of the analysis covers the period 2018-2022 and includes implementing documents and operational arrangements. The Study has a two-pronged evaluative dimension:

- ***retrospective dimension***, 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 dimension***, i.e. to evaluate the extent to which the Policy remains relevant and fit for purpose in the light of emerging needs and challenges.

➢ METHODOLOGY

The Study involved the collection, processing and analysis of data information gathered through different activities and research tools, namely:

- ***Stakeholder consultations.*** The study involved the consultation of various categories of stakeholders directly involved or otherwise concerned by the Policy, and namely: (a) relevant EFSA staff; (b) EFSA Management Board (MB) members; (c) EFSA Advisory Forum (AF) members; (d) the Member States (MS) Focal Points network; (e) 'Experts' (i.e. members of EFSA Panels, Scientific Committee, and Working Groups); (f) representatives of MS Competent Organisations, known as 'Art 36 organisations'; and (g) EFSA Stakeholder Forum's and Stakeholder Bureau's registered members. Specifically, two consultation tools were used:

  1. Overall, 37 ***in-depth interviews*** with various categories of stakeholders were carried out.
  2. A questionnaire-based ***targeted survey*** was implemented, with a total of 256 valid responses.

- ***Desk research.*** This line of work involved the review of EFSA policy and operating documents and of the overall EU legal framework of reference. Additionally, desk work covered EU supervisory institutions reports and case-law (e.g. European Parliament (EP)'s budget discharge Resolutions, European Ombudsman decisions and recommendations, and European Court of Auditor's reports), scientific literature and other miscellaneous sources.

- ***Benchmarking exercise***. The benchmarking exercise consisted in the comparative analysis of independence policy and measures in force in organisations that are similar to EFSA in terms of mandate, and modus operandi. In agreement with EFSA five comparators were selected, of which three are EU 'sister' agencies and two national food safety authorities, i.e.: (1) European Centre for Disease Prevention and Control (ECDC), (2) European Chemicals Agency (ECHA), (3) European Medicines Agency (EMA), (4) Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES, France), and (5) Agence fédérale pour la sécurité de la chaîne alimentaire (AFSCA, Belgium).

2. Overview of the Policy

➢ EFSA'S POLICY FRAMEWORK

According to the *General Food Law Regulation* – including the major amendment adopted in 2019 (the *Transparency Regulation)* independence is one of EFSA's fundamental operating principles. This notion is mirrored in EFSA's corporate strategy, which places ***'independence' among the Authority's overarching values,*** and considers it as essential for improving the relevance and the reputation of EFSA's scientific advice. Further inputs on EFSA's independence can be found in the EU *Financial Regulation*, in the EU *Staff Regulations* as well as in annual EP budget discharge Resolutions, which devote a specific section on 'prevention and management of conflicts of interest'.

The independence policy currently in place in EFSA is spelled out in the document adopted by the Management Board in June 2017 entitled ***EFSA's Policy on Independence*** - *How the European Food Safety Authority assures the impartiality of professionals contributing to its operations.* The Policy is implemented through the 2018's *Decision of the Executive Director on Competing Interest Management* - ***CIM Decision*** - as well as other complementary documents and rules of procedures.

➢ OVERVIEW OF POLICY CONTENT

The purpose of the independence Policy is to ensure the impartiality of individuals participating in EFSA's scientific operations and activities, by preventing conflicts of interest (CoI) and other ethics and integrity issues. It is centred mandatory self-disclosures of interests – the ***Declaration of Interests*** (DoI) - covering previous five years and including the declarant's close family members. Relevant interests are divided into nine areas, some of which are deemed incompatible with involvement in EFSA activities (i.e. industry employment and financial interests) while others need to be verified case-by-case and in relation to the remit of the scientific group concerned (e.g. IPR, research funding, managerial roles, relevant affiliations etc.). In general, interests related to activities carried out for Public Institutions (PI) as part of public interest duty are considered compatible with EFSA work, except for risk management functions. Other activities are subject to a 'cooling-off period', i.e. incompatibility persists for two years after the end of the activity (five years for experts in Chair / Vice-chair position).

EFSA's procedure for ***screening interests*** involves two steps, i.e.: (1) assessment, which is carried out by Scientific Units, and (2) validation, which is under the responsibility of the Legal and Assurance Services. In addition, ex post ***compliance and veracity checks*** are carried out twice per year on a sample of DoIs. The Policy covers also ***transparency*** aspects, such as the publication of DoIs on the Authority's website and the preparation of a specific Annual Report on independence-related activities.

3. Key findings and recommendations

Summary of Main Conclusions

1. EFSA has a robust system in place that ensures a **satisfactory level of independence and prevention of undue conflicts of interest** among staff and experts involved in its scientific processes and outputs. The Policy is **coherent** with objectives and values of EFSA corporate strategy and requirements laid down in the legal framework.
2. There is widespread recognition of EFSA recent **improvements** in relation to independence, which can largely be attributed to the implementation of Policy 2017. Evidence of **positive reputational impact** can be found in EU supervisory bodies' reports in feedback from scientific community and stakeholders.

3. The system involves significant resource investment, and its future **sustainability could be challenged** by the expected increase in EFSA activities, especially through outsourcing of scientific work. Resource allocation seems **not always driven by the specific risk** involved.
4. Other minor issues mainly regarding the **clarity and the consistency** of specific provisions or implementation measures were also detected, which, however, **do not represent substantial and/or urgent threats** to the functioning and achievement of the Policy's objective.

- **REPUTATIONAL IMPACT OF THE POLICY**

EFSA's ***reputation regarding independence*** has substantially improved over time. In the past, EFSA suffered from relatively frequent and severe criticisms for inadequate CoI management. This is no longer the case, and most of EFSA's stakeholders expressed appreciation for EFSA's capacity to ensure impartiality and absence of CoI in its scientific work. The Policy adopted in 2017 and the following implementation efforts can be credited for this general reputational effect. Additionally, EFSA has adopted a more proactive attitude regarding communication and engagement with EU supervisory institutions and stakeholders on independence-related matters, and this also had a positive effect on reputation.

A greater ***awareness of the Policy*** in the EU food safety environment (institutions, researchers, interested parties, etc.) has likely contributed to such reputational impact, although some aspects of the Policy remain poorly familiar to various stakeholders, especially those who are less intensively involved in EFSA's scientific activities - such as Art 36 organisations, AF members, and EFSA Stakeholder Forum representatives. Operational documents – i.e. DoI and CIM Decision – are generally better known than the Policy itself, and only a minority of consulted stakeholders appeared to be familiar with the annual reports on independence that are published in annex to EFSA's Annual Activity Report.

EFSA's reputation is checked regularly, e.g. through surveys and media monitoring. The available indicators suggest that, overall, citizens' trust in the EU food safety system (not limited to EFSA) has not improved over time. This would indicate that the reputational effects achieved on target stakeholders did not spread to the ***general public*** (or did so only partly).

Recommendations:

1. EFSA should continue ***engaging proactively*** with EU institutions, sister agencies, MS and stakeholders on independence-related matters. Constructive dialogue should be maintained on all aspects related to the design and implementation of the Policy, to ensure EFSA's efforts are known and understood by all relevant counterparts. Similarly, in the event of 'critical dossiers' (i.e. scientific opinions on controversial matters), EFSA should foster engagement and dialogue with organisations representing public interests and other relevant stakeholders to raise awareness of the measures in place to ensure independence.
2. EFSA could consider actions to ***strengthen awareness*** of and familiarity with the Policy among its target groups. It could also investigate the reasons for the limited familiarity reported by certain target groups, with a view to finding better ways to enhance interest, visibility, and awareness.
3. EFSA could consider conducting focussed research on the ***general public's knowledge and appreciation of its Policy***. This might subsequently lead to designing and implementing specific actions to improve EFSA's reputation (hence, trust) among EU citizens.

- **TRADE-OFFS BETWEEN INDEPENDENCE AND SCIENTIFIC EXCELLENCE OBJECTIVES**

Compared to previous versions, the current Policy involves more stringent rules to reduce CoI risk and this has had seemingly ***mixed effects on EFSA's capacity to attract and involve highly competent experts*** in its

scientific work. On the one hand, the improved reputation described above acted as a 'pull factor'. On the other hand, evidence from consultations indicates that the new restrictions (e.g. cooling-off periods) reduced the pool of experts eligible for membership in EFSA's scientific groups. Since the adoption of the Policy, it has become increasingly difficult for EFSA to involve experts with the required knowledge, especially in domains where innovation is primarily driven by private sector-funded research and investments. This constraint is demonstrated, among other things, by the increasing recourse to Hearing Experts, whose participation is however limited for CoI risk reasons. In exceptional circumstances, EFSA could grant a waiver to allow the participation of experts with competing interests (but not those triggering 'unconditional restrictions') when no suitable alternatives can be identified. This is a rare instance (some 0.2% of total DoI screened in 2022) but demonstrates that the Policy envisages some degree of flexibility when the 'scientific excellence' objective is threatened.

One of the pillars of EFSA's approach is that a concerned individual's interests must be assessed in relation to the ***specific mandate of the scientific group*** in which he/she shall perform his/her activities, and in relation to the task assigned (e.g. chair, vice-chair, ordinary member). The only exceptions are industry employment and financial investment interests that are assessed in relation to the EFSA's entire remit and may lead to an outright ban. According to this principle, an expert might be eligible for one specific Working Group but not for another. This has preserved the capacity of the pool of experts that EFSA can involve to properly staff working groups. On the other hand, this principle is in contrast with remarks repeatedly formulated in the EP Budget Discharge Resolutions that require EFSA to assess all kinds of interests in relation to the overall Authority's remit. In this regard, ENVI 2023 suggested that the inevitable restrictions caused by the EP's recommendation could be mitigated by excluding 'minor CoI' situations. The results of the Study show that there would be widespread support for the idea of differentiating requirements in accordance with CoI risks – enhancing the partial differentiation that already exists, and in accordance with the practices in place in 'sister' EU agencies.

Recommendations:

4. A radical review of the current scope of experts' interest assessment, extending it to the entirety of EFSA's remit would severely affect EFSA's capacity to involve the experts that are necessary to ensure the 'scientific excellence' of its outputs. This point is indirectly recognised in ENVI 2023. If any, EFSA could ***extend 'unconditional restrictions'*** to other categories of interests, if justified and not leading to an excessive restriction of the pool of eligible experts.
5. EFSA could consider exploring the feasibility and the advantages of a more ambitious reform where Policy ***requirements are further differentiated in relation to CoI risk***. In this sense, EFSA could consider and investigate various criteria for categorising and ranking CoI risk. The categorisation could regard the sensitivity of the mandate at stake and/or the role played by the concerned individual in the process. Regarding the sensitivity of the mandate, it is generally acknowledged that some dossiers are more controversial and subject to CoI risks than others, and that current rules were conceived having such dossiers in mind, so they are somehow disproportionate for 'lower risk' dossiers. At the same time, ranking dossiers by sensitivity is not straightforward and might involve economic considerations, so EFSA should carefully consider pros and cons before adopting this solution. Regarding roles, EFSA could explore the possibility of differentiating the Hearing Expert category. Those who do not hold interests subject to 'unconditional restrictions' might be allowed to provide more structured inputs, also in writing and during discussion. For these occasional contributors EFSA may rely on self-declaration of absence of CoI provided that appropriate CoI risk mitigation measured are applied, e.g. they should not take prominent roles within the Working Groups, their inputs should remain limited and subject to peer review and random checks of DoI are carried and dissuasive sanctions are applied in case of inaccurate / incomplete declarations. For Hearing Experts with interests subject to 'unconditional restrictions', the current limitations and restrictions would not change.

- **POLICY COVERAGE AND EFFECTIVENESS**

The ***Policy's coverage and implementation aspects*** appear largely satisfactory and able to deliver the intended results of ensuring impartiality and managing CoI risk in EFSA's scientific work. The target groups involved in the production of risk assessments and scientific outputs are subject to mandatory disclosure of interests through the submission of DoIs. This covers also close family members, albeit in this respect the Policy adopted a narrower definition than the EU Financial Regulation. In a few non-negligible cases, however, target groups are subject to special regimes, namely: (a) MB members are required to submit DoIs, which are screened by EFSA, but the management of CoI is internal to the MB, through a sort of 'self-rule' mechanism; (b) in some cases – network members and AF members – DoIs are collected but not screened, although EFSA could intervene in the case of serious and well-documented cases (presumably arising from 'whistleblowers'); (c) the DoIs submitted by Hearing Experts are not screened, as they are mainly collected for transparency purposes; (d) in the case of pesticide risk assessments, DoIs are required only for the Rapporteur MS' experts who take part in PRM.

EFSA has set up a two-step process for ***DoI screening***, involving an assessment carried out by the competent Scientific Unit and a validation, carried out by the Legal and Assurance service. In addition, EFSA carries out ***ex post 'compliance and veracity checks'*** on a small sample of DoIs. Ex post checks are conducted purely on a documental basis (e.g. comparing a DoI with the expert's CV) with no recourse to external sources or intelligence activities. In this sense, the effectiveness of these checks in detecting undisclosed interests appears questionable. Indeed, statistics indicate that few serious omissions have been found in recent years (six cases in total, in 2018-2022). The Policy also covers processes connected to independence, like measures to prevent and address ***'revolving door' issues*** with senior staff leaving the Authority. Obligations for senior EFSA staff correspond to what is prescribed in the EU Staff Regulations, but implementation criteria have not yet been adopted. In addition, there is an obligation for MB members to inform EFSA of positions taken after the expiration of their term. Conversely, no specific obligation is envisaged for experts, albeit the 'cooling-off' provision can be seen as a proxy for one.

The CIM Decision spells out the criteria applied to determine whether the interest mentioned in the DoI are compatible with the involvement of the concerned individual and in which position. The Policy places substantial ***emphasis on economic interests***, although a variety of other relevant interests are covered. Explicit reference to national interests and/or political pressure is, however, missing. On the one hand, these interests lend themselves poorly to operationalisation in the DoI, but on the other hand various stakeholders perceive a growing risk in this area, connected to the increased outsourcing of EFSA's scientific work to competent organisations in the MS. ENVI 2023 also noted that the Policy does not cover the possible interests (e.g. partnerships and other sources of relevant private sector funding) of experts' academic employers, assuming that such interests can affect experts' independence, even though they do not directly benefit from it. While the existence of such risk cannot be ruled out, feedback from the scientific community indicates that the risk is low and implementing such requirements would be overly burdensome from an administrative point of view, as it would require processing information that – especially for large institutions – is not readily available.

Overall, the debate on the need to further restrict current rules emerges as moderately polarised. EFSA staff and experts – who are more directly concerned by the implementation of independence rules – frequently expressed concerns regarding the hypothetical adoption of further restrictions, such as longer cooling-off periods, stricter rules on private research funding, etc. Conversely, representatives of stakeholder's organisations and – to a lesser extent – of Art 36 organisations appear more open to these options. Overall, the favourable impact described above, and the generally positive feedback collected on the functioning of the system indicate that ***current rules are generally fit for purpose***, although minor adjustments or clarifications would nonetheless be useful.

Recommendations:

6. The Policy could mention more explicitly ***national interests and political pressure*** among the type of interests that can interfere with the independence of scientific work, and – even though objective screening criteria seem poorly applicable – reflect this concern also in implementation documents and tools. This appears particularly important in the context of outsourcing, where there is a need to ensure that Art 36 organisations benefiting from EFSA grants are not influenced by their country's political agenda and other specific national interests. Additionally, EFSA could clarify the concept of 'indirect' interests, which is established in the GFL and adopted in the CIM Decision.
7. The issue known as ***'revolving doors'*** is increasingly a priority in the debate on public service ethics and integrity within the EU and international organisations, as well as in the relevant academic literature. Recently, at the EU level, this matter has been addressed explicitly by the European Ombudsman and the ECA. As discussed above, EFSA applies the 'revolving door' provision established in the Staff Regulations to its employees, but implementation criteria have not yet been elaborated nor published. In addition, EFSA applies an information obligation to MB members, i.e. they must submit updated DoIs for two years after the expiration of their mandate. It is unclear, however, how this obligation is enforced, and which measures EFSA may adopt against non-compliance cases, i.e. if the DoI is not submitted or it is incomplete. EFSA could consider adopting similar measures also for Panel and SC members – i.e. experts who have a rather stable form of collaboration with EFSA.
8. In the case of ***'low risk' target groups*** for which DoIs are collected but not screened, i.e. network members and AF members, the Policy establishes that EFSA may intervene in case of 'serious and well-documented cases'. However, it is unclear how such cases would be brought to EFSA's attention, e.g. through 'whistleblowers', complaints raised by NGOs, monitoring of media and literature, etc. To prevent negative effects on reputation, EFSA should be able to detect and proactively address such cases at an early stage and consider whether current measures – e.g. on 'whistleblowing', NGO engagement etc. – are fit for purpose.
9. EFSA could consider extending DoI requirements to all the ***Rapporteur MS experts*** who take part in the preparation of draft risk assessment for pesticides, and not only those who participate in Peer Review meetings.
10. The 'self-rule' mechanism according to which ***MB members' CoI*** are addressed by the MB itself appears to be in contrast with the general principle of ensuring impartiality and neutrality in decision-making on these matters. Keeping in mind that the actual risk of the MB having undue influence on specific EFSA output is limited, EFSA – and the MB in particular – could consider alternative set-ups, where CoI issues regarding MB members are evaluated and judged by a subject that is external to the MB. Additionally, the change in MB composition introduced by the Transparency Regulation would require some fine-tuning of the DoI template for MB members, to reflect the fact that members are formally representatives of specific national sectoral interests, and such interests are legally compatible with MB membership positions.
11. ***Ex post 'compliance and veracity' checks*** are currently useful for verifying errors and inconsistencies in the internal DoI screening process, but the number of checks and the effectiveness of these controls in detecting 'voluntary omissions' (i.e. interests not disclosed by the concerned individuals, neither in the DoI nor in his/her CV submitted to EFSA) is limited. Therefore, EFSA could consider enhancing the effectiveness of this tool by outsourcing this task to contractors with audit / intelligence capacity, which would be requested to (a) extend checks to internet sources, and (b) increase the number of checks. The contractor would report any possible undisclosed interests found to EFSA, and EFSA could follow up with the concerned individuals for clarification. For privacy reasons, concerned individuals will need to consent explicitly to these checks at the time of their engagement with EFSA. This would per se act as a further deterrent against voluntary non-disclosure of relevant interests.

- **COST-EFFECTIVENESS AND PROPORTIONALITY OF PROCEDURES**

The ***implementation and enforcement of the Policy is fairly resource intensive***, especially for senior EFSA staff. In recent years, the aggregate efforts for independence-related activities grew from 4 full-time equivalent staff (FTE) in 2019 to an estimated 10 FTE in 2022. However, this figure was partly inflated by a malfunctioning of the IT tool for DoI management, which required the temporary recourse to a 'manual' procedure. Since the beginning of 2023, a new IT system is in place, and the projections for 2024-27 indicate an expected effort that would stabilise at 6.5 FTE. The automated DoI system is currently active only for Panels, Scientific Committee and Working Group experts, but EFSA is reportedly considering extending its coverage to other target groups, like staff and Art 36 organisations. While automation can certainly improve DoI-process efficiency, independence-related efforts are set to increase in the future, due to the planned progressive expansion in the volume of EFSA's activity. This might involve more working groups, more experts and more outsourcing, hence a substantial increase in the DoIs to be screened and validated. In this respect, various stakeholders expressed ***concerns on the sustainability of current independence-related processes***. The resources allocated to these tasks already seem to be overstretched and there is a risk that increasing the burden further translate into lower-quality screening and/or cause delays in EFSA's operational timeline.

EFSA does not currently have sufficiently detailed activity-based monitoring to allow quantification of the efforts connected to each step of the independence-assurance process. This hampers in-depth analysis of possible inefficiencies or bottlenecks. Nonetheless, there is broad consensus on the fact that ***DoI screenings absorb a major share of EFSA's resources*** allocated to the Policy implementation. The first reason is the sheer number of screenings that EFSA needs to carry out, which includes several re-assessments – e.g. anytime experts declare new interests or take on a new involvement in an EFSA Working Group. The second reason is that DoI processing can be burdensome. DoI compilation and screening require processing a significant amount of information. In various instances, the assessment requires non-trivial decisions by the responsible officers, so this task is typically performed by Heads of Unit or senior staff. The two-step process entails the possibility that such decisions be overruled at the validation stage or – more frequently – that requests for clarification / justification are issued, thus triggering further interaction within EFSA and between EFSA and the concerned individuals. This can happen especially with new submissions. Conversely, experts with a long history of collaboration with EFSA have apparently learned how to fill in a DoI properly and do not generally consider the process as being too burdensome.

Recommendations:

12. In perspective, EFSA should consider how to ensure the sustainability of the Policy implementation process, in the light of a possible workload increase due to the expansion of EFSA's activities. Over and above specific operational interventions (discussed below), EFSA could consider a paradigm shift toward a more marked ***'risk-driven' approach.*** Without lowering the aggregate effort, EFSA could re-allocate Policy resources taking into account the CoI risk inherent to the specific process, e.g. in relation to the subject matter, the nature of expert involvement, the rationale for DoI submission ('new submissions' vs. re-submissions), etc. In this sense, EFSA's efforts should focus on high-risk situations, while for 'low risk' cases EFSA could rely more on a declarant's assessment. This form of 'subsidiarity' could be accompanied by more thorough controls on a sample of DoIs and dissuasive sanctions in case of inaccurate declarations. Such controls should ideally be carried out at an initial stage of the work, i.e. well before the issuance of the requested scientific opinions. This shift in paradigm would require some additional efforts in the initial stage to establish methods and criteria for ranking processes by risk level and, ideally, to run tests, before full adoption. An ex ante cost analysis would be required to verify whether such costs would be offset by cost savings that EFSA could obtain by discontinuing screenings on 'low risk' processes.
13. In connection to the previous recommendations, EFSA should gather more granular information on the efforts required by each activity and step in the current system, as this would allow for identifying bottlenecks and possible inefficiencies better and for quantifying costs and cost savings of

hypothetical reforms properly. This could be facilitated by a ***more widespread use of IT solutions***, both extending the DoI tool to other declarants (Art 36 organisations etc.) and by applying automated process monitoring to all independence-related activities.

14. There is possibly room to ***reduce the unit cost of screening*** also through a revision of the DoI template and/or of the assessment / validation process. In principle, a simplification can be obtained by segmenting complex discretionary assessments into binary 'on/off' choices. Advantages would include a reduced need to involve senior staff from scientific units and, possibly, fewer cases where the process is stopped for clarifications at the validation stage. At the same time, there are downsides to consider. In particular, CoI is seldom an on/off situation, so a certain degree of discretionary assessment is necessary as a guarantee for experts, to avoid undue exclusions or undue inclusions. This is especially relevant for 'perceived CoI' as mentioned in the Policy. Again, the granular monitoring of costs described in the previous point appears to be necessary for estimating the net benefit of a hypothetical revision of DoI structure ex ante.

- **APPROPRIATENESS OF INDEPENDENCE RULES FOR OUTSOURCING**

In accordance with its expanded mandate and budget, EFSA's strategy envisages a ***strengthening of networking and partnership*** with food safety ecosystem at the national, EU, and international level. This means, inter alia, to scale up co-operation with a variety of entities and institutions via outsourcing. In recent years, the budget allocation for outsourcing – especially grants with Art 36 organisations – has increased substantially, i.e. from EUR 8-9 million / year in 2019, to nearly EUR 35 million in 2022, and is set to increase further. In parallel, the Transparency Regulation encouraged a qualitative change, reiterating that EFSA may outsource to these organisations also critical tasks like the drafting of risk assessments. In other words, in addition to supporting Working Groups, Art 36 organisations will increasingly be assigned the same role as Working Groups. Enhanced involvement of Art 36 organisations appears necessary to respond to EFSA's future workload and stakeholders perceive this more frequently as an opportunity rather than a threat. However, various experts expressed concern regarding the outsourcing of draft risk assessments to Art 36 organisations. A recurrent argument is that the criteria used by MS to designate Art 36 organisations vary greatly across countries, and not all the organisations on the list are considered suitable, from an independence perspective, to carry out such critical tasks.

An increase in outsourcing would also pose ***new challenges for implementation of the Policy***. First of all, it would translate into an increase in the number of DoIs to be screened and of other independence-related activities. In this sense, EFSA has managed to mitigate in part the CoI burden linked to grant agreements by removing the obligation for grant beneficiaries to submit an institutional DoI and the individual DoI from non-key experts (administrative staff, etc.). The second challenge regards specifically assigning draft risk assessments to Art 36 organisations. In this case, the responsibilities of the selected organisations would coincide largely with the responsibilities of a Working Group, even though independence-related requirements are different - e.g. the cooling-off provision does not apply to experts working for the Art 36 organisations. This misalignment implicates that under the current rules draft risk assessments performed by Art 36 organisations are subject, in principle, to higher CoI risk than if performed by Working Groups.

Recommendations:

15. EFSA may consider examining the criteria and the process that leads to the ***designation of Art 36 organisations by MS***. with a view to foster harmonisation across MS. The matter largely falls outside of the scope of the Policy, and would require the involvement of the MB, which is responsible for drawing up the list of Art 36 organisations that are designated by MS. Still, the Policy envisaged putting in place memoranda of understanding with the bodies EFSA cooperates with to specify applicable independence standards. The adoption of such memoranda has turned out to be too onerous due the large number of bodies involved, still the underlying principle indicated the need for

a more uniform adoption and application of EFSA's independence standards by Art 36 organisations. EFSA may seek – in collaboration with MS - alternative, lighter instruments to achieve this harmonisation objective.

16. EFSA should ensure that the independence ***rules applied to experts performing critical tasks such as the drafting of risk assessments are coherent*** for all concerned individuals, regardless of whether the task is performed by a Working Group or outsourced to Art 36 organisations. All applicable provisions, as well as screening criteria, should be harmonised. This may include devising ways to allow grant recipients to involve experts with profiles comparable to that of Hearing Experts who participate in Working Groups. Such involvement must be subject to the same limitations and restrictions imposed to Hearing Expert, including the presence of EFSA staff to meetings where the participation of these experts is foreseen. Out of analogy with Hearing Experts, the grant recipient should collect and forward to EFSA a DoI for these experts, but no screening would be required.
17. To prevent an undue increase of administrative burden and in accordance with a shift toward a risk-driven system described in Recommendation #12, EFSA could adopt a ***lighter approach to outsourcing***. Based on subsidiarity considerations, the responsibility for ensuring the fulfilment of EFSA's independence standards could rest on contractors and grant recipients (excluding those that perform 'critical tasks' as described in the previous recommendation). This might be implemented through declarations of compliance with EFSA's standards having a contractually binding value. In this framework, EFSA may discontinue screening of individual DoIs and adopt, at the same time, more robust ex post check tools and tougher sanctions (see Recommendation #11) as a deterrent against malpractice.
18. The revised system described in Recommendations #16 and #17 could be improved by a ***strengthening of the role of MS authorities*** in assuring the absence of CoI in the competent organisations that work for EFSA. These organisations are already screened at the time of their inclusion in the Art 36 list, but a further layer can be added for individual grant agreements. MS authorities (e.g. via Focal Points) could, for instance, be required to assure grant beneficiary's compliance with EFSA's standard and commit to remove the organisation from the Art 36 list in case major issues emerge after an ex post control.

- **CLARITY AND TRANSPARENCY ASPECTS**

The ***clarity of documents and procedures*** used in implementing EFSA's independence policy elicited mostly positive ratings from users and stakeholders. In particular, the improved guidance for DoIs – i.e. through the provision of specific examples – proved effective in facilitating completion and reducing errors and requests for clarification. EFSA also conducted several awareness-raising and training sessions for experts and DoI assessors. Target groups' needs were satisfactorily addressed, as the demand for further training or guidance initiatives is currently moderately low. The screening criteria applied by EFSA are clear for experts most of the time, although their application led to judgements that sometimes were seen as excessively strict.

Overall, ***some implementation aspects are still not entirely understandable*** by stakeholders, such as the rationale for collecting DoIs from Hearing Experts if no screening is performed, or the criteria for granting a waiver. As emerged from the review of supervisory authorities' reports, more clarity would also be needed regarding the method for calculating the threshold applicable to relevant private research funding managed by experts, and the application of independence rules to Art 36 organisations.

The implementation of independence is communicated transparently through the publication of an annual report in annex to EFSA's Annual Activity Report. Stakeholders are however not very familiar with this output, and the analysis of the document shows that published figures and data are not always immediately understandable by a non-expert audience. For ***transparency*** purpose, EFSA publishes the DoI of various categories of individual involved in its activities, i.e. Panel and Scientific Committee experts, Working Groups

and Peer Review meeting members, MB members, and senior EFSA staff. The DoIs of experts from Art 36 organisations working for EFSA under a grant agreement are, however, not published.

Recommendations:

19. The Policy should explain why ***Hearing Experts' DoIs*** are not screened. EFSA should clarify that the 'Hearing Expert' position is designed primarily for experts whose profile is assumed to be incompatible with close involvement in EFSA work, and therefore screening would be redundant. Still, for transparency purposes it is useful that Hearing Experts' DoIs continue to be published on EFSA's website. Similarly, EFSA may provide additional clarifications on the criteria and the modality for ***granting waivers*** to experts with conflicting interests, to respond to stakeholders' demand for greater transparency. Thirdly, more explanations could be provided regarding the application of ***independence rules to Art 36 organisations*** that – as emerged inter alia from ENVI 2023 – might appear confusing. EFSA should clarify that according to Art 12 of the CIM Decision, Network Members (including Art 36 organisations) are not subject to DoI screening, but when an Art 36 organisation is awarded an EFSA grant, Art 15 of the CIM Decision applies, hence DoIs are screened by EFSA.
20. EFSA should clarify and remove inconsistencies regarding the ***application of the 25% threshold*** to the relevant private funding that experts can benefit from. While the calculation model provided in the CIM Decision clearly indicates that compliance must be verified on the aggregated relevant funding managed by the expert, the DoI requires that whether the threshold is complied with project-by-project be indicated, thus generating confusion on which calculation method has to be adopted. Secondly, EFSA's internal rules envisage that private funding of projects, received by experts in the context of public co-funding schemes (EU, national, regional or local), is not considered a source of CoI. It is, however, unclear how the 'public' nature of such schemes is verified (especially regional and local schemes), and how the private funding is accounted for in the calculation model provided in the CIM Decision. Given that co-funding schemes likely represent a relevant share of research funding, EFSA should provide additional explanations on how this provision is implemented concretely.
21. It is recommended that ***all gathered DoIs***, including those submitted by experts for Art 36 organisations, ***be published transparently*** on the Authority's website. EFSA may also consider publishing its decision (including mitigation measures etc.) regarding former staff who report the intention to engage in occupational activities. Additionally, EFSA may publish the CV of key staff and MB members – in line with the practices adopted in other EU agencies. Conversely, it does not seem useful to publish the CV of experts that – according to ENVI 2023 – would facilitate control by citizens and NGOs. Transparency appears to be guaranteed already by the publication of DoIs, which reflect the criteria established for an effective management of CoI. CVs could include information such as interests dating before the 'cooling-off period', which are not relevant from a CoI-management perspective but might prompt a negative reaction among the general public, which is not aware of EFSA's independence rules.

FRAMEWORK CONTRACT SANTE/2021/OP/0002 CONCERNING THE PROVISION OF SERVICES IN THE AREAS OF EVALUATION, IMPACT ASSESSMENT, MONITORING OF IMPLEMENTATION AND OTHER RELATED SERVICES IN RELATION TO HEALTH AND FOOD POLICIES

Specific Assignment: RC/EFSA/LA/2023/02 - SC01

Ex post evaluation of the Policy on Independence of the European Food Safety Authority adopted by EFSA Management Board on 21/06/2017

FINAL REPORT

Volume 1 – Main Text

submitted by

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ABSTRACT

This study provides an ex post evaluation of the Policy on Independence adopted by EFSA's Management Board in 2017. The study includes a retrospective (2017-2022) and a forward-looking analysis, focusing on key evaluation criteria such as coherence, effectiveness, efficiency, EU added value and relevance. The methodology applied includes consultations (interviews and survey) of experts, organisations and entities collaborating with EFSA, desk analysis of relevant policy and implementation documents, and a comparative review of independence frameworks in place in similar EU and national agencies.

Findings indicate that EFSA has a robust system in place that ensures a satisfactory level of independence and impartiality in its scientific processes and outputs. The Policy is coherent with the objectives and values of EFSA's corporate strategy and the requirements laid down in the legal framework. On the other hand, the expected increase in EFSA's activities might challenge the future sustainability of the current system, which can be improved by re-focusing efforts and procedures in accordance with the specific risk incurred. The study also identified other minor measures to enhance the clarity and the consistency of specific provisions or implementation aspects.

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TABLE OF CONTENTS

ACRONYMS AND ABBREVIATIONS **3**

1. INTRODUCTION **4**

2. OVERVIEW OF EFSA INDEPENDENCE POLICY **5**

2.1 Overall policy framework 5

2.2 EFSA Policy on Independence 7

2.3 EFSA's approach to independence and relevant rules 9

3. METHODOLOGY **16**

3.1 Desk research 16

3.2 Stakeholder consultation 17

3.3 Benchmarking exercise 18

4. EVALUATION FINDINGS **19**

4.1 Coherence 19

4.2 Effectiveness 25

4.3 Efficiency (including proportionality) 39

4.4 EU-added Value (including subsidiarity) 49

4.5 Relevance 51

5. CONCLUSIONS AND RECOMMENDATIONS **62**

ACRONYMS AND ABBREVIATIONS

AAR	Annual Activity Report
ADoI	Annual Declaration of Interest
AF	Advisory Forum
AFSCA	Agence fédérale pour la sécurité de la chaîne alimentaire
ANSES	Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail
AWGI	Assurance Working Group on Independence
CIM	Competing Interest Management
CoI	Conflict of Interest
DG SANTE	Directorate General for Health & Food Safety
DoI	Declaration of Interest
EC	European Commission
EBA	European Bank Authority
ECA	European Court of Auditors
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
ENVI	Committee for Environment, Public Health and Food Safety
EP	European Parliament
EQ	Evaluation Question
EU	European Union
FC	Framework Contract
FP	Focal Point
GFL	General Food Law
IL	Intervention Logic
LA	Legal Affairs Services
MB	Management Board
MS	Member State(s)
NGO	Non-Government Organisation
PoI 2017	Policy on Independence (2017)
PPT	PowerPoint Presentation
PRM	Peer Review Meeting
RfS	Request for Services
SC	Scientific Committee
SOP	Standard Operating Procedure
ToR	Terms of Reference
TR	Transparency Regulation
WG	Working Group
WHO	World Health Organisation
WIN	Work Instruction

1. INTRODUCTION

➢ NATURE AND STRUCTURE OF THE REPORT

The Final Report (the "Report") is the fourth deliverable submitted for the *Ex post evaluation of the Policy on Independence of the European Food Safety Authority adopted by EFSA Management Board on 21/06/2017* (the "Assignment" or the "Study"). The Report is submitted to the European Food Safety Authority (EFSA or the "Client") by a grouping led by Economisti Associati s.r.l. (the "Consultant").

