

Critical Analysis of the EFSA's Rules for Managing Interests

Version from 18 February 2022

Preamble:

In accordance with the *Law no. 2013-316 of 16 April 2013 regarding the independence of expertise in health and the environment and the protection of whistleblowers* mandates the cnDAspe (Article 2) to "1° Issue general recommendations on the ethical principles specific to scientific and technical expertise in the fields of health and the environment, and (to) proceed to their dissemination ; and 5° Identify best practices, in France and abroad, and issue recommendations concerning the mechanisms for dialogue between scientific organizations and civil society on scientific expertise procedures and the related rules of ethics. "

This mandate aims to ensure the quality and impartiality of the expertise produced in France in support of public policies in the fields of health and the environment, which also informs citizens about the issues in these fields. However, in terms of health and the environment, these public policies are largely embedded in the European Union (EU) context and are also informed by scientific and technical expertise conducted at the community level. This expertise is supported by dedicated agencies and involves, to varying degrees, experts and competent authorities from the various EU Member States.

This is particularly the case for agricultural policy and, specifically within this context, for the use of plant protection products. The approval of the basic substances within these products is discussed at the community level. The marketing authorization of the commercial products derived from them is granted by the Member States, according to three geoclimatic and agronomic zones¹, all within a European regulatory framework.

Since this is so decisive in shaping public policies as well as the practices of the various stakeholders at the national level, execution of the mandate entrusted by law to cnDAspe therefore legitimately leads it to take an interest in the ethical practices of expertise conducted at the European community level.

In this context, the cnDAspe wanted to critically analyze the general policy and the rules for managing interests of the European Food Safety Authority (EFSA). This critical analysis is exposed hereafter.

¹ Northern zone: Denmark, Estonia, Finland, Latvia, Lithuania, Sweden (Norway also participates in the expertise for this zone); Central zone: Austria, Belgium, Czech Republic, Germany, Hungary, Ireland, Luxembourg, Netherlands, Poland, Romania, Slovakia, Slovenia; Southern zone: Bulgaria, Cyprus, Greece, Spain, France, Italy, Malta, Portugal

Decision of the Executive Director of the European Food Safety Authority on Competing Interests² (1/7/2018)

This "Decision" is the operational implementation of EFSA's general policy on independence. The document outlining this general policy is the subject of a short note in the annex.

The following comments on the "Decision", available only in English, concern the areas in which insufficiencies or elements of fragility are identified. These comments are associated with recommendations for improvement.

Other sections of this document are not commented on as they are deemed to reasonably contribute to the prevention of conflicts of interest. Overall, the provisions contained in this "Decision" mark a significant and welcome change from the prevailing situation up until 2017.

One point to highlight is a certain heterogeneity of definitions and rules adopted by EFSA, ECHA and EMA in their respective documents, which does not show an all-encompassing policy of the European Union in terms of the ethics of expertise with regard to its health, environmental and food policies.³

This calls for harmonization efforts.

1. Scope and definitions

Article 2. Definitions

- Item 1: "Experts⁴ (point f) are members of EFSA's Scientific Council, scientific panels and working groups, candidates who have responded to EFSA's calls for expression of interest, and participants in peer review processes, when these are appointed by or represent the authorities of a Member State. This list excludes interviewed experts and personalities invited as observers.

Comment. This definition leaves out the case of experts from the competent authorities of a Member State acting as rapporteur or co-rapporteur by not mentioning them in this list, nor the internal experts of these authorities, nor the members of their governance bodies. These competent authorities of the Member States are also not explicitly mentioned in point (m) "Public Institutions (PI)", i.e. any organization included in the list established by EFSA's Board according to Article 2 of the Commission Regulation (EC) 2230/2004.6; or any other international, national, regional, local or academic public institution, research institute or other entity that conducts tasks within EFSA's mandate. Thus, nowhere in the document are the rules applicable to experts and members of the bodies of these various national authorities defined in this context.

This vagueness is a major point of weakness in the system for preventing conflicts of interest, given the major role played by experts from the competent authorities of the rapporteur and co-rapporteur States in the scientific examination of dossiers. See section 4 below.

