ECONOMISTI ASSOCIATI

mb210624-i5

Framework Contract SANTE/2016/A1/039 Lot 2: Food

Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management

EXECUTIVE SUMMARY REPORT

submitted by

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22 April 2021

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ACRONYMS AND ABBREVIATIONS

ADoI	Annual Declaration of Interest
AI	Artificial Intelligence
CIM	Competing Interest Management
CoI	Conflict of Interest
DoI	Declaration of Interest
EC	European Commission
ECDC	European Centre for Disease Prevention and Control
ECHA	European Chemicals Agency
EFSA	European Food Safety Authority
EMA	European Medicines Agency
EU	European Union
GMO	Genetically Modified Organism
IPR	Intellectual Property Rights
IT	Information Technology
LA	Legal and Assurance Services
MoU	Memorandum of Understanding
NGO	Non-Government Organisation
PI	Public Institution
SDoI	Specific Declaration of Interest
SOP	Standard Operating Procedures
SQ	Survey Question
WIN	Working Instructions

1. INTRODUCTION

1.1. Introduction

The present Executive Summary Report (the "Report") was prepared in the framework of the *Review of the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management* (the "Assignment" or the "Review") and is submitted to the European Food Safety Authority (EFSA) by Economisti Associati s.r.l. (the "Consultant"). It summarises the main findings from the Draft Comprehensive Report, and includes conclusions and recommendations.

1.2. The Assignment

The Assignment focused on the rules outlined in the Decision of the Executive Director of the European Food Safety Authority on Competing Interest Management (the "Decision") and the way they were implemented at EFSA in the period running from 1 July 2018 to 31 December 2020. It only indirectly extended to EFSA Independence Policy (the "Policy"), considering the strategic principles outlined in the Policy as the reference framework for the Decision. The Decision covers rules applicable to external experts and procurement contracts and grants and does not concern EFSA internal staff.

The exercise aimed to evaluate the effectiveness, sustainability, efficiency, relevance, proportionality and coherence of the Decision and the way it was implemented. In particular, it focused on identifying needs for clearer definitions, possible inefficiencies, existing gaps and possible room for improvement of the existing workflows and procedures.

The Assignment included three main activities:

- a desk review of relevant sources, covering over 70 documents;
- an interview programme, entailing 19 semi-structured interviews with selected counterparts, including (i) 12 EFSA staff members (seven from legal, administrative and communication services, and five from Scientific Units); (ii) three scientific experts; (iii) two representatives of grant recipients; and (iv) two similar Agencies (the European Chemicals Agency or ECHA, and the European Medicines Agency or EMA); and
- a web-based survey of EFSA staff, with the invitation sent to 52 recipients and 22 responses received.

2. THE DECISION

2.1. Reform of EFSA Independence Policy

EFSA Independence Policy was reformed in 2017 following a number of requests made by the European Parliament and civil society organisations in response to several allegations of Conflict of Interest (CoI) cases. The reform was then implemented through the 2018 Decision, adopting a number of strategic prescriptions formulated in the Policy document approved the previous year by the EFSA Management Board. EFSA Independence Policy can now be considered as being in all likelihood one of the most stringent and advanced among EU Agencies.

In particular, the Decision strengthened several provisions on contentious topics and regulated the related Declaration of Interest (DoI) requirements, including:

- a two-year "cooling-off" period from any EFSA scientific activity for experts employed by the food or feed industry or by lobbying organisations (e.g. Non-Governmental Organisations or NGOs) concerned by EFSA's scientific outputs;
- a two-year "cooling-off" period for experts in case a wide range of their professional interests overlap with the type of work they will carry out for EFSA;
- a sliding scale of mandatory restrictions depending on the expert's own financial DoI, up to a two-year "cooling-off" period from any EFSA scientific activity based on the nature of the declared interests;
- new requirements for experts to calculate and declare the financial impact of their interests on their annual earnings;
- a two-year "cooling-off" period when private research funding in the area concerned by the Panel or Working Group mandate exceeds 25% of the relevant research funds managed by the expert in the two years preceding the submission of the DoI;
- new requirement for pesticide peer-review experts from national authorities in the Member States to be subject to transparency measures and DoI screening rules;
- extension of the Decision to all procurement contracts and grants concerning EFSA's scientific activities (previously, only the ones deemed particularly at risk were covered);
- strengthened enforcement measures for breaches of the independence rules, up to a ban on working with EFSA for 10 years.

2.2. Main Features and Implementation Mechanisms

The Competing Interest Management (CIM) system put in place by the Decision is characterised by a number of notable, and in certain cases almost unique, features and implementation mechanisms, and namely:

- it is semi-centralised and foresees two levels of DoI scrutiny for Panel and Working Group experts, with the responsibility for final validation lying with the Legal and Assurance Service (LA) Unit to ensure harmonisation of practices. As a result, a certain level of interaction is needed between the units concerned and higher resources are invested compared to similar EU organisations;
- to partly compensate for the above, the DoI process is carried out online and heavily relies on an Information Technology (IT) tool, except for procurement contracts and grants, whose DoIs are processed manually and based on paperwork;
- it foresees a continuous process of classification of "public institutions" (PI) in accordance with the criteria described in the Decision. The IT tool automatically updates organisations status based on EFSA classification on a weekly basis, and informs the LA Unit via e-mail of the status of the new organisations notified in the system and of changes in the status of organisations. EFSA seems intentioned to push with IT automation even further and has invested in a project to assess the possible contribution of Artificial Intelligence (AI) and text mining to the enforcement of the Decision;
- it is the only CIM procedure in Europe to envisage the possibility of granting a waiver on a recognised CoI situation to exceptionally allow the expert's participation in EFSA activities, although with restrictions on the role;

