

EFSA's policy on independence

How the European Food Safety Authority assures the impartiality of its scientific experts and all professionals contributing to its operations.

Table of content

EFSA’s policy on independence.....	3
1. Independence at EFSA – What are we discussing?	3
2. Aim of this policy – Ensuring the impartiality of EFSA’s actors	4
3. A risk-based approach to prevent the occurrence of conflicts of interest	4
3.1 Financial investments or employment in regulated companies – A red line	6
3.2 Cooling off periods: An effective way of preventing conflicts of interest	6
3.3 Cooperation with national and international authorities, universities or research institutes.....	7
3.4 Managing conflicting interest in research funding. A balanced approach.....	8
4. Transparency and communication on competing interests management	8
5. Policy implementation and enforcement.....	9
6. Entry into force and review.....	9

DRAFT

EFSA's policy on independence

How the European Food Safety Authority assures the impartiality of its scientific experts and all professionals contributing to its operations

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, as amended by the Transparency Regulation⁵, 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 EFSA⁶ confirms EFSA's commitment to achieve the independence of its scientific experts⁷ and all professionals contributing to its operations, methods and data from any external influence⁸.

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, 28 and 37 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 a 28 and 43-45 of Regulation (EC) No 178/2002.

⁵ Regulation (EU) 2019/1381 of the European Parliament and of the Council of 20 June 2019 on the transparency and sustainability of the EU risk assessment in the food chain and

amending Regulations (EC) No 178/2002, (EC) No 1829/2003, (EC) No 1831/2003, (EC) No 2065/2003, (EC) No 1935/2004, (EC) No 1331/2008, (EC) No 1107/2009, (EU) 2015/2283 and Directive 2001/18/EC, OJ L 231, 6.9.2019, p. 1–28.

⁶ European Food Safety Authority, EFSA Strategy 2027 – Science, safe food, sustainability, 2021.

⁷ Members of Scientific Committee, Scientific Panels and external experts participating in the working groups of the Scientific Committee or the Scientific Panels.

⁸ See Article 37 (2) of Regulation (EC) No 178/2002 EFSA's founding Regulation.

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

This policy endeavors to ensure the impartiality of the persons participating in EFSA’s operations based on the reassurance provided by processes securing the neutrality of the methods and data the Authority uses. 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 a certain matter. This means that the definition of what the Authority considers a CoI is of particular significance in order not to harm unnecessarily 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.⁹

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,

⁹ 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.

universities and their spin-offs, research bodies, ministries and risk management bodies, risk assessment bodies or intergovernmental organisations¹⁰).

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 endeavor 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 based on 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.¹¹

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.

When EFSA outsources part of its scientific work to contractors, in compliance with its Founding Regulation and the Financial Regulation¹², it ascertains that the outsourced activities are performed with independence by scrutinising contractors according to criteria developed by EFSA and detailed in the implementing rules. When outsourcing to competent organisations designated by Member States ("Article 36 Organisations") activities equivalent to those carried out by EFSA's working groups, EFSA applies *mutatis mutandis* the independence and transparency requirements applicable to members of EFSA's Scientific Committee and Scientific Panels' working groups. When EFSA outsources activities which are not equivalent to those carried out by EFSA's working groups, to competent organizations designated by Member States, their inclusion in the Article 36 list ensures the independence in the performance of those activities.

¹⁰ With the exceptions of activities captured by the approach set out in § 3.3. – Cooperation with national and international authorities, universities or research institutes.

¹¹ 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.

¹² Regulation (EU, Euratom) 2018/1046 of the European Parliament and of the Council of 18 July 2018 on the financial rules applicable to the general budget of the Union, amending Regulations (EU) No 1296/2013, (EU) No 1301/2013, (EU) No 1303/2013, (EU) No 1304/2013, (EU) No 1309/2013, (EU) No 1316/2013, (EU) No 223/2014, (EU) No 283/2014, and Decision No 541/2014/EU and repealing Regulation (EU, Euratom) No 966/2012, OJ L 193, 30.7.2018, p.1, as last amended.

Due to their ambassadorial role, members of EFSA's Management Board are subject, among others, to independence and 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 Executive Director, upon advice of the EFSA Ethics Advisor, and may result in the adoption of preventive measures. The Management Board may convey observations to the Executive Director for his/her consideration.