The Report consists of two volumes. ***Volume 1*** includes four more sections beyond this introductory one, as follows:

- ***Section 2*** contains a brief ***overview of EFSA's independence policy*** including the legal and policy framework, the intervention logic, and salient implementation features;
- ***Section 3*** describes the ***methodology*** used in the Study, including caveats and limitations;
- ***Section 4*** addresses the ***evaluation questions*** of the Study, providing detailed responses to all questions;
- ***Section 5*** provides a set of ***conclusions and recommendations*** for the way forward***.***

Volume 2 of the Report contains four Annexes, namely:

- ***Annex I*** – Methodological aspects, i.e. questionnaires, mapping of sources, etc.
- ***Annex II*** – Synopsis Report from stakeholder consultation activities;
- ***Annex III*** - Benchmarking report, with description of independence frameworks adopted by selected comparators;
- ***Annex IV*** – Bibliography.

➢ OVERVIEW OF THE ASSIGNMENT

The ***purpose*** of the Assignment is to conduct an ex post evaluation of the Policy on Independence adopted by EFSA's Management Board in 2017 (the "Policy"),[1] in accordance with the provision laid down in the Policy itself, which requires such evaluation be implemented not later than five years after its entry into force. The Assignment has a two-pronged evaluative dimension:

- ***retrospective dimension***, 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 dimension***, 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 ***scope*** of the analysis includes the Policy document adopted in 2017 as well as the implementation documents and arrangements put in place to address the Policy's principles and objectives. The period covered by the Assignment is 2018-2022, i.e. from the year when the Policy was fully operational.

The Assignment also includes a ***comparative dimension***, which consists in 'benchmarking' EFSA's Policy and arrangements with independence frameworks in place in 'sister' EU agencies and other relevant national bodies.

[1] See: EFSA's policy on independence. How the European Food Safety Authority assures the impartiality of professionals contributing to its operations. https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf

2. OVERVIEW OF EFSA'S INDEPENDENCE POLICY

2.1 Overall policy framework

As spelled out in the ***General Food Law Regulation (GFL)***[2], independence is one of EFSA's fundamental operating principles. Specifically, Article 22(7) establishes that "*the Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it"* (emphasis added). More specifically, Article 37 of the GFL requires that "*the members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest […] the members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence*." To this end, the members of those EFSA bodies must provide annual, written declarations of commitment and declarations of interest (DoI) indicating any direct or indirect interests which might be considered prejudicial to their independence or the absence of any such interest. Similarly, any relevant interest must be declared at any meeting in relation to the items on the agenda.

The ***Transparency Regulation (TR)***[3] adopted in 2019 introduced a series of revisions of the GFL that changed EFSA's scope and organisation set-up significantly. In particular:

- It introduced a 'risk communication' section, with objective principles and a general plan involving new tasks for EFSA concerning public information and communication on food-related risks in the EU.
- It modified the composition of EFSA's Management Board (MB), which is now formed by (i) representatives from each MS; (ii) two members appointed by the Commission; (iii) two members appointed by the EP; (iv) four members representing civil society and food chain interests.[4]
- It provided a set of specific instructions and rules of procedure regarding the selection and appointment of experts who are members of the Scientific Committee (SC) and of Panels (hereinafter 'Experts'). These include, inter alia:
    - (i) The establishment of three fundamental criteria for the selection of Experts, i.e. high level of scientific expertise, independence, and absence of CoI, and multidisciplinary and linguistic competences.
    - (ii) Prohibition for MS and employers of selected Experts to provide any instruction that is incompatible with their assigned tasks or related responsibilities and with EFSA's independence.
    - (iii) The possibility of supporting Experts' activities through preparatory work done by national competent organisations referred to in Article 36 of the GFL ('Art 36 organisations'), which may include the preparation of draft opinions to be peer-reviewed by Panels before adoption.[5]
- It substantially expanded the operational provisions related to submission of scientific studies, in relation to pre-submission advice, notification of studies, third-party consultation and study verification.
- It substantially revised transparency rules, disclosure procedures, personal data protection, confidentiality arrangements and obligations, and access to documents.

[2] 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.
[3] Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain.
[4] Specifically, these four members represent (1) consumer organisations, (2) environmental NGOs, (3) farmer organisations, and (4) industry organisations. These members are appointed by the Council, in consultation with the EP, and based on a list drawn up by the Commission.
[5] Actually, this option was already provided for in Commission Regulation 2230/2004 laying down detailed rules regarding networking, but it was not explicitly mentioned in the GFL, which might explain why it was seldom used in the past.

From a financial perspective, EFSA is also subject to the provisions and rules to prevent and manage conflict of interests (CoI) that are spelled out in the ***Financial Regulation.***[6] The Financial Regulation devotes a specific article to CoI in EU budget implementation (Article 61). According to the definition provided, *"conflict of interests exists where the impartial and objective exercise of the functions of a financial actor or other person, [as defined in the Regulation], is compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other direct or indirect personal interest."*[7] Additional provisions deal with CoI in relation to internal controls on budget implementation (Article 36), award of contracts (Article 167)[8], recruitment of remunerated external experts (Article 237), and others. In 2021, the Commission adopted a ***technical guidance*** document on the avoidance and management of CoI under the Financial Regulation.[9] The purpose of the guidance is to support staff and bodies involved in implementing, monitoring, and controlling the EU Budget and it addresses how to interpret and apply EU rules. With the support of concrete examples, the guidance document explains the CoI definition laid down in the Financial Regulation, examines situations which may be perceived as a CoI and spells out the obligations in such circumstances. The *EFSA Financial Regulation* in force (2019) contains a specific article on conflicts of interest (Art 42) applied to financial management.[10]

According to the Financial Regulation, the European Parliament – upon recommendation of the Council, and verification of annual accounts by an independent, external auditor – provides the discharge for the implementation of EFSA's budget on an annual basis. The resolutions accompanying the Parliament's decision on ***budget discharge*** generally contain various observations and recommendations regarding prevention and management of CoI and transparency. Similarly, specific recommendations on CoI management may be included in the annual report that the ***European Court of Auditors (ECA)*** prepares for each body in the scope of the Financial Regulation, including EFSA.

The prevention and management of CoI is also addressed in ***EU Staff Regulations***[11]***,*** which establish rules that are applicable also to EFSA staff***.*** Article 11 requires that, before recruiting an official, the appointing authority examine whether the candidate has any personal interest which could impair his independence or whether there is any other conflict of interest. To that end, the candidate must inform the appointing authority of any actual or potential conflict of interest. Furthermore, the Regulation establishes that an official should not deal with a matter in which, directly or indirectly, he has any personal interest which could impair his independence. Additionally, Article 16 regulates the conduct of officials after leaving the service and possible breaches of integrity and discretion that might arise. Among other things, the Regulation establishes that: "*In the case of former senior officials […], the appointing authority shall, in principle, prohibit them, during the 12 months after leaving the service, from engaging in lobbying or advocacy vis-à-vis staff of their former institution for their business, clients or employers on matters for which they were responsible during the last three years in the service*".

[6] Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council on the financial rules applicable to the general budget of the Union.

[7] Ibidem, Art 61(3).

[8] Regarding award procedures, different situations should be distinguished: (i) conflicts of interest, falling under the abovementioned Article 61; (ii) attempts to unduly influence an award procedure or obtain confidential information (which should be treated as grave professional misconduct); (iii) involvement in the preparation of documents used in the award procedure; and (iv) professional conflicting interests, which recital 104 of the Financial Regulation describes as follows: "In addition, economic operators might be in a situation where they should not be selected to implement a contract because of a professional conflicting interest. For instance, a company should not evaluate a project in which it has participated, or an auditor should not be in a position to audit accounts it has previously certified." These distinctions are elaborated in greater detail in a guidance document issues by the Commission in 2021, i.e.: Commission Notice, Guidance on the avoidance and management of conflicts of interest under the Financial Regulation (2021/C 121/01).

[9] Commission Notice, Guidance on the avoidance and management of conflicts of interest under the Financial Regulation (2021/C 121/01).

[10] See: EFSA Financial Regulation, 2019. https://www.efsa.europa.eu/sites/default/files/2021-12/finregulation-019.pdf

[11] Regulation No 31 (EEC), 11 (EAEC), laying down the Staff Regulations of Officials and the Conditions of Employment of Other Servants of the European Economic Community and the European Atomic Energy Community.

Finally, CoI-related matters in EU institutions and bodies fall in the remit of the ***European Ombudsman***. In addition to addressing specific complaints, its mandate includes proactive examination and reporting of broader systemic issues in the EU. In this sense, the Ombudsman's orientations emerging from specific cases and broader analysis are relevant to the debate on the independence policy of EU agencies like EFSA, as also confirmed by the references to specific Ombudsman's decisions and recommendations that can be found in the above-mentioned EP budget discharges and ECA opinions.

2.2 EFSA's Policy on Independence

➢ EFSA'S POLICY AND IMPLEMENTATION DOCUMENTS

The independence policy currently in place in EFSA (the "Policy") is based on the document adopted by the Management Board in June 2017 entitled *EFSA's Policy on Independence - How the European Food Safety Authority assures the impartiality of professionals contributing to its operations.* [12] The 2017 ***EFSA's Policy on Independence (PoI)*** replaced the preceding policy document that had been in place since 2011.[13] Previously, EFSA had no comprehensive policy in place[14], but rather had procedural documents aimed at implementing the DoI requirement laid down in Art 37 GFL, e.g. the 2007 *Guidance Document on Declarations of Interests*.[15]

At the executive level, the main act adopted by EFSA to implement the Policy is 2018's ***Decision of the Executive Director on Competing Interest Management*** ('CIM Decision')[16], which replaced the analogous 2014 *Decision on Declarations of Interest*.[17] Specific provisions on independence-related matters can also be found in other executive acts that relate to specific EFSA bodies or activities, such as:

- the *Code of Conduct of the Management Board* (2022),[18] and the *Rules of Procedure of the Management Board* (2022)[19] which devote specific articles to Management Board (MB) members' independence;
- the *Declaration of Intent of the EFSA Advisory Forum* (2019),[20] which establishes the principles governing the impartiality of risk assessment in the areas of food, feed, plant health and animal health & welfare;
- the *Decision of the Executive Director concerning Pesticides Risk Assessment Peer Review* (2015)[21], which sets inter alia the independence rules for experts and observers participating in Peer Review Meetings (PRM) (Article 8);
- the MB Implementing Rule *laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups* (2022),[22] which makes explicit reference to experts' independence in Article 37;
- the MB Decision concerning the *establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission*,[23] extending CIM Decision rules to network participants;
- the *Guidelines on Gifts and Hospitality* (2015), establishing – in accordance with the Staff Regulations (Art

[12] See: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/policy_independence.pdf
[13] Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority of 15 December 2011. See: https://www.efsa.europa.eu/sites/default/files/efsa_rep/blobserver_assets/independencepolicy.pdf
[14] While DoI requirements exist since the founding of EFSA, a specific legal reference to the 'independence policy' was introduced by the TR (Art 28.5a), which states that scientific experts should comply with various criteria including: "*independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementation of that policy in respect of the members of the Scientific Panels*" (emphasis added).
[15] See: https://www.efsa.europa.eu/sites/default/files/event/2007/mb070911-ax9.pdf
[16] EFSA (European Food Safety Authority), 2018. EFSA rules on competing interest management.
[17] Decision of the Executive Director of the European Food Safety Authority on Declarations of Interest, 2014
[18] See: https://www.efsa.europa.eu/en/corporate-pubs/code-conduct-efsa-management-board
[19] See: https://www.efsa.europa.eu/sites/default/files/assets/mbrules.pdf
[20] See: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/190703_independence_AF_decl_of_intent.pdf
[21] See: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/eddecisionppr.pdf
[22] See: https://www.efsa.europa.eu/sites/default/files/paneloperation.pdf
[23] See: https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/networksoperation.pdf

11(2)) – the rules of conduct for EFSA staff regarding favours, gifts, or payment from sources outside of the Agency.

At a more operational level, the various processes associated with the submission, screening and validation of DoIs are established in the ***Standard Operating Procedure (SOP) on Management of Competing Interests***.[24] Other SOPs may contain references to independence-related aspects, such as: (1) *Establishing, updating and closing a scientific Working Group*; (2) *Selection, evaluation and appointment of External Experts for the Scientific Committee and Scientific Panels*; (3) *Managing scientific meetings*; (4) *Recruitment and Selection of statutory staff.*[25] Further procedural aspects are established in ad hoc Work Instructions (WIN) for internal use. Cases in point are the WIN on Competing Interest Management (adopted in 2018), the WIN on Competing Interest Management for EFSA staff members (adopted in June 2023)[26], and the WIN on compliance and veracity checks (last update in June 2023).

Finally, it is worth underlining that 'independence' also figures among the Authority's overarching values, which are spelled out in ***EFSA Strategy 2027.***[27] As such, independence informs all EFSA activities and, at a more specific level, it is presented in the Strategy as functional to achieving one of the primary expected outcomes of the Strategy, namely: "*Increased relevance and improved reputation of EFSA's scientific advice*".

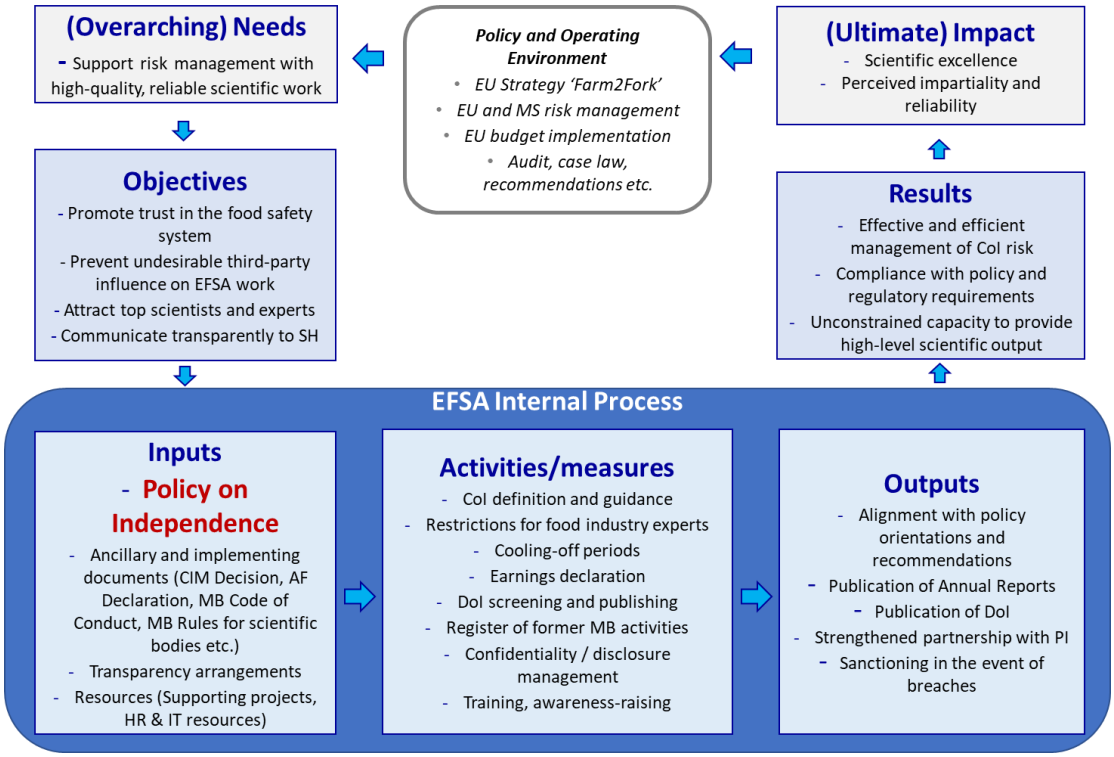
- **INTERVENTION LOGIC ANALYSIS**

Figure 2.1 below provides the Consultant's reconstruction of the intervention logic (IL) underpinning the Policy. In the proposed IL framework, the ***'Input'*** is represented by the Policy and related implementing documents (e.g. CIM Decision). According to the proposed reconstruction, these inputs are meant to address a few specific ***objectives***, namely: to promote trust in the food safety system, to prevent undesirable third-party influence on EFSA work while preserving EFSA's capacity to attract top scientists and experts, and to communicate transparently with stakeholders. At a more general level, these objectives address the ***overarching need*** to support policymakers' risk management activities through the provision of high-quality and dependable scientific work. Such needs are set in the overall EU policy.

The Policy, along with related 'inputs', encompasses definitions, rules, procedures and supporting measures – '***activities'*** in IL terminology – associated with the delivery of specific ***'outputs'***, such as Policy implementation reports, DoI publication, sanctions for breaches of trust, etc. (see Section 2.3 for a detailed review).[28] The intended ***results*** of the inputs and outputs constituting EFSA's internal process are defined in relation to the initial objectives, and consist in ensuring effective and efficient CoI management and compliance with regulatory requirements while leaving EFSA's scientific capacity unaffected. The ***ultimate impacts*** of the intervention concern EFSA's reputation for impartiality and scientific excellence in the production of risk assessments and other outputs, which in turn informs risk management decisions at MS and EU levels as well as EU policy at large.

[24] SOP_039_A - Management of Competing Interests.
[25] i.e. SOP_006_S, SOP_002_S, SOP_005_S, SOP_043_A.
[26] This WIN covers also candidates for EFSA staff members vacant positions and trainees proposed as co-authors of EFSA scientific outputs.
[27] https://www.efsa.europa.eu/sites/default/files/2021-07/efsa-strategy-2027.pdf
[28] In this specific framework, the IL standard concepts of 'activities' and 'outputs' are strictly connected, and the distinction may appear blurred.

Figure 2.1 – Reconstruction of the Intervention Logic



Source: *Author's elaboration*

2.3 EFSA's approach to independence and relevant rules

➢ **GENERAL CONCEPTS AND PILLARS**

As discussed in the previous section, EFSA addresses the theme of independence in various documents, but overarching principles and strategic pillars are governed by its 2017 Policy on Independence (PoI 2017). PoI 2017 elaborates the concept of independence in the context of EFSA's corporate values and broader EU public service principles and rules. The initial section of PoI 2017 clarifies that the concept of independence covers various aspects including legal independence, financial independence, regulatory autonomy, personal independence, and the perception thereof. The ***definition of CoI*** provided in PoI 2017 is: "*any situation where an individual has an interest that may compromise or be reasonably perceived to compromise his or her capacity to act independently and in the public interest in relation to the subject of the work performed at EFSA*".[29] This definition is largely in line with generally accepted academic definitions[30] and definitions adopted at national[31] and international levels.[32] It is interesting to note that an emphasis on the 'perception' of CoI is present also in other agencies' definitions of CoI, e.g. ECHA and ECDC, as well as ANSES.

[29] Source: EFSA Policy on Independence, 2017.

[30] For instance: "*A conflict of interest is a set of conditions in which professional judgment concerning a primary interest (….) tends to be unduly influenced by a secondary interest (such as financial gain*)"; Thompson, D. (1993). 'Understanding Financial Conflicts of Interest', The New England Journal of Medicine, 329 (8), 573–576.

[31] For instance the OECD definition, which is widely accepted internationally: "*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*" (OECD 2005: 13). Managing Conflicts of Interest: A Toolkit. Paris: OECD.

[32] For instance, in French Law (Art 2, *loi du 11 octobre 2013 relative à la transparence de la vie publique*), CoI is defined as *« toute situation d'interférence entre un intérêt public et des intérêts publics ou privés qui est de nature à influencer ou paraître influencer l'exercice indépendant, impartial et objectif d'une fonction ».* Interestingly, the French definition includes the concept of 'perceived CoI' that also characterises EFSA's definition.

The stated purpose of the Policy is to ensure the ***impartiality***[33] of individuals participating in EFSA's scientific operations and activities, by preventing CoI and other ethics and integrity issues. To this end, a mandatory ***self-disclosure***[34] mechanism is in place, as stated in PoI 2017: "*the Authority requires all concerned actors to declare all interests held (…) falling under EFSA's remit*".[35] To this end, PoI 2017 proposes a ***risk-based approach*** that rests on four pillars, namely:

1. outright incompatibility between membership in EFSA Panels, SC or Working Groups and ***employment*** and/or ***financial investments*** with business actors (including NGOs and lobbying organisations) directly or indirectly impacted by EFSA's operations;[36]
2. enforcement of a two-year ***'cooling-off' period*** for experts with previous involvement with entities pursuing private or commercial interests (e.g. a managerial role, consultancy, or memberships in scientific advisory bodies) before they are allowed to become members of EFSA's scientific groups working on overlapping matters;
3. ***cooperation with national or international authorities, universities and research institutions*** aimed at involving scientific experts from these bodies, but subject to compliance with EFSA's independence rules and in absence of parallel risk management functions and/or performance of activities other than in public interest in the same areas pertaining to the mandate of the concerned EFSA scientific groups.
4. Establishment of a ***25% ceiling on the relevant research funding from private entities*** (i.e. the budget which funds research activities carried out in areas which pertain to the mandate of the concerned EFSA scientific groups), which is deemed acceptable from a CoI perspective.

As PoI 2017 underlines, ***transparency*** is a fundamental component for communicating independence and impartiality.[37] In this sense, the Policy includes EFSA's commitment to publishing the annual Declaration of Interest (ADoI) of all relevant experts and staff and to prepare and publish information on its independence-related control activities in *EFSA Consolidated Annual Activity Report* (AAR). ***Compliance*** with PoI 2017 is considered a shared responsibility between (1) the concerned individuals, who commit to providing a complete and truthful DoI, and (2) EFSA, which screens and validates DoI, takes the necessary measures to prevent and manage CoI, and ensures the enforcement of the Policy, including applying sanctions for omissions.

[33] For a comparative analysis of the concept of 'impartiality' in academic literature, see: (1) Rothstein, B. & Teorell, J. 2008. What Is Quality of Government? A Theory of Impartial Government Institutions. Governance: An International Journal of Policy, Administration, and Institutions, Vol. 21, No. 2, April 2008 (pp. 165–190); and (2) Hooley, I. (2023), Impartiality: A critical Review. Journal of the National Institute for Career Education and Counselling, April 2023, Issue 50. In particular, Hooley 2023 identifies three pillars for the operationalisation of the concept of impartiality / independence: (i) definition (including institutional independence, neutrality of outcome and neutrality from politics); (ii) outcomes (including autonomy and 'best outcome' assurance) and (iii) other related concepts like transparency, trustworthiness and freedom of speech.

[34] There is a rich debate on 'disclosure' policies in the relevant literature. For an overview of different positions see: (i) support to 'full disclosure' - Wiersma M, Kerridge I, Lipworth W. Dangers of neglecting non-financial conflicts of interest in health and medicine. J Med Ethics. 2018 May;44(5):319-322. doi: 10.1136/medethics-2017-104530. Epub 2017 Nov 24. PMID: 29175967; (ii) criticism towards disclosure - Ben-Shahar, O./Schneider, C., 2014, More than you wanted to Know, Princeton University Press; (iii) criticism towards reporting non-financial interests - Bero LA, Grundy Q (2016) Why Having a (Nonfinancial) Interest Is Not a Conflict of Interest. PLoS Biol 14(12): e2001221. doi:10.1371/journal. pbio.2001221. Regarding disclosure practices, an operational review is provided in Rossi, I. 2017. Getting the Full Picture on Public Officials, A how-to guide for effective disclosure, the World Bank / UNODC, Washington D.C.

[35] As discussed in Annex III - disclosure of interests by concerned individuals is the fundamental principle underpinning all EU and MS agencies considered for comparison purposes. However, exceptions exist. For instance, it is reported that in some circumstances partial disclosure of confidential interests is allowed. In the case of interests relating to the obligation of professional or contractual secrecy held in a former position dealing with specific clients, it is only allowed to declare employment with a certain organisation, but not information on specific clients.

[36] Financial and employment-related interests often trigger automatic exclusion within other agencies, too. Nonetheless, ECHA has established a EUR 10,000 threshold for financial interests in a commercial entity within the agency's field (partly in contrast with European Ombudsman advice in a similar situation). As opposed to EFSA, a threshold for financial interest in a commercial entity was deemed appropriate in order to cover the broad scope of chemicals, which are employed in a wide range of industries (see EA 2021).

[37] The concept of transparency applied to public service and governance processes is developed, inter alia, in: (1) Bianchi, A. & Peters, A. 2013.Transparency in International Law. Cambridge University Press, 2013; and (2) Hood, C. & Heald, D. 2006. Transparency: The Key to Better Governance?, Oxford: Oxford University Press.

The general principles and pillars laid down in PoI 2017 are ***articulated in detail in the CIM Decision***. Specifically, the CIM Decision establishes the definitions, general requirements, specific rules applicable to different concerned individuals and entities, rule implementation and enforcement, and other common rules regarding, e.g. training, transparency, protection of personal data, etc. The CIM Decision also envisages the establishment of an internal Advisory Working Group on independence-related matters.

➢ OVERVIEW OF RULES AND PROCEDURES

The highly articulated rules and procedures adopted by EFSA to implement and enforce the Policy are summarised in Table 2.1 below, with a special focus on implementing mechanisms and other relevant features that are subject to evaluation in the following sections of this report.

Table 2.1 – Salient features of EFSA's independence policy and implementation measures

Scope of interests	• The scope of the Policy is stated in PoI 2017 and detailed in the DoI that concerned individuals have to submit. The relevant interests to be declared cover nine areas: i. ***Financial investments*** (economic stake or share in an entity with an interest directly or indirectly falling within EFSA's remit, field activity of the organisation on which the investment is made, influence over it) ii. ***Managerial role*** (participation, paid or unpaid, in the internal decision-making process of an entity with an interest falling within EFSA's remit) iii. ***Member of a scientific advisory entity*** iv. ***Employment*** (any form of regular occupation or business, and how it relates to the EFSA's remit and/or of the relevant EFSA's scientific groups) v. ***Occasional consultancy*** vi. ***Research funding*** (grants, rents, reimbursement of expenses, sponsorship, and fellowship; whether funding exceeds 25% of the total relevant research budget managed for the area under concern, including funding received by the employing organisation) vii. ***Intellectual property rights*** (topic covered by the granted right, role - e.g. patent holder, contributor, etc. - and how the IPR relates to the remit of the relevant EFSA scientific group). viii. ***Other membership and affiliation*** (professional associations, learned society, NGOs, etc.) ix. ***Other relevant interest*** • The declarant must also indicate overlapping interests held by '***close family members***'.[38] • The interests to be declared are those currently held or held in the ***past five years*** (exact period must be indicated in the DoI).
Target groups	• The subjects addressed by the Policy (i.e. who must submit DoIs) include: a) ***Experts*** – i.e. members of EFSA's Panels, SC and Working Groups, Peer Reviewers (including appointed by MS), and candidates to these positions[39]; b) ***Hearing Experts***;[40] c) ***Network members*** – i.e. members of EFSA's networks of scientific organisations operating in the fields within the Authority's remit;

[38] "Close Family Member" is defined as: (i) a spouse, meant as the person engaged in the marital relationship with the concerned individual; (ii) a partner with whom a concerned individual has contracted a registered partnership, on the basis of the legislation of the relevant legal system; (iii) the direct descendants and ascendants who are financially dependent on the concerned individual.

[39] As discussed, the members of Working Groups who are not also members of Panels or the Scientific Committee, and the Peer Review meeting members are designated as 'external experts' in the GFL. For simplicity, in this Report the term 'Experts' is used in a broad sense and also includes external experts.

[40] As established in the Implementing Rule of the MB on the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups (2o22), Hearing experts are "*individuals invited by EFSA who are in the possession of specific information, data, expertise or knowledge considered instrumental to achieving the desired level of accuracy and completeness of the relevant scientific output". (…) "Hearing experts shall not draft scientific outputs, participate in the deliberations, vote, chair the meetings or be a rapporteur."*

	d) ***Management Board members***; e) ***Advisory Forum members***; f) ***Focal Points,*** i.e. a network of national bodies acting as connecting hubs between EFSA and their relevant national scientific actors; g) Participants to ***procurement and grant awarding*** procedures concerning EFSA's scientific activities. • ***EFSA staff***, including the Executive Director, are also subject to the DoI obligation in accordance with the Staff Regulations (EFSA staff is not covered in the CIM Decision). • The CIM Decision establishes that the DoIs collected from (b) are ***not screened***. In the case of (c) and (e) screenings are also not performed but EFSA may follow up on CoI cases that are brought to its attention, submitting the issue to the attention of the MB. In the case of ***observers***[41], no DoI is required. • ***Contractors*** falling under (f) are required to submit an institutional DoI in addition to individual DoIs for all proposed team members. A similar provision applied to ***competent organisations (Art 36)*** upon the awarding of an EFSA grant, but it has reportedly been lifted, and grantees currently need to submit only individual DoIs for team members, with the exclusion of non-scientific staff involved (e.g. administrative staff).
DoI completion and submission	• DoIs are submitted prior to recruitment / involvement in EFSA activities and renewed on a yearly basis through the submission of an ***Annual DoI*** (ADoI). An ADoI needs to be revised and resubmitted: o anytime a ***new interest emerges*** or an ***already declared interest changes*** during the period of validity of the ADoI (the revision must be completed within 45 days); o anytime the concerned individual takes on a ***new involvement*** with EFSA (e.g. membership in a new Working Group). • Concerned individuals must also declare orally at the beginning of each meeting any relevant interest not previously declared. Based on ***Oral DoIs*** (ODoI), concerned individuals may be excluded from the meeting or to the discussion of specific points in the agenda. ODoIs are recorded in meeting minutes. • Experts may complete and submit their DoIs through a web interface, i.e., the ***DoI Tool***. It is planned to extend the use of the DoI Tool to EFSA staff and members of governance bodies within a few months. Arrangements to extend the DoI Tool also to contractors and grantees are under discussion.[42] • The DoI template requires the provision of ***detailed information in narrative form*** for each interest declared. No recourse to yes/no questions is made. To this end, the template contains instructions and – as of recently – also ***practical examples*** to guide declarants to correct completion. In case of missing or unclear information, EFSA may ask the declarant to provide integration / clarifications before proceeding with validation of the DoI.
Screening criteria	• A general screening principle requires distinguishing interests, as follows: o ***Unconditional restrictions*** – i.e. outright ban for any involvement in EFSA's scientific activity that arises from incompatible interests, namely 'financial investments in an entity with a direct or indirect interest falling within EFSA's remit' and 'industry employment' (in entities – including lobbying organisations – directly or indirectly concerned with EFSA's scientific output). o ***Qualified restrictions*** – i.e. restrictions that need to be assessed on a case-by-case basis, as arising from interests that may be compatible with the task assigned (all other types of interests except the above). • With the exception of interests subject to 'unconditional restrictions', PoI 2017 establishes that interests must be assessed in relation to the ***matters discussed in the relevant EFSA group(s)*** where the concerned individual is serving or is expected to serve. In other words, while the DoI covers all interests that fall within EFSA's overall remit, a CoI may arise only in relation to interests that are specifically overlapping with the mandate of the scientific group

[41] EFSA may invite observers to attend the meetings of the Scientific Committee, the Scientific Panels, and the Working Groups. Observers shall not in any way participate or intervene in the discussions, drafting, voting or in other activities carried out in the meetings they attend.

[42] For about 1.5 years the DoI Tool was unavailable due to a severe IT system failure. During that period, the automated submission was replaced by a manual procedure. This reportedly created a bottleneck that was partly overcome through an extension of validity of ADoI.

	of involvement. In this sense, the same DoI might be screened as many times – and with different outcomes – as the number of areas in which the concerned individual is involved. • For the screening of interests, it is of fundamental importance to classify entities that benefit from the concerned individual's activities as ***Public Institutions (PI***) or ***non-Public Institutions (non-PI).*** Activities performed with PIs as part of public interest duties are deemed compatible with involvement in EFSA work, whereas for other activities a ***cooling-off period of two years*** applies (i.e. incompatibility persists for two years after the end of the activity). The cooling-off period is extended to five years for experts holding a Chair or Vice-chair position, in the case of industry employment or financial investment interests. • Experts shall also not participate in scientific work involving the ***review of his/her own work***. • The DoI template requires that the declarant specifies whether he/she collaborates with organisations that carry out risk management activities, and whether he/she is entitled to perform ***risk management*** functions. In such a case, incompatibility extends also to activities performed with PIs as part of public interest duties. • Less strict criteria[43] are applied to ***Peer Reviewers*** with ongoing employment in a PI (typically the *Rapporteur MS*, responsible for drafting risk assessments in the area of pesticides). • PoI 2017 states that "*more stringent rules and procedures are applied to areas **where CoIs with commercial interests are likely to occur**. The same applies in cases where multiple items are discussed in the same forum*" (emphasis added). This point is not explicitly developed in the CIM Decision, even though the underlying principle informs various implementing rules (e.g. unconditional restrictions in case of employment in food/feed industry, etc.).