- it identifies a number of cases where DoIs are requested for transparency purposes only (e.g. hearing experts, EFSA network members, etc.), but are not screened by EFSA. In particular, for EFSA network members the provisions are so light that experts are allowed to take part in the network activities even if an Annual Declaration of Interest (ADoI) has not been submitted;
- since CoIs are often defined based on the mandate of the respective Panel or Working Group, ADoIs have to be re-submitted each and every time the expert is invited to contribute to a new Scientific Group. Consequently, multiple ADoI submissions are needed also for hearing experts.

3. SUMMARY OF MAIN FINDINGS

3.1. Relevance and Coherence with EFSA Independence Policy

The relevance of the Decision was assessed in terms of (i) alignment with the transparency objectives of the EFSA Founding Regulation and the overall European Union (EU) set of CIM policy guidance principles, as defined over the years; and (ii) responsiveness of current provisions to the perceived needs. In addition, EFSA is almost unique among EU Agencies in having a CIM mechanism articulated in different levels of accountability: the overarching EFSA Independence Policy is outlined into a Policy document that contains its main principles and orientations, and is approved by the Management Board; for these principles to apply, however, an implementing Decision of the Executive Director needs to enter into force. In light of the above, the coherence of the Decision with the principles outlined in EFSA Independence Policy was also analysed. The main results from the exercise are the following:

- The Decision complies with the principles outlined in EFSA Independence Policy in all areas. In some cases, however, ambiguities may arise in the way these principles are defined in the Policy document and implemented in the Decision. As a result, the spirit and the original intentions of EFSA Independence Policy are unclear, and might appear contradictory. The issue primarily concerns: (i) the interpretation of involvement in risk management; (ii) public interest in a PI as criterion to distinguish between legitimate interests and CoI in a number of areas; (iii) the criteria used to define a PI; and (iv) the treatment of employment for a lobbying organisation concerned by EFSA's scientific outputs.

- The publication of the ADoIs of hearing experts tends to be considered as redundant within EFSA. In addition, if only eligibility restrictions are considered, the rationale behind having unscreened ADoIs for hearing experts is not straightforward. The matter is perceived of practical consequence for efficiency and external communication considerations. In particular, some consider that the sheer recourse to the ADoI format may engender the false but reasonable expectation that these ADoIs undergo the same scrutiny procedure as those from Panel and Working Group members, and this might cause confusion among the general public.

- Due to the widely acknowledged difficulties in coming to a workable sectoral definition of the EFSA remit in general, or of the Panels/Working Groups' in particular, some interviewees would be substantially in favour of strengthening the assistance provided and relieve the expert from the need to identify CoIs himself/herself – at least the first time an expert comes into contact with EFSA. This can be achieved through an interview with the expert made by dedicated specialised staff or through other means (helpdesks, online tools, etc.). Once classified in terms of remit, the results would be sent back to the expert for confirmation and then appraised. Interestingly, organizations that for simplicity purposes have so far relied on a sectoral definition of their remit are considering moving towards EFSA's "remit-based" approach should the range of their activities expand in the future.

- The Decision follows the same approach as the Founding Regulation and defines CoIs with reference to direct and indirect interests falling within the EFSA remit. At the same time, it separately identifies the same categories (consultancy, management, research, etc.) used by other EU Agencies to define what "indirect interests" are. Since no clear definition of "indirect interests" can be found in the Decision, however, the interpretation of this concept is currently unclear within EFSA.

- Although the distinction between matters included in the Policy and those dealt with in the Decision is not necessarily clear to all, it is generally recognised that a joint review of the Policy and the Decision would be ideally preferable to the current piecemeal evaluation and review mechanism, where the two are evaluated and reviewed separately.

3.2. Effectiveness and Impact on Reputation

The effectiveness and the impact on reputation of the Decision were assessed with reference respectively to: (i) the likelihood that CoIs go undetected and, therefore, a long-term threat to EFSA scientific credibility and standing; and (ii) the overall improvement in the external perception that CIM matters are managed in a professional way and in line with best practices. The main results are the following:

- A consensus exists that the accuracy of CoI scrutiny and EFSA capacity of detecting CoIs have increased over the last few years and the majority of respondents to the survey confirmed that CoIs are less likely to go undetected. One of the factors explaining the improved quality of the scrutiny is the existence of a centralized system and a dedicated specialized team responsible for harmonizing assessments among the Scientific Units providing secretariat services to the Scientific Groups. The effectiveness of the Decision is also reflected in the results of the yearly set of compliance and veracity checks performed by the LA Unit, although this is considered by survey respondents as a slightly less important factor. In this context, some interviewees wonder whether it would be possible to expand the scope of ex post compliance and veracity checks also to patents and other information available on the web by means of text mining or other AI tools. Finally, the high level of compliance can also be explained by the relatively good understanding of and awareness about CoIs among the concerned EFSA staff members. This compounds with a high level of satisfaction with the interaction with the LA Unit and the assistance provided in clarifying complex or borderline situations.

