

EFSA's policy on independence

How the European Food Safety Authority assures the impartiality of professionals contributing to its operations.

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1. Independence at EFSA – What are we discussing?

In accordance with the European Union (EU) constitutional setting, the EU administration is required to operate in an impartial manner¹ so as to ensure the achievement of its objectives in line with good administration principles². The principles of impartiality, equal treatment and non-discrimination represent a bulwark for institutions, agencies and bodies impacting on the daily lives and rights of hundreds of millions of citizens, taxpayers and business operators. This holds true also for the European Food Safety Authority ("EFSA" or "the Authority"). EU legislators put a particular emphasis on EFSA's independence.³ However, independence is a multi-faceted concept, covering, *inter alia*, aspects such as legal independence, financial independence, regulatory autonomy, personal independence and perception thereof.

In 2002, EFSA was set up as part of a broader legislative reform aimed at restoring the confidence of EU institutional fellows and citizens in the ability of the EU to ensure safety of the food chain. The Authority was created with a strong focus on its legal autonomy from the EU institutions, Member State

governments and stakeholders in the public or private sector. Also for these reasons, EFSA's compliance with its Founding Regulation⁴ and other secondary legislation ensures the attainment of legal, financial, and regulatory independence.

"Every person has the right to have his or her affairs handled impartially, fairly and within a reasonable time by the institutions and bodies of the Union" Article 41, Charter of Fundamental Rights of the European Union.

At EFSA, independence is of such importance that it is acknowledged as one of the agency's main corporate values. The most recent strategic document issued by EFSA⁵ at the time this policy was adopted confirms EFSA's commitment to achieve the independence of its experts, methods and data from any external influence⁶.

2. Aim of this policy – Ensuring the impartiality of EFSA's actors

This policy ensures the impartiality of the persons participating in EFSA's operations based on the reassurance provided by

¹ Article 298 of the Treaty on the Functioning of the European Union.

² Article 41 of the Charter on Fundamental Rights of the European Union.

³ See e.g. Articles 22 of Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ L 031, 01/02/2002, 1 - 24.

⁴ See e.g. Articles 25, 26, 27, 28 and 43-45 of Regulation (EC) No 178/2002.

⁵ European Food Safety Authority, EFSA Strategy 2020 Trusted science for safe food Protecting consumers' health with independent scientific advice on the food chain, 2016.

⁶ See Article 37 (2) of Regulation (EC) No 178/2002 EFSA's founding Regulation.

projects securing the neutrality of the methods and data the Authority uses.⁷ Given the importance that experts' judgment has in EFSA's work, this 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. This presupposes, among other things, that these individuals are devoid of conflicts of interest (CoI) harmful to the Authority's work. This policy also outlines how EFSA prevents the occurrence of CoI.

EFSA's compliance with its Founding Regulation and secondary legislation ensures legal, financial, and regulatory independence.

EFSA's approach to impartiality rests on: (i) the commitment that persons having an impact on the Authority's operations are not allowed to operate in situations where a CoI exists according to EFSA's policy and its implementing rules; and (ii) the independence assured by its extensive rules and procedures regulating the prevention of CoIs, other ethics and integrity issues, and its scientific operations.

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

It is widely acknowledged that having interests does not necessarily mean there is a CoI. On the contrary, it is precisely interests, experiences and activities held that qualify an individual as an expert in

⁷ E.g. Expertise Management Programme, MAXTRIX project and Prometheus project: see EFSA, Annual Activity Report 2016. Available online: <http://www.efsa.europa.eu/en/aboutefsa/keydocs.htm>.

a certain matter. This means that the definition of what the Authority considers a CoI is of particular significance in order not to harm legitimate professional activities contributing to EFSA's mission.

A CoI is deemed to exist whenever the Authority identifies: 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.⁸

However, the actual impact of this definition on EFSA's independence related processes mainly depends on the way the Authority defines the sources of potential CoI.