Screening implementation and controls	• The ***screening procedure*** involves two steps: (1) assessment and (2) validation.
	  ○ The ***assessment*** is carried out by the relevant EFSA Scientific Unit (i.e. responsible for the Panel, Working Group, etc. at stake), and implies a judgement on whether each declared interest constitutes a CoI, and which role the concerned individual is eligible for. The CIM Decision provides detailed guidance on the application of screening criteria. In the case of Experts, such ***criteria differ slightly*** between the role of 'Chair / Vice-chair' of a scientific group and the role of 'Member'. Where the declarant is deemed not eligible for any of these positions, he/she may still be involved as ***Hearing Expert***.
	  ○ The ***validation*** is centralised and under the responsibility of the Legal Affairs Services (LA). The validation process consists in a review of the assessment, which may lead to confirmation, attribution of different roles, requests for clarification / additional information or overruling of the assessment conclusion.
	• Organisations mentioned in the DoIs are ***classified as PIs*** if they (a) are included in the Art 36 List, (b) are public legal entities according to the Commission's ABAC identifier, or (c) meet three cumulative criteria, i.e. carry out tasks related to EFSA's remit, pursue public interest objectives, and receive more than 50% of their budget from public entities. The LA systematically assesses and classifies new organisations and, where relevant, changes the classification of previously scrutinised organisations. The full list of PIs is published on EFSA's website.
	• In exceptional circumstances, EFSA may grant a ***waiver*** to members of Working Groups and PRM to allow their participation despite the identification of a CoI. The procedure is adopted when the contribution from the Expert is deemed essential (and the Hearing Expert role appears insufficient) and no suitable alternative could be found. The Expert cannot take the role of Chair, Vice-Chair or Rapporteur. Waivers are issued by the Executive Director.
	• The CIM Decision also provides guidance regarding the assessment of interests declared in the context of ***procurement*** (contractors) and ***grant awarding procedures*** (Art 36 organisations). While the interest categories are the same as those used for experts, the eligibility criteria applied are less strict. In particular no 'cooling-off' periods are applied to experts recruited through outsourcing.

[43] As stated in Article 7(12) of the CIM Decision, such derogations may regard: past activities classified as employment, managerial roles, scientific advisory roles, consultancy with, or Research Funding exceeding 25% from, non-PIs. The derogation does not apply if the declarant holds interests related to dossiers submitted by legal or natural persons with whom they, or their Close Family Members: a. were employed; b. held managerial or scientific advisory positions or; c. to whom they tendered advice, in the two years prior to DoI submission.

	• Differentiated screening procedures apply to ***ODoI submitted prior to meetings***, which may lead to allowing or not the participation of the declarant in the meeting. Typically, the decision is taken at the meeting, and does not involve the two steps described above, except in some circumstances where a substantial risk of CoI is perceived. • The validation of ***DoIs submitted by MB members*** follows a partly different procedure. EFSA's assessment (which is carried out by the Executive Director) is submitted to the MB which, in case of identified CoI, may require a follow-up action from the concerned member, or in some circumstances may lead to a request for the replacement of the MB member. The MB is also responsible for taking action in case of identified CoI affecting AF members, including asking the relevant MS to replace the concerned individual. • Art 22 of the CIM Decision provides for the establishment of an internal advisory committee responsible for reviewing and advising on assurance- and independence-related matters. The ***Assurance Working Group on Independence*** (AWGI) has been created for this purpose.
Ex post controls and sanction regime	• Twice a year, EFSA conducts '***compliance and veracity checks***' on a sample of DoIs submitted by experts, contractors, and grant beneficiaries.[44] The exercise is coordinated by the LA. The compliance check aims at verifying the conformity of DoIs, while the veracity check verifies any relevant omission or misrepresentation. According to the CIM Decision, EFSA may require concerned individuals to provide an income declaration and/or other supporting documents to check the veracity of the information provided. In practice[45], checks are primarily made comparing the DoI with the declarant's CV and only in case of discrepancies is further information sought. • The omission of information that would have resulted in a CoI constitutes a ***breach of rules***. The severity of the breach is assessed against a set of established criteria[46], and it is sanctioned accordingly with measures ranging from a reprimand letter to suspension from participation in EFSA activities (from 6 to 12 months) or, in the most severe cases, dismissal from the relevant body or scientific group, possibly combined with a 1- to 10-year ban from EFSA's activities.
'Revolving door' provisions	• The CIM Decision includes a provision that requires ***MB members*** to inform EFSA of any professional engagement overlapping with EFSA's mission or tasks for two years after the expiration of their mandate. For transparency, EFSA maintains a 'register of activities' undertaken by former MB members (in the form of updated DoIs). • The Policy does not directly address 'revolving door' issue for ***EFSA employees*** as the matter is regulated in the Staff Regulations. Based on the Staff Regulations, EFSA staff have to inform the Authority, if they plan to take up a job within two years after leaving the service, and EFSA has the right to forbid the person from taking the job if it finds that it would conflict with EFSA's interests. Additionally, EFSA can prohibit former senior officials from lobbying the Authority's staff during the 12 months after leaving the service. • ***Experts and other target groups*** of the independence policy are not subject to specific provisions.
Transparency and communication	• PoI 2017 envisages transversal transparency and communication activities aimed at "*building and maintaining trust in EFSA's independence policy and any actions the authority takes to enforce it.*" These includes, *inter alia*: ○ The ***publication of DoIs*** submitted by Experts, MB and AF members and the senior staff of the EFSA Management Team. Other staff's DoIs and DoIs submitted in the context of outsourcing activities, as well as CVs, are instead not published.[47]

[44] For each reporting period, the sample consists of 15 DoIs from experts and 15 from contractors / grant beneficiaries. Ex post checks were temporarily suspended during the COVID19 pandemic. Since June 2023, ex post checks have been extended to a sample of EFSA staff member's DoIs.

[45] EFSA Work Instruction - Compliance and veracity checks according to Article 19 of the ED Decision on Competing Interest Management

[46] i.e. wilful conduct vs. negligence, importance of the interest, financial impact of the interest, role of the concerned individual in the scientific group, timing of the omission.

[47] As clarified in the CIM Decision (Art 25), the legal basis for processing DoI data differs. Specifically, the GFL provisions do not cover entities taking part in outsourcing activities. Declaration obligations for these entities are instead governed by the financial rules applicable to the general EU budget which, however, do not establish a transparency requirement.

	○ Publication of the ***list of PIs***. PoI 2017 also envisages the establishment and publication of memoranda of understanding (MoU) with PIs, but this component was not implemented due to the very high number of entities involved.[48] ○ ***Training*** for relevant EFSA staff and Experts. ○ Other ***engagement*** activities to raise awareness and explain to interested parties how EFSA manages and addresses CoI-related matters. ○ Publication of information on independence-related activities in annex to ***EFSA Consolidated Annual Activity Report*** (AAR). • The Annual Report on the Implementation of EFSA's Policy on Independence provides information and data in various areas covered in the Policy. In particular: ○ Number of ***DoIs screened and CoIs prevented***. ○ Number of ***'waivers'*** granted. ○ Outcome ***of ex post controls*** and remedial actions taken. ○ Activities undertaken by ***former EFSA staff***. ○ ***Staff and financial resources*** allocated to independence-related processes.

[48] The most recent list of PIs includes 762 bodies, while Article 36 organisations amount to 320.

3. METHODOLOGY

3.1 Desk research

The main focus of desk research was EFSA's Independence Policy (including implementation and operational documents) and the overall legal and policy framework (i.e. relevant legislation, caselaw, reports from supervisory authorities, etc.). Additionally, desk research encompassed a variety of other secondary sources, as summarised in Table 3.1 below. The Study's bibliography is provided in Annex IV.

Among other things, particular attention was paid to the study on EFSA's independence and transparency commissioned by the ENVI Committee of the European Parliament and published in April 2023 ('ENVI 2023').[49] ENVI 2023 is based on a desk analysis of EFSA documents and formulates a set of recommendations for future improvement of EFSA's Policy on Independence.

Table 3.1 – Scope of desk review

Desk research components	Type of documents
A. EFSA policy and operating documents	• Independence Policy (including legacy versions) • CIM Decision and relevant SOP and implementing rules • Annual implementation reports • Previous evaluation reports (Deloitte 2017[50], EA 2021[51]) • DoI template, IT tool, guidance, and instructions • Implementation data (time input and resources allocated) • EFSA Reputation Barometers (2017 and 2020)
B. Overall EU legal framework	• General Food Law • Transparency Regulation • EU Staff Regulations • Financial Regulation • Regulation on Plant Protection Products[52] • Commission Regulation on EFSA networking[53]
C. EU Supervisory Institutions Reports and Case Law	• EP budget discharge Resolutions • European Ombudsman decisions and recommendations • ECA reports • CJEU rulings and opinions • EP-commissioned studies and reports (i.e. ENVI 2023, PETI 2020[54])
D. Independence Policies from other agencies selected for the 'benchmarking exercise'	• Policy and implementation documents • EP Budgetary Discharge reports • External evaluations and reviews (i.e. ENVI 2023, PETI 2020, EA 2021)
E. Scientific literature and miscellaneous sources	• Academic papers and publications on the subject matter • Policy and guidelines of international bodies (e.g. OECD) • Stakeholders' position papers and publications

[49] Ellen VOS, Annalisa VOLPATO, Guido BELLENGHI, Independence and transparency policies of the European Food Safety Authority (EFSA), study requested by the European Parliament's Committee on Environment, Public Health and Food Safety (ENVI), April 2023.
[50] Deloitte Belgium, "Ex post Evaluation of the Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority (EFSA) and of its Implementing Rules on Declaration of Interest", March 2017.
[51] Economisti Associati, "Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management", April 2021.
[52] REGULATION (EC) No 1107/2009 OF THE EUROPEAN PARLIAMENT AND OF THE COUNCIL of 21 October 2009 concerning the placing of plant protection products on the market and repealing Council Directives 79/117/EEC and 91/414/EEC.
[53] 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 Authority's mission.
[54] PETI committee of the EP, "EU Agencies and Conflict of Interest", January 2020.

3.2 Stakeholder consultation

The second major source of information for the Study consists of direct consultation of EFSA's stakeholders. The term 'stakeholder' is used here in a broad sense and also includes EFSA staff and Management Board members. The categories addressed by consultation activities are as follows[55]:

- ***EFSA staff*** - framed in scientific units, and/or in other services dealing with implementation of the Independence Policy);
- ***Management Board (MB) members*** – including MS, EU Institutions, and stakeholder organisations' representatives;
- ***Advisory Forum (AF) members*** - i.e. representatives of national food safety authorities;
- ***Focal Points (FP)*** - often representatives of the same body of affiliation of AF members, and of Art. 36 organisations;
- ***Experts*** - including members of EFSA Scientific Panels and the SC, as well as the experts involved in Working Groups (WG) who are not members of Panels or the SC[56];
- ***Art 36 organisation representatives*** – i.e. Competent Organisations designated by MS and included in the 'Art 36 List', which are eligible to receive grants;
- ***EFSA Stakeholder Forum's and Stakeholder Bureau's*** registered members.

The various categories of stakeholders considered by the Study have different knowledge and experience of the Policy, so the consultation tools were designed to capture all different perspectives and placed special emphasis on 'key informants', i.e. stakeholders who are directly concerned with the Policy and who have directly witnessed the transition from the legacy system to the system put in place by PoI 2017. Specifically, two consultation tools were used:

1) **In-depth interviews.** Overall, 37 interviews were carried out with a variety of stakeholders, as reported in Table 3.2. The interviews were semi-structured, i.e. based on checklists of discussion topics prepared in advance by the Consultant and tailored to the profile and the actual experience of interviewees.
2) **Targeted survey.** In addition to interviews, primary information has been collected from stakeholders through an online survey. The aim of the survey was to reach out to a larger number of stakeholders and substantiate interview findings with more structured, quantitative feedback, especially regarding EFSA's reputation as an independent, transparent organisation, as well as on the relevance and impact of the system in place. Overall, 256 valid, complete responses were received, as detailed in Table 3.2 below.

[55] In agreement with EFSA, Scientific Network members were not included in the survey, even though these entities are often also in the Art 36 organisations list, so some survey participants are also Scientific Network members.

[56] In EFSA's terminology, 'expert' applies to members of Scientific Panels and the Scientific Committee, while 'external expert' designates Working Group members who are not members of Scientific Panels nor the Scientific Committee nor Peer Review meeting members (see: Regulation (EC) No 178/2002, and EFSA's *Implementing rules laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Group*). For simplicity, in this Study, all experts surveyed – including Scientific Panels and Scientific Committees members as well as other Working Group members are collectively referred to as 'Experts'.

Table 3.2 – Participants in stakeholder consultations

A) In-depth Interviews

	No. of interviews
EFSA staff	12
MB members (incl. MS, EU Institutions and interested parties)	10
Scientific partners – AF/FP, Experts and Art 36 org.	7
EFSA Stakeholder Forum and Bureau	3
Benchmarking interviews (EU and MS agencies)	5
TOTAL	**37**

B) Targeted Survey

	Unique respondents by subgroup*	Response rate**
EFSA staff	14	29%
MB Members	19	26%
AF / FP	35	31%
Experts	91	17%
Art 36 organisations	84	3%
EFSA Stakeholder Forum and Bureau	13	5%
TOTAL	**256**	**7%**

Note: *(*) Some survey respondents were involved in EFSA with multiple roles, such as Expert and representative of an Art 36 organisation, etc. For a straightforward analysis, respondents with multiple roles (26 in total) have been classified based on the 'main' role, i.e. membership of a statutory body (MB, AF) – where relevant – or involvement as a WG expert. (**) The response rate is calculated on the number of entities addressed for each category (3,742 in total).*

3.3 Benchmarking exercise

The benchmarking exercise consisted in a ***comparative analysis*** of independence policy and independence relevant measures in force in organisations that are similar to EFSA in terms of mandate (risk assessment), and modus operandi (i.e. substantial reliance on external scientific expertise). In agreement with EFSA, five comparators were selected for the benchmarking, of which three are EU 'sister' agencies and two are national food safety authorities:

1. ***European Centre for Disease Prevention and Control (ECDC),***
2. ***European Chemicals Agency (ECHA),***
3. ***European Medicines Agency (EMA),***
4. ***Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail (ANSES, France),***
5. ***Agence fédérale pour la sécurité de la chaîne alimentaire (AFSCA, Belgium).***

The benchmarking exercise was primarily based on ***desk research***, covering comparators' independence policy documents, relevant documents issued by EU institutions and authorities, and previous comparative analysis[57]. Desk research was complemented by ***in-depth interviews*** with relevant staff of the selected agencies.

Based on the information collected, the Consultant prepared individual fiches for each comparator (see Annex III). The information was then used to make comparisons with EFSA and draw the lessons and indications for the way forward that are included in the evaluation findings.

[57] In particular, comparison with ECHA's and EMA's policy frameworks can be found inter alia in ENVI 2023, PETI 2020, and EA 2021.

4. EVALUATION FINDINGS

This Section reports the findings from the evaluation of EFSA Policy, providing articulated responses to the Evaluation Questions (EQ) of the Assignment. The EQ are structured in accordance with the ***five standard evaluation criteria*** established in the *Better Regulation* framework, namely: coherence, effectiveness, efficiency, EU added value, and relevance.[58] Sometimes, EQs cover more than one criterion but, to avoid unnecessary repetitions or fragmentations, they have been classified and addressed under the criterion that appeared to be most pertinent. In most cases, the response to an EQ is articulated in various sub-sections, as it involved the analysis of different perspectives and the formulation of separate evaluative judgments.

In addition to EQs, the Assignment involves three other research questions regarding proportionality and subsidiarity principles. These questions regarded aspects that are pertinent to the 'efficiency' and 'EU value added' criteria, therefore they have been included in the corresponding sections.

4.1 Coherence

EQ - Does the Policy address the independence provisions enshrined in the relevant applicable legislation (e.g.: General Food Law, EU Staff Regulations, EU Financial Regulation, etc.)?

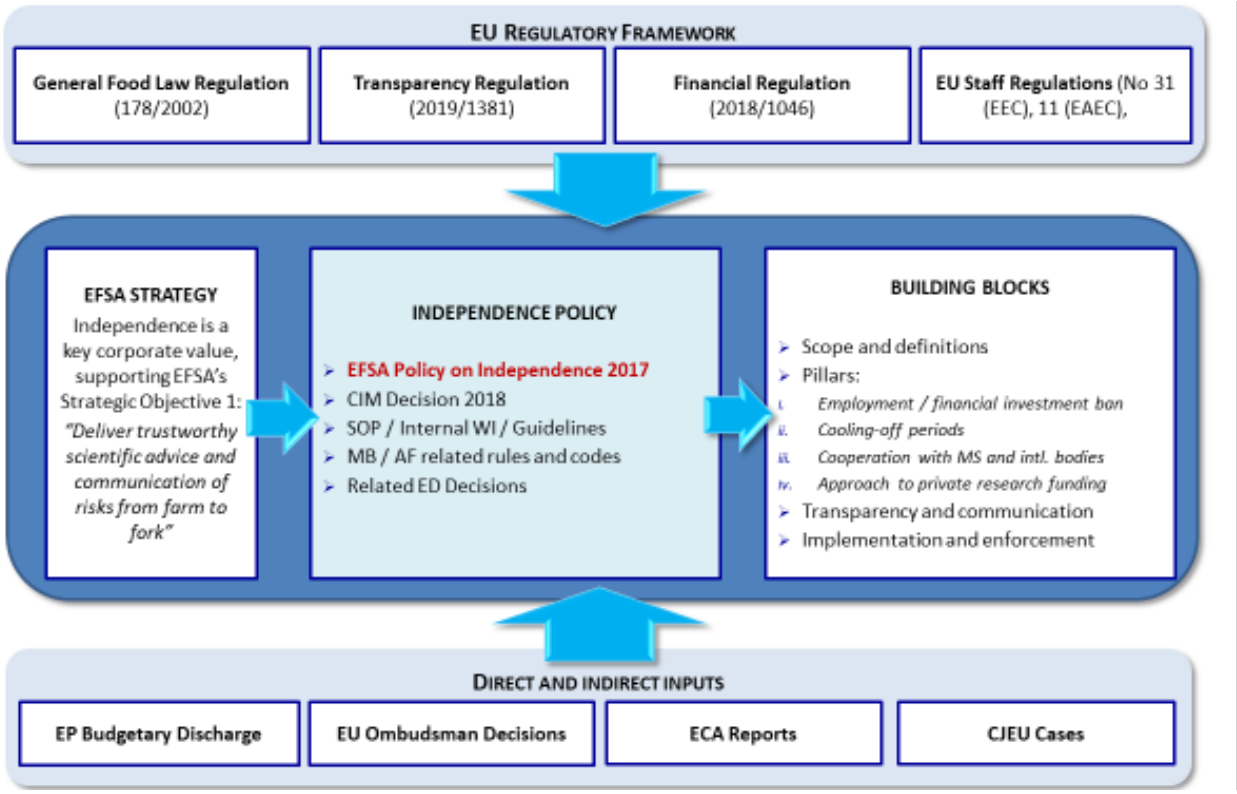
- **OVERVIEW**

As discussed in Section 2.3, independence-related provisions are laid down in a set of EU Regulations which constitute the Policy's legal framework of reference. In particular, relevant provisions can be found in the General Food Law (as amended by the Transparency Regulation), the EU Staff Regulations, and the EU Financial Regulation. So, the first evaluative dimension to be investigated is whether the Policy satisfactorily addresses the requirements of the applicable legal framework and how. In this Section, the analysis focuses on 'coherence', i.e. whether the Policy is aligned formally with the relevant articles of EU legal texts concerned, while considerations on achievement of objectives etc. are discussed in Section 4.2. Also, possible revisions required by recent changes in the legal framework (especially, after the introduction of the Transparency Regulation) are not discussed here, but in Section 4.5.

It should be noted that the EU legal framework is not the only source of inputs for EFSA's Policy. More specific indications and recommendations can be found in a variety of other sources, such as the EP Budget Discharge Resolutions, the European Ombudsman's Decisions, the European Court of Auditor's Report, the EU Court of Justice's case-law etc. (see Figure 4.1 below). The alignment with these inputs is covered by a specific EQ and is discussed in Section 4.5.

[58] Source: Better Regulation Guidelines, SWD(2021) 305 final.

Figure 4.1 – The overall legal and policy framework of EFSA's Policy on Independence



Source: *Author's elaboration*

- **COHERENCE WITH THE RELEVANT APPLICABLE LEGISLATION**

Table 4.1 below examines in detail the coherence of the Policy with the relevant EU regulatory framework. The analysis of coherence is made primarily with the overall Policy – i.e. the text of PoI 2017. However, regardless of concrete implementation aspects, reference to CIM Decision and other implementation documents is made, where relevant. For each piece of regulation, all relevant articles are analysed separately.

Table 4.1 – Policy's coherence with EU legislation

1) General Food Law Regulation (178/2002)
Article 22(7): "The Authority shall carry out its tasks in conditions which enable it to serve as a point of reference by virtue of its independence, the scientific and technical quality of the opinions it issues and the information it disseminates, the transparency of its procedures and methods of operation, and its diligence in performing the tasks assigned to it."
Coherence of the Policy. This provision is included in the general Article of EFSA's 'mission'. It establishes 'independence' as one of the Authority's core values. The general aim of the Policy is aligned with this provision as it states, inter alia, that the Policy "*focuses on the Authority's ability to ensure that professionals contributing to the work of EFSA perform their tasks in an impartial manner, without favour or discrimination. […] these individuals are devoid of conflicts of interests harmful to the Authority's work".*
Article 37: "1. The members of the Management Board, the members of the Advisory Forum and the Executive Director shall undertake to act independently in the public interest. For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing. 2. The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence. For this purpose, they shall make a declaration of commitment and a declaration of interests indicating either the absence of any interests which might be considered prejudicial to their independence or any direct or indirect

interests which might be considered prejudicial to their independence. Those declarations shall be made annually in writing. 3. The members of the Management Board, the Executive Director, the members of the Advisory Forum, the members of the Scientific Committee and the Scientific Panels, as well as external experts participating in their working groups shall declare at each meeting any interests which might be considered prejudicial to their independence in relation to the items on the agenda."
Coherence of the Policy. This is the fundamental GFL article on independence, which is in place since the Authority's establishment. The various provisions of this article are explicitly addressed in the Policy: (i) while a definition of 'independence' is not offered, the emphasis on public interest is explicitly echoed in the Policy's definition of CoI: "*any situation where an individual has an interest that may compromise or be reasonably perceived as compromising his or her capacity to act independently and in the public interest in relation to the subject of the work performed at EFSA*". The latter part of the definition offers a restricted interpretation, which has been repeatedly addressed in EP Budgetary Discharge Resolutions (see Section 4.5). (ii) The target groups mentioned in Art 37 are covered in the Policy. Actually, the scope is extended to all "*persons having an impact on the Authority's operations*", including EFSA employees, all WG members and participants to PRM, and entities involved in outsourced activities. (iii) Art 37 establishes the mechanisms of DoIs, which are taken up in the Policy – both annual, written declarations (ADoI) and pre-meeting oral declarations (ODoI). The GFL establishes only the obligation for concerned individuals to submit declarations, while screening approach and screening methods are added in the Policy. (iv) Art 37 requires "*any direct or indirect interests*" be declared, but it does not specify what 'indirect interests' consist of. The Policy elaborates a list of relevant interests to be declared, but a clear distinction between 'direct' and 'indirect' is not elaborated (although it is frequently referred to in the CIM Decision).
Article 28(5a) and (5c): "[…] (c) the selection procedure and the appointments of the members of the Scientific Committee who are not members of the Scientific Panels, and the members of the Scientific Panels shall be made on the basis of the following criteria: (i) a high level of scientific expertise; (ii) independence and absence of conflict of interests in accordance with Article 37(2) and the Authority's independence policy and implementation of that policy in respect of the members of the Scientific Panels; (iii) meeting the needs for the specific multi-disciplinary expertise of the Scientific Panel to which they will be appointed and the applicable language regime. […] The Management Board shall adopt, on the basis of a proposal of the Executive Director, rules on the detailed organisation and timing of the procedures set up in paragraph 5a […]".
Coherence of the Policy. This article regards the Scientific Committee and Scientific Panels and was introduced by the TR. It is the only GFL article that explicitly mentions the Authority's independence policy, implying that the existence of such Policy is required by (hence coherent with) the GFL. As required in paragraph 5c, the "Implementing rule of the Management Board"[59] establishes a set of rules and procedures for the recruitment, appointment and management of experts participating in EFSA Panels, Scientific Committee and Working Groups, including the obligation for such experts to comply with the Policy and the requirements to "*not represent the opinion of a Member State, of their employers or of any other organisation*".
Article 28(5d): "Member States and employers of the members of the Scientific Committee and of the Scientific Panels shall refrain from giving those members, or the external experts participating in the working groups of the Scientific Committee or the Scientific Panels, any instruction which is incompatible with the individual tasks of those members and experts, or with the tasks, responsibilities and independence of the Authority."
Coherence of the Policy. This article regards the Scientific Committee and Scientific Panels and was introduced by the TR. It aims at reinforcing the independence of members of the Scientific Committee and of the Scientific Panels (but not of other WG or PRM members) by establishing a non-interference obligation on MS and expert's employers. Leaving aside any considerations on the 'enforceability' of this provision, it is worth noting that this dimension is not mentioned in the Policy, possibly because at the time of Policy adoption, this article was not yet in place. The Policy contains only a point partly related to this requirement, that is the obligation for MS and international organisations to ensure the independence of experts who represent their views in EFSA's network or networking meetings (i.e. Focal Points), but this does not include Panels and other WG members, and no reference to an obligation of expert's employers can be found in the Policy.

[59] The latest version was adopted in October 2022. *Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups.*

Article 28(5e): "The Authority shall support the tasks of the Scientific Committee and Scientific Panels by organising their work, in particular the preparatory work to be undertaken by the Authority's staff or by designated national scientific organisations referred to in Article 36, including by organising the possibility for preparing scientific opinions to be peer-reviewed by the Scientific Panels before they adopt them."
Coherence of the Policy. This article concerns independence only in an indirect way. It was introduced by the TR and reiterates at the GFL level a point which was already established in the Commission Regulation on EFSA networking, i.e. the possibility to entrust the drafting of EFSA scientific opinions to Art 36 organisations.[60] This provision would substantially equate the responsibilities of an Art 36 organisation to those of a WG, despite the fact that these organisations are not explicitly included in the independence-related articles of GFL. They are instead covered in the abovementioned Commission Regulation, which includes 'independence' among the criteria for designation of these organisations and demands EFSA to define applicable independence rules in relation to the tasks assigned. The Policy rules are coherent with this framework in that ad hoc rules for independence for Art 36 organisations have been developed. However, possible uncertainties remain about whether differentiated rules for entities performing (in principle similar) tasks are in line with the spirit of general Article 22.7 GFL.
Article 38(1): "The Authority shall carry out its activities with a high level of transparency. It shall in particular make public: […] (d) the annual declarations of interest made by the members of the Management Board, the Executive Director and the members of the Advisory Forum, the Scientific Committee and the Scientific Panels, as well as the members of the working groups, and the declarations of interest made in relation to items on the agendas of meetings;"
Coherence of the Policy. This article was introduced by the TR and regards the transparency of DoI, thus is relevant for coherence assessment. The Policy explicitly addresses this point (Section 4 of PoI 2017). However, while formal coherence with legal text is assured, the lack of publication of DoIs from other concerned individuals performing critical tasks in EFSA scientific work – i.e. experts from Art 36 organisations – seems in contrast with the general principles.
Article 25(1) and (1b): "Each Member State shall nominate a member and an alternate member as its representatives to the Management Board. […] the Management Board shall include: […] four members and four alternate members with the right to vote as representatives of civil society and food chain interests, namely one member and one alternate member from consumer organisations, one member and one alternate member from environmental non- governmental organisations, one member and one alternate member from farmer organisations, and one member and one alternate member from industry organisations".
Coherence of the Policy. This is an article introduced by the TR that reformed the composition of the MB. It is not strictly related to independence, but it seems noteworthy that Art 37 GFL prescribes for MB members the absence of any interests "*which might be considered prejudicial to their independence*", while at the same time MB members are representing the interests of their MS or of a specific stakeholder group, including economic operators. The Policy was adopted before the TR, i.e. under the previous board's composition and applies to MB members the same DoI applied to scientific experts, thus propagating the above contradiction at the implementation level. This matter is discussed specifically in Section 4.5.
2) Financial Regulation (2018/1046)
Recital 104. "It is appropriate that different cases usually referred to as situations of conflict of interests be identified and treated distinctly. The notion of a 'conflict of interests' should be solely used for cases where a person or entity with responsibilities for budget implementation, audit or control, or an official or an agent of a Union institution or national authorities at any level, is in such a situation. Attempts to unduly influence an award procedure or obtain confidential information should be treated as grave professional misconduct which can lead to the rejection from the award procedure and/or exclusion from Union funds. In addition, economic operators might be in a situation where they should not be selected to implement a contract because of a professional conflicting interest. For instance, a company should not evaluate a project in which it has participated, or an auditor should not be in a position to audit accounts it has previously certified."
Coherence of the Policy. In the preamble to the Financial Regulation it is clarified that the notion of CoI applies only to certain categories of subject with responsibility in EU budget implementation, audit, control etc. This is different from the use of the term 'CoI' in the Policy, which refers to a broader set of individuals involved in EFSA scientific activities. To some extent, the notion of CoI used in the Policy seems more coherent with the notion of 'professional conflicting interest' laid down in the Financial Regulation. As the Guidance adopted by the

[60] See Art 4 of Commission Regulation (EC) No 2230/2004: *"The tasks which may be entrusted to the organisations on the list, either to one organisation or to several working together, are those which consist in: […] preparing the Authority's scientific opinions, including preparatory work relating to the assessment of authorisation dossiers."*

Commission in 2021 explains[61], 'professional conflicting interest' encompasses a variety of situations where a CoI may negatively affect the performance of an economic operator recruited for a specific assignment. In this sense, this can be the case of Experts or Art 36 organisations that EFSA involves in the production of scientific opinions. The Policy is coherent with the Guidelines as concerns: (1) the Guidelines' requirement for conducting ex ante assessment of applicants' CoI; and (2) the need to refer to objective criteria and factual elements for CoI assessment, to ensure non-discrimination, equal treatment, and transparency.

Article 61 - Conflict of interests. "1. Financial actors within the meaning of Chapter 4 of this Title and other persons, including national authorities at any level, involved in budget implementation under direct, indirect and shared management, including acts preparatory thereto, audit or control, shall not take any action which can bring their own interests into conflict with those of the Union. They shall also take appropriate measures to prevent a conflict of interests from arising in the functions under their responsibility and to address situations which can objectively be perceived as a conflict of interests. […]

3. For the purposes of paragraph 1, a conflict of interests exists where the impartial and objective exercise of the functions of a financial actor or other person, as referred to in paragraph 1, is compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other direct or indirect personal interest."

Coherence of the Policy. As discussed in the previous point, the notion of 'CoI' in the Financial Regulation refers to EU budget implementation while the CoI discussed in the Policy has a different scope, more similar to what the Financial Regulation defines as 'professional conflicting interest'. In this sense, there is no 'incoherence' in the fact that the Policy defines CoI differently (see Section 2.1). In practice, some 'compromising factors' listed in the Financial Regulation's definition are explicitly covered in EFSA's Policy implementation, i.e. (i) the Policy devotes particular attention to economic / commercial interests; (ii) the coverage of 'partners or dependent family members'.[62] On the other hand, the Policy does not explicitly mention anything similar to 'political or national affinity', albeit this is included in the broad notion of 'any situation' laid down in the Policy's CoI definition. Secondly - as discussed previously, in relation to Art 37 GFL – the interpretation of 'indirect personal interest' remains unclear, and the Policy does not address this explicitly.

3) Staff Regulations (31 EEC, 11 EAEC)

Article 11. "An official shall carry out his duties and conduct himself solely with the interests of the Union in mind. He shall neither seek nor take instructions from any government, authority, organisation or person outside his institution. He shall carry out the duties assigned to him objectively, impartially and in keeping with his duty of loyalty to the Union.

An official shall not without the permission of the appointing authority accept from any government or from any other source outside the institution to which he belongs any honour, decoration, favour, gift or payment of any kind whatever, except for services rendered either before his appointment or during special leave for military or other national service and in respect of such service.

Before recruiting an official, the appointing authority shall examine whether the candidate has any personal interest such as to impair his independence or any other conflict of interest. To that end, the candidate, using a specific form, shall inform the appointing authority of any actual or potential conflict of interest. In such cases, the appointing authority shall take this into account in a duly reasoned opinion. If necessary, the appointing authority shall take the measures referred to in Article 11a(2). This Article shall apply by analogy to officials returning from leave on personal grounds."

Coherence of the Policy. The first article of EU Staff Regulations on 'rights and obligations' establishes the general framework for EU officials' independence, including the obligation to declare and screen candidates' interests. This article is explicitly quoted in PoI 2017, i.e. "*EFSA employees, including the Executive Director, are subject to CoI checks prior to receiving a job offer under Article 11 of the Staff Regulations and to Annual Declaration of Interests (ADoI) and screening requirements*". The direct reference ensures coherence of the Policy with the regulatory

[61] European Commission, Guidance on the avoidance and management of conflicts of interest under the Financial Regulation (2021/C 121/01)

[62] However, the Financial Regulation's definition seems to have a larger coverage than the Policy. The Regulation mentioned both family and emotional life, suggesting that independence may be compromised also by relations outside of formal family ties. Conversely, according to CIM Decision, CoI rules apply to 'close family members' defined as: (1) spouse; (2) formally registered partners (according to the relevant legal system); (3) direct descendants and ascendants who are financially dependent.

framework. Regarding policy implementation, it should be noted that EFSA staff is not covered in the CIM Decision. Procedures and operational aspects are set out, inter alia, in ad hoc SOP[63] and internal WIN.[64]

Article 11a. "1. An official shall not, in the performance of his duties and save as hereinafter provided, deal with a matter in which, directly or indirectly, he has any personal interest such as to impair his independence, and, in particular, family and financial interests. […]"

Coherence of the Policy. This aspect is not explicitly mentioned at general Policy level, but is specifically addressed at the operational level, namely under Step 10 "Ordinary mitigating measures and extraordinary measures" of the abovementioned WIN addressing Competing Interest Management among EFSA staff.