- Training and information sessions were also deemed, all in all, adequate, even though possibly not the key driving factor in determining the effectiveness of operations. Differently, the introduction of simple summary tables in the Annex has greatly improved the clarity of the DoI process and these were unanimously praised as one of the most useful innovations introduced with the 2018 reform. On the contrary, the instructions available for first-time DoI compilers were not considered as very clear. The Decision is written in too complex a legal language to be of any use as guidance document for non-specialist users, particularly as a number of concepts are at a variance with the traditional understanding of CoI for scientific publication purposes. In this context, the use of a plainer language and a more extensive recourse to examples or explanatory videos in the IT tool[1] were generally deemed to be of help.

- Some interviewees proposed a radical reshuffling of existing procedures and would like to introduce centralised online interviews managed by trained administrative assistants the first time a DoI is filled in. These could also be used as a motivational tool for experts and reduce the perception of a bureaucratic exercise. Some survey respondents also considered that this opportunity is currently underexploited and too little time and resources are invested there. This will be even more true if the ethical approach to CIM at the EU level eventually prevails. In this case, the Scientific Units would be involved in the process just to provide their expertise on the remit of the mandate, an area that everybody agreed can hardly be centralised. Others are more cautious and would like to introduce the possibility of having, upon request, a human interaction component by means of a helpdesk/helpline, while having greater recourse to explanatory videos and pop-ups in the tool. An interactive learning mechanism could be created, with the contents of the guidance refined over time based on the frequency of certain requests for clarification, which tend to concentrate on the same topics.

- A number of elements seem to confirm that overall EFSA reputation on independence and the detection of CoIs among its scientific experts have improved since the Decision was adopted in 2018. EFSA now has a reputation for being at the forefront in CIM innovation and identification of best practices among EU Agencies, as also publicly acknowledged by the European Ombudsman in a recent public event[2]. A number of features were praised as particularly advanced and worth considering as a source of inspiration

[1] Presentations prepared by the LA Unit are made available to guide and help concerned individuals when filling in their DoIs. In 2018 an e-learning tool was also developed to guide and help Panel members to fill in their DoIs in accordance with the requirements set out in the CIM rules.

[2] Ombudsman Event, "How to manage the risk of reputational damage", 18 October 2017. Summary available at: https://www.ombudsman.europa.eu/en/event-document/en/84866

by the CIM expert community, and namely: i) the management of DoIs by means of an automated IT tool; ii) the semi-centralized system; iii) an eligibility restriction system leaving little room for discretion; iv) a formalized procedure in case of breaches of the rules with clear sanctioning steps; and v) the treatment of the financing of research activities.

3.3. Efficiency of Operations and Room for Simplification

The efficiency of operations was reviewed from two different perspectives: (i) by specifically focusing on the implementation procedures and the workflows of the Decision itself; and (ii) by assessing the impact that the implementation of the Decision has had on the routine activities of the different units concerned. In both cases the objective was to identify possible ways of simplifying activities in order to reduce the overall burden on the organisation, streamline the use of resources and save time.

- As generally recognised, the abolition of the Specific Declarations of Interest (SDoIs) by the 2018 Decision has greatly simplified the overall organisation of CIM activities and reduced the burden on DoI screeners, including the need for dedicated staff, although not necessarily the overall amount of time devoted to CIM matters. As mentioned above, the distinctive feature of the EFSA screening process lies in being semi-centralised and articulated into two layers of control for Panel and Working Group experts. As a result, some wondered whether, after some years of experience, the current organisation of activities can be further simplified and turned into a fully-centralised system by removing the first layer altogether. The prevailing view, however, was that a full centralisation of DoI screening activities is not feasible, as the LA Unit lacks sufficient expertise to judge on key aspects related to the remit of the mandate of both Panels and Working Groups and this single issue already represents a sizeable share of resources required by the need for interaction between the two.

- While the conditions to move to a fully-centralised DoI screening mechanism do not seem to exist, resources can be saved by streamlining the first DoI compilation process and reducing the need for interaction with DoI screeners, as already foreseen in the EFSA Complete Solution project due to become operational soon. In other words, simplification opportunities are to be found mainly in the phase of submission of the DoI by the experts, especially when they are hired for the first time. First of all, part of the information requested is already available from recruitment data and DoI templates could be precompiled if the two databases were bridged. The expert would then just need to complement his or her DoI with information on financial aspects and the other items typically reported in the “other interests” section (honorary positions, etc.). Then, some also proposed that the IT tool should allow to retrieve information from previous assessments that has not changed in the meantime. Another feature deemed worth maintaining is the current conditional award procedure according to which full DoIs are requested to contractors and grant-holders only when they have been tentatively awarded the contract.

- One of the most appreciated features of current CIM practices is the IT tool for DoI processing. Actually, some interviewees wondered why it is not extended to procurement contracts and grants as well. However, the IT tool is not without its own shortcomings. At present, the IT system requires a dedicated data inputting and formal submission procedure each and every time an expert starts working for a different Working Group, even if no formal scrutiny of his/her ADoI is required. In addition, if a scientific expert is also a grantee, he/she needs to fill in the template from scratch, as EFSA does not reuse information already present in the system because it does not apply to procurement contracts and grants. Moreover, many would like to have a tool to “automatically” eliminate interests that are too old to be relevant any longer. Finally, the tool does not provide for a facility to help calculate the share of research funds from the same industry client in any reference period in a manner that is common to all.