EFSA recognises the main patterns of CoI affecting actors contributing to its operations in activities concerning:

- their "economic or financial" sphere (e.g. deriving from research funding, financial investments, professional fees, salary, reimbursement of expenses, gifts, prizes or donations);
- creations of the mind (such as patents, trademarks, symbols, images, models, designs, software, etc); and
- affiliations or other involvements (such as involvement in business operators, industry associations, non-governmental organisations, universities and their spin-offs, research bodies, ministries and risk management bodies, risk assessment bodies or intergovernmental organisations⁹).

⁸ Based on the definition of "conflict of interest" set out in Article 2(4) of Commission Decision of 30.5.2016 establishing horizontal rules on the creation and operation of Commission expert groups, C(2016) 3301 final.

⁹ With the exceptions of activities captured by the approach set out in § 3.3. – Cooperation with national and international authorities, universities or research institutes.

To prevent all potential CoIs, the Authority requires concerned actors to declare all interests held by them, their partners or dependent family members, in a timeframe covering the five years preceding the declaration, falling under EFSA's remit and belonging to the following fields: financial investments, managerial roles, scientific advisory roles, employment or self-employment, full or occasional consultancy, research funding, intellectual property rights, memberships of professional or learned societies, and other relevant interests that may cause the perception of CoI and are not captured by the above.

EFSA defines a conflict of interest as “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”.

In order not to go beyond what is necessary to ensure the actors' impartiality, the Authority identifies CoIs related to activities that overlap with matters discussed in the relevant EFSA group(s) where the individual is serving or is expected to serve. In this way, the Authority ensures that this policy does not hinder the availability of expertise needed to accomplish EFSA's duties in line with the principle of scientific excellence.

In line with the concept of proportionate administrative action, 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.¹⁰

EFSA identifies cash flows from entities with an interest in EFSA's activities to be a main driver for potential lack of impartiality and for CoIs. EFSA therefore asks all its actors to declare the proportion of their annual earnings (at the time of submission) that originate from such entities. This information is made publicly available and contributes to the assessment made by EFSA to determine whether conflicts of interest exist.

Since as per its Founding Regulation EFSA also outsources part of its scientific work to contractors and national competent authorities, tenderers responsible for the provision of scientific services in the area of regulated products are subject to the same requirements, *mutatis mutandis*, applicable to members of EFSA's Scientific Committee and Scientific Panels.

Due to their ambassadorial role, members of EFSA's Management Board are subject, among others, to transparency requirements obliging them to submit a declaration of interest at least once a year, and to update it as soon as new interests emerge. The scrutiny of declared interests is exercised by the Board, upon advice from the Executive Director, and may result in the adoption of preventive measures by the Management Board.

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 Interest (ADoI) and screening requirements.

¹⁰ E.g. BSE TSE validation tests, Feed Additives, Feed Materials, Food Contact Materials, Food Additives, Food Enzymes, Infant foods, Food supplements, Genetically Modified Organisms, Novel Foods, Nutrition and Health claims, Recycling Processes, Pesticides Active Substances or Maximum Residue Levels thereon,

In addition, they are required to obtain preliminary clearance for all “outside activities” during their time at EFSA, and for all gainful activities in which they intend to engage for two years after their employment with EFSA ceases¹¹.

EFSA’s actors declare all interests overlapping with EFSA’s remit in the previous five years and belonging to the following fields: financial investments, managerial roles, scientific advisory roles, employment or self-employment, consultancy, research funding, intellectual property rights, sworn statements, memberships in professional or learned societies, and interests not captured by the above.

The following paragraphs outline the key features of EFSA’s policy to prevent CoIs among the actors who contribute to its work. More detailed provisions and procedures will be set out in forthcoming implementing rules.

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

EFSA considers financial investments with business actors directly or indirectly impacted by EFSA’s operations as a source of potential CoI irrespective of their magnitude.¹² The same holds true for current employment engagements. The Authority adopts a zero tolerance approach to these two interests, resulting in a total ban on financial investments in,

or employment by, industries that EFSA helps to regulate, industry associations or other corporate funded organisations. This exclusion applies to any professional wishing to become a member of EFSA’s Scientific Committee, Scientific Panels, Working Groups or peer review meetings. Employment with these bodies is “banned” irrespective of whether or not it concerns the mandate of the relevant EFSA scientific group. This approach will be equally applied to the screening of financial investments in, or employment by, NGOs or other lobbying organisations.