Article 12b. "1. Subject to Article 15, an official wishing to engage in an outside activity, whether paid or unpaid, or to carry out any assignment outside the Union, shall first obtain the permission of the Appointing Authority. Permission shall be refused only if the activity or assignment in question is such as to interfere with the performance of the official's duties or is incompatible with the interests of the institution. […]"

Coherence of the Policy. This article of the Staff Regulations is also directly and explicitly addressed in PoI 2017, which states that "[*EFSA employees] are required to obtain preliminary clearance from all 'outside activities' during their time at EFSA".* On the other hand, there appears to be no (published) operational documents detailing how this is implemented in practice.

Article 16. "An official shall, after leaving the service, continue to be bound by the duty to behave with integrity and discretion as regards the acceptance of certain appointments or benefits.

Officials intending to engage in an occupational activity, whether gainful or not, within two years of leaving the service shall inform their institution thereof using a specific form. If that activity is related to the work carried out by the official during the last three years of service and could lead to a conflict with the legitimate interests of the institution, the appointing authority may, having regard to the interests of the service, either forbid him from undertaking it or give its approval, subject to any conditions it thinks fit. The appointing authority shall, after consulting the Joint Committee, notify its decision within 30 working days of being so informed. If no such notification has been made by the end of that period, this shall be deemed to constitute implicit acceptance.

In the case of former senior officials as defined in implementing measures, the appointing authority shall, in principle, prohibit them, during the 12 months after leaving the service, from engaging in lobbying or advocacy vis-à-vis staff of their former institution for their business, clients or employers on matters for which they were responsible during the last three years in the service.

In compliance with Regulation (EC) No 45/2001 of the European Parliament and of the Council, each institution shall publish annually information on the implementation of the third paragraph, including a list of the cases assessed."

Coherence of the Policy. Article 16 deals with the issue conventionally referred to as a 'revolving door' (see Section 2.1). Coherence with the Policy is ensured by a cross reference to this article (footnote 11 of PoI 2017) and the explicit requirement for EFSA staff to obtain preliminary clearance for *"all gainful activities in which they intend to engage for two years after their employment with EFSA ceases."* Also in this case, internal implementation criteria and modalities are not publicly disclosed but, reportedly, EFSA plans to do it soon.
The Policy extends similar obligations to MB members, also establishing a register of the activities undertaken by former MB members for two years after their term of office has ended. This is concretely implemented via the publication on EFSA's website of former members' DoIs. However, unlike former employees, former MB members do not have to disclose any activity, but only professional engagement overlapping with EFSA's mission or tasks and – most importantly – they do not need to obtain clearance from EFSA before engaging in such activities (i.e. there is only an obligation to inform).

EQ - Does the Policy address EFSA's independence value, as in the Strategy 2027?

Independence is one of the Authority's five overarching values. As spelled out in ***EFSA Strategy 2027,***[65] independence consists of the following pillars: (1) impartiality of scientific outputs; (2) absence of CoI among staff and experts; (3) bias-free data and methodologies; and (4) group decision-making and review among peers. The Strategy makes explicit reference to PoI 2017, thus ensuring formal coherence. However, PoI 2017

[63] Standard Operating Procedure on the Recruitment and Selection of statutory staff.
[64] WIN/SOP039/04, EFSA WIN on Competing Interest Management for candidates for EFSA staff members vacant positions, EFSA staff members and trainees proposed as co-authors of EFSA scientific outputs.
[65] https://www.efsa.europa.eu/sites/default/files/2021-07/efsa-strategy-2027.pdf

focuses primarily on impartiality and absence of CoI (the first and second pillars mentioned above), while methodologies and processes are governed by other EFSA policies and procedures.

Independence is also functional to achieving one of the primary expected outcomes indicated in the Strategy, namely: "Expected Outcome 1.1 - Increased relevance and improved reputation of EFSA's scientific advice". In this respect, the Strategy prescribes that both assessment for regulated products and generic scientific advice is delivered with quality and efficiency and "*in accordance with the principles of independence and transparency* […]".[66] The Strategy does not articulate this concept further, so the analysis of coherence remains limited to the general level.

4.2 Effectiveness

EQ - To what extent has the Policy contributed to EFSA's reputation in independence?

- **PERCEIVED INDEPENDENCE OF EFSA OVER TIME**

EFSA's reputation regarding independence from external influence has ***improved substantially over time***. In the past, EFSA suffered from relatively frequent and severe criticism for inadequate conflict of interest management, as emerges from the commentaries accompanying the EP budgetary discharge, ECA reports, as well as the publications of various environmental and public health NGOs, to name some examples. The existence of a structural issue of public trust – fuelled inter alia by specific cases that became popular in the media (especially in the fields of GMOs, pesticides, sweeteners, and contaminants) – has been largely confirmed by experts and staff members with decades-long work experience with the Authority. In that period, which for some interviewees corresponds approximately to 2010-2017, repeated CoI allegations affected EFSA's reputation in the eye of the scientific community and general public alike.

All evidence indicates that EFSA's reputation has changed significantly since then and largely ***in connection with adoption of PoI 2017.*** In many respects, the policy itself was motivated by the abovementioned reputational cases and, in this sense, intended to redress the Authority's deteriorated image. In recent years, the independence remarks that were repeatedly raised in past EP budgetary discharges have substantially thinned out, and various EU-level reports released over the past five years expressed an overall appreciation of efforts made by EFSA in this field. This is the case for instance of the REFIT Evaluation on GFL (2018), which affirmed that "*EFSA has one of the most advanced and robust systems ensuring its independence*."[67] More recently, ENVI 2023 stated that "*overall, EFSA's independence policy is assessed positively*".[68]

The results of consultation largely confirmed the perception of substantial improvements in the area of independence. Experts and senior staff with many years of experience with EFSA affirm that, compared to the past, independence issues have nearly disappeared, so the matter is no longer at the top of the agenda. Similarly, a vast majority of survey respondents registered a ***moderate or substantial improvement in EFSA's capacity to ensure independence*** in its scientific work, especially when compared to 10 years ago (89% of respondents who could provide an assessment), but also in the short time span of two years (71%). Scientific experts and EFSA staff are among the most satisfied regarding long-term improvements, while MB members expressed the most positive views on short-time changes.

Improvements were registered also by EFSA's ***Reputation Barometer*** surveys. Between the first edition (2017) and the second edition (2020), the aggregate reputation score for 'independence and objectivity'

[66] Expected Operational Results #1.1.1 and #1.1.2.
[67] SWD(2018) 37 final
[68] ENVI 2023, *ibid.*

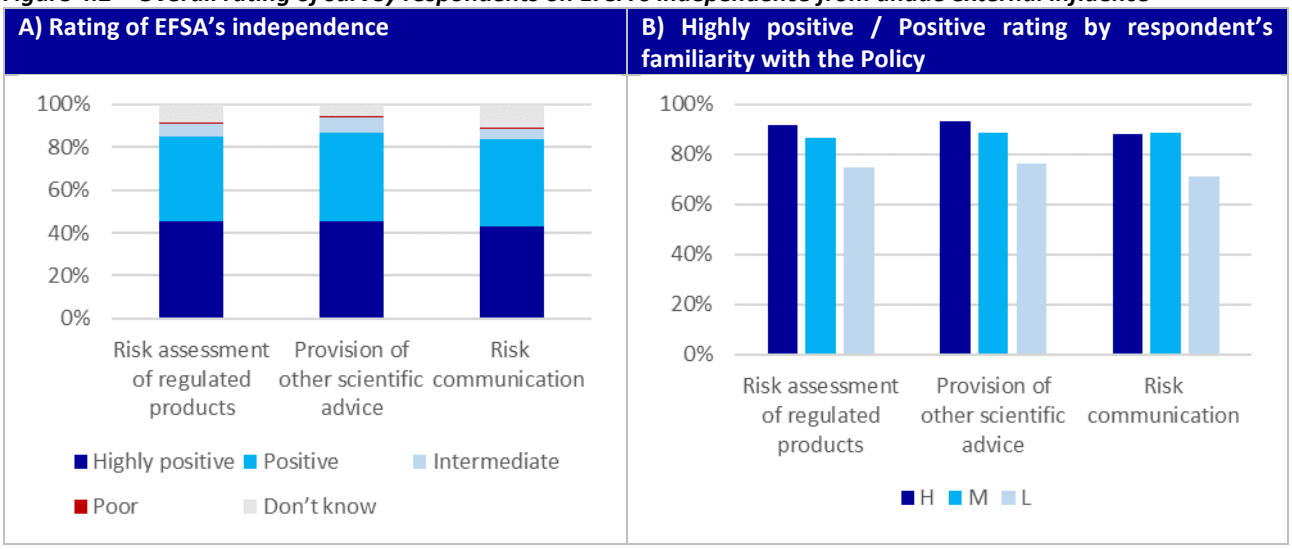
increased from 47 to 50.[69] The Annual Strategy Survey conducted in 2022[70] gave a lower score for independence (46), however the methodology is not comparable to the previous exercises. The reported percentage of favourable feedback on EFSA's ability to foster independence is 82%. The food safety ***Eurobarometer*** surveys of EU citizens that are periodically carried out do not address specifically EFSA independence but includes a general question testing citizens' agreement with the '*independence of scientific advice on food risks from commercial or political interests*'. The formulation of the question has changed across editions, so no direct comparison is possible, still feedback suggests that EU citizens' confidence has not changed substantially over time. Specifically:

- In 2010, 10% of respondents agreed with the statement, and 37% 'tended to agree'. On the other hand, 12% disagreed and 29% 'tended to disagree'.
- In 2019, only 21% expressed agreement with the sentence. Disagreements were not recorded.

➢ **CURRENT EFSA REPUTATION ON INDEPENDENCE**

As shown in Figure 4.2 below, the share of people who have a ***positive outlook on EFSA's independence largely exceeds 80% of respondents***, with no substantial difference between risk-assessment and risk-communication activities. Ratings do not change significantly across target groups, with slightly higher appreciation among Experts, MB members and EFSA staff. Conversely, ***greater familiarity with the independence Policy appears to be associated with a higher share of positive reviews*** (92-93% of positive feedback regarding risk assessment activities, and 88% regarding risk communication activities).

Figure 4.2 – Overall rating of survey respondents on EFSA's independence from undue external influence



Source: *Targeted survey.* ***Legend:*** *H=high familiarity; M=medium familiarity; L=low familiarity*

Stakeholders have also been surveyed regarding EFSA's ***reputation for independence within specific groups***. The results indicate that for an overwhelming majority of respondents, EFSA has a positive reputation among decision-makers (91% of respondents who provided an assessment) and in the scientific community (84%). The evidence from interviews with policymakers and experts suggests that reputation has positive repercussions on the trust that risk assessors and risk managers in the MS place on EFSA's scientific outputs. The reputation is perceived as less positive among industry stakeholders (according to 56% of respondents), as well as by NGOs (49%) and the general public (54%). Indeed, 21% of the total survey respondents believe that NGOs have maintained a critical position towards EFSA's independence, coherently with the views expressed in the past.

[69] ICF, Reputation Barometer 2.0: State of EFSA's reputation and lessons for future monitoring. Final Report, November 2020.
[70] Kantar Public, Annual Strategy Survey 2022, December 2022.

Regarding possible reasons for dissatisfaction, two recurrent views emerge from stakeholders' views:

- some respondents found the current CoI-related ***restrictions are excessive*** and might jeopardise EFSA's objective of scientific excellence – even though there seems to be recognition of the need to adopt such rules to put EFSA's reputation 'back on track';
- other respondents note the persisting – and potentially increasing – ***influence of risk managers*** (MS and EU level) on EFSA's agenda and on the neutrality of experts involved.

➢ **COMMUNICATION AND ENGAGEMENT ACTIVITIES**

PoI 2017 introduced a set of restrictions on the eligibility of experts and staff involved in EFSA's scientific work, including specific rules – e.g. on 'cooling-off' periods – that meet the requests made by EU supervisory authorities. These new rules marked a discontinuity with the past and had tangible effects on EFSA's operations, e.g. in the composition of Working Groups, PRM, etc. and, by consequence, on stakeholders' perceptions regarding EFSA independence. At the same time a non-negligible contribution to reputational effects was provided by a ***change in the Authority's communication and engagement modalities***. As various interviewees described it, the past approach to independence issues – from CoI allegations in the media, to requests made by supervisory authority – was reactive and defensive. While issues with potential legal implications were duly followed up, limited efforts were reportedly made to address reputational aspects in a more comprehensive manner.

In recent years, this approach has substantially changed. EFSA engages ***more closely and frequently*** with relevant supervisory authorities (EP budgetary discharge authorities, European Ombudsman, etc.) on independence-related matters, also for explaining and discussing the rationale behind its policy. Internally, ***awareness raising actions*** were undertaken – including ad hoc trainings - to mainstream independence principles and rules among EFSA's staff engaged in the production of scientific outputs as well as among experts, thus helping to build their knowledge of independence principles and practice.[71]

Similarly, a more ***proactive communication*** strategy was put in place toward external stakeholders, consisting inter alia of:

- regular media ***monitoring*** for early detection of complaints and other relevant cases,
- rapid ***follow-up*** on emerging issues (through the most appropriate channels and tools),
- ***early engagement*** of stakeholders ahead of publication of critical dossiers,
- greater ***transparency*** regarding scientific opinion development processes and experts involved.

On a side note, it is worth noting that one of the criticisms that certain NGOs make about the current policy regard precisely the emphasis placed on communication. In summary, the new policy is perceived by these entities primarily as a Public Relations operation that has not produced the change desired on EFSA's modus operandi.

[71] As one interviewee described it, the typical attitude of scientists in this respect used to be: "*we are honourable persons, so our integrity should be taken for granted*". This attitude had to be dismantled through the adoption of a set of concrete and objectively verifiable eligibility criteria.

EQ - Does the Policy implement EFSA's independence value in all decision-making or administrative processes carried out by the Authority, or are certain independence dimensions or processes "uncovered"?

- **GENERAL SCOPE**

The general aim of PoI 2017 is to mainstream the principle of impartiality in EFSA's operations. Impartiality is an overarching value of EU administration that, in EFSA's case, acquires special importance in relation to the scientific work that the Authority carries out to discharge its mandate and the professional expertise engaged to this end. However, PoI 2017 does not restrict the scope of application to scientific operations so, in principle, ***any EFSA process is covered***. At the implementation level, the CIM Decision has a more explicit focus on scientific work, stating that the scope of the Decision is to ensure that "*the scientific outputs produced by the Authority are trusted and compliant with the principles laid down in EFSA's policy on independence*" (emphasis added). On the other hand, as discussed in Section 3, independence-related provisions can be found also outside the CIM Decision (e.g. MB Code of Conduct, AF Declaration of Commitment, rules applicable to EFSA staff, etc.). In this sense, PoI 2017 deals with 'independence' in a broader sense than what is covered specifically in the CIM Decision.

A second distinct feature is that EFSA's independence relies – according to PoI 2017's architecture – on the impartiality of the professionals involved in relation to the subject of the work performed at EFSA. In this sense, impartiality needs to be ***ensured at the individual level*** and taking into account the tasks assigned. In general terms, PoI 2017 makes reference to mechanisms securing the neutrality of methods and data used by EFSA, but these aspects are developed outside PoI 2017 (e.g. good risk assessment practice, etc.), which instead remains focussed on the profile of professionals engaged in EFSA work.

In practical terms, impartiality is operationalised through the notion of ***'conflict of interest' (CoI)***. In this context, the concept of CoI does not (necessarily) have a legal connotation. It is rather linked to ethics and integrity values, as well as to the reputational dimension discussed in the previous section. In this sense, the logic underpinning PoI 2017 is that the overall Authority's independence would be guaranteed by the absence of CoI situations among the individuals that contribute to its operation. Indeed, the presence or absence of CoI is assumed as objectively verifiable, while 'independence' and 'impartiality' are concepts that are too immaterial to be measured. It should be clarified that 'absence of CoI' does not mean 'absence of interests'. On the contrary, PoI 2017 explicitly states that "*it is precisely interests, experiences and activities held that qualify an individual as an expert*", so there is a need to distinguish between legitimate professional activities (beneficial also to EFSA) and interests that are or that can be perceived as sources of bias.[72] In connection to this, implementation is centred on the concept of ***'management' of conflicting interests*** rather than on a virtually impossible eradication of CoI risk. At the implementation level, the CIM Decision clarified that the whole Policy revolves around two combined tasks: (1) preventing CoI; and (2) managing competing interests.

- **COVERAGE OF TARGET GROUPS**

The independence policy covers comprehensively all professionals involved in EFSA operations linked to the provision of scientific outputs. Indeed, the CIM Decision explicitly identifies various target groups involved and establishes applicable rules accordingly. The only category of professional not covered in the CIM Decision is ***EFSA staff***, who is however in the scope of PoI 2017 and subject to independence provisions in connection with EU Staff Regulation requirements, namely at the time of recruitment and on a yearly basis

[72] A similar concept can be found in ANSES's policy, in relation to non-financial interests, which ANSES defines "connection of interest" (*lien d'intérêts*). ANSES' assessment guidelines for declared interests note that, while connections (in the sense of relationships) are a natural occurrence for individuals with members of their family, professional, associative, or other environment, such links may constitute or not a CoI, depending on circumstances such as their frequency, their degree of proximity, their seniority or the material or moral advantages they confer.

through the submission of ADoI. EFSA staff needs also to respect the Authority's ethics standards regarding authorised external activities, gifts, hospitality etc. and needs to obtain clearance before taking on employment positions for two years after leaving EFSA[73]. The last point is deemed particularly relevant by some interviewed stakeholders, due to past 'revolving door' cases which occurred with EFSA senior staff. Beside this, the independence of EFSA staff does not seem to pose any relevant concern among stakeholders, as confirmed inter alia by the positive feedback gathered through the survey.

The first category addressed in the CIM Decision regards ***Experts***, i.e. members of Panels, SC and WG as well as experts participating in PRM.[74] Experts are bound to submitting and annually updating DoIs, which are screened by EFSA in accordance with the criteria and procedures described in Section 3. In comparison with the legacy version, coverage has expanded slightly, as DoI obligations currently apply also to MS representatives involved in PRM. However, a few distinctions apply within this category:

- the roles of Chair and Vice-Chair imply stricter rules, e.g. (a) ineligibility, in the case of past employment with feed or food industry or other lobbying organisations directly or indirectly concerned by EFSA's scientific output up to 5 years since the end of the declared interests; (b) current IPR interests overlapping with the mandate.
- Peer reviewers are exempted from cooling-off periods when currently employed in a PI (except in the case of interests directly related to the dossier at stake).

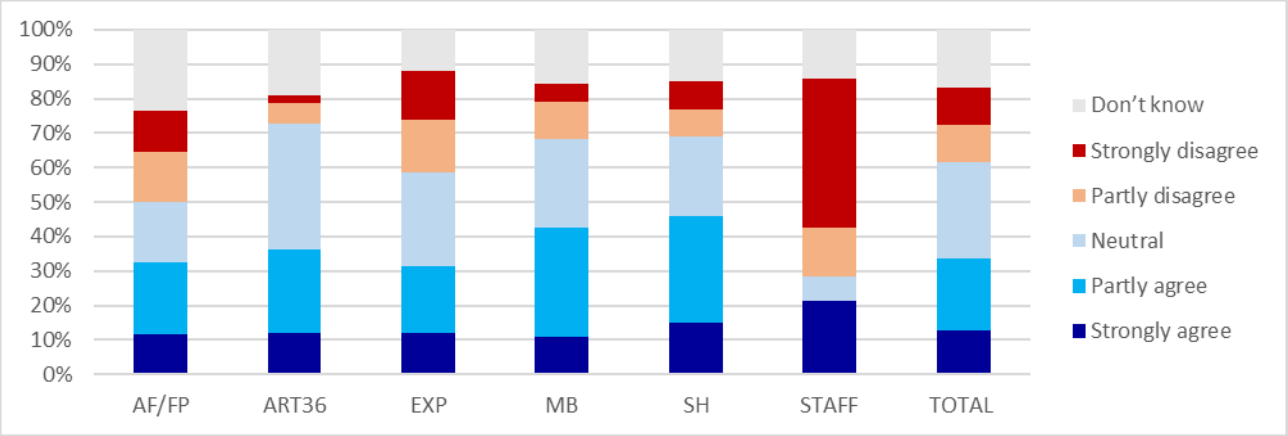
The extent of coverage of the Policy for this category is rated as being satisfactory by approximately half of surveyed stakeholders. Unsurprisingly, the most positive ratings come from experts themselves, while EFSA staff and EFSA Stakeholder Forum's and Stakeholder Bureau's members expressed slightly more tepid positions. Dissatisfaction is comparatively more frequent (albeit still limited) in relation to WG experts who are not members of Scientific Panels.

Regarding ***Hearing Experts*** and ***Observers,*** the CIM Decision establishes different rules. Hearing Experts are required to submit a DoI, which is however not screened by EFSA. There is instead no obligation for Observers to submit a DoI. Hearing Experts are experts invited to speak occasionally to WG meetings by virtue of specific knowledge or competence on the subject matter under analysis, which is not available within the WG. Sometimes an expert is involved as Hearing Experts because his/her intervention concerns a limited, self-contained portion of the mandate, more frequently the position of Hearing Experts is offered to experts whose DoI presents items that are deemed incompatible with full membership of the WG. This second modality of involvement has triggered some criticisms, as it is viewed as a backdoor through which undue interests can access and influence the WG. In this respect, a demand is registered - including in ENVI 2023 – for ***extending the screening of DoIs to Hearing Experts***. It should be added that other stakeholders expressed perplexity with the current rules from quite a different perspective, i.e. they questioned the efficiency of collecting DoIs that are not assessed. On this point, EFSA's explanation – which might need to be better communicated to stakeholders - is that Hearing Experts' DoIs are collected and published for transparency purposes, since the existence of potentially incompatible interests is inherent to the position. The risk of undue influence is mitigated by the fact that Hearing Experts cannot participate in the WG discussion and cannot provide written inputs. The results of the survey showed quite diverging views on the need to apply stricter CoI management rules to Hearing Experts (Figure 4.3). In particular, the majority of EFSA staff surveyed strongly disagreed with this option. Actually, the possibility of expanding the room for collaborating with Hearing Experts is reportedly being considered.

[73] This requirement is laid down in Art 16 of the Staff Regulations: "*Officials intending to engage in an occupational activity, whether gainful or not, within two years of leaving the service shall inform their institution thereof. If that activity is related to the work carried out by the official during the last three years of service and could lead to a conflict with the legitimate interests of the institution, the Appointing Authority may, having regard to the interests of the service, either forbid him from undertaking it or give its approval subject to any conditions it thinks fit.*"

[74] The definition provided in the CIM Decision also includes candidates who applied to EFSA's call for expression of interests for positions in the Scientific Committee and the Panels.

Figure 4.3 – Survey respondents' opinion on the need to apply stricter CoI management rules to Hearing Experts



Source: *Targeted survey.* ***Legend:*** *AF/FP: members of the Advisory Forum and/or Focal Points; ART36: representatives of Article 36 organisations; EXP: scientific experts, members of EFSA scientific groups; MB: members of the Management Board; STAFF: EFSA staff ('CIM community'); SH: other stakeholders (i.e. representatives of the business and food industry, farmers, environmental / health NGOs and practitioner and academic organisations).*

Another category covered in the CIM Decision is ***Network Members***, defined as "*members of EFSA Networks, focal points or other networking activities carried out pursuant to Article 36 [GFL]*"[75]. Scientific Networks are mechanisms established to address the GFL objective of promoting close cooperation and involvement of MS expertise in support of EFSA's mission. Network participants and their alternates need to comply with an ADoI submission obligation,[76] however, the CIM Decision establishes that EFSA should not perform any screening, assessment, or validation of their DoIs. EFSA's Guidelines for Network Members state that the purpose of ADoI is to "*allow the identification of any interest that might be considered prejudicial to their independence.*"[77] The CIM Decision does not explain how such identification is possible without screenings, but it states that EFSA "*follows up on serious and well-documented cases of CoI (…)*" suggesting that such identification could come from third parties and/or 'whistleblowing'. The definition of Network Members as laid down in the CIM Decision also includes ***Art 36 organisations.*** These organisations may be part of EFSA's Scientific and Communication Networks and may also participate in grant awarding procedures, in which case the CIM Decision requires a screening of DoI.[78] The rationale is arguably linked to proportionality, i.e. Scientific and Communication Networks play a general advisory role (exchange of information, coordination, etc.) while grants are awarded for the provision of inputs that are used in the drafting of specific risk assessment. This distinction does not emerge clearly from the Policy documents and is seemingly a source of confusion.[79]

Article 6 of the CIM Decision lays down rules and procedures for entities participating in ***grant awarding procedures*** (i.e. Art 36 organisations) and ***procurement*** (contractors). This also includes ***Focal Points*** (FP), which is a network that receives support from EFSA through grant agreements. Entities participating in 'science call' need to submit an Institutional DoI and individual DoIs for all members of the proposed team. The institutional DoI largely corresponds to the individual one, but completion of the form's fields 'managerial role' and 'employment' is evidently not required. Recently, EFSA stopped collecting institutional DoIs from Art 36 organisations for proportionality reasons, as the eligibility check carried out by the designating MS already includes independence scrutiny. One of the criteria that these organisations should meet states: "*they must be legal entities pursuing public interest objectives, and their organisational arrangements must include specific procedures and rules ensuring that any tasks entrusted to them by the Authority will be*

[75] Source: Art 2(g) of the CIM Decision.
[76] Decision of the Management Board concerning the establishment and operation of European Networks of scientific organisations operating in the fields within the Authority's mission, 2021.
[77] See: https://www.efsa.europa.eu/sites/default/files/afguidelinesnetworkrepresentatives.pdf
[78] In other words, a Competent Organisation is subject to Article 12 of the CIM Decision ('Rules applicable to Network Members') unless it takes part in EFSA's grant awarding procedures, in which case Article 15 of the CIM Decision (hence DoI screening) applies.
[79] For instance, ENVI 2023 recommends defining more clearly rules which are applicable to experts from Art 36 organisations who take part in the preparation of scientific opinions.

performed with independence and integrity".[80] Additionally, EFSA no longer requires individual DoIs from non-scientific members of the team proposed for a science call (e.g. administrative staff). As mentioned in Section 2, the DoI screening criteria applied to Art 36 organisations and contractors differ in part from Expert criteria, as the two-year cooling-off period required after the end of a competing interest is not necessary. This aspect is examined in greater detail below.

Finally, the CIM Decision covers Governance Bodies members, i.e. ***MB Members*** and ***AF Members***. AF Member's DoIs are collected but not screened. The same logic of 'follow up on serious and documented cases' described for Network Member applies here. Additionally, in 2019 AF Members signed a *Declaration of Intent*[81] spelling out the principles governing the impartiality of risk assessment. The Declaration includes a specific article on independence, which covers inter alia the independence of individuals from 'instructions deriving from State authorities' and experts' employing organisations. The DoIs submitted by MB Members are instead subject to EFSA assessment, but the 'validation' is carried out by the Board itself. In case a CoI that threaten EFSA's reputation is identified, the Management Board can ask for replacement of the concerned member. This self-rule mechanism – highlighted also in ENVI 2023 – appears to be poorly in line with ethics standards for this kind of body.

All in all, the independence policy of comparators examined in the benchmarking exercise have similar coverage, but actual 'target groups' may vary in accordance with the specific bodies and modus operandi of the institutions considered. It is interesting to note that comparators have opted for different approaches regarding the scope of policy documents. ANSES is a main example of an integrated approach, with a comprehensive ethics framework in place, which applies to employees as well as to external collaborators and any implementation activities and relations with interested parties. Conversely, ECDC has opted for two distinct policy documents which respectively apply to ECDC staff and non-staff.[82]

Another difference that can frequently be observed when comparing EFSA's framework with those of other agencies' regards outsourcing. EFSA applies to contractors and grant beneficiaries CoI rules that are in many respects similar to the rules applied to Experts – i.e. same DoI template, similar screening, etc. This is seemingly not the case in other agencies, where procurement is generally not subject to detailed CoI assessment but rather is subject to 'declarations on honour' or similar statements.[83] Evidently, this reflects also the differences of modus operandi across agencies and the often less relevant role that outsourcing of scientific activities plays in other institutions, especially at MS level.[84] I

- **COVERAGE OF RELEVANT INTERESTS**

According to PoI 2017, EFSA recognises three main patterns that can result in a CoI situation:

1. Interests concerning the ***economic and financial sphere***, which covers a range going from wages to financial investments, research funding, donations, etc. The DoI requires relevant interests in monetary terms be quantified and that it be indicated whether their incidence exceeds or not 25% of the declarant's annual earnings, or – in the case of research funds – of the relevant total managed funding. While the 25% threshold is conventional, this provision was reportedly introduced to

[80] COMMISSION REGULATION (EC) No 2230/2004
[81] https://www.efsa.europa.eu/sites/default/files/event/af160928/160928_af_declaration.pdf
[82] Also the new ECHA Policy (not yet published at the time of writing) will separate the duties applicable to ECHA staff from those applicable to members of ECHA bodies into two self-standing documents, but under a common, overarching CoI policy document.
[83] ECDC applies a procedure based on 'declaration of honour' in the case of seconded national experts. The declaration states that there is no conflict of interest between the functions the seconded national expert performs for his employer or the professional activities of the seconded national expert's close family, and the tasks he/she will undertake for ECDC.
[84] For instance, ANSES do not typically outsource risk assessment to external scientists and experts. ANSES can conclude special "research and development agreements" which are scientific partnership contracts. In this case, before the finalisation of the contract, a check of the connections of interest is generally performed.

pressure declarants to make an accurate assessment of the financial stake involved in the declared activities.

2. ***Creation of the mind***, such as patents, trademarks and other IPRs (but not authorships and publications). These interests are deemed relevant irrespective of whether they grant a financial gain or not.
3. ***Affiliations and other involvements,*** such as in business operators, industry, lobbying organisations, or risk management bodies etc. (the applicable rules and criteria vary across different organisation types). At the implementation level, the incidence on declarant's earning from these involvements contributed to determining whether such interest classifies as 'employment', 'occasional consultancy' or 'managerial role'.

The time span of interest covered in the DoI is ***five years***. When ADoI are updated, interests older than five years are deleted. For 'benchmarking' it can be noted that the same time span is adopted also by ECDC, ECHA and the French ANSES, while EMA applies a shorter period of three years. In the case of ECHA, it is reported that relevant interests held beyond the preceding five years could also be subject to DoI if they have the potential to jeopardise the independence of the declarant. The Belgian AFSCA requires declarants report past interests without specifying the cut-off date, but typically consider interest existing at the time of the declaration.

The DoI covers also interests held by ***Close Family Members***, with only two exceptions: (i) the incompatibility of Expert's participation in the review of his/her own work (which in this case would read Close Family Member's work); and (ii) the outright ban on industry employment, which in the case of Close Family Member does not extend to any activities concerned by EFSA's remit but is limited to the specific mandate of the concerned scientific group. A slight inconsistency can be noted with the terms used in PoI 2017 "*partners or dependent family members*" (page 5).[85] Additionally, as noted in EA 2021, there are still inconsistencies across EU agencies in the extent to which family-related interests are taken into account. These inconsistencies would be effectively addressed adopting at EU level a definition valid for all institutions.

As noted in ENVI 2023, academic experts are requested to declare only their own economic and financial interests but not the financial relationship between their university and commercial partners. The point is that there are ***interests concerning the Expert's employer*** – e.g. funding from the food and feed industry - that are not captured in the current DoI but might be perceived to be a relevant source of influence. In principle, this falls outside of the scope of relevant interests, as Experts who participate in scientific groups are involved in their personal capacity and not as representatives of their institutions. However, some interviewees confirmed that 'affiliation matters', and Experts can develop a sense of belonging to their organisations which can translate into bias, if the organisation closely works with industrial sectors. The results of the targeted survey indicate that around 50% of respondents would agree to requiring Experts to mention in the DoI his/her employer's financial relationship with industry partners. On the other hand, this recommendation runs into practical issues, namely (1) Experts' access to such information, especially in the case of large institutions; (2) complexity of application to institutions of the calculation model developed by EFSA to determine the incidence of private sector funding overlapping with the mandate of the relevant scientific group; and (3) objective difficulty of operationalising the abovementioned 'sense of belonging', and the need to apply time-consuming discretionary assessment.