- In terms of impact on EFSA operations, the rules mainly result in a restricted access to expertise. In areas where research is strictly interlinked with industry (e.g. Genetically Modified Organisms or OGMs, novel foods, flavourings, etc.), the share of experts deemed ineligible has been reportedly as high as 30%. This has been partly compensated by increasing the recourse to hearing experts and external contractors, and has not resulted in a worsened performance in terms of quality of the scientific outputs or compliance with internal key performance indicators. In other areas the impact is lower, at around 20%, but still substantial.

Even the likelihood that experts appointed by Member States are confirmed after DoI screening has decreased by 10%.

3.4. Proportionality to the Policy Objectives and Sustainability in the Light of the Transparency Regulation

Proportionality was reviewed from two different and complementary angles: (i) from the viewpoint of compliance with the principle of proportionality of administrative action, i.e. that all rules and procedures should be modulated in function of the underlying CoI risks; and (ii) from the traditional viewpoint of compliance with subsidiarity principles. In addition, the main provisions of the Transparency Regulation that are likely to impact on the future effectiveness and overall consistency of the Decision were sketched out and analysed in more detail.

- The current definition of "industry employment" is the provision of the Decision that, extending to the whole remit of EFSA activities, triggers most eligibility restrictions and, as such, was often considered as disproportionate. However, the consequences in terms of restriction of access to expertise derive from the Policy and not from the Decision. Several interviewees also requested to clarify rules applicable to learned societies and universities, and make a clearer distinction between financing from industry and profit-seeking entities that do bear a risk of CoI, on the one side, and other forms of private and charitable funding from private foundations that are not generally perceived as source of possible CoIs by the general public, on the other, also relieving existing restrictions on the latter.

- The rationale behind requiring a DoI from contractors' and grant-holders' administrative and technical staff (secretaries, technicians, laboratory personnel, etc.) is not straightforward and seems to depend on the definitions, considering as concerned experts all contractors' or grant-holders' staff, irrespective of their concrete role in a project. Such an approach seems disproportionate. The current practice of exempting from DoI requirements grants referred to in article 36 which are not directly related to the production of EFSA scientific outputs draws from the Decision main principles, but is not explicitly spelled out in writing in the text of the Decision.

- A minority of stakeholders insisted that CIM rules should be modulated based on the nature and contents of the activities undertaken in the different Panels and were probably right on theoretical grounds. Yet, this seems a too impractical and complicated solution to be considered in the reasonable future, however sophisticated IT assistance might be.

- The definition of a consistent set of CIM rules is increasingly being hindered by working practices that have evolved at a variance with what was originally envisaged in EFSA organisation of work. Unless definitions are aligned with emerging practices and roles are better clarified and formalised, little consistency in terms of administrative proportionality is likely to be achieved any time soon. The changes which are likely to be triggered by the Transparency Regulation add to this situation. The choice of allowing a special status to peer-review experts appointed by Member States vis-à-vis other external experts has created the pre-conditions for any set of CIM rules appearing as either disproportionate or internally inconsistent until internal CIM rules at Member State level are aligned with principles prevailing for EU staff. The developments which are likely to be triggered by the Transparency Regulation are no exception in this respect and will make the problem more acutely perceived. Some officers believe that a neglected aspect of the application of the Transparency Regulation is that strengthened transparency and publicity requirements will increasingly put the spotlight on somehow neglected impartiality aspects.

- As acknowledged, in implementing the Transparency Regulation a trade-off exists between reputation requirements and the need to broaden the expert basis. Should the first prevail, the current set of CIM rules appears hardly sustainable in the long run. The majority of survey respondents, however, noted that the Transparency Regulation is likely to bring into the light the issue of independence from national pressure and Member States' political agendas. So far, this has hardly informed EFSA Independence Policy considerations but the growing role attributed to Member States is expected to move the focus precisely

towards independence from national pressure, as is already the case for EMA and ECHA. This is perceived as possibly the most significant issue ahead, together with internal inconsistency of rules.

3.5. Trends in Legal and Policy Developments at the EU Level

The main legal and policy developments from the European Ombudsman, the European Court of Auditors, and the General Court of the EU and the Court of Justice of the EU were reviewed with a view to identifying the main trends, and highlighting areas where the provisions of the Decision are likely to be maintained over time and others that appear, conversely, more critical.

- At the EU level citizens' impartiality rights increasingly tend to be considered immediately enforceable, irrespective of the content of the Decisions regulating CIM in the various EU Agencies. As a result, the relevance of topics that have traditionally been neglected in these documents has increased, such as undue influence from national interests, the experts' own confirmatory bias of positions held in the past and potential biases from interests in rival products.

- Linked to the above, the importance of previous knowledge of the subject matter or the relevance of thematic expertise increasingly tend to be played down, as compared with the perceived need that the different stages of the opinion elaboration process are run independently from each other and with limited interference in the expertise involved.