Financial investments in, and employment with, business operators directly or indirectly impacted by EFSA’s outputs are incompatible with Scientific Committee, Scientific Panels or Working Groups membership.

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

EFSA values prior experience gained by professionals contributing to its work in the sectors it helps to regulate. However, EFSA considers that when certain types of professional involvement with the food industry become part of an expert’s professional life, there is a perception of regulatory “capture” that has to be addressed. For this reason, and to avoid CoIs, the Authority enforces thorough cooling off periods on certain activities. This is why having worked as a self-employed professional or as an employee for a legal entity pursuing private or commercial interests in the sphere of the relevant expert group is deemed incompatible with membership of the Scientific Committee, Scientific Panels and Working Groups for two years *after*

¹¹ Articles 11, 11a, 12 and 16 of 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, OJ 45, 14.6.1962, as last amended, as well as implementing measures thereof.

¹² With the exclusion of financial instruments on which the individual has no control.

the conflicting activity has ended.¹³ This cooling off period applies to all managerial roles, employment and consultancies, even of an occasional nature, membership in a scientific advisory body and research funding¹⁴ on matters falling under the mandate of the relevant EFSA scientific group.

EFSA enforces a **two years cooling off period on** managerial, employment, consultancy activities, memberships in scientific advisory bodies undertaken by its experts with, or research funding¹⁵ from, legal entities pursuing private or commercial interests.

3.3 Cooperation with national and international authorities, universities or research institutes

Two of the main objectives of EFSA's Strategy 2020¹⁵ are: cooperation with national or international academies, academic institutions, public authorities, research institutes and other bodies subject to public control or funding and pursuing public interest objectives; and the strengthening of the risk assessment community. Therefore, the Authority takes pride in recruiting to its Scientific Committee, Scientific Panels, Working Groups and peer review meetings¹⁶ professionals cooperating with, advising or employed by these institutional fellows, and is grateful for the possibility granted by their employers to cooperate with the EU food risk assessment project.

¹³ Irrespective of whether the legal entity is of a commercial nature or an association of activists pursuing a common interest or objective.

¹⁴ Defined as per § 3.4, below.

¹⁵ See e.g. the first operational objective of the third strategic objective of the Strategy: *op.cit.*, p. 17.

¹⁶ E.g. peer review meetings organised by EFSA in accordance with Regulation (EC) No 1107/2009.

This notwithstanding, EFSA will implement a thorough screening of activities unrelated to public interest duties to experts participating to these meetings. Similarly, their Annual Declarations of Interest will be made publicly available on EFSA's website. However, the independence of experts representing the views of Member States or international organisations in EFSA's network or networking meetings¹⁷ is to be ensured by each appointing authority in accordance with the applicable legislative and regulatory framework.

With the exception of risk management functions, **expert's activities with national and international authorities, teaching or research are compatible** with all roles in EFSA's scientific groups.

Although the Authority relies on the ability of these bodies' legal systems to achieve impartiality of their respective representatives, EFSA will put in place memoranda of understanding (MoU) to specify applicable standards and follow-up on serious and well documented cases brought to its attention.

3.4 Managing conflicting interest in research funding. A balanced approach

Research is the fundamental activity of scientists. Therefore, EFSA encourages professionals contributing to its work to pursue projects with the global research community in order for them to be at the forefront of scientific developments and innovation. EU-wide policies and policy papers encourage private-public

¹⁷ E.g. "EFSA focal points" in Member States.

partnership and collaboration.¹⁸ As a decentralised agency of the EU responsible for assessing food safety risks, EFSA acknowledges the importance of close cooperation between these two spheres.

Research funding from the private sector benefiting EFSA's experts should not exceed 25% of the total research budget.