Another point raised in ENVI 2023 is that PoI 2017 does not explicitly mention ***'political pressure'*** and ***'national interests'*** in the CoI definition provided, and it recommends revising the definition accordingly. This

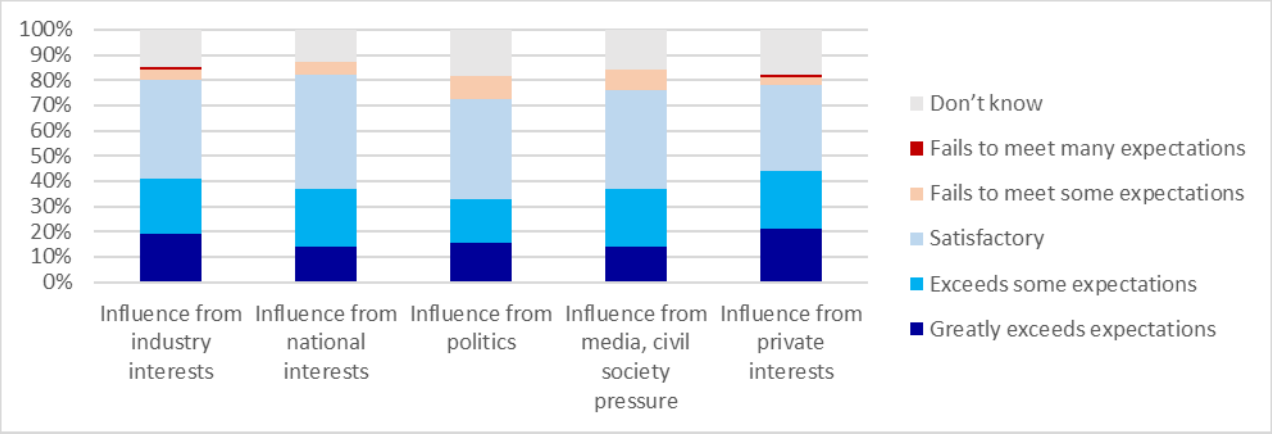
[85] Furthermore, Art 61 of the Financial Regulation states that a CoI exists "where the impartial and objective exercise of the functions of a financial actor or other person, as referred to in paragraph 1, is compromised for reasons involving family, emotional life, political or national affinity, economic interest or any other direct or indirect personal interests" (emphasis added). 'Family' and 'emotional life' are mentioned separately, suggesting that an emotional bond between family members is therefore not required for a person's impartiality to be compromised by reasons involving family. In this sense, the concept of CoI according to the Financial Regulation goes beyond the notion of 'close family members' as mentioned in the CIM Decision (but its precise contours are neither universally recognised nor defined in EU legislation, except in specific policy areas, notably migration).

omission (common to various sister agencies) appears to be relevant, especially considering the emphasis placed on partnership with MS in the GFL and the TR. On the other hand, it should be noted that participation in ***risk management*** activities is a substantial discriminating factor for DoI screening criteria. As stated in the CIM Decision, activities carried out for PIs as part of their public interest duty do not constitute a CoI except in the case of risk management functions. This provision is aimed at separating pure scientific advisory roles that the concerned expert may hold vis-à-vis his/her MS institutions from other roles that have an influence on policymaking. In practice, this separation is not always clear cut, as in the case of small MS, where institutional arrangements cannot afford a strict separation from risk assessment and the risk management function, or because of unclear boundaries in an expert's involvement with national administrations, as emerged in some interviews.

Another possible source of external pressure which is not explicitly mentioned in PoI 2017 is the ***pressure exerted by media and civil society*** on Experts working on particularly sensitive dossiers. As reported by some interviewees, this was indeed an issue in the past, i.e. "*experts perceived themselves on the frontline, putting their reputation at risk, and receiving little support from EFSA*". This condition has been substantially resolved, in connection with the new communication and engagement approach adopted by EFSA on critical dossiers. The Experts interviewed reported there is no longer any problem in this respect.

In conclusion, the results of the survey show that EFSA's policy largely ***exceeds stakeholder's expectations*** in all areas considered (Figure 4.4). Respondents' feedback regarding EFSA's capacity to manage influence from industry and other private interests is particularly positive. Comparatively less satisfactory is the management of influence from politics. Experts appear to be the most satisfied with the policy among target groups consulted, while EFSA Stakeholder Forum's and Stakeholder Bureau's members are among the least satisfied (but the number of respondents is limited).

Figure 4.4 – Survey respondents' satisfaction regarding EFSA's capacity to manage external influence



Source: *Targeted survey.*

- **COVERAGE OF INDEPENDENCE-RELATED PROCESSES**

PoI 2017 outlines the various components of the independence-assurance cycle, namely:

1. ***scope and objectives***, including the underlying principles, connection to EFSA's mission and the CoI definition;
2. approach to ***prevention of CoI occurrence***;
3. ***implementation and enforcement***, inclusive of ex post compliance checks and dissuasive sanctions to deter breaches;
4. ***transparency and communication*** policy, addressing both concerned professionals and external stakeholders, as well as reporting on implementation.

In this sense, as a strategic and policy orientation document, PoI 2017 is comprehensive. On the other hand, PoI 2017 is a rather succinct document that establishes the rationale and the purpose of the various components of the policy but does not go into detail on processes and measures, which are spelled out in the CIM Decision and other complementary and operational documents (see Section 3). Based on the evidence reviewed, the processes that appear to be not-entirely developed and that possibly require more extensive coverage include:

- ***'Revolving door'*** policy. The issue known as 'revolving door' is increasingly a priority in the debate on public service ethics and integrity within the EU and international organisations, as well as in the relevant academic literature.[86] As highlighted inter alia by ENVI 2023, EFSA has not published specific criteria to operationalise the prohibition for senior staff to take up certain positions after the end of their term of office.[87] EFSA's decisions regarding former staff who intend to engage in occupational activities are not publicly available, as is the case for instance for ECHA and EMA. Regarding former MB members, EFSA publishes updated DoI for two years after the expiration of mandate. However, it is unclear how this process is enforced as, apparently, not all former members have provided their updated DoI, and EFSA has no instrument to prevent the taking-on of overlapping positions. In the case of Experts, there are no provisions at all in this regard. On the other hand, the cooling-off period provision established in the Policy entails that if an expert takes on an industry employment or another employment position that is in contrast with EFSA CoI rules, any involvement with EFSA would automatically terminate, and the expert would not be able to collaborate again with EFSA until the end of the envisaged cooling-off period (2-5 years).
- ENVI 2023 also pinpointed the need for clarifying rules applicable to ***experts from Article 36 organisations***. Indeed, some operational aspects (e.g. DoI requirements, PI classification) are not detailed in the CIM Decision, however the main point here is rather the validity of current criteria, in the light of the expanded role attributed to Art 36 organisations.
- A transparency aspect related to independence raised again in ENVI 2023[88] regards the ***publication of CVs*** of EFSA's key actors, such as the Executive Director, MB members and Experts.[89] The rationale would be "*to facilitate control by citizens and NGOs*". The results of the survey, however, show little support for this measure (primarily from representatives of Art 36 organisations). Indeed, this measure would likely imply a substantial increase in efforts with limited added-value – as the relevant information are already available to the public through the DoIs, and there would be a risk of fuelling confusions and misunderstanding.
- The ***granting of waivers*** is another provision that various stakeholders (especially those who are more critical of EFSA's independence policy) consider insufficiently explained. The CIM Decision is indeed not especially detailed on criteria and processes for granting waivers, but these aspects are covered in EFSA's internal documents (Work Instructions).
- Finally, some interviewed MB Members consider EFSA's ***whistleblowing policy*** to be insufficient (despite the existence of measures for whistleblower protection is acknowledged in the latest Resolution of the budget discharge authority[90]). Indeed, EFSA's coverage of this matter appears to be weaker than that of

[86] See, for instance: Agustí Cerrillo-i-Martínez (2017) Beyond Revolving Doors: The Prevention of Conflicts of Interests Through Regulation, Public Integrity, 19:4, 357-373, DOI: 10.1080/10999922.2016.1225479; and – on practical aspects (ii) United Kingdom, House of Commons (2017). Public Administration and Constitutional Affairs Committee, Managing Minister´s and Officials Conflicts of Interest: Time, for Clearer Values, Principles and Action, 13th report 2016-2017. London. 'Pro-revolving doors' perspectives can also be found in the academic literature, e.g.: David Zaring. 2013. Against Being Against the Revolving Door, University of Illinois Law Review, Vol. 2, pp. 507-548.

[87] ECDC and EMA are in a similar situation, instead ECHA has reportedly adopted specific rules and criteria.

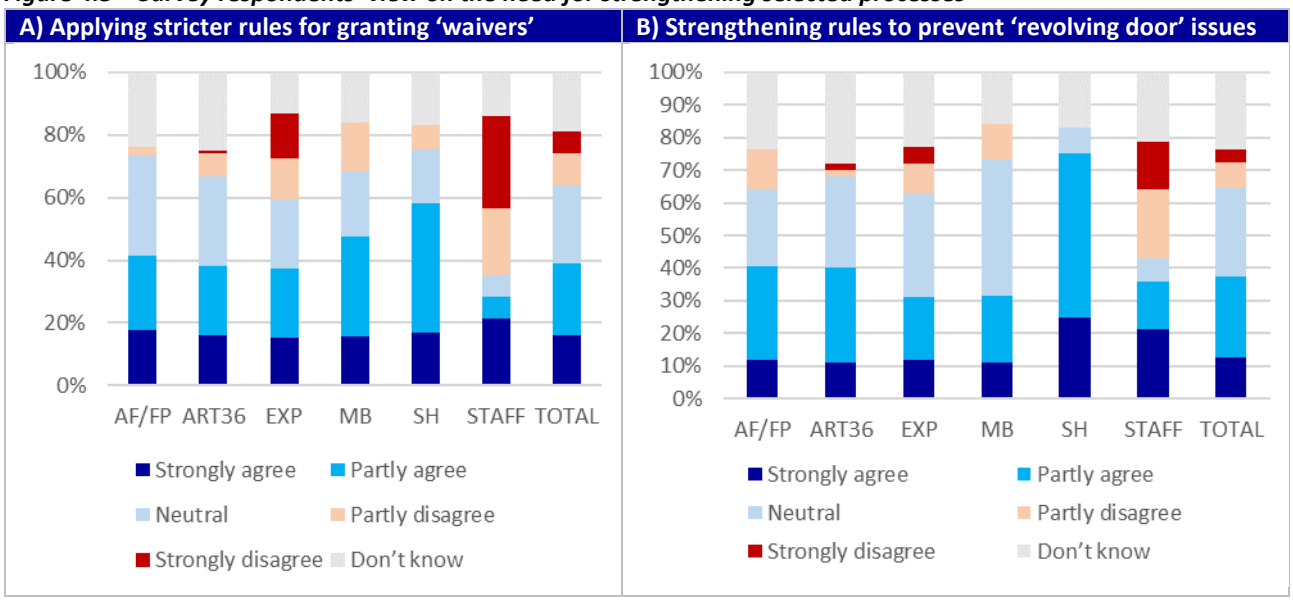
[88] As discussed below, this is also a recommendation of the budgetary authority.

[89] For 'benchmarking', ECHA publishes on its website the CVs of the members of the Management Board, the Member State Committee, and various other committees (Committee for Risk Assessment, the Committee for Socio-Economic Analysis, etc.). EMA publishes on its website the CVs of the members of the scientific committees and the Agency's other bodies, including the Management Board. ECDC publishes the CVs of the Director and Heads of Unit, whereas for other ECDC staff members publication regards only specific cases, and for the staff whose names are already public on the ECDC website.

[90] European Parliament resolution of 10 May 2023 with observations forming an integral part of the decision on discharge in respect of the implementation of the budget of the European Food Safety Authority for the financial year 2021 (2022/2104(DEC)).

EMA - which has put in place a whistleblowing policy that aligns specifically with the EU Whistleblowing Directive[91] - or ANSES, where whistleblowing privileges for employees and external collaborators are laid down, along with other independence provisions, in the Ethics Code.[92]

Figure 4.5 – Survey respondents' view on the need for strengthening selected processes



Source: *Targeted survey.* ***Legend:*** *AF/FP: members of the Advisory Forum and/or Focal Points; ART36: representatives of Article 36 organisations; EXP: scientific experts, member of EFSA scientific groups; MB: members of the Management Board; STAFF: EFSA staff ('CIM community'); SH: other stakeholders (i.e. representatives of the business and food industry, farmers, environmental / health NGOs and practitioner and academic organisations).*

EQ - Does the Policy support EFSA in attracting the best scientific expertise on the market?

➢ **IMPACT ON SCIENTIFIC EXCELLENCE**

The ***tension between independence and scientific excellence*** objectives is a recurrent issue that informed the development of EFSA's past and current policy. For various years before PoI 2017's adoption, budgetary discharge authorities and other stakeholders were insisting on the need to adopt strict CoI rules to redress EFSA's reputation which had been undermined by a few controversial cases. Such requests intended to make it more difficult for EFSA to engage experts who could be perceived as having ties with food industry and private research. On the other hand, the Authority made clear that overly strict rules could result in depriving EFSA of the knowledge and the specific competences necessary to discharge its mandate, thus jeopardising the fundamental principle of 'scientific excellence'. Sine PoI 2017's adoption, which eventually introduced most of the requested rules, the demand for tighter CoI policy has shrunk substantially (see Section 4.5) and, as discussed, EFSA's reputation has improved notably. However, diverging views on the sustainability of the current framework remain.

Firstly, it should be noted that independence rules can have, in principle, two quite opposite effects on scientific excellence, namely:

- A ***hindering effect***, due to the abovementioned risk of excluding prominent experts from the activities of EFSA's scientific group -- The key argument is that scientific research is driven by innovation processes that are largely promoted and funded by private sector interests. Private-public scientific partnerships

[91] Directive ((EU) 2019/1937 on the Protection of Persons Who Report Breaches of Union Law. EMA was recently commended for this, in the EP report on discharge in respect of the implementation of the budget of the European Union agencies for 2021.
[92] Code de déontologie de l'Agence nationale de sécurité sanitaire de l'alimentation, de l'environnement et du travail, 2018.

are actively fostered by EU policy, and there are areas where industry is *de facto* at the forefront of technology and research. So, not only would it be very difficult to find knowledgeable experts with no ties to the private sector, but it would be also desirable from a scientific-quality perspective that such knowledge be properly taken into account in the development of EFSA's scientific advice. By setting eligibility criteria which is too demanding, as well as stigmatising all forms of collaborations with the private sector excessively [93], the source of scientific expertise that EFSA needs might eventually be dried up.

- A ***fostering effect***, as the improved reputation – including of the scientific outputs produced within EFSA – has a pull effect on professionals.

It is difficult to measure the respective magnitude of these opposite trends objectively, but some indications in this sense come from the ***survey results*** (Figure 4.6). In particular:

- Overall views on the potential hindering effect of the policy appear polarised. Around 46% of respondents believe there is a high or moderate risk of impairing EFSA's capacity to attract high-level expertise, while for a not too-different share (39%), such risk is limited or absent.
- The most concerned categories of respondents are EFSA staff and MB Members. A similar picture emerged also from interviews with EFSA staff – who deals with this matter on a daily basis – expressing more frequently concerns on the sustainability of current arrangements. Conversely, the majority of representatives of Art 36 organisations tends to downplay this issue, possibly because of the somewhat lighter obligations that they are subject to.
- Some differences can also be observed by segmenting respondents by the length of their experience with EFSA. Those who have been collaborating with EFSA for more than five years tend to be more frequently concerned with 'hindering effects' (55%) than the rest of respondents (31%).
- A large share of respondents (40%) was not able to judge the evolution in the quality of EFSA's scientific output, but those who could make an assessment largely registered an improvement. The most positive feedback comes from MB members and representatives of Art 36 organisations. Conversely, the least positive assessment was voiced by EFSA Stakeholder Forum's and Stakeholder Bureau's members. The latter reflects the fact that most of respondents in this group expressed the industry's perspective, which is sceptical regarding certain aspects of EFSA's work, but not related to the independence policy.

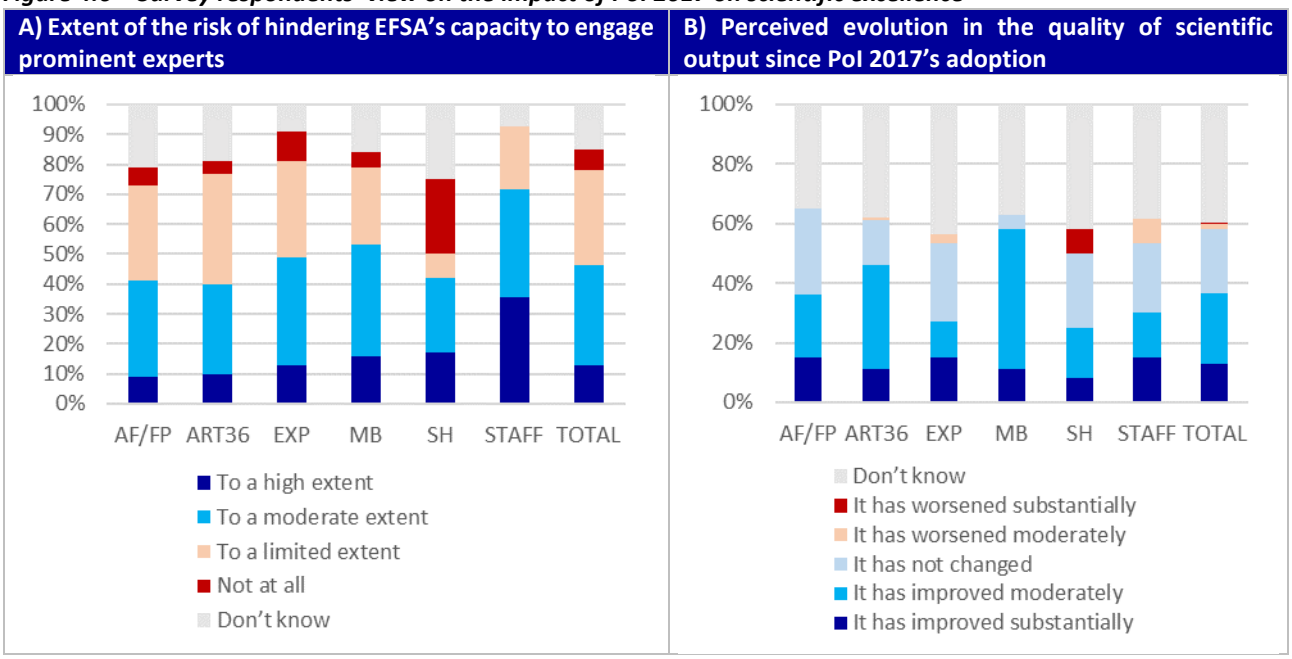
Indirectly, the increasing relevance of EFSA's scientific output is registered also by ***bibliometrics indicators*** related to the *EFSA Journal.* As highlighted in the Annual Activity Report from 2022, the number of citations from the *EFSA Journal* has increased by approximately 60% since 2020, while the *h-index* of impact has grown from 122 to 132 in one year.

Based on the qualitative feedback gathered, cooling-off periods and the 25% threshold to relevant research funding from private sources are perceived as the most constraining rules. Various interviewees with long-time experience with EFSA confirmed that the adoption of the new rules led to the ***exclusion of experts*** deemed of great value for Panels and WG. At the same time there is fairly widespread recognition that draconian measures were needed to sort out the previous reputational crisis. More frequently, Experts lament EFSA's overly strict interpretation of minor situations, such as occasional participation in meetings or other forms of dialogue with the private sector. Researchers consider such dialogue as necessary to stay on top of scientific and technological developments but, in their view, EFSA would tend to 'overreact' to this. Similarly, some interviewees noted that current rules were conceived in reaction to criticisms that emerged in relation to a few specific dossiers, but apply to all kinds of scientific work, including in areas that never

[93] EFSA might exclude experts based on interests that, according to the concerned expert, do not constitute a CoI but, from EFSA's perspective, might be perceived as posing such risk. In other words, EFSA may label as CoI an interest that the concerned expert holds legitimately vis-à-vis his/her employers, MS and EU authorities, and the scientific community on the whole. The terms 'CoI' in academic settings has a strong connotation and reputational implications. As emerged from interviews, some high-level experts may refrain from being involved in EFSA activities to avoid being exposed to such risk.

posed any problem. In this sense, a proportionality question was raised, which is discussed in Section 4.3, along with the possibility of introducing further rule differentiation.

Figure 4.6 – Survey respondents' view on the impact of PoI 2017 on scientific excellence



Source: *Targeted survey.* ***Legend:*** *AF/FP: members of the Advisory Forum and/or Focal Points; ART36: representatives of Article 36 organisations; EXP: scientific experts, members of EFSA scientific groups; MB: members of the Management Board; STAFF: EFSA staff ('CIM community'); SH: other stakeholders (i.e. representatives of the business and food industries, farmers, environmental / health NGOs and practitioner and academic organisations).*

As discussed in the previous section, experts who are ineligible for full membership positions but deemed valuable for the work of a scientific group may be involved as ***Hearing Experts***. It is interesting to note that the 2014 version of the CIM Decision explicitly mentioned that "*Hearing Experts may be invited (…) irrespective of whether they would be considered to have a CoI*"[94] while in the 2018 version currently in force this is not clearly stated.[95] The absence of such specifications might explain why certain interviewees thought the Hearing Expert position was associated to a limited, collateral involvement in the work of a scientific group, rather than a way to sidestep independence rules when beneficial for scientific quality.[96] Additionally, the CIM Decision envisages the possibility of granting ***waivers*** to experts in a CoI situation who are deemed essential for the drafting of the scientific output, and it is not sufficient to involve them as Hearing Experts. While a Hearing Expert's participation is limited to his/her presentation, a waiver allows full membership to a scientific group, including participation to debate and drafting of outputs. The only limitation is that a waiver is not compatible with the role of Chairman, Vice-chairman, and Rapporteur. Again, this provision serves the purpose of introducing some flexibility in the independence rules when scientific excellence so requires.

Waivers are used only in exceptional circumstances, and some interviewed Experts were not even aware that such possibility exists (waivers are even not mentioned in PoI 2017). The available statistics show that in the

[94] https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/independencerules2014.pdf

[95] However, the CIM Decision makes reference to the Hearing Expert definition laid down in the 2014 *Decision of the Executive Director concerning the selection of members of the Scientific Committee the Scientific Panels, and the selection of external experts to assist EFSA with its scientific work*, which stated that "*Given the limited role as non-member attendees to stand witness and answer questions, hearing experts may have conflicts of interests regarding the relevant topic*" (emphasis added). In the 2022 *Implementing Rule of the Management Board of the European Food Safety Authority laying down the rules on the selection, appointment and operations of the Scientific Committee, Scientific Panels and of their Working Groups* any reference to the irrelevance of CoI for Hearing Expert has disappeared.

[96] It is also possible that the demand for screening of Hearing Expert's DoI formulated, e.g., in ENVI 2023, stems from lack of clarity with the CoI-related motivation behind the Hearing Expert position.

2018-2022 period ***less than 12 waivers per year*** have been adopted – i.e. around 0.3% of the total DoIs screened - and the number declined over time. Conversely, ***Hearing Experts' DoIs are increasing*** in relation to the total DoI, i.e. from 4.5% in 2018 to 10.8%. Statistics for the years before 2018 are not available, and therefore the net effect of PoI 2017 cannot be appreciated; however, this trend suggests that, indeed, CoI rules are possibly pushing EFSA toward a greater recourse to this instrument.

- **IMPACT ON SCIENTIFIC PARTNERSHIPS**

EFSA's most recent corporate strategy[97] placed an unprecedented emphasis on cooperation and partnership within the EU food safety ecosystem. Specifically, the document defines the role of EFSA as an "*enabler of collective action*". This vision follows the revisions introduced by the TR to EFSA's founding regulation in the sense of a greater involvement of MS competent bodies in EFSA's governance (Management Board) and scientific activities. In parallel, the Authority's ***budget for outsourcing*** – in particular to grants assigned to Art 36 organisations – has increased substantially, i.e. from EUR 8-9 million / year until 2019, to nearly EUR 35 million in 2022.[98]

The increasing extent of collaboration suggests that PoI 2017 did ***not create any apparent obstacle*** to the involvement of national competent organisations in EFSA's work, and this occurred despite the fact that rules set in the current CIM Decision are stricter than in the 2014 version. On the other hand, it should be noted that current rules are still lighter than those applied to Experts, even though Experts may carry out, in principle, analogous tasks. Specifically, the TR underlined that Art 36 organisations may *"[prepare] scientific opinions to be peer-reviewed by the Scientific Panels before they adopt them*" (Art 28.5e). This matter is discussed further below.

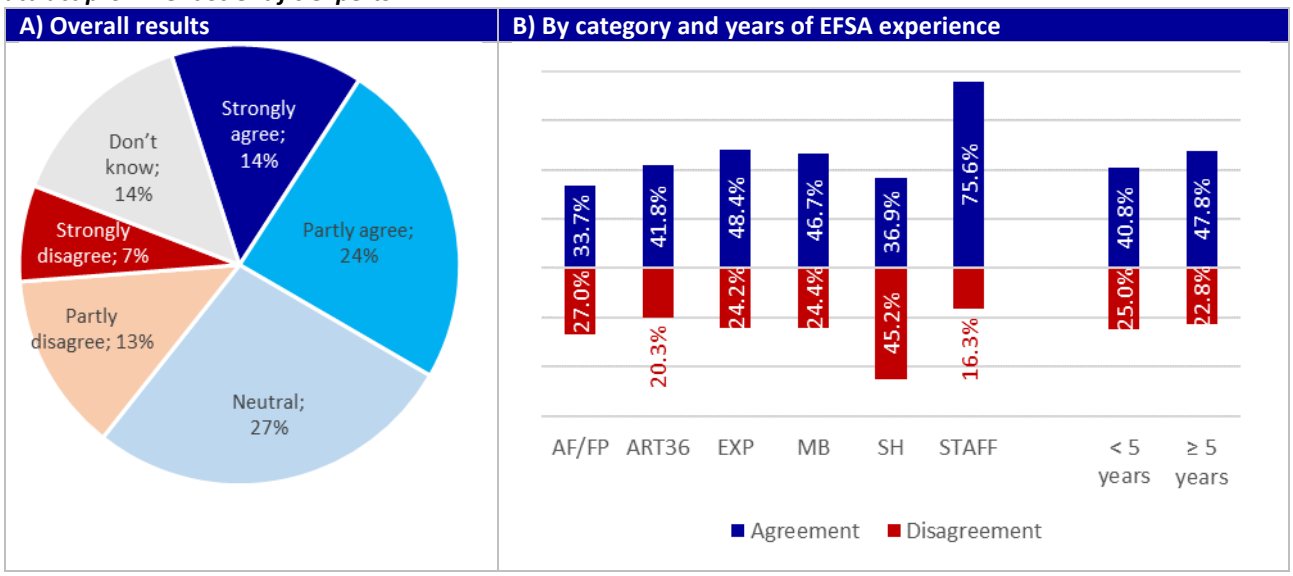
- **PERSPECTIVES ON THE WAY FORWARD**

Various interviewees expressed doubts on the sustainability of current arrangements in the light of the objective of ensuring EFSA's access to high-level expertise. The perspective of further tightening rules or adding obligations – as recommended inter alia in the EP budgetary discharge (see Section 4.5) and in ENVI 2023 – was very rarely welcomed by the consulted stakeholders. If any, few interviewees expressed perplexity with the lighter regime applied to Art 36 organisations or with the 'waiver' instrument. However, more frequently, interviewees' feedback went in the direction of a slight re-focusing of current rules toward a risk-based approach – e.g. in the case of interests deemed negligible – and/or greater flexibility in the implementation of current rules.

The matter of a possible 'relaxation' of the rules was investigated through the targeted survey. The results (Figure 4.7) show that indeed the percentage of respondents who are somehow in favour of '***relaxing' current rules*** to guarantee access to scientific excellence (38%) exceeds those who oppose it (20%). Clearly, the results can be influenced by respondents' direct engagement with the subject matter. Indeed, more than three-quarters of consulted EFSA employees would support a reconsideration of current rules; also among Experts – who are the main targets of CoI rules – near half of total respondents agree with the hypothesis of lighter rules. Conversely, disagreement prevails among EFSA Stakeholder Forum's and Stakeholder Bureau's members – especially NGOs. As Figure 4.7 shows, the percentage of agreement tends to increase among respondents with a longer experience of collaboration with EFSA, i.e. those who are best positioned to see how current independence rules have impacted EFSA's capacity to attract prominent scientists. It should be noted that approximately 40% of respondents did not take a clear position.

[97] EFSA Strategy 2027, adopted by the Management Board in June 2021.
[98] Source: Consolidated Annual Activity Report, 2022.

Figure 4.7 – Survey respondents' view on a possible relaxation of current rules to avoid impairing EFSA's capacity to attract prominent scientific experts



Source: *Targeted survey.* ***Note:*** *In panel B, percentages have been recalculated excluding Don't know answers, and displaying only agreement v. disagreement ('neutral' views not displayed).* ***Legend:*** *AF/FP: members of the Advisory Forum and/or Focal Points; ART36: representatives of Article 36 organisations; EXP: scientific experts, member of EFSA scientific groups; MB: members of the Management Board; STAFF: EFSA staff ('CIM community'); SH: other stakeholders (i.e. representatives of the business and food industries, farmers, environmental / health NGOs and practitioner and academic organisations).*

4.3 Efficiency (including proportionality)

EQ - Are the resources invested in the implementation (e.g. financial resources and HR) adequate and proportionate for the achievement of the Policy's objectives?

- **OVERALL RESOURCES INVESTED IN INDEPENDENCE-RELATED ACTIVITIES**

The implementation and enforcement of the Policy are ***resource-intensive, and the resources required are growing over time***.[99] As indicated in the Annual Activity Reports (AAR) for the 2018-2020 period,[100] the global efforts required by the various implementing activities amounted to approximately 3-4 full-time equivalents (FTE). Additionally, the AARs report financial investments ranging from EUR 0.2 to EUR 0.5 million in the same period. The malfunctioning of the IT tool for DoI management which occurred in 2021-22 led to a substantial increase in effort due to the need to make recourse to a 'manual' procedure. Based on EFSA projections, overall independence-related effort has temporarily risen to approximately 10 FTE. Since the beginning of 2023, a new IT system is in place, and projections for 2024-27 indicate an expected effort that would stabilise at 6.5 FTE / year, i.e. nearly two times the effort required in 2019.

The figures available from EFSA projections indicate that half of the human resource effort was ***borne by the Legal Affairs Services (LA)***, which is responsible for 'validation' in the two-step DoI screening process[101]. Significant resources (a fifth of the total) are absorbed by the Risk Assessment Logistics unit, while the rest is divided among 15 other services. Based on available estimates, the most resource-intensive processes among

[99] Detailed comparisons with other agencies are not feasible for a lack of data. Interestingly, in the past, AFSCA experienced a substantial burden linked to declarations of interest, so it revised the scope of interests that employees were required to declare to narrow it.

[100] Figures for 2021 and 2022 are not provided in the AARs.

[101] FTE effort estimates do not only refer to DoI processing. In particular, as far as LA is concerned, other independence-related activities are encompassed, such as: the 'compliance and veracity checks' secretariat, the collection of data and the drafting of the independence Annual report, the training activities on independence matters provided for staff, the replies on independence matters to EP, ECA etc.

Scientific Units are registered with PLANTS (Pesticide Residues and Plant Health), FIP (Food Ingredients and Packaging) and BIOHAW (Biological Hazards, Animal Health and Welfare) units, with approximately 0.3 - 0.5 FTE / year. This seems due primarily to the highest number of Expert DoIs that needs to be processed by these units,[102] although efforts do not appear to be strictly proportional, suggesting that other qualitative aspects are also at play.

Feedback from interviews indicates that there are widespread doubts – especially among EFSA staff – on the sustainability ***of the current effort level,*** especially considering the expansion of EFSA's budget since TR adoption that, however, was not accompanied by parallel larger staffing. The heaviness of current arrangements leaves EFSA with little room when the ordinary flow is disrupted by critical events, like the Covid 19 pandemic or the recent failure of the previous IT system for DoI management. In these circumstances, EFSA had to revert to manual processing of DoIs and adopt contingency measures like automatic extension of DoIs' validity for previously validated DoIs that did not present any change. Looking ahead, one of the priorities that clearly emerged from discussions is the need to find ways to improve the process' cost-effectiveness to ensure its sustainability vis-à-vis a workload increase.

- **SCREENING ACTIVITIES**

The available figures do not clarify the efforts required during each step of the process and the overall duration of the procedure, i.e. from the date of DoI submission to the date of validation. Therefore, a structured analysis of the process and of possible inefficiencies is not feasible, even though, reportedly, the new IT system that is currently being deployed will make collecting and elaborating process indicators possible. Anecdotal feedback indicates that the effort required – hence the efficiency of DoI screening process – vary greatly case-by-case. In particular, first-time submissions are typically more time-consuming to process than annual updates; there are two main reasons for this:

- Experts submitting DoIs for the first time are, evidently, less familiar with EFSA requirements than more experienced ones. To address this issue, EFSA provides instructions and concrete examples in the DoI, to guide respondents during the compilation. Still, first-time submissions often require one or more interactions with the declarant for integration / clarification purposes. Requests for clarification may emerge during the assessment conducted by the Scientific Unit or during the validation done by the LA. These two steps are not simultaneous, so repeated interactions are sometimes required. Back-and-forth exchanges with Experts to ***obtain clarifications is generally cited as the most time-consuming activity*** of the entire process. The difference in the length of the processing time across Units described in the previous section can largely be attributed to the incidence of new submissions on the total, which depends on how frequently new WG with ad hoc mandates are created in a specific work area.[103]
- The DoI Tool set up by EFSA – currently available only to Experts – allows straightforward renewal of the ADoI in case no new interests and no change in existing interests have emerged in the meantime. Furthermore, in the case of updates, the system allows for smooth identification of the changes made. However, in the case of revision, EFSA is bound to ***re-assess the entire ADoI and not only the new interests declared***.

- **ENFORCEMENT ACTIVITIES**

As discussed in Section 3, two times per year, EFSA carried out compliance and veracity checks on a sample of 30 DoIs submitted by Experts and Art 36 Organisations. The compliance check focuses on the correct

[102] FIP, BIOHAW and PLANTS have the three highest number of WG experts.

[103] The two-step process established by EFSA cannot be found in 'sister agencies', where CoI assessment follows a decentralised procedure (i.e. it is conducted entirely by the responsible person of the concerned body or service, with no 'validation' by a central service (except in the case of uncertain cases, as reported by ECHA).

application of the independence legal framework, while the veracity check is mainly carried out by comparing the DoI with the concerned expert's CV to verify the correctness of the submitted DoI, hence the identification of possible omissions or discrepancies.[104] Ex post checks do not involve additional research in external sources, so the instrument is not designed for in-depth investigation and – as the results reported in the AAR confirms – very few and mostly-unintentional omissions are detected through it. For this reason, some interviewees questioned the significance of these checks. Similarly, survey results show that the share of respondents in favour of an ***increase in ex post veracity checks*** (32%) largely exceeds the share of those who disagree with it (11%) – the latter being especially EFSA staff and Experts themselves.