- Both the European Parliament and the European Court of Auditors tend to consider CIM matters as an ethical issue, funding studies[3] and formulating proposals[4] along these lines. This contributes to making their scope vaguer and all-encompassing, and to strengthening the importance attributed to controls and sanctions. These proposals are being elaborated having in mind internal staff or experts that, being appointed by Member States, are usually paid for their job and tasks. As such, they do not necessarily tally well with the set of incentives available to EFSA experts, who are largely remunerated on an honorary basis and could find these rules disproportionate to their perceived benefit. Most probably, this trend could also increasingly push to questioning the exemption of certain categories of experts from DoI scrutiny by EFSA Independence Policy.

- Both the scope of the definition of "close family member" and Intellectual Property Rights (IPR), and the way related CoIs are being dealt with, are likely to be the subject of the increasing pressure on EU harmonised CIM practices. The same applies to CIM rules on gifts and entertainment.

3.6. Changes in CIM Rules and Procedures in Similar EU Agencies and Committees.

Changes to the CIM rules implemented by the main EFSA comparators since the Decision was enacted were also reviewed. Comparators include organisations either heavily relying on external expertise for their deliverables or for which a rigid distinction between risk assessment and risk management roles matters, such as ECHA, the European Centre for Disease Prevention and Control (ECDC), EMA and the European Commission (EC) Non-Food Scientific Committees. The EC Scientific Advice Mechanism was also included.

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

[4] The European Parliament's Policy Department for Citizens' Rights and Constitutional Affair commissioned a study titled "Strengthening transparency and integrity via the new 'Independent Ethics Body'" (available here: https://www.europarl.europa.eu/RegData/etudes/STUD/2020/661110/IPOL_STU(2020)661110_EN.pdf) which provides an overview of transparency and integrity-related elements in the current EU setting, covering both substantive elements (including, in particular, CoI and revolving-doors) as well as the body in charge of ethical control and guidance. Based on a comparison covering France, Ireland and Canada, this study proposes an 'Independent Ethics Body' (IEB) via a new interinstitutional agreement. The study was also discussed in a joint Constitutional Affairs (AFCO) and Legal Affairs (JURI) committee meeting of the European Parliament last November (see here: https://www.europarl.europa.eu/news/en/press-room/20201113IPR91601/independent-ethics-body-strengthening-transparency-and-integrity-in-the-eu).

- Despite the different policy tools adopted by ECHA, the ECDC, EMA and the EC, a certain degree of harmonisation has been reached on the main principles underlying CIM. In particular, for some operational aspects such as the adoption of Annexes that include summarising tables, the sliding pattern of restrictions related to the different remits of the experts has entered as a best practice in all Agencies reviewed.

- ECHA has found some difficulties in pursuing the Memorandum of Understanding (MoU) approach in relations with Member States. In this regard, given the importance of Member State experts in the decision-making process, EMA has opted for pre-screening their DoIs, a practice which is similar to the screening by EFSA of the DoIs of Member State representatives in pesticide peer-review meetings.

- Over the last couple of years, the strengthening of the definition of "close family member" to fill emerging gaps and close loopholes has been among the areas attracting considerable attention from the other EU Agencies. In addition, IPR have possibly been one of the most relevant areas where practices have been diverging so far. To some EU Agencies, IPR are tantamount to financial interests and therefore blacklisting is more appropriate: the ownership of a patent counts in this respect and not the original copyright of the author. Differently, other Agencies focus on the latter and accordingly apply milder restrictions.

4. CONCLUSIONS AND RECOMMENDATIONS

4.1. Main Conclusions

As generally recognized, the 2017 Policy reform and the ensuing 2018 Decision have contributed to EFSA improved reputation and put the Agency at the forefront with regard to CIM matters. This is due to a number of factors, including (i) having agreed to a number of long-standing European Parliament requests to have "cooling-off" periods introduced also for external experts; and (ii) considering research funding from non-public operators as a competing interest worth monitoring and a cause of ineligibility above a certain threshold. A substantial reduction in discretionary decisions has also contributed to enhancing the overall credibility of EFSA when it comes to its willingness to actually implement its own rules.

Disentangling the specific contribution of the Decision to this improved climate is more difficult. The choice to centralise the CIM system, ensuring the harmonised enforcement of rules and minimising agency problems and conflicting incentives within the Secretariats, has certainly played a role and is increasingly considered as a best practice among CIM practitioners. EFSA heavy investment in reporting results from ex ante screenings, and ex post compliance and veracity checks, as well as in providing details on the procedures opened for breaches of the rules, can be considered as a best practice too. At the same time, a specific provision of the Decision has negatively impacted EFSA reputation[5] and cast doubts on the whole process because of its apparent inconsistency, namely the requirement for hearing experts and EFSA network members to submit DoIs that are not screened. In this context, the balance between independence objectives, transparency requirements and efficiency considerations ultimately remains a value-laden policy decision. However, EFSA has wide room for improvement when it comes to avoiding sending confusing and conflicting messages to the public. Instead of mixing up screened and unscreened procedures under the same ADoI format, and pretend this alternatively fulfils independence and transparency aims, means could be found to at least clearly distinguish the different status and aims of these documents, either lexically and for communication purposes (e.g. by introducing the concept of self- declarations of interests or of CoIs).