² https://www.efsa.europa.eu/sites/default/files/corporate_publications/files/competing_interest_management_17.pdf

³ This heterogeneity had already been pointed out by a recent report of several General Inspections (<https://www.vie-publique.fr/report/281523-la-sante-environnement-recherche-expertise-et-decision-publiques>). See in particular the section 2.2.2.1 of Annex III: The various agencies involved in health-environment issues fall under different bodies of law varying standards of transparency and conflict of interest management

⁴ Note that according to item 2 "For the purpose of declaring Interests as defined under paragraph 1, letter d, of this Article", income from outside activities of experts is considered as "Occasional Consultant" if it exceeds 5% of the total annual income, and "Employment" if it exceeds 25% of the total income.

Article 3. Requirements for a complete Declaration of Interest.

Experts and other "Concerned individuals"⁵ are required to provide EFSA with a Public declaration of interest (PDI, Declaration of Interest, "DoI") covering the last 5 years.⁶

Article 4. Annual Declaration of Interest

These PDI must be updated annually and no more than 45 days after any new activity involving an interest with regard to EFSA's missions.

2. Rules applicable to Experts

Article 7. General principles of screening of Experts' Interests

- Item 5: This item describes the activities considered incompatible with the exercise of certain tasks for EFSA and refers to the principles set out in the document "EFSA's policy on independence" (see the analysis in the appendix).
- While Public Declarations of Interests (PDIs) provide information on 5 years of interests, the incompatibilities that would result from identified interests only relate to activities that took place in the 2 years prior to the task or position at the EFSA.

Comment and recommendation. This "cooling off" period is too short. In a realistic scenario, a stakeholder with a strong intention to influence EFSA's future activities could give leave to a personality with great potential by having prepared this 2-year "cooling off" period while maintaining discreet relations with him/her to prepare his/her taking over. Considering the possible major long-term effects at stake, a medium-term "investment" is undoubtedly worth it. This "quarantine" period should be extended to 4 years, or even to the entire 5-year period covered by the PDI, to make such an influence strategy more costly.

- Item 12. The short duration of the "cooling off" period is all the more problematic since an exemption from the general rules of incompatibility, due to interests, applies to persons involved in "peer review", under EFSA conducted expertise, when these persons are agents of public institutions at the time their task for EFSA is to be carried out.

Comment and recommendation. The great heterogeneity of the rules of prevention of conflicts of interest between Member States - on which EFSA currently has no power to intervene - could thus lead to an expert acting in a "peer review" on behalf of a country with less restrictive requirements, while having an interest with stakeholders related to the subject investigated by EFSA. The resulting recommendation is the same as the one explained in chapter 4 (second paragraph).

Similarly, item 12 allows an expert to intervene in a peer review process even if a close relative has an interest in the file, as long as they are more than 2 years old. Here again, this "cooling off" period is too short and should be extended to 4 years, or even to the entire 5-year period covered by the PDI.

3. Rules applicable to Hearing Experts and Observers

No comment

4. Rules applicable to Network Members

The status of a competent authority acting on behalf of a rapporteur or co-rapporteur State is not explicit, as has already been pointed out. Is it part of the EFSA "Network", as mentioned in point g of article 1.2 and defined by regulation 178/2002 of the European Parliament and of the Council?⁷

⁵ In addition to experts, these include members of EFSA's "network" (point g), members of EFSA's governance bodies, experts interviewed, staff of EU institutions and other agencies attending EFSA meetings in an *intuitu personae* capacity. Internal or external experts from Member States involved in EFSA's activities as rapporteur or co-rapporteur states are not identified as "Concerned individuals"

⁶ This IPR is assessed by EFSA according to the criteria presented in Annex 1 (table 'Assessment approach')

⁷ <https://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:2002R0178:20080325:FR:PDF>

Comment and Recommendation. In general, paragraph 3 of Article 4.12 is not very precise. Nowr, it refers to entities that can provide scientific and technical support to EFSA's missions.⁸ The question of interests that could bias this support is not limited to possible individual cases, but involves more systemically the general policy of managing interests by the entities admitted to this network. Memoranda of Understanding (MoU) should be established between EFSA and each of its Network members. In addition to the elements specific to the particular activities in which each entity engages, these should include a common framework of minimum requirements for the prevention of conflicts of interest applicable to all Network members.