In line with the EU approach to research funding, EFSA considers that for actors contributing to its operations, the acceptable level of research directly funded by the private sector is 25% of the total budget of the expert and his/her research team, for the sector of relevance. Private funding includes also funding coming from private organisations representing industry interests, such as industry associations. Private contributions to projects funded by public actors, such as those financed under the EU Research and innovation Framework Programmes (e.g. Horizon 2020), or equivalent programmes funded by international, national, regional or local public actors, do not count for this purpose.

4. Transparency and communication on competing interests management

Communications and transparency are important elements in building and maintaining trust in EFSA's independence

¹⁸ See e.g. Europe 2020 Strategy, COM(2010) 2020 and Communication from the Commission to the European Parliament, the Council, the European Economic and Social Committee and the Committee of the Regions Public-private partnerships in Horizon 2020: a powerful tool to deliver on innovation and growth in Europe, COM/2013/0494 final.

policy and any actions the Authority takes to enforce it.

Since its establishment, EFSA has ensured a high level of transparency across all its activities. This is also the case for independence-related processes. Indeed, the Authority publishes all ADols of the members of its Management Board and Advisory Forum, members of its Scientific Committee, Scientific Panels and their Working Groups, all participants to pesticides peer review meetings or to meetings where EFSA's scientific outputs are developed, its Executive Director and members of its Operational Management Team.¹⁹

Every year, EFSA reports on comprehensive information about independence-related activities in its Annual Report, including numbers of Dols screened, potential ColS prevented, and breaches of trust procedures initiated. Furthermore, with this policy, EFSA commits to make publicly available:

- Decisions on the cooperative approach outlined in section 3.3.;
- Decisions confirming breach of the rules on independence;
- A register of activities undertaken by former members of its Management Board for two years after their term of office has ended;
- Following the positive conclusion of technical and feasibility considerations, all the decisions performing the ex-ante scrutiny of Dols submitted by the concerned individuals.

Finally, EFSA will systematically create engagement opportunities for interested parties to explain how it manages experts' interests and to address specific concerns.

¹⁹ Do you want to know more about EFSA's experts' interests? Check online EFSA's database of declarations of interest at <https://ess.efsa.europa.eu/doi/doiweb/doisearch>.

5. Policy implementation and enforcement

Even the most ambitious policy commitment is hollow unless it is properly implemented, its compliance checked, mistakes acknowledged and addressed and breaches or omissions sanctioned.²⁰

Compliance with this policy and its implementing rules is a shared responsibility between the concerned actors, for the submission of a complete and truthful declaration, and EFSA, for the identification and prevention of potential CoIs and enforcing its decisions. Within the sphere of attributed powers delegated to EFSA by EU legislators, the Authority has put in place a system of compliance checks coupled with proportionate, effective and dissuasive sanctions for actions or omissions in breach of this policy and of its implementing procedures and rules. These range from a reprimand letter issued by the Authority to the dismissal from the relevant body or scientific group by the Board.

The Authority enforces this policy with a system of compliance checks coupled with **proportionate, effective and dissuasive sanctions** for actions or omissions ranging from a **reprimand letter to dismissal** from the relevant body or scientific group or **follow up with law enforcement bodies**.

In the most serious cases, where the active conduct of the concerned individual(s) assumes the contours of wilful criminal action, EFSA will cooperate with EU or national competent authorities to ensure the most appropriate enforcement and follow up.

6. Entry into force and review

Without prejudice to Article 110 of the Staff Regulations of the European Union, this policy comes into effect as of the adoption of the implementing decision and procedure on competing interest management. As of then, it shall repeal and replace the Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority of 15 December 2011.

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

The Management Board shall be informed on a yearly basis about progress made in the implementation of this Policy and of its processes.

Adopted in Parma on 21 June 2017
For EFSA's Management Board

Jaana Husu-Kallio
Chair of the Management Board

²⁰ If you are interested in facts and figures related to the implementation of this policy, have a look at EFSA's Annual Reports at <http://www.efsa.europa.eu/en/publications/corporate>.