A number of steps have already been taken to minimise the impact on access to expertise and EFSA tendency to get engulfed in complex bureaucratic procedures[6]. The first objective has been reasonably achieved and the impact in terms of quality of the scientific outputs is limited. Differently, based on the overall interview results, EFSA's reputation for being an organisation keen to a detailed implementation of policy and legal requirements has seemingly been impacted even further by CIM implementation. Some procedural aspects are difficult to simplify because of the way the EFSA remit and that of the single Panels and Working Groups have been used as a benchmark for defining the scope of CIM rules. In a number of areas, however, further simplifications are possible and worth considering, making the system more user-friendly for experts and thereby reducing the impact of CIM rules on the overall reputation of EFSA.

While EFSA has made a great effort to reduce discretion in the enforcement of the rules, work has just started on making the assessment of the long-term sustainability of the rules in the light of policy and judicial developments and internal needs more systematic and documented within the Assurance Working Group on Independence. In addition, preparatory work for the implementation of the Transparency Regulation has focused in 2019 and 2020 on the newly established processes. The screening system in place could be considered as in need of a revision in light of the sourcing approach being developed in view of the need for EFSA to expand its sourcing strategy. In other cases, the long-term sustainability of the rules appears

[5] The 2018 Parliament Discharge Report regretted the lack of a CoI screening procedure for some external experts (in particular, experts attending hearings or members of the Advisory Forum, focal points, or scientific networks). Much in the same vein also the "EU Agencies – Conflicts of Interest" study commissioned by the European Parliament (January 2020) continued remarking with reference to EFSA that "*external experts (like hearing experts, or members of the advisory forum, focal points, or scientific networks) are not subject to a CoI screening. Any (potential) conflict of interest in this area might go unnoticed. The fact that these actors do have to submit a DoI shows EFSA's awareness of such potential problems, but if no screening is applied, this is without practical relevance*" (ditto page 62).

[6] See two reports drafted for EFSA, and namely ICF (2019), Reputation barometer follow-up study - European Parliament discourse analysis; and ICF (2020), Reputation Barometer 2.0: State of EFSA's reputation and lessons for future monitoring.

conditional on a revision of the Policy principles that, as implemented, might appear either ambiguous in terms of their rationale or disproportionate to the risks at hand. Both judicial and policy trends at the EU level compound this need to reconsider certain aspects in a strategic long-term perspective, rather than as drivers for immediate change.

4.2. Recommendations: Needs for Clarification.

Several concepts (see list below) could be clarified. A few requests for clarification were also made by the Panels themselves. This clarification exercise, however, seems unlikely to play any substantial role in simplifying/clarifying the process for first-time DoI compilers, as for them the issue is the lack of examples in plain non-legal language.

The written explanations will therefore mainly serve the purpose of limiting the scope for misunderstanding within the Secretariats or between the assessors and the legal validators. In turn, this will increase staff awareness about concepts and definitions, thereby reducing the level of internal uncertainty in the system. This will be a good thing for the internal working climate and for ensuring smooth relations between the LA and the other units. Most probably, however, as the issue does not appear to be major, the clarification of definitions will not be a game changer in how smoothly the Decision will be implemented in the next few years. Having said that, the areas where clarification should be sought are the following.

- ***Risk management.*** In the EFSA practice, the performance of a risk management function is defined as either the actual power of making a decision on risk management issues, or the participation in a decision-making or regulatory group advising decision makers on risk management matters (e.g. national registration committees or EC Standing Committees on Plants, Animals, Food and Feed). While the first part of the definition is clear, considerable uncertainty remain among interviewees and experts alike as to the second part. In particular, it should be clarified whether a CoI can exist when the expert acknowledges participation as an advisor in a decision-making body or even in the Minister's cabinet office but at the same time claims that he/she participated in a risk assessment capacity and without contributing to the decision-making process itself.

- ***Industry employment.*** In the CIM rules, "industry employment" is defined as any employment with companies, business operators, business associations, lobbying organisations as per the EU regulations on the subject, as well as any other corporate funded organisations directly or indirectly concerned by EFSA's scientific outputs. As consumer NGOs that are targeted by the Policy are also included, the definition risks appearing counterintuitive and potentially misleading. In light of the above, EFSA should separately identify and clarify eligibility restrictions linked to the participation in NGO activities related to the EFSA remit mainly for external communication transparency purposes.

- ***Public institution.*** At present EFSA uses the EU ABAC[7] list of EC payments as a source of information to verify the criteria for granting the status of PI. However, this could be clarified in the Decision. The matter, however, appears of very limited interest to the Secretariats in the Scientific Units, as current procedures leave to the LA Unit the duty of defining whether an entity falls within the definition of PI or not.

- ***Indirect interests.*** As a legacy of the Founding Regulation, EFSA still makes extensive use of the concept of indirect interests in the text of the Decision. Its meaning, however, remains allegedly open to different interpretations, and could therefore be either cancelled or clarified.

[7] Since 2005 DG Budget has been using ABAC as payment system for the Commission accrual accounting purposes and the system has been extended also to EU Agencies. ABAC includes unique identifiers for each recipient of EU funds. The unique ABAC legal entity record distinguishes between natural persons, and private law and public law bodies. The ABAC records represent means of proof of compliance with specific obligations in the Financial Regulation and for budgetary discharge purposes.

- ***Review of the expert's own work***. Even though the matter has hardly been raised formally with the LA Unit, some interviewees would like to make sure that the eligibility criterion applies only when the author's work "is in the agenda" in an eminent way. To the contrary, the criterion is not meant to cover cases when there can be a list of references consisting of several dozen, if not hundreds, of articles in a review and just one or few of them refer to the expert concerned.