This common framework of minimum requirements for the prevention of conflicts of interest should in particular be applicable to any authority involved in the preparation of EFSA opinions as rapporteur and co-rapporteur state. The rules set out in this decision of the EFSA Executive Director could form the basis of these common minimum requirements. A country that does not comply with these requirements could not be a rapporteur or co-rapporteur State. Such a provision is likely to have a strong incentive effect in reducing the current heterogeneity of conflicts of interest prevention rules within the various competent authorities of the different Member States.

5. Rules applicable to members of EFSA's Governance bodies

Article 13. Members of the Management Board.

Item 6 of this article states that the members of the Board shall, during the 2 years following the end of their mandate, inform EFSA of any commitment that could be related to the missions and tasks of EFSA.

Recommendation. Even if its purpose is different, this "cooling off" period for new activities to come is too short, as has already been pointed out with regard to the time limit for this period after having held positions related to those held in or for the EFSA. This period should be extended to 4 years, or even to the entire 5-year period covered by the PDIs.

6. Procurement and grant awarding procedures

No comment

7. Implementation and enforcement

Article 19. Compliance and veracity checks and omissions by Experts

The procedure by which EFSA conducts a twice-yearly verification of compliance with the rules that apply and the veracity of the information provided by the experts' PDIs is strong, as is the provision that the findings of this monitoring exercise will be made public.

Article 20. Process regarding breaches of EFSA's rules on CIM by Experts

The decisions that can be taken in the case of non-compliance with EFSA's rules on interests are also strong and welcome.

Article 21. Granting of waivers.

This article provides that the participation of an expert with interests that would normally have constituted grounds for incompatibility, may benefit from a special authorization ("waiver") from the Executive Director of EFSA if their contribution is deemed essential. However, this expert may not be the chairperson or vice-chairperson or the rapporteur of the expert group in question.

⁸ Article 36 of Regulation 178/2002 states that the Management Board of EFSA, acting on a proposal from the Executive Director, shall "draw up a list, which shall be made public, of competent bodies designated by the Member States, which may assist the Authority, either individually or in a network, in the performance of its tasks. The Authority may entrust these bodies with certain tasks, in particular preparatory work for scientific opinions, scientific and technical assistance, data collection and the identification of emerging risks. Some of these tasks may be supported financially.

Recommendations. This justified provision should be consolidated by an obligation of information of the other members of the group of experts considered, by its president, whom should have the information for this purpose.

In addition, the Director's draft decision should be submitted to the Board for advice in order to make it more communal.

8. Common rules

Article 23. Training

EFSA will have to ensure that its staff that is supposed to implement this Decision, as well as "Concerned individuals", will be trained on how to meet the Decision.

Recommendation. This training objective should also extend to the Advisory Committee, in order to spread a common culture.

Article 24. Transparency

The EFSA Executive Director's decision includes a strong commitment to the publication of PDIs from all Agency officials and experts, including experts participating in the peer reviews (see the exception criticized above in 2.7.12). This is also the case for the annual report, which indicates the number of inspections carried out, the non-compliances identified, and the measures adopted.

Article 25. Protection of personal data

PDIs are kept for a reasonable period time of 10 years.

Article 26. Entry into force

This decision is enforceable as of 1.7.2018. It was to be evaluated in December 2020 and at least every 2 years. The first external evaluation report was issued in April 2021.⁹

General comment: the analysis of the interests based on the PDIs (which also takes into account the oral declarations at the beginning of each working group meeting) leads to a binary assessment of the participation of the person in question in EFSA's Scientific Councils and working groups: compatibility or incompatibility (with some specific exemptions if necessary).

Considering the great diversity of the types of connections that can exist, this categorization without nuance can lead to many cases of classification "by excess" or, on the contrary, "by default".

Recommendation: A more modulated approach would be based on a three-level qualification of interests: (1) "major" interests; (2) "minor" interests; and (3) no interest. Incompatibility would apply to the former. The latter would be subject to a "simple" participation regime (without responsibility for chairmanship, vice-chairmanship or rapporteur) accompanied by information delivered to all members of the working groups and bodies concerned about the existence and nature of these connections. Full compatibility, with possible assumption of responsibility, would apply to the third degree.