For 'benchmarking' purposes, it should be noted that other agencies experience similar obstacles in enforcing checks - i.e. the lack of a 'real' investigation power that limits ex post checks to mere 'compliance' checks. However, in some cases (e.g. ECHA) it is reported that, in addition to expert's CV, checks may occasionally extend to on-line searches. Overall, comparators' investments in these activities are often smaller than EFSA's, with ANSES conducting a compliance audit every two years, and ECDC having currently suspended ex post checks.

From the administrative burden perspective, ex post checks likely absorb a ***minimal part of the total resources*** that EFSA allocates to independence-related activities. Exact data are not available, but the number of DoIs subject to ex post checks is a small fraction of the total DoIs screened so, in principle, it would seem logical to consider expanding this component some. On the other hand, in the current systems the added value of these checks appears to be modest, so an increase in this component can be recommended only if a reduction in the effort spent on ex ante screening is adopted in parallel. This option is discussed in Section 4.4.

- **OUTPUTS OF IMPLEMENTATION ACTIVITIES AND PROPORTIONALITY**

The outputs of the implementation activities described in the previous sections are reported in the Annex on independence of EFSA's Annual Activity Report (AAR). In particular the AAR provides data on:

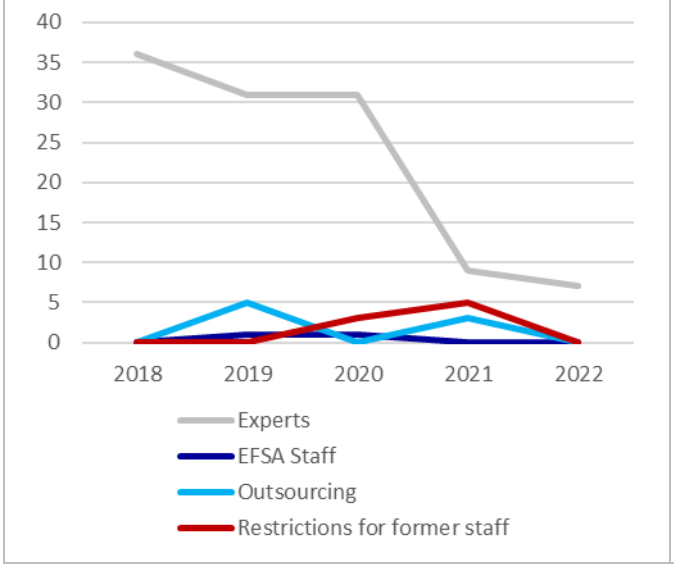
- The CoI ***identified and prevented at the screening stage***, broken down by category, i.e. Expert (by Panel), EFSA staff, candidates and selection board members, MB members, procurement, and grant awarding procedures.
- Issues identified during ex post ***compliance and veracity checks***, categorising them by typology of problem and remedial measures adopted.
- ***Restrictions applied to former staff*** who wish to engage in occupational activities after leaving EFSA.

Overall, the number of CoI detected and prevented at the screening stage is fairly small and declined overall in the period considered in the Study (Figure 4.8). In terms of incidence, CoI are generally found in 1% or fewer of the DoIs screened. Similarly, a very limited number of issues are found during compliance and veracity checks, typically two or fewer per year, if minor non-compliances (not requiring any remedial action) are excluded.

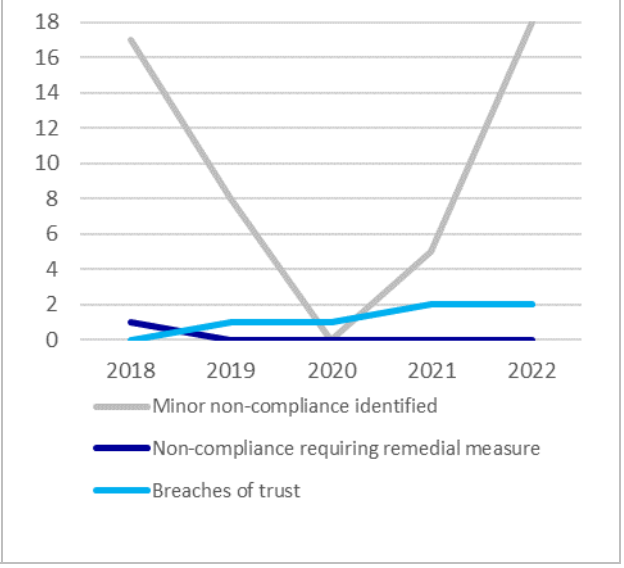
[104] Interestingly, as reported in EA 2021, EMA also conducts cross-checks of CVs and DoIs but at an 'ex ante' stage.

Figure 4.8 – Statistics on the implementation of independence-related activities

A) CoI identified and prevented at DoI screening stage, and restrictions applied to former staff



B) Outcomes of compliance and veracity checks



Source: *EFSA Annual Activity Reports.*

In pure efficiency terms, the ***'unit cost' of preventing CoI appears to be substantial*** given that the 'output' – i.e. number of CoI identified and prevented – is small compared to the 'input' – i.e. resources invested in implementation and enforcement of the Policy. However, the small number of identified CoI could be the result of prevention measures in place, so no firm conclusions can be drawn as to whether the current level of effort is proportionate or disproportionate.[105] On a qualitative level, it should be noted that periodic risk analysis conducted on the various areas of EFSA's management found ***independence-related risk to be 'significant'***, with 'moderate' likelihood (score 3, on a 1-5 scale) and of 'serious' impact (score 3, on a 1-5 scale)[106]. The 'impact' variable is not (or only marginally) under EFSA control[107], so risk can only be properly managed with measures to reduce 'likelihood' of events, which is precisely the purpose of the current, fairly onerous system.

In essence, the system mitigates the above 'likelihood' by maximising the probability of identifying a CoI risk at a very early stage. The probability of detecting a CoI risk during the screening process[108] depends on two variables: (1) frequency of incompatible interests in an Expert's DoI; and (2) a coefficient representing contingent factors (e.g. field of expertise required, variability in the assessment made by staff, etc.). Contingent factors vary constantly so the second variable is not objectively measurable. For this reason, despite the evident correlation between the frequency of incompatible, declared interests and the extent of prevented CoI risk, the correlation is not linear. Still, it can be assumed that the existence of a strong, ex ante screening mechanism acts as a deterrent for experts in a situation where there is the potential for CoI. In other words, the low probability of identifying a CoI during screening is reasonably due to the fact that

[105] A precise quantification of the effectiveness of the current Policy on CoI risk would require a counterfactual analysis, where the DoIs of experts working for EFSA before the adoption of the Policy are reviewed based on current rules to ascertain how many of them would not be eligible. However, the exercise would encounter substantial limitations as the assessment and validation process cannot be reconstructed ex post on DoIs submitted more than five years ago and in the absence of the DoI instructions that are provided at present. Furthermore, the type and the number of experts that EFSA needs vary from time to time, depending on the Agency's work programme and the requests received. This analysis can therefore be conducted only in qualitative terms. Relevance evidence on the dismissal of certain experts after the introduction of the new Policy is reported in Section 4.2.

[106] Based on excerpts from EFSA's periodic risk assessment exercise (still under finalisation at the time of writing).

[107] As discussed, in the past, EFSA faced serious reputation issues in connection with alleged CoI cases that gained visibility in the general media.

[108] Such probability can be expressed in terms of incidence on total DoI.

experts in a potential CoI situation do not express interest for membership in EFSA scientific groups.[109] Indeed, as some interviewees confirmed, a large share of 'CoI prevention' occurs when EFSA reviews the profile of available experts in its internal database, to select possible members of newly established WGs.

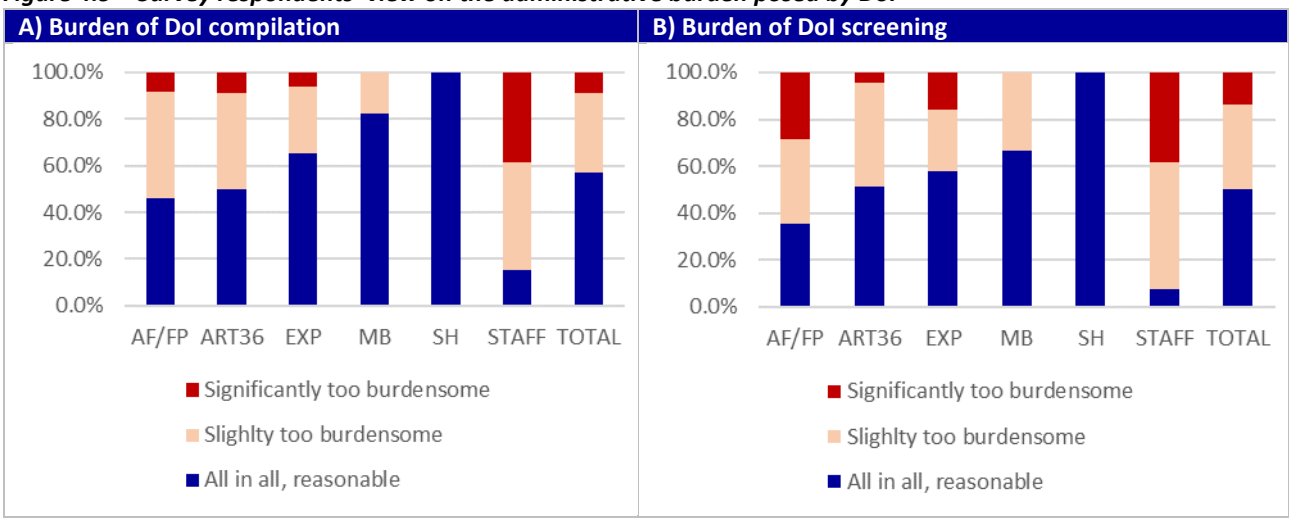
When combined with thorough screening processes, the low incidence of prevented CoI entails a reduction of risk related to independence, in terms of both absence of bias in scientific output and stakeholders' perceptions. So, the substantial unit costs of preventing CoI might be justified by its direct impact on actual and perceived independence.

EQ - Is the form of action as simple as possible and coherent with satisfactory achievement of the objective and effective enforcement?

- **PERCEPTION OF THE OVERALL BURDEN**

Complementary to the above considerations on the sustainability of current DoI procedures, this section reports feedback from EFSA's stakeholders on the overall ***proportionality of the burden*** that such procedures pose, respectively, to declarants and to assessors. The results are reported in Figure 4.9, with the exclusion of 'don't know' answers, as their incidence varies greatly across target groups.

Figure 4.9 – Survey respondents' view on the administrative burden posed by DoI



Source: *Targeted survey.* ***Note:*** *Percentages have been recalculated excluding Don't know answers, as their incidence varied greatly across target groups.* ***Legend:*** *AF/FP: members of the Advisory Forum and/or Focal Points; ART36: representatives of Article 36 organisations; EXP: scientific experts, member of EFSA scientific groups; MB: members of the Management Board; STAFF: EFSA staff ('CIM community'); SH: other stakeholders (i.e. representatives of the business and food industries, farmers, environmental / health NGOs and practitioner and academic organisations).*

The main findings can be summarised as follows:

- Around half of the respondents qualified the administrative burden required for DoI compilation (56%) and DoI screening (50%) as 'reasonable'.
- DoI screening is generally perceived as more burdensome by all categories surveyed. Nearly 14% of total respondents consider it to be 'significantly too burdensome' against 9% who expressed this judgment in relation to DoI compilation.
- Coherently with the sustainability concerns described in the previous section, EFSA staff is by far the category of respondents that most frequently expressed dissatisfaction with the current burden imposed by the DoI procedure – both compilation and screening. Conversely, MB members and EFSA Stakeholder

[109] Cases of applicants with CoI situations remain, but they appear to be decreasing, as the scientific community becomes more and more aware of EFSA CoI rules, also thanks to the Authority's improved reputation.

Forum's and Stakeholder Bureau's members (based on very few responses, however) tend to consider the burden as non-problematic. More balanced views are registered in the other categories.
- Critical views are registered more frequently among Experts with more than five years of experience with EFSA than among the rest.

➢ AREAS FOR POSSIBLE DOI SIMPLIFICATION

This section briefly examines the areas for possible simplification of current arrangements that have emerged from consultations, complemented – where relevant – with the findings of EA 2021 and ENVI 2023. The analysis focuses specifically on operational and procedural aspects linked to DoIs, as more general considerations on the proportionality of current provisions are provided in the next section.

- ***IT tool for DoI management***. EFSA has put in place an IT tool covering the various steps of DoI submission, assessment, and validation. The current system replaces a previous version that was discontinued in 2021. The initial implementation of the new IT tool was fraught with malfunctions that caused a postponement of around 1.5 years, during which the tool was replaced by a time-consuming manual procedure. The new DoI Tool is currently available only for Experts' DoIs, but there are plans to extend it to the other categories also. These plans respond to a demand that was already identified in the EA 2021 review and reiterated in ENVI 2023. In particular, the results of the survey showed that 42% of respondents support extending the tool to DoIs submitted in the framework of procurement and grant awarding procedures (against only 6% of disagreements).

- ***Automaticity of DoI assessment***. The DoI screening criteria involve, as discussed, 'unconditional restrictions' i.e. conditions that automatically trigger a CoI situation, and 'qualified restrictions', which concern interests that may or may not represent a CoI, thus requiring a discretionary judgement from DoI assessors. Evidently, the assessment of interests subject to 'unconditional restrictions' is more straightforward and resource efficient than the assessment of interests subject to 'qualified restrictions'. The application of screening criteria is guided partly by objective features which allow for an 'automatic' assessment, such as how old the interest considered is, or whether private research funding exceeds the established threshold. However, other criteria have more blurred boundaries and require a discretionary assessment (e.g. 'overlapping' with the mandate of the scientific group, a connection with risk management functions in some hybrid settings, etc.). For the sake of efficiency, ENVI 2023 recommended that EFSA consider adopting a more automatic procedure, although it also recognised that "*such automaticity may appear to be rigid and in particular hindering the availability of experts*" and suggested possibly combining automaticity with a wider range of 'intermediate' forms of participation (see Section 4.5). Indeed, the results of the consultation activities return a mixed picture on this point, i.e.:

    - ***EFSA staff*** would largely be in favour of more automaticity in screening procedures to reduce the current burden.
    - Conversely, ***Experts*** appear to be largely sceptical on this option. As emerged from interviews, they consider flexibility to be an essential feature of DoI assessment as the contexts of declared 'interests' need to be taken into account properly.
    - Among the other surveyed categories – AF / FP, MB members, and representatives of Art 36 organisation – neutral positions prevail.

EQ - Does the measure go beyond what is necessary to achieve the objectives?

➢ ASSESSMENT OF SPECIFIC MEASURES

The first part of this EQ entails an assessment of the specific measures that EFSA has put in place to achieve the independence policy objectives. The analysis focuses on three main screening criteria, combining survey results with qualitative evidence. The overall results of the survey are presented in Figure 4.10.

- Assessment of CoI against the ***remit of the scientific group***. As discussed, this is one of the pillars of EFSA's approach to independence and the main criterion adopted for reasons of 'proportionality', i.e. to avoid a shortage of expertise. Reportedly, it is not always straightforward to identify an overlap between declared interests and the mandate. So, one of the arguments in support of extending screening to the entire EFSA mandate is linked to efficiency, as the involvement of scientific EFSA units in DoI screening would be considerably reduced. As the survey results show, this item is quite divisive, with almost the same proportion of supporters and opponents of a hypothetical broadening of the screening's scope. However, it should be noted that Experts and EFSA staff – i.e. those who are more directly concerned by the provision – are largely against this option, while most positive feedback comes from representatives of Art 36 organisations. Furthermore, disagreements are significantly more frequent among respondents who are familiar with PoI 2017 and have worked with EFSA for more than five years. In other words, the distribution of results suggests that those who support this option are poorly aware of the adverse impact that it would have on EFSA operations.

  Comparisons with other EU and MS agencies show that – despite some formal differences – EFSA rules are not very dissimilar in practice. ANSES, for instance, requires that experts and members of specific monitoring committees declare interests that are relevant to the field of activity specifically related to an individual's mandate(s) rather than to the general ANSES remit. As for interests to be declared, ECHA's policy defines the scope to be the regulatory field of ECHA's activity, meaning that only interests which can interfere with its work fall within the scope, construed to be "all interests in a commercial entity or other organisation which is subject to the authority of ECHA (e.g. duty-holders under REACH, CLP, Biocides or PIC) or which has dealings with ECHA". At the same time, interests which are not relevant to the work of the respective ECHA body are considered to be 'cleared', so they do not constitute a CoI.

- Admissible ***share of private funding*** on the ***total relevant research*** managed. EFSA has established a 25% threshold below which relevant private research funding is not deemed to be problematic from a CoI perspective. This threshold has attracted some criticism. The EP budgetary discharge authority finds that cooling-off should be applied in the case of any private sector funding, and similar views have been voiced by some stakeholder NGOs. Among 'comparators', it can be interesting to note that ECHA's policy does not provide for the incompatibility between research funding and membership of scientific groups. Nevertheless, it prevents staff and members of ECHA's bodies who receive research funding above 25% of the total research budget from a specific commercial entity from participating in any decision-making procedure which directly concerns that commercial entity.[110]

  The survey results show a marked polarisation between supporters and opponents of stricter rules, with EFSA staff and Experts mostly against this option and representatives of Art 36 organisations largely in favour of it. It should be noted that the threshold of 25% is conventional, i.e. there is no specific reason supporting this level. At the same time, it was considered important to establish a level, to somehow force Experts to make the effort of estimating it.[111] Opponents often remark that the reality of academic research largely consists of private sector co-funding, especially in the area of innovation and advanced technology and that private-public partnership in research is a policy objective encouraged by the EU, e.g. under the *Horizon Europe* research funding programme. In this respect, it is worth noting that at the

[110] See: ENVI 2023.

[111] The CIM Decision also provides a step-by-step calculation model.

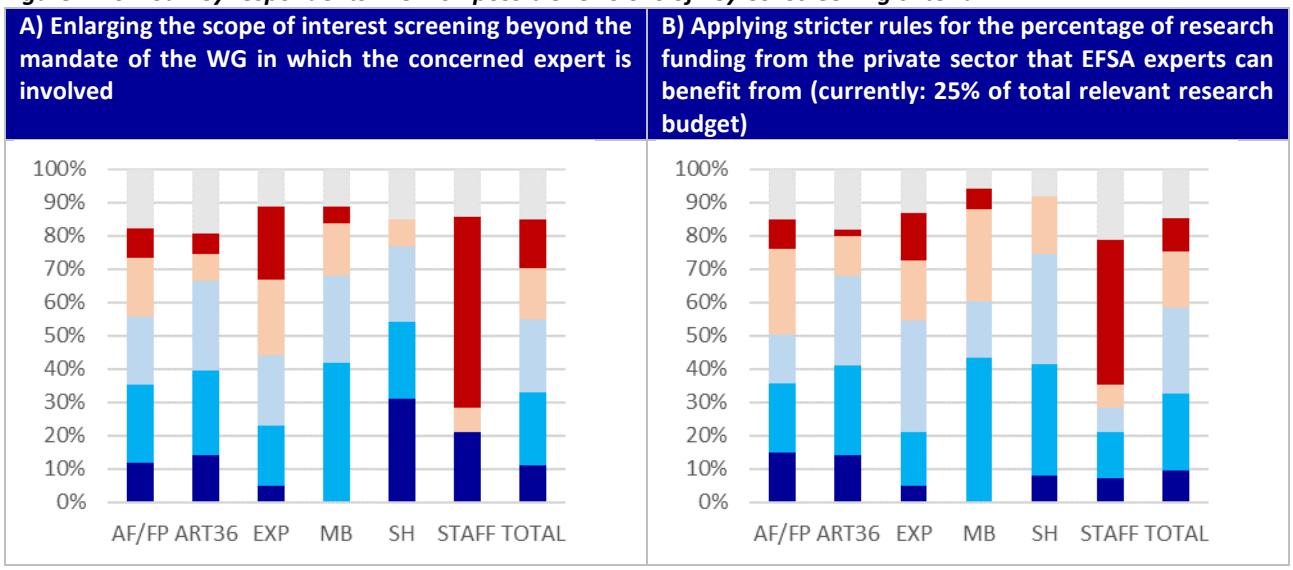
operational level, EFSA does not assess private funding of projects received in the context of public co-funding schemes (e.g. FP7, Horizon 2020, national, regional, or local funding programmes).[112] The rationale is that co-funding schemes promoted by public institutions are assumed to be pursuing public interests. However, it is unclear how the 'public' nature of such schemes is verified (especially regional and local schemes), and how the private funding is accounted for in the calculation model provided in the CIM Decision.

- ***Cooling-off periods***. The introduction of cooling-off periods is one of the main changes introduced with PoI 2017, in response to specific calls from the EP. ENVI 2023 noted that EFSA applies the shortest cooling off period among the EU agencies with similar modus operandi (ECHA and EMA), without providing a clear explanation. In the case of EMA, for the majority of declared interests, a three-year cooling-off period is foreseen, with restrictions gradually decreasing over time. ECHA applies cooling-off periods ranging from two to five years depending on the interest.

  Regarding the option of applying longer cooling off periods, survey respondents appear almost evenly split between opponents, supporters, and respondents with a neutral view on this subject. The distribution of responses shows – once again – the opposition of those who would be directly affected (EFSA staff and Experts) and more receptivity from non-affected parties like Art 36 Organisations.[113]

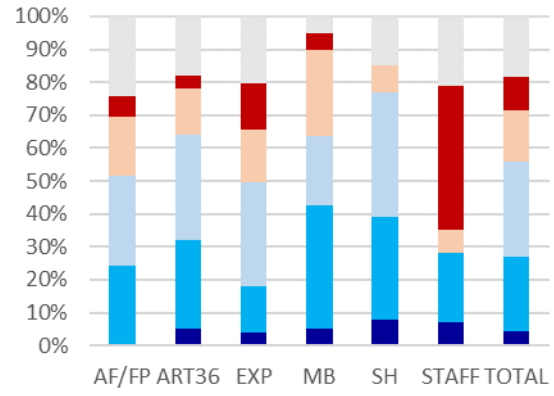
The results of the survey illustrate, albeit indirectly and in quite general terms, the existence of ***diverging views on the justification underpinning current rules*** and the scope and direction of possible changes. The agreement with greater restrictions expressed by a substantial share of respondents should be combined with the large demand for 'relaxing rules' described in Section 4.2 (see Figure 4.7). The different views can hardly be reconciled unless a different system is designed, as discussed in the next section.

Figure 4.10 – Survey respondents' view on possible revisions of key CoI screening criteria



[112] This clarification is provided in the internal Working Instructions on Competing Interest Management adopted by EFSA in 2018 (unpublished). From a coherence perspective, this interpretative instruction raises a few questions: (1) it presupposes that the private funding occurred under a research project that is part of a public-driven research programme, but the DoI does not request this information, (2) there is no criteria or assessment procedure to ascertain whether the concerned co-funding schemes meet the 'public interest' requirement (e.g. a maximum percentage of private funding admitted), (3) PoI 2017 and the CIM Decision indicate that the assessment must be cumulative and not project-by-project, and are unclear about how the private co-funding discussed here should be considered for aggregation purposes.

[113] As discussed, the application of cooling-off periods is the main difference between the DoI assessment criteria applied to Experts and to Art 36 Organisations.

C) Applying longer 'cooling-off' periods to experts prior to their involvement in EFSA scientific activities	*legend*
	

Source: *Targeted survey*

➢ **ALIGNMENT OF RULES WITH COI RISK**

The main obstacle for the adoption of more stringent CoI rules is – as discussed – the risk of excessively restricting the pool of experts eligible to participate in EFSA's scientific work. To cope with this problem, ENVI 2023 suggests the adoption of mitigating measures – i.e. 'intermediate' solutions that would make it possible to ***differentiate expert's involvement in EFSA activities*** in relation to the extent of the CoI risk. This proposed approach is found in two of ENVI 2023's recommendations, i.e.:

1) associated to a possible enlargement of the scope of CoI screening to cover the entire EFSA remit – where 'intermediate solutions' would consist of reduced participation in the presence of 'minor CoI'; and
2) associated to the possible adoption of more centralised and automatic – hence rigid – implementation of CoI rules, where the availability of experts could be ensured by establishing a wider range of 'intermediate forms of participation'.

Limited details are provided in ENVI 2023 on how such mechanisms should work (it is left for EFSA to decide what a 'minor CoI' is and how this can be operationalised in the Policy), but the introduction of a 'rule differentiation' concept might open alternative scenarios for the management of competing interests, which potentially go beyond the two specific aspects mentioned in ENVI 2023. The underlying principle of this approach would be to somehow ***align rules and requirements with the actual CoI risk and impact***, modulating CoI criteria and controls in accordance with the reputational risk incurred.

Actually, some differentiation is already in place in EFSA's system, e.g. in the distinction between 'unconditional' and 'qualified' restrictions, in the different criteria applied to Chair / Vice-chair vis-à-vis other WG members, or in the derogation to cooling-off periods for PRM members employed in a PI. Nonetheless, ENVI 2023 seems to suggest a more structural categorisation, in line with the systems adopted by other agencies. Indeed, some form of categorisation and interest ranking can be found in all the comparators examined in the 'benchmarking exercise':

- ***ECHA*** has a three-tiered categorisation in place: Level A corresponds to 'cleared interest' (not considered linked to a possible CoI); Level B is assigned to interests requiring an ad hoc assessment' (i.e. a discretionary assessment); and Level C applies to most substantial CoI risk, and the application of specific restrictions.
- ***EMA*** firstly distinguishes among three levels at the DoI stage: direct interests declared (level 3), indirect interests declared (level 2), and no interests declared (level 1). Then, based on the nature of the declared interest, three possible situations are identified: Category 1 - declarant's leading role during previous employment or involvement, which results in non-involvement during the term of the mandate of the

committee or other body member or expert; Category 2 - for declared interests deemed to be expired at the time of involvement, resulting in full engagement in EMA's activities; and Category 3 - for the remaining declared interests, not listed in categories 1 and 2, a three-year cooling-off period is applied after the expiration of the interest.

- ***ECDC*** also categorises CoI risk levels with a three-level ranking, from A to C.
- ***ANSES*** ranks the intensity of interests as: 'major' when expert's main activity (remunerated or not) is for an entity that would directly take an advantage or a disadvantage from ANSES opinions, decisions etc.; 'minor' when such entity would not take a direct (dis)advantage but operates in a field that falls within ANSES' remit; 'not relevant' in all other cases. As a general rule, after three years, an interest connection is deemed to be minor and is a priori compatible with involvement in ANSES' activities.
- ***AFSCA*** classifies declared interests on a four-level scale – from 1 to 4 - where 1 corresponds to 'no CoI' (hence no restriction is applied), while 4 means 'incompatible CoI' for which no derogation can be granted. The classification takes into account also the declarant position and hierarchical level, so level 4 is generally applied to top officers.

In principle, modulation may regard different aspects of the policy, which are examined below, i.e. (1) the type of interest declared; (2) the sensitivity of the task; and (3) the role assigned to the expert.

- A ***differentiation by type of interests*** is already in place, namely between interests subject to 'unconditional restrictions' (employment, financial interests) and interests subject to 'qualified restriction'. The assessment of the latter is made against the specific mandate of the scientific group of involvement and requires some degree of discretionary judgement. Furthermore, distinctions exist also in relation to whether the declared activity is carried out within PIs as part of public interest duties or not. In this sense, the articulation by type of interests appears already fairly developed and the introduction of additional distinctions might add to the complexity of the system. Still - and in accordance with remarks frequently made by interviewees – solutions for streamlining the management of interests subject to 'qualified restrictions' could be envisaged.
- PoI 2017 states that "*more stringent rules and procedures are applied to areas where CoIs with commercial interests are likely to occur. The same applies in cases where multiple items are discussed in the same forum*". This principle seems to introduce the concept of ***CoI sensitivity by task*** and a possible differentiation of CoI-risk between specific mandates, but no specific implementing action appears in place. As some interviewees noted, the tightening of CoI rules occurred as a consequence of a reputational crisis caused by a few controversial dossiers, while in several other work areas EFSA has never experienced any CoI-related issues. So, the possibility of modulating procedures also in relation to the sensitivity of the dossiers could be explored.[114] On the other hand, categorisation of dossiers by 'sensitivity' might entail a series of complications, such as the need for ex ante considerations on the socio-economic aspects involved, as well as discretion and timing of the risk assessment.
- The formal role that an expert can undertake in EFSA's scientific group is basically limited to three options: (1) Chair / Vice-chair; (2) Member; or (3) Hearing Expert. ENVI 2023 seemingly suggests considering further ***differentiation of roles*** that experts may take in the process**.** At first sight, this solution appears to be far from straightforward, as it could imply procedural changes at various levels, including in the modus operandi of Panels, WG and PRM. On the other hand, the possibility of differentiating the screening procedures by role (as is currently the case only with Hearing Experts' whose DoI are not screened) might be explored, especially for experts who are not members of Panels or SC, including experts involved through grants assigned to Art 36 organisations (as discussed in Section 4.5 below). This option was 'tested' in the targeted survey, and feedback indicates that the majority of respondents from all categories would agree with introducing some form of differentiation based on an expert's role.

[114] A possible complication to this option is that categorisation of dossiers by 'sensitivity' would require ex ante considerations on the socio-economic aspects involved.

The introduction of differentiation measures as outlined above, should be preceded by an accurate cost-effectiveness analysis, to avoid the reform translating into an increased burden rather than a simplification. In fact, drawing a distinction implies an administrative act, so the more numerous distinctions are, the greater is, in principle, the effort in differentiation. This risk can be overcome by introducing distinctions that are as objective as possible, which can, ideally, be verified automatically.

4.4 EU Added Value (including subsidiarity)

EQ - Is the form of action the most appropriate/necessary at EFSA level?

- **OVERALL EFSA APPROACH TO INDEPENDENCE**

EFSA's overall approach to CoI management is characterised by ***joint assurance from concerned individuals and EFSA itself***. On the Expert's side, the standard process involves, as discussed, the submission of a detailed DoI accompanied by a signed statement where the declarant is requested to self-assess his/her CoI status, based on the interests declared, which he/she pledges is 'truthful and complete'. The Expert is assumed to be familiar with EFSA rules (he/she must declare to have read the CIM Decision), still the declarative sentence reads "*I think I [have / do not have] a conflict of interests (…)*" (emphasis added), which implies some degree of uncertainty in the self-assessment. In this sense, the DoI is then subject to EFSA screening – as described in the previous sections – which may eventually validate or overturn the expert's self-assessment. By doing this, EFSA somehow 'certifies' the Expert's independence, thus becoming co-responsible – from a reputational perspective – of issues that might arise. In this respect, it should be highlighted that EFSA bases its decision exclusively on the information provided by the expert so, strictly speaking, it is the DoI and not the actual CoI status of the expert that is validated. On the one hand, this maintains the expert's being accountable – hence co-responsible – for the information provided; on the other hand, EFSA does not have full control on the accuracy and reliability of the declaration, and the risk of reputational issues cannot be entirely ruled out.

It must be said that such ***risk is duly mitigated*** by the system in place, in particular:

- Experts are trained and instructed on how to complete the DoI properly. Especially those who have a long experience with EFSA are highly familiar with EFSA CoI rules and standards.[115]
- EFSA's screening substantially reduces the probability of incorrect self-assessment by experts.
- There are sanctions applied in case of omissions or untruthful declarations.
- EFSA also carries out ex post veracity checks on a sample basis, which add a further layer of control, although essentially it consists of the re-assessment of the DoI against the expert's CV (no additional research is carried out).

To sum up, overall, EFSA's approach to CoI appears to be aimed at ***minimising the probability of CoI occurrence***, but it ***does not protect EFSA from reputational damage*** in the case that, despite controls, a CoI emerges at a later stage compared to the preliminary DoI assessment, nor from CoI allegations formulated by external entities based on their own assessment.

From a 'subsidiarity' perspective, independence assurance is delivered in a different way in the case of the members of EFSA's governing bodies EFSA, specifically:

- The DoIs submitted by ***MB members*** are assessed by EFSA but conclusions and follow up actions are taken by the Board itself, including possible exclusions and requests for replacement. In this sense, the

[115] This is also confirmed by the results of the survey, which involved 90 Experts. Self-declared familiarity with PoI 2017 and implementing rules is largely correlated with the years of collaboration experience with EFSA.

responsibility (and the associated risk) leans on the side of MB members (MS representatives, to a large extent).

- In the case of ***AF members***, EFSA's role is even more detached. EFSA's duty is to follow up on "*serious and well documented cases of CoI*" by submitting the issue to the Board again (i.e. MS representatives). However, such cases do not emerge from EFSA's own assessment, as the screening of AF members' DoIs is not envisaged.

There are various reasons for the disparities between the CoI approach applied to MB / AF members and to Experts, which relates e.g. to the institutional profile of members and the overall governance arrangements of the Authority. However, from a substantial perspective, the main reason appears to be that MB and AF members are not directly involved in the production of EFSA's outputs, so they can hardly influence the contents of scientific opinions. On the other hand, it should be noted that Experts – albeit engaged on their individual capacity – are often employed in MS Competent Organisations, and sometimes in the organisations that represent MS in EFSA's Governance Bodies (i.e. 50 cases out of 528 Experts have been detected, i.e. nearly 10%). Hence, it would perhaps be worth exploring the possibility of CoI arrangements involving ***'more subsidiarity' also in the case of Experts***, i.e. arrangements where – as in the case of Governance bodies members – assurance of absence of CoI rests primarily on the declarant's side. In this respect, specific considerations can be made on:

(1) Expert's affiliation – e.g. assuming that experts employed in MS bodies represented in MB, AF and/or Art 36 organisations (see next section) have at least in part already completed a CoI screening.
(2) Expert's role – e.g. differentiating the approach depending on the position of experts within a WG and/or a Panel (Chair, Vice-Chair, Rapporteur, 'ordinary' members etc.), extending the same logic that is already in place for DoI screening criteria.