4.3. Recommendations: Correction of Content

The need to possibly revise or change the substantial content of the Decision is explained by three main reasons. The first is the need to ensure some degree of harmonisation at the EU level and alignment among prevailing practices in EU Agencies. The second is the necessity to respond to the operational needs voiced by the Secretariats of EFSA Scientific Units with regard to cases where the CoI risk perceived is not sufficient to justify restrictions. Thirdly, in some areas the need to broaden the scope of CIM rules is somehow perceived but clashes with strong a priori resistances to further restricting access to expertise. The first of those areas relates to the management of CoIs among family members, and the way IPR-related interests are being dealt with and potential financial interests defined. The second more specifically relates to restrictions on hearing experts to contribute to opinion drafting, the requirements for having access to waived experts and the use of the concept of PI as a primary reference criterion for defining certain interests (e.g. managerial roles, membership of a scientific advisory entity, occasional consultancy, etc.). The third area refers to impartiality issues and the need for revision that may be considered appropriate in the Decision in view of EFSA's approach to the implementation of the Transparency Regulation, as experts playing similar roles in opinion drafting would be subject to different sets of eligibility restrictions.

- ***Close family members***. The Decision sticks to the EU Guidelines[8] definition of "close family member". That definition is very restrictive and is becoming increasingly not aligned anymore to developments in other EU Agencies where the subject has attracted considerable attention in the recent past and the definition has been broadened to better cover both the household dimension and other forms of partnership. The need for better harmonisation in this regard has also entered the European Court of Auditors' agenda. However, as the definition is enshrined there, the matter will first require a revision of the Policy.

- ***IPR.*** Eligibility restrictions related to IPR and the sheer identification of IPR interests have been not harmonised among EU Agencies, even though no apparent rationale behind such a development exists. It could be speculated that different Agencies emphasise different aspects of IPR-related CoIs: while some highlight the economic interest component, others focus on the threat to expert impartiality and take the "conflict of opinion approach". Whatever the explanation, this results in diverging practices that do not seem to external observers to be fully justified by the different nature of the interests at stake. While harmonisation of eligibility restrictions and the rationale behind them should be discussed among Agencies to come to a common position, EFSA could consider to already responding to the European Ombudsman requests of considering within the scope of IPR also applications for patents which have not been granted yet. In addition, it should decide how to deal with patents whose term expired before the ordinary deadline because the maintenance tax/fee had no longer been paid.

- ***Warrants and options***. Again for the sake of harmonisation with other EU Agencies, EFSA might consider to explicitly expanding the scope of financial interests under the word "equity" to cover warrants or options on shares, even when not directly issued by the industry. As it happens, these tools lend themselves to be exploited for forms of insider trading on the consequences of EFSA opinions.

- ***Hearing experts***. Among other things, the Decision changed the way Panels and Working Groups work, in particular by increasing recourse to hearing experts and in certain cases external contractors. Some anticipated that this will further expand to grant holders following the entry into force of the Transparency Regulation, where a role for networking organisations referred to in article 36 is envisaged for direct

[8] European Commission (2013), Guidelines on the prevention and management of conflicts of interest in EU decentralised agencies, available here: https://europa.eu/european-union/sites/europaeu/files/docs/body/2013-12-10_guidelines_on_conflict_of_interests_en.pdf.

opinion preparation. EFSA is not the only one going through this comprehensive reform of the way it works by expanding the recourse to expert witnesses. Such an approach triggers an increasing demand to change the restrictions applying to the role to be played in drafting. Elsewhere, complaints about the lack of adequate specialist expertise among experts holding the decision-making power have been expressed by applicants as threats of legal actions to make the related outputs null and void. The scope for changing the content of CIM restrictions on hearing experts is limited within the current set of EU CIM principles and in the light of the current European Parliament orientations. This is even more true pending a clarification of the roles in the scientific opinion production process. However, since the problem is common also to other Agencies, it can be worth exploring with the EC whether the role of "expert witness in writing" can be introduced EU-wide subject to transparency requirements on the contribution and mandatory quotation marks in the scientific output clarifying what the source is. Such a solution would also meet requests by NGOs for more transparency on expert witness contributions.

- ***Waived experts***. Of more direct operational interest seems the clarification in the Decision of the preconditions to be met for requests for waivers. At present, the Decision only states that a report to the Executive Director needs to be drafted to request a waiver for an expert. Everything else is left to the related SOP and the template for the request.

- ***Separate regulation of employment for NGOs.*** The Decision would be improved if matters related to employment with NGOs in the remit of EFSA were dealt with in a separate article and clearer principles were defined.

- ***Requirements for PIs and their role in the CIM architecture.*** At EFSA, fees and charges are considered as financing modalities for PIs only with regard to universities. For the sake of internal consistency, the principle should be extended to all PIs. In addition, EFSA should re-examine whether a broader definition of "eligible financing", focused on non-profit seeking or industry-related entities, would be more appropriate for certain intermediate institutions like scientific societies or private universities, and assimilate them to "public entities", particularly if NGOs with industry-related interests are defined separately.