It is this principle of distinguishing between "major" and "minor" connections that applies in France.

In practice, considering the agenda of each meeting of a working group or scientific commission, the EFSA Secretariat would first draw up a map of the identified interests. This mapping would be presented to the members of the working group or scientific commission by its chair. The persons concerned, informed in advance, could contest the analysis showing the interests.

⁹ <https://www.efsa.europa.eu/sites/default/files/event/management-board-210624/16-review-competing-interest-rules-10.mb210624-i5.pdf>

Appendix

EFSA's policy on independence¹⁰

How the European Food Safety Authority assures the impartiality of professionals contributing to its operations (21/6/2017)

3. A risk-based approach to prevent the occurrence of conflicts of interest

This chapter clearly states the activities that can lead to a situation of conflict of interest.

All EFSA staff members are subject to prior approval for any "outside activity" during their tenure at the agency and for any proposed source of income within 2 years after leaving EFSA.

As noted in the previous document on the "Decision" of the Executive Director of EFSA, this 2-year period is too short and should be extended to 4 years, or even to the entirety of the 5-year period covered by the PDI.

A paragraph on page 5 specifies that EFSA may entrust part of its scientific work to contractors or national competent authorities, who are then subject to the same requirements, *mutatis mutandis*, as those applicable to the members of its Scientific Committee and Scientific Panels.

Comment and recommendation. Nowhere is it detailed how compliance with these requirements is verified; whether that be through the observation that conflict of interest prevention procedures are established and robust in these entities or through desk and on-site audits. This gap should be explicitly addressed.

3.1 Financial investments or employment in regulated companies - A red line

Any employment or investment (under the control of the person concerned) in a company subject to EFSA regulations is incompatible with a role as an expert within EFSA (participation in a working group, in the Scientific Committee, etc.).

3.2 Cooling off periods: An effective way of preventing conflicts of interest

Having worked as an employee in or having consulted for an entity with commercial interests in the area covered by a panel is considered to be incompatible with membership in the various working groups, scientific committees and panels of EFSA for a period of 2 years following the instance.

Recommendation. With regard to the activity of consultant, this radical criterion of incompatibility, which does not take into account the extent of the connection created, does not make it possible to tune the attitude adopted. This can lead in some cases to a drying up of the pool of available experts. The general recommendation made in the conclusion of the previous chapter, which aims to distinguish between "major" and "minor" connections, applies here.

¹⁰ https://www.google.com/search?q=EFSA%E2%80%99s+policy+on+independence&rlz=1C1VDKB_frFR963FR968&oq=EFSA%E2%80%99s+policy+on+independence&aqs=chrome..69i57j69i60.847j0j1&sourceid=chrome&ie=UTF-8

On the other hand, the 2-year "cooling off" period is too short, and should be extended to 4 years, or even to the entire 5-year PDI period, as outlined in the previous document.

3.4 Managing conflicting interests in research funding. A balanced approach

It is not considered acceptable for experts from research institutions to participate in EFSA missions if it has a share of the funding of its research activities exceeding 25% of the total budget of its laboratory (term used in the document: 'its operations'). However, if a part of these resources of private origin is part of public-private co-financing, it is not taken into account in the estimation of the 25% percentage.

Recommendations. This 25% share represents an important contribution to the total budget of a research laboratory. Even if it can add up sources of various origins, there is no guarantee that a situation of dependence on the largest funders will not be created. Lowering this share to 15% of the total budget is likely to reduce the risk of such dependence. Furthermore, the exclusion of private sources that contribute to the budget of projects co-financed with public institutions can also lead to situations of strong dependence on private funding, and thus create a strong interest. The percentage of 25% (which should be lowered to 15%) should include all resources of private origin, regardless of the form and channel, direct or indirect.

4. Transparency and communication on competing interests' management

The commitment to transparency is clear and strong.

6. Entry into force and review (21/6/2017)

This policy shall be subject to an *ex post* evaluation not later than five years after its entry into force.