➢ SUBSIDIARITY IN THE CONTEXT OF COOPERATION

The overall approach described in the previous section does not change in the case of outsourcing scientific activities. Grant beneficiaries (Art 36 organisations) and contractors selected through public procurement are required to submit DoI, which are assessed and validated by EFSA through the same process, but partly different criteria, used for Experts. Therefore, also in this case, EFSA is taking de facto responsibility for certifying the CoI status of grantees and contractors rather than limiting its action to hold counterparts accountable for assuring absence of CoI. This is even more remarkable considering that EFSA has arguably less control on grantees and contractors than on Experts, whose DoI are published, thus subject to closer public scrutiny.[116] Moreover, in the case of Art 36 organisations, the obligation to submit an Institutional DoI has been removed recently (but not for contractors), considering the public interest nature of such organisations and – more importantly – the fact that they are already subject to screening by MS at the time of their designation for inclusion in the Art 36 List. The same ***'subsidiarity' logic, however, is not applied to the experts working for these organisations***, despite the fact that their involvement in EFSA's scientific work is not based in an individual capacity – as is true for the Experts involved in WG – but is based rather on the fact that grant agreements have been concluded with their employers.

In this respect, stakeholders' views on possible alternative arrangements have been investigated. In particular, survey respondents were asked to express agreement/disagreement on the option of establishing mechanisms for ***sharing the responsibility for CoI screening with MS authorities*** in the case of experts from competent organisations that collaborate with EFSA. As Figure 4.11 shows, a relative majority of respondents (41%) would agree – at least in part – with this option, while 16% expressed disagreement. Supporters appear more frequently among MB members and EFSA Stakeholder Forum's and Stakeholder Bureau's members.

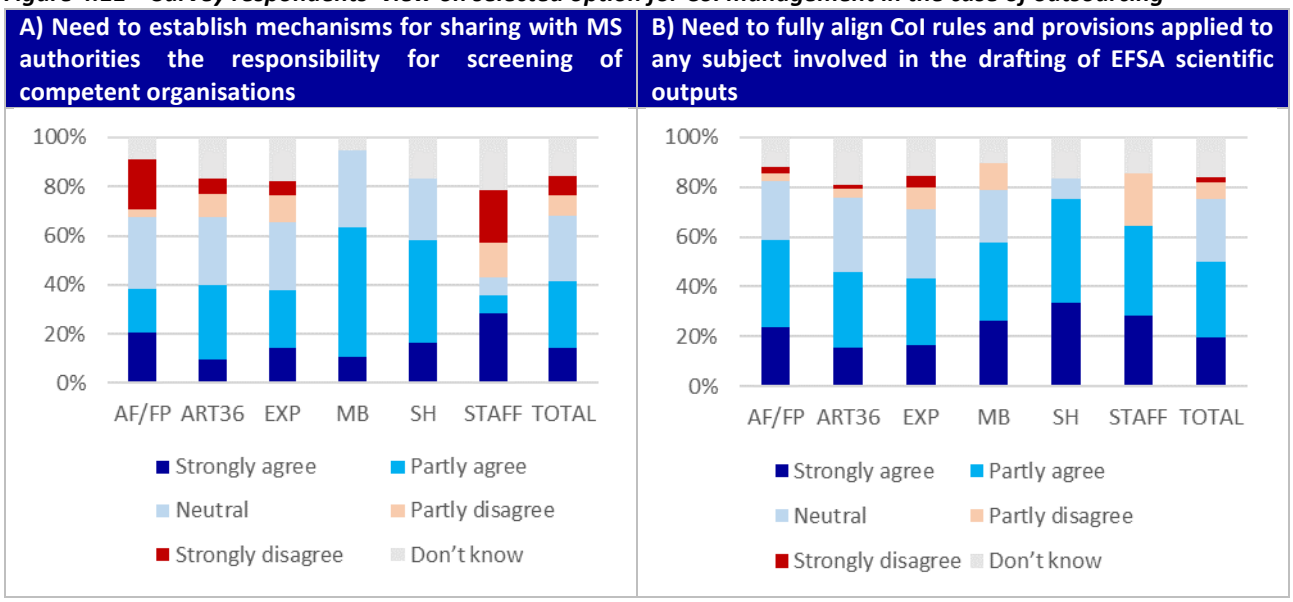
[116] In this respect, it is not surprising that the CoI-related cases requiring remedial actions are even less frequent than among experts. Anecdotally, less than one case per year is registered.

Instead, rather polarised views are registered among EFSA staff and the Advisory Forum / Focal Point respondent category.

Feedback from interviews clarified that while the option is generally considered worth exploring, an essential pre-requisite would be the ***adoption by MS of harmonised standards*** in line with EFSA's principles and rules. This would be essential, inter alia, to ensure the same CoI rules are applied to any experts engaged in the preparation of EFSA's scientific advice – a requirement that becomes even more fundamental as the TR explicitly permits the outsourcing to Art 36 organisations of critical pieces of work such as the drafting of opinions that EFSA Panels may adopt upon peer review. As the results of the survey indicate (Figure 4.11), there is already a demand for ***alignment of CoI rules applied to all experts*** who are responsible for scientific work, irrespective of 'insourced' or 'outsourced'. As discussed in the next Section, a possible solution would be differentiating CoI requirements depending on the tasks assigned, aligning them to Experts in the case of critical pieces of work (drafting of scientific opinion), while externalising CoI management to MS - for subsidiarity reasons – in the case of non-critical supporting tasks.

Lighter processes could also be devised for ***contractors*** recruited through procurement, considering that the legal framework does not allow contractors to perform critical tasks. In particular, an option could be to maintain the Institutional DoI screening and replace expert's individual DoI assessment with a sworn declaration of absence of CoI, legally assured by the contractor. The option of asking and assessing individual DoIs could be maintained in the case of tasks or dossiers requiring special CoI management.

Figure 4.11 – Survey respondents' view on selected option for CoI management in the case of outsourcing



Source: *Targeted survey.* ***Legend:*** *AF/FP: members of the Advisory Forum and/or Focal Points; ART36: representatives of Article 36 organisations; EXP: scientific experts, member of EFSA scientific groups; MB: members of the Management Board; STAFF: EFSA staff ('CIM community'); SH: other stakeholders (i.e. representatives of the business and food industries, farmers, environmental / health NGOs and practitioner and academic organisations).*

4.5 Relevance

EQ - To what extent does the Transparency Regulation require adaptations of the Policy?

➢ **OVERVIEW**

With the adoption of the Transparency Regulation (TR) in 2019 (in force since 2021), EFSA entered a phase of substantial renewal spanning mandate, governance, implementation, and delivery aspects. The purpose of the TR is to improve the ***transparency of risk assessment in the food chain and to strengthen reliability,***

objectivity and independence of the processes underpinning EFSA's scientific output. The TR established, among other things, provisions on access to documents, confidentiality, strengthened engagement, integrated risk communication, and a fundamental revision of the MB's composition, with the inclusion of MS representatives and stakeholder representatives along with EU Institutions. In parallel, EFSA's ***budget has rapidly increased***, from EUR 80 million in 2019, to EUR 120 million in 2021 and EUR 147 million in 2023 (forecast).[117] As discussed in Section 4.3, a budgetary item that substantially increased consists of outsourced activities, i.e. public procurement and – in particular – grants assigned to Art 36 organisations.

From the independence policy perspective, the change in governance set-up and the increased outsourcing of scientific work (including of critical tasks) are the two main aspects that need to be examined in this Section, to verify whether current rules are still fit for purpose. Other, less crucial transparency-related aspects are discussed in a dedicated EQ at the end of this Section.

- **RELEVANCE OF INDEPENDENCE RULES FOR THE MANAGEMENT BOARD**

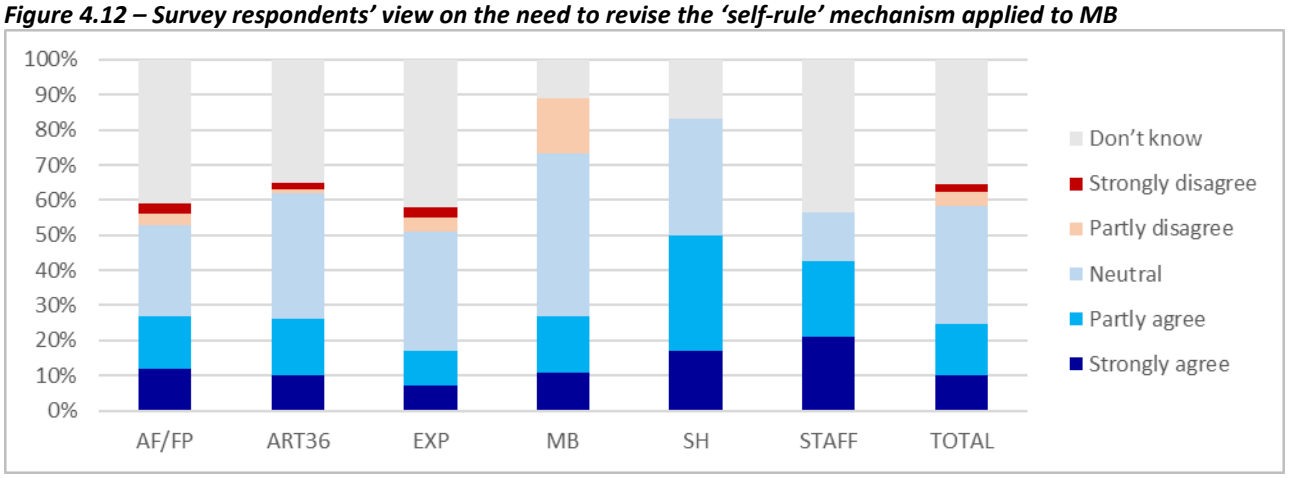
The TR reformed the composition of the MB deeply, which includes at present MS representatives and representatives of civil society and of the food-chain interests (consumers, food industry, farmers, and environmental NGOs). The DoIs submitted by MB members are subject to preliminary assessment by EFSA, but the 'validation' – and possible management actions - falls under the responsibility of the Board itself. As already discussed in Section 4.2, this '***self-rule' mechanism*** appears to be poorly in line with ethics standard for this kind of body.[118] A similar mechanisms is found in EMA, while in ECHA the procedure involves consultation with a nominating authority, which is responsible for taking eventual remedial actions. A relative majority of survey respondents would support a revision of this 'self-rule' mechanism. As Figure 4.12 shows, this position was more frequently voiced by EFSA staff, while opponents more frequently belong to the MB itself, even though in several cases respondent did not express any view on this point.

In terms of the functioning of the Policy, the revised composition of the MB adds complexity to the picture. On the one hand, the TR establishes that MB members act as representatives of MS, EU Institutions and interested parties, thus representing the interests of the entity they are affiliated with; on the other hand the Policy – in accordance with Art 37 GFL – requires that all concerned individuals act independently and in the public interest. In legal terms, these two sources of interests are compatible, but in substantial terms ***situations where competing interests arise cannot be ruled out***. The CIM Decision states that the assessment of MB members' DoIs should consider: (a) the decision of the Council appointing the Board's members; and (b) the notarial function of the MB regarding EFSA's scientific process. In other words, it is somehow acknowledged that the profile of MB members should be considered with due flexibility and – more importantly – in light of the fact that MB members have no influence on the production of scientific opinions. So, any potential frictions between the public interests and the specific interests that MB members represent would have ***no consequence on the independence of EFSA scientific work***. Additionally, the evidence from interviews indicates that MB members do not perceive any substantial risk of bias in MB work, precisely because the integrity of processes is guaranteed by the ample representation of competing interests, which somehow balance each other out.

[117] https://www.efsa.europa.eu/sites/default/files/event/mb93/mb221215-a4.pdf

[118] Regarding the problems of self-rule, see: Dennis F. Thompson, Overcoming the Conflict of Interest in Congressional Ethics, Woodrow Wilson International Center, Washington, D.C., January 16, 2007. Similarly, for a review of why external and independent monitoring is not a good predictor of the robustness of the ethics regulations, see: Susana Coroado & Luís de Sousa (06 Jul 2022): Regulating Ethics in Parliaments: Measuring Regime Robustness, Public Integrity, DOI:10.1080/10999922.2022.2075640.

Figure 4.12 – Survey respondents' view on the need to revise the 'self-rule' mechanism applied to MB



Source: *Targeted survey.* ***Legend:*** *AF/FP: members of the Advisory Forum and/or Focal Points; ART36: representatives of Article 36 organisations; EXP: scientific experts, member of EFSA scientific groups; MB: members of the Management Board; STAFF: EFSA staff ('CIM community'); SH: other stakeholders (i.e. representatives of the business and food industry, farmers, environmental / health NGOs and practitioner and academic organisations).*

➢ **RELEVANCE OF INDEPENDENCE RULES FOR OUTSOURCING ACTIVITIES**

EFSA Strategy 2027 explicitly envisages the "*broader participation of Member State competent organisations in EFSA risk assessments*" as one of the building blocks to increase relevance and improved reputation of EFSA's scientific advice.[119] The envisaged participation is broader both in quantitative terms and qualitative terms. It is broader on the quantitative side in that the enlarged scope of EFSA's mandate and the structural backlog in certain fields of the Authority's work plan have led in that direction. On the qualitative side, as discussed, the TR explicitly mentioned the possible involvement of Art 36 organisations in drafting scientific opinions that EFSA Panels may adopt upon peer review. This represents an extension of the roles typically assigned to Art 36 organisations, which consisted in the preparation of supporting studies – such as literature review, data gathering, etc. – that the relevant EFSA WG would use in the drafting of opinions. In other words, scientific work traditionally carried out by EFSA's WG ***may be outsourced to Art 36 organisations***. The Panel would remain responsible for adopting it, similarly to the procedure currently applied to pesticides authorisation. Actually, such possibility already existed but, reportedly, was seldom used; also, after the adoption of the TR, the outsourcing of draft scientific opinions has rarely been used.[120] The TR did not change the scope of activities that can be outsourced through procurement, so the possibility of drafting scientific opinions is still not offered to contractors.

The outsourcing of critical tasks like the drafting of opinions is generally viewed by the professionals interviewed as an unavoidable measure as EFSA does not (and cannot) have the internal resources to effectively implement its enlarged mandate. At the same time, ***outsourcing poses well-known CoI challenges***[121]. Some scepticism was also registered, especially among Experts, based primarily on two connected arguments:

- Art 36 organisations are currently subject to lighter eligibility criteria than Experts (cooling-off periods are not applied). This is justified by their involvement in the production of EFSA's scientific output as a

[119] Expected Operational Results 1.1.1 related to Expected Outcome 1.1 of EFSA Strategy 2027, https://op.europa.eu/webpub/efsa/strategy-2027/en/

[120] In part, this is because the TR is in force since March 2021, but it does not apply retroactively to activities that were ongoing at the time of entry into force.

[121] An overview and introduction into the outsourcing challenge and relation with CoI is provided in: Clark, C. 2012. Ethics, Employees and Contractors: Financial Conflicts in and out of Government, Washington University in St. Louis, Legal Studies Research Paper, No. 11/02/03, February 2012. Also, see: Rybnicek, R. et al. 2020, Risks in Public – Private Partnerships: A Systematic Literature Review of Risk Factors, their Impact and Risk Mitigation Strategies, Public Performance & Management, No. 5, pp. 1174-1208.

provider of supporting study. However, according to various Experts, in case of outsourcing of more sensitive tasks, these organisations and their staff should be subject to the same rules of WG members. On the other hand, there is a concrete risk that more restrictions would lead to ***hindering rather than facilitating the engagement of competent organisations***.[122] Inter alia, this would also go against a clear demand for streamlining DoIs and related procedures for both Art 36 organisations and contractors expressed by most survey respondents (especially, MB members and EFSA staff).

- Some Experts expressed concern regarding outsourcing EFSA's arguably 'core business', i.e. the preparation of scientific opinions, and are sceptical regarding the outputs that an external body would produce regarding both (a) quality; and (b) independence – as ***Art 36 organisations are not always considered per se free from CoI***, including CoI related to national interests. Some interviewees underlined the need to remove disparities in the criteria that MS apply to designate Art 36 organisations; others highlighted that when peer reviewers are not satisfied with the draft received, they may want to review data used etc. thus leading to a duplication rather than a streamlining of the process.

As discussed in the previous section 4.4, a possible solution is offered by ***differentiating rules for proportionality purposes***. Applying stricter rules for supporting activities that Art 36 organisations have carried out is not needed. On the other hand, in the case of 'critical tasks', EFSA could consider applying to Art 36 organisations the same rules it applies to Experts (at least to team leaders and other senior staff). Similarly, in response to the second arguments mentioned above, EFSA could revise its approach to the independence of Art 36 organisations, delegating part of the responsibility to MS (as described in the previous Section), but imposing a more harmonised approach and maintaining in-house monitoring in the case, again, of critical tasks.

Regarding the partnership framework with competent MS authorities, the approach adopted by ECHA may offer a useful benchmark. ECHA has developed guidelines for MS authorities on CoI prevention, which aims to ensure a common understanding and approach towards independence and impartiality, with a view to streamline the process, previously centred on the signing of the Memorandum of Understanding.[123] The guidelines refer to the OECD Guidelines for Managing Conflict of Interest in the Public Service, upheld by ECHA in their own independence policy.

EQ - To what extent do recommendations or case law developments from the European Ombudsman, European Court of Auditors, General Court of the EU or the Court of Justice suggest or require adaptations of the Policy under evaluation?

- **OBSERVATIONS IN EFSA BUDGET DISCHARGE**

EFSA has progressively adapted its independence policy following, inter alia, observations and recommendations made by a variety of supervisory authorities. Among them, of particular relevance are the EP's annual *Resolutions* that accompany the ex post discharge *Decision* regarding the implementation of EFSA's budget. The Resolutions include a specific section on "Prevention and management of conflicts of interest, and transparency", which have been reviewed synoptically (the 2016-2023 period) to verify which recommendations of Parliament have been put in place and which ones are still pending.

- One of the most recurrent and firm requests from Parliament regarded the introduction of ***cooling-off*** periods covering all material interests susceptible to actual or perceived CoI. Such provision was introduced by the PoI 2017. Parliament expressed satisfaction, but also expressed some critiques, which can be summarised as follows:

[122] Reportedly, EFSA is already facing more frequent calls that receive no response or with a declining number of applicants.
[123] A similar provision on the signing of a Memorandum of Understanding with competent authorities of the MS also exists in EFSA's PoI 2017, but it was not implemented since, with the large number of organisations involved, it would have required a disproportionate effort.

- the provision is applied only in relation to the mandate of the scientific group that the expert is applying to – or is serving in – and not to EFSA's overall remit;
- research funding from companies falling under the Authority's remit is not considered relevant to the cooling-off provision if the amounts at stake do not exceed 25%[124];
- additionally, EP Resolution 2020 criticised that over the threshold of 25% "*is applied to individual sources as opposed to all private sources combined*", which is however in contrast with how EFSA calculates it, indicating a possible need for more clarity from EFSA on implementation methods[125];
- in general, EFSA should adopt stricter cooling-off period as regards financial CoI and clear policy guidelines on the use of experts.

Since 2022, specific criticisms on cooling-off periods can no longer be found in budgetary discharge resolutions and the above points appear subsumed to a generic demand for stricter measures.

- Partially connected with the above, one of the main unresolved concerns laid out in *Resolutions* regards the scope of the independence policy. In various instances, Parliament called for an update of the policy to ensure that experts' ***interests are viewed within the context of the Authority's overall remit,*** and not only on matters falling under the mandate of the relevant EFSA scientific group, which is considered too narrow. As discussed in Section 4.2, this request has not been accommodated by EFSA to avoid incurring in a shortage of qualified experts and jeopardise, by consequence, its scientific excellence objective.

- Another area of concern frequently found in Resolutions regards ***'revolving door'*** issues. Discussions on this matter have gained momentum after the recommendations issued in 2020 by the European Ombudsman[126] and Annual report on EU agencies 2021 by the European Court of Auditors (ECA), which devoted a section to the weaknesses in agencies' handling of potential revolving-door situations.[127] In the 2023 *Resolution*, the budgetary authority noted that relevant developments within EFSA are ongoing. In particular, the Authority planned to adopt a new post-employment approach which includes the criteria and procedure to discontinue access to confidential information for staff leaving the service. More detailed observations can be found in Parliament's 2023 discharge resolution addressing all EU agencies, which essentially reiterate the observations made by ECA (see below).[128]

There are some other specific requests formulated in the Resolutions which are not currently implemented regarding aspects reviewed in other sections of this Report; they include (1) the need to screen the DoI of Hearing Experts, AF members, Focal Points and members of scientific networks; (2) the need for academic experts to declare the details of financial relationships between their university employers and their university employers' industry partners; and (3) the need to publish CVs (in the latest Resolution, the request regards only MB members). Another persistent demand regards the strengthening of the accounting officer's independence by making him directly responsible to the Authority's Director. This request comes from ECA's observations discussed here below.

Despite the persisting requests outlined in this section, it is important to highlight that the budgetary authority's *Resolutions* clearly show ***increasing satisfaction with the EFSA's progress*** in the field of independence. Criticisms were prevalent in the documents published before the adoption of PoI 2017, while

[124] It is worth noting that the EP Resolution does not refer to the 'relevant' research funding, which is how EFSA assess compliance with the threshold, but refers more generically to "research funding from companies in the Authority's remit", i.e. not necessarily overlapping with the specific mandate at stake.

[125] The EP 'misinterpretation' might be induced by the fact that while the calculation model provided in the CIM Decision clearly indicates that compliance must be verified on the aggregated relevant funding managed by the expert, the DoI requires to indicate project-by-project whether the threshold is complied with.

[126] Decision in case 2168/2019/KR on the European Banking Authority's decision to approve the request from its Executive Director to become CEO of a financial lobby group.

[127] European Court of Auditors, 2021 Annual report on EU agencies for the financial year 2021.

[128] Source: Discharge 2021: Performance, financial management and control of EU agencies.

more recent *Resolutions* openly acknowledge EFSA's improvements, and independence-related remarks are fewer and more generically raised.

- **EUROPEAN COURT OF AUDITORS (ECA) REPORTS**

The European Court of Auditors (ECA) is tasked with the annual examination of the accounts for EU institutions, agencies, and other EU bodies, including EFSA. In addition to the auditor's opinion on the reliability of accounts and the regularity of financial management, the yearly ECA report draws attention to possible areas for improvements, including on CoI management, regarding both specific bodies and the overall decentralised EU system. Regarding EFSA, ECA made only few observations in the past five years. In particular, in 2017 ECA emphasised the need to strengthen the ***accounting officer's independence*** – a recommendation later endorsed also by the discharge authority. As of the latest ECA report (2021), corrective actions had been partly adopted by EFSA.[129]

More generally, from ECA reports transpire a widespread need for more robust CoI management across EU agencies, especially as concerns public procurement and employment. In particular, the 2021 report devoted a specific section to the examination of ***'revolving doors'*** weaknesses and good practices. ECA explains that EU agencies are particularly prone to the risk of 'revolving door' situations because of their reliance on temporary staff, which entails high rates of staff turnover, and their governance model, which includes boards whose members tend to serve for relatively short terms. In the case of EFSA, this risk is further heightened – according to ECA – by significant links to industry. ECA considers the current legal framework lacking clear requirements and monitoring regarding agency's board members as well as members of scientific committees, expert groups, and other similar bodies, albeit some agencies have adopted internal rules in this respect. While agencies are generally compliant with the minimum legal requirements, ECA stressed that they seldom go the extra mile for effectively monitoring and handling 'revolving doors' situations.

On a more general level, in 2019 ECA published a special report on the ***Ethical Frameworks of the Audited EU Institutions*****,** which covered also various independence-related matters[130]. The report did not specifically focus on EU agencies but formulated general considerations on the EU system. Among its most relevant conclusions, it is noted the absence of EU adequate, common ethical frameworks and of efforts to improve staff awareness and perception of the ethical framework and culture. In other words, the report underlined that compliance with legal provisions is necessary but is possibly not sufficient on CoI-related matters, and there is a need to reinforce the ethical dimension to properly enforce citizens' rights to impartiality.

- **EUROPEAN OMBUDSMAN'S RECOMMENDATIONS**

The European Ombudsman's remit includes investigating complaints about maladministration by EU institutions and bodies that involve, among others, CoI-related matters. In addition to addressing specific complaints, its mandate includes proactive examination of broader, systemic issues and reporting at the EU

[129] The matter is described in detail in EFSA's Annual Activity Report 2022: "*One ECA audit finding from 2017 on the need to strengthen the accounting officer's independence, where ECA and EFSA have a difference in opinion, is not included in the overview of outstanding audit recommendations. In EFSA's opinion, the formal requirements set by the financial regulation to ensure the independence of the accounting officer are already in place. The EFSA Management Board appointed the current accounting officer in 2008. The accounting officer reports to the Head of the Empower Department and to ensure the functional independence of the accounting officer in the performance appraisal workflow, the Head of Empower Department is the reporting officer and the Chair of the Audit Committee the Countersigning officer. The accounting officer may at any time be suspended temporarily or definitely from his duties by the Management Board. The Court did modify the outstanding observation on the independence of the accounting officer and the Court now agreed that the independence of the accounting officer towards the Management Board was in place in EFSA. There is still a difference in opinion between the Court and EFSA in making the accounting officer directly responsible to the Executive Director*".

[130] European Court of Auditors (2019). Special report no 13/2019: The ethical frameworks of the audited EU institutions: scope for improvement.

level. In this sense, the Ombudsman's orientation emerging from specific cases and broader analysis are of relevance for the debate on the independence policy of EU agencies like EFSA; this assertion finds confirmation in the fact that references to specific decisions and recommendations of the Ombudsman that can be found in the aforementioned EP's budget discharges and ECA's opinions.

The European Ombudsman has conducted various inquiries on the subject of '***revolving door***' issues in EU institutions, which contributed to defining standards on this matter. The Ombudsman defines 'revolving doors' to be *"[w]hen a public official moves to the private sector"* adding that *"this can present a risk to the integrity of EU institutions because valuable inside knowledge can move into the private sector, or because former officials may lobby their former colleagues or existing officials may be influenced by possible future employment*."[131] In relation to a recent case regarding the European Banking Authority's decision to approve the request from its Executive Director to become CEO of a financial lobby group, the Ombudsman's inquiry found a case of maladministration and issued three recommendations that, while addressing the European Banking Authority (EBA), provided policy orientations also for other EU agencies like EFSA, namely[132]:

- First, the EBA should, where necessary, ***invoke the option of forbidding*** its senior staff from taking on certain positions after their term-of-office. Any such prohibition should be time-limited, for example, for two years.
- Second, the EBA should ***set out criteria*** for when it will forbid such moves in the future, so as to give clarity to senior staff. Applicants for senior EBA posts should be informed of the criteria when they apply.
- Third, the EBA should put in place internal procedures so that once it is known that a member of its staff is moving to another job, their ***access to confidential information is cut off*** with immediate effect.

In 2021, the Ombudsman formulated similar recommendations addressing the European Defence Agency regarding the handling of the application of its former chief executive to take on senior positions at Airbus[133]. In this Decision, the Ombudsman also suggested that the specific form for those applying for authorisation for intended jobs is drafted in such a way that (former) staff members provide the relevant information to enable a meaningful assessment from the outset.

In only three cases, the Ombudsman issued ***Decisions directly addressing EFSA***, all pre-dating the adoption of PoI 2017. Specifically, the Decisions regarded:

- Following EFSA's failure to request that a WG member clarify the financial relationship between his university employer and a biotechnology company active in the field of the WG's mandate (i.e. genetically modified insects), the Ombudsman suggested that EFSA revise its CoI rules to cover such instances and adjust DoI templates and instructions accordingly – a request later endorsed by the budgetary discharge authority and re-iterated in ENVI 2023.[134]
- Following a joint EFSA-WHO expert workshop on Threshold of Toxicological Concern, an NGO complained that various participants were allegedly in a CoI situation. The Ombudsman found that EFSA was not obliged to screen participants' CoI, which were already screened by WHO. However, the Ombudsman recommended carrying out such screening when the actual or perceived purpose of such events is to inform EFSA's decision-making.[135]
- In 2014, a complaint was filed against EFSA's public consultation procedure for the renewal of the approval of the herbicide glyphosate. In response to it, EFSA promptly fixed the procedure, so the Ombudsman declared the case as settled. The issue did not concern 'independence' strictly speaking, but

[131] https://www.ombudsman.europa.eu/webpub/2022/revolving-doors/en/
[132] Decision in case 2168/2019/KR, *ibid.*
[133] How the European Defence Agency (EDA) handled the application by its former Chief Executive to take on senior positions at Airbus (Case OI/3/2021/KR).
[134] Decision of the European Ombudsman closing the inquiry into complaint 346/2013/SID against the European Food Safety Authority ('EFSA').
[135] Decision in case 747/2016/PL on the European Food Safety Authority's use of the Threshold of Toxicological Concern

constituted one of the elements that later led to a substantial revision of transparency procedures through the TR.[136]

Other Ombudsman Decisions have not directly addressed EFSA, but some touch on independence-related aspects that could be relevant for the Authority's policy. They are summarised in Table 4.2.

Table 4.2 – Other relevant Ombudsman's Decisions (issued since 2018)

Decisions and recommendations	Summary
Decision in case 560/2019/KR on alleged conflicts of interest of experts who participate in the European Commission's Scientific Advice Mechanism.	The case concerned whether the European Commission had in place processes to ensure that scientific experts involved in advisory positions were not in a CoI situation. No maladministration was found but, with a view to improving these systems, the Ombudsman asked the Commission to ensure that (1) all relevant financial interests be included in experts' DoI – and not only those related to fields about which they are consulted, and which exceed EUR 10,000; and (2) these declarations be assessed and published.
Decision of the European Ombudsman in joint inquiry 853/2020/KR on the European Commission's decision to award a contract to BlackRock Investment Management to carry out a study on integrating environmental, social and governance (ESG) objectives into EU banking rules	The Ombudsman found that the company's bid gave rise to concerns since it has a financial interest in the sector at issue in the study, being the world's largest asset manager. Given the limitations of EU rules on public procurement, no instance of maladministration was reported, but the Ombudsman suggested, that the Commission update its guidelines for public procurement procedures for policy-related service contracts, giving clarity to staff as to when to exclude bidders due to CoI. The Ombudsman also suggested the Commission reflect on whether a specific update to the applicable rules is also necessary to make them more relevant to the EU's current policy ambitions. The EU is planning a period of unprecedented levels of spending and investment, which will inevitably involve significant linkages with the private sector.
Decision on how the European Commission handled concerns about the composition of the High Level Forum on Capital Markets Union and alleged conflicts of interest of some of its members (case 1777/2020/KR)	The case concerned the High Level Forum on the proposed EU Capital Markets Union, a Commission expert group. The Ombudsman's inquiry found maladministration in that the Commission failed to apply specific CoI measures to certain members who were appointed in their personal capacity to act independently and in the public interest.

- **GENERAL COURT OF THE EU AND COURT OF JUSTICE CASE LAW**

In the past 10 years, a total of 15 cases concerning EFSA were brought before the EU Court of Justice (CJEU) and the General Court.[137] With the exception of a couple of employment-related cases, the majority of cases regard transparency-related matters, i.e. failure to disclose access to documents – including landmark cases linked to the glyphosate dossier[138] – and protection of commercial interests, i.e. refusal to grant confidential treatment to applicants, in the context of submission of applications for plant protection products. Conversely, ***none of the cases reviewed involved EFSA's independence policy***.

On the other hand, independence-related issues were raised in the jurisprudence applicable to other EU agencies – notably EMA – which provide relevant orientations also for EFSA. An in-depth review of such jurisprudence was carried out in EA 2021, and salient findings are reproduced in Box 4.1 below.

[136] Decision in case 952/2014/OV on the European Food Safety Authority's (EFSA) public consultation procedure for the renewal of the approval of the herbicide glyphosate

[137] Based on a review of *Curia* database (consulted on 01 August 2023).

[138] Case C-616/17 Blaise and Others, Case T-329/17 Hautala and Others v EFSA, Case T-716/14 Tweedale v EFSA.

Box 4.1 – EA 2021 findings on relevant EU jurisprudence addressing independence-related matters.

The review of EU jurisprudence carried out in the framework of the EA 2021 study identified three relevant aspects concerning independence policies, namely:

- ***Independence from National Interests as an Impartiality Requirement*.** EA 2021 noted that the issue of independence from national interests and political pressure has become somewhat salient in EU Case Law, especially regarding EMA. In 2019, the EU Court of Justice ruled on a case[139]of alleged lack of impartiality concerning an EMA decision that limited the marketing authorization for a pharmaceutical product. This product had already been restricted in Germany by the Federal Institute for Drugs and Medical Devices (BfArM). The applicant appealed the decision, but while that judiciary case was still ongoing, the BfArM initiated a referral procedure with EMA to extend marketing restrictions EU-wide. The rapporteur role was given to an employee of BfArM itself. EMA subsequently reached the same conclusion as BfArM and limited the marketing authorization of the product. The applicant then claimed (1) that the rapporteur had been biased, also because the German court procedures were still ongoing, and (2) that the referral procedure was, therefore, not conducted in an impartial manner. The Court concluded in agreement with the applicant that objective impartiality requires that: '*there must be sufficient guarantees to exclude any legitimate doubt as to possible bias on the part of the institution concerned*'. Furthermore, it stressed that a rapporteur has an important role in the assessment procedure and responsibilities of his/her own. The Court therefore found an infringement of the objective impartiality requirement, concluding that the applicant could have legitimately considered that the rapporteur was pursuing a national-level interest. The Court found that no procedural safeguard could disperse these doubts. Thus, on the basis of an infringement of the right to good administration, it annulled the Commission decision in question.
- **Relevance of Impartiality to the Decision-Making Process.** In 2019, the EU General Court decided[140] against an alleged CoI concerning an expert who had been consulted by an EMA scientific committee before taking a decision. The expert involved had previously been a judicial consultant in a national class action against the applicant. The main question for the Court in determining the impartiality of the procedure was whether the expert had a decisive impact on either the conduct or the outcome of that procedure. The General Court could not find such an impact, as the expert was not a member of the responsible EMA committee and, additionally, a second expert group, not including the expert in question, had been consulted as well. This ruling indicates the relevance of distinguishing between the roles of concerned experts in the risk assessment process.
- ***Impartiality with Reference to Rival Products*.** A recent judgment of the EU General Court[141] concerned, again, an application for market authorisation of a medical product submitted to EMA. The applicant claimed that one expert involved in the assessment held current and multiple CoI in the development of a rival product. The Commission replied that the policy does not provide for restrictions based on interests relating to rival products of the product being examined. However, the General Court found that the procedure did not provide sufficient guarantees to exclude any legitimate doubt as to possible bias and annulled the decision on the application.