- ***Participation in closed events and other industry-sponsored initiatives.*** Closed events and industry-sponsored initiatives have been gaining importance over the last few years. At the same time, these events can potentially carry a CoI and, consequently, information obligations arise before these take place. While these interests are addressed in a consistent manner in practical implementation practices, clarity and transparency would benefit from considering these matters in a separate article of the Decision defining procedural aspects, including eligibility restrictions and related sanctions. This should be extended, more in general, to speaking engagements, sponsored publications and other external activities that are currently regulated by rules which are de facto decided within the Assurance Working Group on Independence.

- ***Impartiality.*** Some Panel members strongly perceive the need to be better informed about aspects related to experts' possible impartiality issues which at the moment are not expressly covered in the DoI (pre-judgements expressed in scientific articles, witness roles in judicial or parliamentary procedures, involvement in potentially rival products, previous involvement in risk assessing the same subject, etc.). They are very reluctant, however, to have these aspects monitored by means of the formal DoI mechanism and expressly declared by the experts themselves, as this carries the risk of further increasing the perceived complexity of the DoI process. As an alternative, these aspects could be addressed by means of other or less informal mechanisms. In this context, various general solutions were proposed for "the selection process" or scrutiny of expert backgrounds by means of AI tools or text mining programmes. Since there is a parallel trend at the EU judicial level to increase scrutiny of impartiality matters, EFSA could monitor these evolutions and eventually reconsider the issue in the framework of its next Policy revision. By then, times will be riper for consensus building and the issue is expected to become more acute, also as a possible consequence of the Transparency Regulation. In this context, some consideration could be given to impartiality from national interests and political pressure other than risk management, currently triggering a two-year "cooling-off" period. Those aspects are not being dealt with in the Decision and might include employment with organisations that have already taken an explicit policy stance on a controversial item

subject to EFSA risk assessment or with governments that are under judiciary litigation with applicants on the subject matter or related topics.

- ***"Cooling-off" provisions.*** The application of the Transparency Regulation risks creating a situation where draft opinions are submitted for final approval by the Panel through procedures subject to different sets of CIM rules. In other words, experts playing a comparable role, although with different functions, risk being subject to different rules. These risks endangering EFSA's reputation. When operational procedures for implementing the Transparency Regulation are defined and matters that can be subcontracted decided, the issue should be reconsidered with a view to ensuring internal consistency of CIM provisions.

4.4. Recommendations: Procedural Simplifications

Philosophy. A set of proposals are made that aim to radically simplify the first DoI process and turn the exercise from an operational constraint, as it is currently perceived, into a motivational tool and an opportunity. This can accompany an emerging trend at EU level towards an ethics-based approach to CIM matters. These proposals are variously articulated in: i) a move towards an open declaration system managed by means of interviews; ii) the establishment of helpdesks/helplines; and iii) the provision of online guidance conceived by communication experts. All proposals could be considered based on the resources available and only after a cost-benefit assessment that could justify the related investment.

Other proposals are conversely intended as standalone interventions within the framework of the current mechanism and aim at a series of marginal improvements. These include:

- ***Decision review process.*** Reviewing the Decision and the Policy at different moments in time is not sensible and EFSA should consider realigning the timing of the two processes. In addition, it could also build on EMA experience and use the annual reporting process to identify items for subsequent inclusion in the Decision review based on cases discussed at the Assurance Working Group on Independence, and the analysis of the consequences of relevant judicial decisions on EFSA operations and CIM practices carried out there. This would also contribute to increasing transparency in the decision-making process as to how and why rules should be changed.

- ***Procurements and grants*.** EFSA should consider including procurements and grants within the scope of the IT tools. In addition, it should refrain from requiring DoIs from administrative and technical staff who are in no position to exert an influence on the scientific deliverable. Moreover, exemptions for networking or training grants with network partners could be better formalised. Finally, financial thresholds for attributing DoI approval roles to different types of authorising officers could be reconsidered.

- ***Repeated DoI requirements for hearing experts*.** Once a hearing expert is included in the system, there is no need to recompile his/her DoI each and every time he/she contributes with his/her expertise to other Working Groups. The related procedural requirement should therefore be dropped.

- ***Income threshold*.** Experts should be offered a simple online tool to calculate compliance with thresholds for funding in common accrual terms, if they so wish.

- ***Automated updating***. EFSA should consider the automated updating of information included in the IT tool, with the removal of outdated data and the possibility of automatically exporting data which are still valid to DoIs relating to the same individual. Automatic transfer of data from CVs should also be considered.

- ***Breach of rules procedures*.** EFSA should consider simplifying and streamlining breach of rules procedures by minimising involvement of high-level governance bodies for minor cases. Other EU Agencies have introduced transparency requirements to report instances where a breach of rules procedure was commenced but not followed up, including the reason why.

- ***Scope of compliance and veracity checks.*** EFSA should plan to expand the scope of compliance and veracity checks, also on a pilot basis, by means of AI tools or text mining facilities.

- ***Identification of the EFSA remit.*** Particularly if AI tools and text mining devices are introduced, EFSA could consider expanding the recourse to iterative IT-driven processes, not only to refine the classification of PIs, as is currently the case, but also to come to a definition of the EFSA remit by means of consecutive iterations of examples for machine learning. The current reference to the food and feed industry as a proxy of the EFSA remit is rather imprecise and of limited usefulness for controversial cases. This could be complemented by reference to green, yellow, white, etc. biotechnologies, although this terminology is still poorly known.