EQ - To what extent can the provisions in the Policy under evaluation be made clearer for the end user and for the general public?

➢ CLARITY FOR END USERS

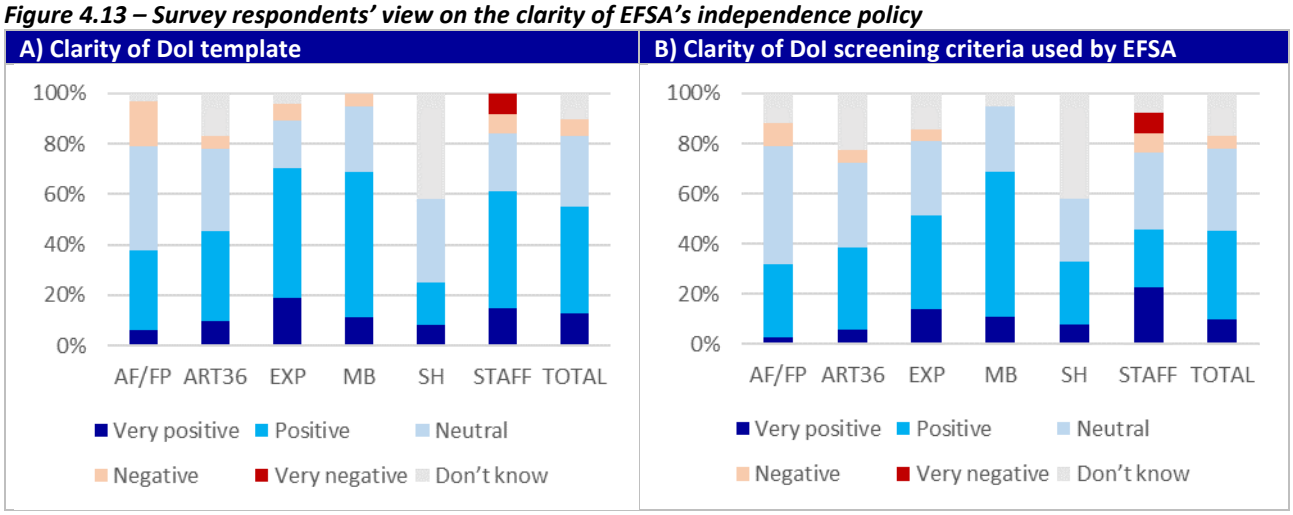
The clarity of documents and procedures implementing EFSA's independence policy is generally rated positively by users and stakeholders. The majority of survey respondents expressed appreciation for the clarity of the DoI template (55% of total respondents) and – to a slightly lower extent – of the DoI screening criteria used by EFSA (45% of total respondents). Regarding the ***DoI template***, the highest rate of positive feedback comes from those who are more directly involved, i.e. Experts (71%) and EFSA staff (61%), indicating that EFSA's efforts in this respect – e.g. the provision of concrete examples to help declarants properly fill in the DoI – were rewarded. Correspondingly, the share of positive feedback is higher among respondents who

[139] EU Court of Justice (2019), C-680/16 P - August Wolff and Remedia v Commission.
[140] EU General Court (2019), T-783/17 - GE Healthcare v Commission.
[141] ECG (2020), Case T-594/18 - Pharma Mar, v. European Commission.

are more familiar with the independence policy. As discussed, further improvements in this area are possible from an efficiency perspective, such as extending the DoI Tool to categories of declarants other than Experts and the introduction – where feasible – of binary questions to streamline the assessment process, but as far as clarity is concerned, there appears to be no need for major revisions.

Similar results were registered for the clarity of ***DoI screening criteria*** used by EFSA. In this case, most positive ratings came from MB members, while both Experts' and EFSA staff's views were more frequently neither positive nor negative. Feedback from interviews suggest that Experts are sometimes puzzled with EFSA's attribution of CoI to certain interests, which appears to be caused by an overly rigid application of screening criteria.

Figure 4.13 – Survey respondents' view on the clarity of EFSA's independence policy



Source: *Targeted survey.* ***Legend:*** *AF/FP: members of the Advisory Forum and/or Focal Points; ART36: representatives of Article 36 organisations; EXP: scientific experts, member of EFSA scientific groups; MB: members of the Management Board; STAFF: EFSA staff ('CIM community'); SH: other stakeholders (i.e. representatives of the business and food industries, farmers, environmental / health NGOs and practitioner and academic organisations).*

Regarding ***familiarity*** with specific components of EFSA's independence policy, the results of the survey show that:

- Nearly half of the respondents affirmed being highly familiar with the ***DoI template***. Conversely, about one quarter of the respondents have limited or no familiarity with it (mostly individuals who are not directly concerned with DoI).
- Regarding ***PoI 2017,*** respondents' feedback is almost evenly split between those who reported 'moderate' or 'great' familiarity, and those who affirmed having little or no familiarity at all with this document.
- Despite the fact that the DoI requires familiarity with the ***CIM Decision***, most respondents (60%) have limited knowledge of it, while only 13% declared great familiarity (primarily EFSA staff).
- The ***Annex on Implementation of the Policy on Independence*** included in Annual Activity Reports is the least known of the items examined, with only one-third of respondents reporting 'great' or 'moderate' familiarity.

To ensure that all concerned subjects – EFSA staff, Experts, and other categories subject to DoI obligation – are properly instructed about and guided through the implementation processes, one specific article of the CIM Decision is devoted to ***training*** and the provision of working instructions and supporting materials. The delivery of training activities is tracked in the Annual Activity Report (AAR). Since 2018, some 37 awareness-raising and training sessions were delivered, of which 12 addressed Experts and 17 DoI assessors and validators. According to survey results, the demand for further training or guidance initiatives is moderate. Respondents who consider it necessary are a minor share (24%) and only slightly higher than the share of those who do not see any need for it (17%). Most respondents have a neutral position on this aspect,

although it is worth highlighting that Experts are more resolutely against the delivery of further trainings (34%) than the other categories of respondents.

- **EXTERNAL COMMUNICATION**

PoI 2017 envisages transversal transparency and communication activities aimed at "*building and maintaining trust in EFSA's independence policy and any actions the authority takes to enforce it.*" As discussed in Section 4.2, this objective translated into a change of approach in EFSA's communication and engagement strategy, from a 'reactive' to a 'proactive' approach, involving regular monitoring, rapid follow up to emerging issues, early engagement of stakeholders and, in general, greater transparency and access to information.

Looking ahead, survey respondents suggest a ***further increase in communication efforts***, targeting the media and general public especially (59% of respondents support this) and, to a smaller extent, also NGOs, policymakers and the scientific community (between 43 and 49% of respondents).

5. CONCLUSIONS AND RECOMMENDATIONS

➢ INTRODUCTION

This final section provides the Study's conclusions and recommendations. Conclusions are organised by theme and are based on a summary of the evaluative findings presented in different parts of Section 4. Recommendations stem directly from conclusions. Where relevant, references have been added to recommendations put forward in the ENVI 2023 study, as well as in the EA 2021 review of the CIM Decision.

A few caveats regarding recommendations are worth highlighting. Firstly, as discussed throughout Section 4, the Policy has performed well overall, and the evidence collected indicates that there is no pressing need or demand for revision. Further improvements appear possible and, in some cases, are warmly recommended, but none of them appears critical from the perspective of the overall independence objective of the Authority. In this sense, in accordance with the 'ex post' nature of the exercise, the Study does not provide any indication on whether and how a re-opening of the Policy is necessary, as this falls outside of the scope of the analysis. Secondly, an ex ante impact assessment of the recommendations put forward was also not in the scope of the Assignment. The purpose of recommendations is primarily to foster discussion within EFSA on possible interventions worth exploring. Needless to say, a fully-fledged analysis of costs and benefits as well as of feasibility and coherence of the suggested solutions is required before their adoption, especially in the case of the most ambitious revisions of the current system.

➢ REPUTATIONAL IMPACT OF THE POLICY

EFSA's ***reputation regarding independence*** has substantially improved over time. In the past, EFSA suffered from relatively frequent and severe criticisms for inadequate CoI management. This is no longer the case, and most of EFSA's stakeholders expressed appreciation for EFSA's capacity to ensure impartiality and absence of CoI in its scientific work. The Policy adopted in 2017 and the following implementation efforts can be credited for this general reputational effect. Additionally, EFSA has adopted a more proactive attitude regarding communication and engagement with EU supervisory institutions and stakeholders on independence-related matters, and this also had a positive effect on reputation.

A ***greater awareness of the Policy*** in the EU food safety environment (institutions, researchers, interested parties, etc.) has likely contributed to such reputational impact, although some aspects of the Policy remain poorly familiar to various stakeholders, especially those who are less intensively involved in EFSA's scientific activities - such as Art 36 organisations, AF members, and EFSA Stakeholder Forum representatives. Operational documents – i.e. DoI and CIM Decision – are generally better known than the Policy itself, and only a minority of consulted stakeholders appeared to be familiar with the annual reports on independence that are published in annex to EFSA's Annual Activity Report.

EFSA's reputation is checked regularly, e.g. through surveys and media monitoring. The available indicators suggest that, overall, citizens' trust in the EU food safety system (not limited to EFSA) has not improved over time. This would indicate that the reputational effects achieved on target stakeholders did not spread to the ***general public*** (or did so only partly).

Recommendations:

1. EFSA should continue ***engaging proactively*** with EU institutions, sister agencies, MS, and stakeholders on independence-related matters. Constructive dialogue should be maintained on all aspects related to the design and implementation of the Policy, to ensure EFSA's efforts are known and understood by all relevant counterparts. Similarly, in the event of critical dossiers, i.e. scientific opinions on controversial matters, EFSA should foster engagement and dialogue with organisations

representing public interests and other relevant stakeholders to raise awareness of the measures in place to ensure independence.
2. EFSA could consider actions to ***strengthen awareness*** of and familiarity with the Policy among its target groups. It could also investigate the reasons for the limited familiarity reported by certain target groups, with a view to finding better ways to enhance interest, visibility, and awareness.
3. EFSA could consider conducting focussed research on the ***general public's knowledge and appreciation of its Policy***, with a view to designing and implementing specific actions to improve EFSA's reputation (hence, trust) among EU citizens.

- **TRADE-OFF BETWEEN INDEPENDENCE AND SCIENTIFIC EXCELLENCE OBJECTIVES**

Compared to previous versions, the current Policy involves more stringent rules to reduce CoI risk and this has had seemingly ***mixed effects on EFSA's capacity to attract and involve highly competent experts*** in its scientific work. On the one hand, the improved reputation described above acted as a 'pull factor'. On the other hand, evidence from consultations indicates that the new restrictions (e.g. cooling-off periods) reduced the pool of experts eligible for membership in EFSA's scientific groups. Since the adoption of the Policy, it has become increasingly difficult for EFSA to involve experts with the required knowledge, especially in domains where innovation is primarily driven by private sector-funded research and investments. This constraint is demonstrated, among other things, by the increasing recourse to Hearing Experts, whose participation is however limited for CoI risk reasons. In exceptional circumstances, EFSA grant a waiver to allow the participation of experts with competing interests (but not those triggering 'unconditional restrictions') when no suitable alternatives can be identified. This is a rare instance (some 0.2% of total DoI screened in 2022), but demonstrates that the Policy envisages some degree of flexibility when the 'scientific excellence' objective is threatened.

One of the pillars of EFSA's approach is that a concerned individual's interests must be assessed in relation to the ***specific mandate of the scientific group*** in which he/she shall perform his/her activities, and in relation to the task assigned (e.g. chair, vice-chair, ordinary member). The only exceptions are industry employment and financial investment interests that are assessed as being against the EFSA's entire remit and that lead to an outright ban. According to this principle, an expert might be eligible for one specific working group but not for another. This has preserved the capacity of the pool of experts that EFSA can involve to properly staff working groups. On the other hand, this principle is in contrast with remarks repeatedly formulated in the EP Budget Discharge Resolutions that require EFSA to assess all kinds of interests against the overall Authority's remit. In this regard, ENVI 2023 suggested that the inevitable restrictions caused by the EP's recommendation could be mitigated by excluding 'minor CoI' situations. The results of the Study show that there would be widespread support for the idea of differentiating requirements in accordance with CoI risks – enhancing the partial differentiation that already exists, and in accordance with the practices in place in 'sister' EU agencies.

Recommendations:

4. A radical review of the current scope of experts' interest assessment, extending it to the entirety of EFSA's remit would severely affect EFSA's capacity to involve the experts that are necessary to ensure the 'scientific excellence' of its outputs. This point is indirectly recognised in ENVI 2023. If any, EFSA could ***extend 'unconditional restrictions'*** to other categories of interests, if justified and not leading to an excessive restriction of the pool of eligible experts.
5. EFSA could consider exploring the feasibility and the advantages of a more ambitious reform where Policy ***requirements are further differentiated in relation to CoI risk***. In this sense, EFSA could consider and investigate various criteria for categorising and ranking CoI risk. The categorisation could regard the sensitivity of the mandate at stake and/or the role played by the concerned individual in the process. Regarding the sensitivity of the mandate, it is generally acknowledged that some dossiers are more controversial and subject to CoI risks than others, and that current rules were conceived

having such dossiers in mind, so they are somehow disproportionate for 'lower risk' dossiers. At the same time, ranking dossiers by sensitivity is not straightforward and could involve economic considerations, so EFSA should carefully consider pros and cons before adopting this solution. Regarding roles, EFSA could explore the possibility of differentiating the Hearing Expert category. Those who do not hold interests subject to 'unconditional restrictions' might be allowed to provide more structured inputs, also in writing and during discussion. For these occasional contributors EFSA may rely on self-declaration of absence of CoI provided that appropriate CoI risk mitigation measured are applied, e.g. they should not take prominent roles within the Working Groups, their inputs should remain limited and subject to peer review and random checks of DoI are carried and dissuasive sanctions are applied in case of inaccurate / incomplete declarations. For Hearing Experts with interests subject to 'unconditional restrictions', the current limitations and restrictions would not change.

- **POLICY COVERAGE AND EFFECTIVENESS**

The ***Policy's coverage and implementation aspects*** appear largely satisfactory and able to deliver the intended results of ensuring impartiality and managing CoI risk in EFSA's scientific work. The target groups involved in the production of risk assessments and scientific outputs are subject to mandatory disclosure of interests through the submission of DoIs. This covers also close family members, albeit in this respect the Policy adopted a narrower definition than the EU Financial Regulation. In a few non-negligible cases, however, target groups are subject to special regimes, namely: (a) MB members are required to submit DoIs, which are screened by EFSA, but the management of CoI is internal to the MB, through a sort of 'self-rule' mechanism; (b) in some cases – network members and AF members – DoIs are collected but not screened, although EFSA intervene in the case of serious and well-documented cases (presumably arising from 'whistleblowers'); (c) the DoIs submitted by Hearing Experts are not screened, as they are mainly collected for transparency purposes; (d) in the case of pesticide risk assessments, DoIs are required only for the Rapporteur MS' experts who take part in PRM.

EFSA has set up a two-step process for ***DoI screening***, involving an assessment carried out by the competent Scientific Unit and a validation, carried out by the Legal Affairs Services. In addition, EFSA carries out ***ex post 'compliance and veracity checks'*** on a small sample of DoIs. Ex post checks are conducted purely on a documental basis (e.g. comparing a DoI with the expert's CV) with no recourse to external sources or intelligence activities. In this sense, the effectiveness of these checks in detecting undisclosed interests appears questionable. Indeed, statistics indicate that few serious omissions have been found in recent years (six cases in total, in 2018-2022). The Policy also covers processes connected to independence, like measures to prevent and address ***'revolving door' issues*** with senior staff leaving the Authority. Obligations for senior EFSA staff correspond to what is prescribed in the EU Staff Regulations, but implementation criteria have not yet been adopted. In addition, there is an obligation for MB members to inform EFSA of positions taken after the expiration of their term. Conversely, no specific obligation is envisaged for experts, albeit the 'cooling-off' provision can be seen as a proxy for one.

The CIM Decision spells out the criteria applied to determine whether the interest mentioned in the DoI are compatible with the involvement of the concerned individual and in which position. The Policy places substantial ***emphasis on economic interests***, although a variety of other relevant interests are covered. Explicit reference to national interests and/or political pressure is, however, missing. On the one hand, these interests lend themselves poorly to operationalisation in the DoI, but on the other hand various stakeholders perceive a growing risk in this area, connected to the increased outsourcing of EFSA's scientific work to competent organisations in the MS. ENVI 2023 also noted that the Policy does not cover the possible interests (e.g. partnerships and other sources of relevant private sector funding) of experts' academic employers, assuming that such interests can affect experts' independence, even though they do not directly benefit from it. While the existence of such risk cannot be ruled out, feedback from the scientific community indicates that

the risk is low and implementing such requirements would be overly burdensome from an administrative point of view, as it would require processing information that – especially for large institutions – is not readily available.

Overall, the debate on the need to further restrict current rules emerges as moderately polarised. EFSA staff and Experts – who are more directly concerned by the implementation of independence rules – frequently expressed concerns regarding the hypothetical adoption of further restrictions, such as longer cooling-off periods, stricter rules on private research funding, etc. Conversely, representatives of stakeholder's organisations and – to a lesser extent – of Art 36 organisations appear more open to these options. Overall, the favourable impact described above, and the generally positive feedback collected on the functioning of the system indicate that ***current rules are generally fit for purpose***, although minor adjustments or clarifications would nonetheless be useful.

Recommendations:

6. The Policy could mention more explicitly ***national interests and political pressure*** among the type of interests that can interfere with the independence of scientific work, and – even though objective screening criteria seem poorly applicable – reflect this concern also in implementation documents and tools. This appears particularly important in the context of outsourcing, where there is a need to ensure that Art 36 organisations benefiting from EFSA grants are not influenced by their country's political agenda and other specific national interests. Additionally, EFSA could clarify the concept of 'indirect' interests, which is established in the GFL and adopted in the CIM Decision.
7. The issue known as ***'revolving doors'*** is increasingly a priority in the debate on public service ethics and integrity within the EU and international organisations, as well as in the relevant academic literature. Recently, at the EU level, this matter has been addressed explicitly by the European Ombudsman and the ECA. As discussed above, EFSA applies the 'revolving door' provision established in the Staff Regulations to its employees, but implementation criteria have not yet been elaborated nor published. In addition, EFSA applies an information obligation to MB members, i.e. they must submit updated DoIs for two years after the expiration of their mandate. It is unclear, however, which measures EFSA may adopt against non-compliance cases, i.e. if the ADoI is not submitted or it is incomplete. EFSA could consider adopting similar measures also for Panel and SC members – i.e. experts who have a rather stable form of collaboration with EFSA.
8. In the case of ***'low risk' target groups*** for which DoIs are collected but not screened, i.e. network members and AF members, the Policy establishes that EFSA may intervene in case of 'serious and well-documented cases'. However, it is unclear how such cases would be brought to EFSA's attention, e.g. through 'whistleblowers', complaints raised by NGOs, monitoring of media and literature, etc. To prevent negative effects on reputation, EFSA should be able to detect and proactively address such cases at an early stage and consider whether current measures – e.g. on 'whistleblowing', NGO engagement etc. – are fit for purpose.
9. EFSA could consider extending DoI requirements for all the ***Rapporteur MS experts*** who take part in the preparation of draft risk assessment for pesticides, and not only those who participate in PRM.
10. The 'self-rule' mechanism according to which ***MB members' CoI*** are addressed by the MB itself appears to be in contrast with the general principle of ensuring impartiality and neutrality in decision-making on these matters. Keeping in mind that the actual risk of the MB having undue influence on specific EFSA output is limited, EFSA – and the MB in particular – could consider alternative set-ups, where CoI issues regarding MB members are evaluated and judged by a subject that is external to the MB. Additionally, the change in MB composition introduced by the Transparency Regulation would require some fine-tuning of the DoI template for MB members, to reflect the fact that members are formally representatives of specific national sectoral interests, and such interests are legally compatible with MB membership positions.
11. ***Ex post 'compliance and veracity' checks*** are currently useful for verifying errors and inconsistencies in the internal DoI screening process, but the number of checks and the effectiveness of these

controls in detecting 'voluntary omissions' (i.e. interests not disclosed by the concerned individuals, neither in the DoI nor in his/her CV submitted to EFSA) is limited. Therefore, EFSA could consider enhancing the effectiveness of this tool by outsourcing this task to contractors with audit / intelligence capacity, which would be requested to (a) extend checks to internet sources, and (b) increase the number of checks. The contractor would report any possible undisclosed interests found to EFSA, and EFSA could follow up with the concerned individuals for clarification. For privacy reasons, concerned individuals will need to consent explicitly to these checks at the time of their engagement with EFSA. This would per se act as a further deterrent against voluntary non-disclosure of relevant interests.

- **COST-EFFECTIVENESS AND PROPORTIONALITY OF PROCEDURES**

The ***implementation and enforcement of the Policy is fairly resource intensive,*** especially for senior EFSA staff. In recent years, the aggregate efforts for independence-related activities grew from 4 full-time equivalent staff (FTE) in 2019 to an estimated 10 FTE in 2022. However, this figure was partly inflated by a malfunctioning of the IT tool for DoI management, which required the temporary recourse to a 'manual' procedure. Since the beginning of 2023, a new IT system is in place, and the projections for 2024-27 indicate an expected effort that would stabilise at 6.5 FTE. The automated DoI system is currently active only for Panels, SC, and Working Group experts, but EFSA is reportedly considering extending its coverage to other target groups, like staff and Art 36 organisations. While automation can certainly improve DoI- process efficiency, independence-related efforts are set to increase in the future, due to the planned progressive expansion in the volume of EFSA's activity. This might involve more working groups, more experts and more outsourcing, hence a substantial increase in the DoIs to be screened and validated. In this respect, various stakeholders expressed ***concerns on the sustainability of current independence-related processes***. The resources allocated to these tasks already seem to be overstretched and there is a risk that increasing the burden further translate into lower-quality screening and/or cause delays in EFSA's operational timeline.

EFSA does not currently have sufficiently detailed activity-based monitoring to allow quantification of the efforts connected to each step of the independence-assurance process. This hampers in-depth analysis of possible inefficiencies or bottlenecks. Nonetheless, there is broad consensus on the fact that ***DoI screenings absorb a major share of EFSA's resources*** allocated to the Policy implementation. The first reason is the sheer number of screenings that EFSA needs to carry out, which includes several re-assessments – e.g. anytime experts declare new interests or take on a new involvement in an EFSA working group. The second reason is that DoI processing can be burdensome. DoI compilation and screening require processing a significant amount of information. In various instances, the assessment requires non-trivial decisions by the responsible officers, so this task is typically performed by Heads of Unit or senior staff. The two-step process entails the possibility that such decisions be overruled at the validation stage or – more frequently – that requests for clarification / justification are issued, thus triggering further interaction within EFSA and between EFSA and the concerned individuals. This can happen especially with new submissions. Conversely, experts with a long history of collaboration with EFSA have apparently learned how to fill in a DoI properly and do not generally consider the process as being too burdensome.

Recommendations:

12. In perspective, EFSA should consider how to ensure the sustainability of the Policy implementation process, in the light of a possible workload increase due to the expansion of EFSA's activities. Over and above specific operational interventions (discussed below), EFSA could consider a paradigm shift toward a more marked ***'risk-driven' approach***. Without lowering the aggregate effort, EFSA could re-allocate Policy resources taking into account the CoI risk inherent to the specific process, e.g. in relation to the subject matter, the nature of expert involvement, the rationale for DoI submission ('new submissions' vs. re-submissions), etc. In this sense, EFSA's efforts should focus on high-risk

situations, while for 'low risk' cases EFSA could rely more on a declarant's assessment. This form of 'subsidiarity' could be accompanied by thorough controls on a sample of DoIs and dissuasive sanctions in case of inaccurate declarations. Such controls should ideally be carried out at an initial stage of the work, i.e. well before the issuance of the requested scientific opinions. This shift in paradigm would require some additional efforts in the initial stage to establish methods and criteria for ranking processes by risk level and, ideally, to run tests, before full adoption. An ex ante cost analysis would be required to verify whether such costs would be offset by cost savings that EFSA could obtain by discontinuing screenings on 'low risk' processes.

13. In connection to the previous recommendations, EFSA should gather more granular information on the efforts required by each activity and step in the current system, as this would allow for identifying bottlenecks and possible inefficiencies better and for quantifying costs and cost savings of hypothetical reforms properly. This could be facilitated by a ***more widespread use of IT solutions***, both extending the DoI tool to other declarants (Art 36 organisations etc.) and by applying automated process monitoring to all independence-related activities.
14. There is possibly room ***to reduce the unit cost of screening*** also through a revision of the DoI template and/or of the assessment / validation process. In principle, a simplification can be obtained by segmenting complex discretionary assessments into binary 'on/off' choices. Advantages would include a reduced need to involve senior staff from scientific units and, possibly, fewer cases where the process is stopped for clarifications at the validation stage. At the same time, there are downsides to consider. In particular, CoI is seldom an on/off situation, so a certain degree of discretionary assessment is necessary as a guarantee for experts, to avoid undue exclusions or undue inclusions. This is especially relevant for 'perceived CoI' as mentioned in the Policy. Again, the granular monitoring of costs described in the previous point appears to be necessary for estimating the net benefit of a hypothetical revision of DoI structure ex ante.

- **APPROPRIATENESS OF INDEPENDENCE RULES FOR OUTSOURCING**

In accordance with its expanded mandate and budget, EFSA's strategy envisages a ***strengthening of networking and partnership*** with food safety ecosystem at the national, EU, and international level. This means, inter alia, to scale up co-operation with entities and institutions via outsourcing. In recent years, the budget allocation for outsourcing – especially grants with Art 36 organisations – has increased substantially, i.e. from EUR 8-9 million / year in 2019, to nearly EUR 35 million in 2022, and is set to increase further. In parallel, the Transparency Regulation encouraged a qualitative change, reiterating that EFSA may outsource to these organisations also critical tasks like the drafting of risk assessments. In other words, in addition to supporting Working Groups, Art 36 organisations will increasingly be assigned the same role as Working Groups. Enhanced involvement of Art 36 organisations appears necessary to respond to EFSA's future workload and stakeholders perceive this more frequently as an opportunity rather than a threat. However, various experts expressed concern regarding the outsourcing of draft risk assessments to Art 36 organisations. A recurrent argument is that the criteria used by MS to designate Art 36 organisations vary greatly across countries, and not all the organisations on the list are considered suitable, from an independence perspective, to carry out such critical tasks.

An increase in outsourcing would also pose ***new challenges for implementation of the Policy***. First of all, it would translate into an increase in the number of DoIs to be screened and of other independence-related activities. In this sense, EFSA has managed to mitigate in part the CoI burden linked to grant agreements by removing the obligation for grant beneficiaries to submit an institutional DoI and the individual DoI from non-key experts (administrative staff, etc.). The second challenge regards specifically assigning draft risk assessments to Art 36 organisations. In this case, the responsibilities of the selected organisations would coincide largely with the responsibilities of a Working Group, even though independence-related requirements are different - e.g. the cooling-off provision does not apply to experts working for the Art 36

organisations. This misalignment implicates that under the current rules draft risk assessments performed by Art 36 organisations would be subject, in principle, to higher CoI risk than if performed by Working Groups.

Recommendations:

15. EFSA may consider examining the criteria and the process that leads to the ***designation of Art 36 organisations by MS*** with a view to foster harmonisation across MS. The matter largely falls outside of the scope of the Policy, and would require the involvement of the MB, which is responsible for drawing up the list of Art 36 organisations that are designated by MS. Still, the Policy envisaged putting in place memoranda of understanding with the bodies EFSA cooperates with to specify applicable independence standards. The adoption of such memoranda has turned out to be too onerous due the large number of bodies involved, still the underlying principle indicated the need for a more uniform adoption and application of EFSA independence standards by Art 36 organisations. EFSA may seek – in collaboration with MS - alternative, lighter instruments to achieve this harmonisation objective.
16. EFSA should ensure that the independence ***rules applied to experts performing critical tasks such as the drafting of risk assessments are coherent*** for all concerned individuals, regardless of whether the task is performed by a Working Group or outsourced to Art 36 organisations. All applicable provisions, as well as screening criteria, should be harmonised. This may include devising ways to allow grant recipients to involve experts with profiles comparable to that of Hearing Experts who participate in Working Groups. Such involvement must be subject to the same limitations and restrictions imposed to Hearing Expert, including the presence of EFSA staff to meetings where the participation of these experts is foreseen. Out of analogy with Hearing Experts, the grant recipient should collect and forward to EFSA a DoI for these experts, but no screening would be required.
17. To prevent an undue increase of administrative burden and in accordance with a shift toward a risk-driven system described in Recommendation #12, EFSA could adopt a ***lighter approach to outsourcing***. Based on subsidiarity considerations, the responsibility for ensuring the fulfilment of EFSA's independence standards could rest on grant beneficiaries (excluding those that perform 'critical tasks' as described in the previous recommendation). This might be implemented through declarations of compliance with EFSA's standards having a contractually binding value. In this framework, EFSA may discontinue screening of individual DoIs and adopt, at the same time, more robust ex post check tools and tougher sanctions (see Recommendation #11) as a deterrent against malpractice.
18. The revised system described in Recommendations #16 and #17 could be improved by a ***strengthening of the role of MS authorities*** in assuring the absence of CoI in the competent organisations that work for EFSA. These organisations are already screened at the time of their inclusion in the Art 36 list, but a further layer can be added for individual grant agreements. MS authorities (e.g. via Focal Points) could, for instance, be required to assure grant beneficiary's compliance with EFSA's standard and commit to remove the organisation from the Art 36 list in case major issues emerge after an ex post control.

- **CLARITY AND TRANSPARENCY ASPECTS**

The ***clarity of documents and procedures*** used in implementing EFSA's independence policy elicited mostly positive ratings from users and stakeholders. In particular, the improved guidance for DoIs – i.e. through the provision of specific examples – proved effective in facilitating completion and reducing errors and requests for clarification. EFSA also conducted several awareness-raising and training sessions for experts and DoI assessors. Target groups' needs were satisfactorily addressed, as the demand for further training or guidance initiatives is currently moderately low. The screening criteria applied by EFSA are clear for experts most of the time, although their application led to judgements that sometimes were seen as excessively strict.

Overall, ***some implementation aspects are still not entirely understandable*** by stakeholders, such as the rationale for collecting DoIs from Hearing Experts if no screening is performed, or the criteria for granting a waiver. As emerged from the review of supervisory authorities' reports, more clarity would also be needed regarding the method for calculating the threshold applicable to relevant private research funding managed by experts, and the application of independence rules to Art 36 organisations.

The implementation of independence is communicated transparently through the publication of an annual report in annex to EFSA's Annual Activity Report. Stakeholders are however not very familiar with this output, and the analysis of the document shows that published figures and data are not always immediately understandable by a non-expert audience. For ***transparency*** purpose, EFSA publishes the DoI of various categories of individual involved in its activities, i.e. Panel and SC experts, WG and PRM members, MB members, and senior EFSA staff. The DoIs of experts from Art 36 organisations working for EFSA under a grant agreement are, however, not published.

Recommendations:

19. The Policy should explain why ***Hearing Experts' DoIs*** are not screened. EFSA should clarify that the 'Hearing Expert' position is designed primarily for experts whose profile is assumed to be incompatible with close involvement in EFSA work, and therefore screening would be redundant. Still, for transparency purposes it is useful that Hearing Experts' DoIs continue to be published on EFSA's website. Similarly, EFSA may provide additional clarifications on the criteria and the modality for ***granting waivers*** to experts with conflicting interests, to respond to stakeholders' demand for greater transparency. Thirdly, more explanations could be provided regarding the application of ***independence rules to Art 36 organisations*** that – as emerged inter alia from ENVI 2023 – might appear confusing. EFSA should clarify that according to Art 12 of the CIM Decision, Network Members (including Art 36 organisations) are not subject to DoI screening, but when an Art 36 organisation is awarded an EFSA grant, Art 15 of the CIM Decision applies, hence DoIs are screened by EFSA.
20. EFSA should clarify and remove inconsistencies regarding the ***application of the 25% threshold*** to the relevant private funding that experts can benefit from. While the calculation model provided in the CIM Decision clearly indicates that compliance must be verified on the aggregated relevant funding managed by the expert, the DoI requires that whether the threshold is complied with project-by-project be indicated, thus generating confusion on which calculation method has to be adopted. Secondly, EFSA's internal rules envisage that private funding of projects, received by experts in the context of public co-funding schemes (EU, national, regional, or local), is not considered a source of CoI. It is, however, unclear how the 'public' nature of such schemes is verified (especially regional and local schemes), and how the private funding is accounted for in the calculation model provided in the CIM Decision. Given that co-funding schemes likely represent a relevant share of research funding, EFSA should provide additional explanations on how this provision is implemented concretely.
21. It is recommended that ***all gathered DoIs***, including those submitted by experts for Art 36 organisations, ***be published transparently*** on the Authority's website. EFSA may also consider publishing its decision (including mitigation measures etc.) regarding former staff who report the intention to engage in occupational activities. Additionally, EFSA may publish the CV of key staff and MB members – in line with the practices adopted in other EU agencies. Conversely, it does not seem useful to publish the CV of experts that – according to ENVI 2023 – would facilitate control by citizens and NGOs. Transparency appears to be guaranteed already by the publication of DoIs, which reflect the criteria established for an effective management of CoI. CVs could include information such as interests dating before the 'cooling-off period', which are not relevant from a CoI-management perspective but might prompt a negative reaction among the general public, which is not aware of EFSA's independence rules.

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