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. 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 ceases¹³.

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, 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 updated implementing rules.

¹³ Articles 11, 11a, 12 and 16 of Regulation No 31 (EEC), (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

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.¹⁴ 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, industry associations or other corporate funded organisations, directly or indirectly concerned by EFSA's scientific outputs. 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 regulated on the basis of EFSA risk assessment activities. However, EFSA

Community, OJ 45, 14.6.1962, as last amended, as well as implementing measures thereof.

¹⁴ With the exclusion of financial instruments on which the individual has no control.

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** the conflicting activity has ended.¹⁵ 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 funding¹⁶ on matters falling under the mandate of the relevant EFSA scientific group.

Without prejudice to the above, under strict and exceptional circumstances regulated in the implementing rules of this Policy, scientific experts may be granted with a waiver allowing them to contribute exclusively to the work of EFSA's working groups and peer review meetings notwithstanding the identification of a conflict of interests different than those outlined under paragraph 3.1 of this Policy. The granting of waivers shall be transparently communicated and result in the ineligibility of the concerned scientific experts to cover the position of chair, vice-chair or rapporteur in the scientific group at stake.

EFSA enforces a **two- year cooling off period** on managerial, employment, consultancy activities, memberships in scientific advisory bodies undertaken by its scientific

experts with, or research funding from, legal entities pursuing private or commercial interests.

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

Partnership 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 has been deep-rooted in EFSA's activities. One of the main objectives of EFSA's Strategy 2027 is the strengthening of the risk assessment community by increasing partnerships within the EU food safety ecosystem¹⁷. Therefore, the Authority takes pride in recruiting to its Scientific Committee, Scientific Panels, Working Groups and peer review meetings¹⁸ 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 system.

Notwithstanding this, EFSA will implement a thorough screening of activities unrelated to public interest duties to scientific experts participating in these meetings. Similarly, their ADoIs will be made publicly available on EFSA's website. However, the independence of experts representing Member States or international organisations in EFSA's network or networking meetings¹⁹ is to be ensured by each appointing authority in accordance with the applicable legislative and regulatory framework.

With the exception of risk management functions, teaching, research or scientific **expert's activities performed in the public interest with national and**

¹⁵ Irrespective of whether the legal entity is of a commercial nature or an association of activists pursuing a common interest or objective.

¹⁶ Defined as per § 3.4, below.

¹⁷ See strategic objective 1 of the Strategy, op cit., p. 11.

¹⁸ E.g. peer review meetings organised by EFSA in accordance with Regulation (EC) No 1107/2009.

¹⁹ E.g. "EFSA focal points" in Member States.

international authorities 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 independence standards and follow-up on serious and well documented cases brought to its attention, by the means established and detailed in the implementing rules.

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 community²⁰ in order for them to be at the forefront of scientific developments and innovation. EU-wide policies and policy papers encourage private-public partnership and collaboration.²¹

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 relevant 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 scientific 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, 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 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 ADoIs of the members of its Management Board and Advisory Forum, members of EFSA's networks, 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, experts of Article 36 Organisations entrusted with activities equivalent to those carried out by EFSA's working groups, its Executive Director and members of its Operational Management Team.²²

EFSA also publishes ADoIs submitted by hearing experts invited to EFSA's scientific groups solely to present specific information and expertise. The role and tasks of hearing

²⁰ Recital 17 of the Transparency Regulation, *cit. op.*

²¹ 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.

²² Do you want to know more about EFSA's experts' interests? Check online EFSA's database of declarations of interest at <https://open.efsa.europa.eu/experts>

experts are detailed in the implementing rules in line with this Policy.

Every year, EFSA reports on comprehensive information about independence-related activities in its Annual Report, including numbers of DoIs screened, potential CoIs 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.

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

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.²³

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. EFSA is committed to facilitate this process through the deployment of enhanced IT tools and automatization, monitored and further developed throughout the years in light of advancements in technology. Within the

sphere of attributed powers delegated to EFSA by EU legislators, the Authority has put in place a system of compliance checks. These checks are carried out by EFSA as well as external controllers, 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 Management 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 by the Management Board.

In the most serious cases, where the active conduct of the concerned individual(s) assumes the contours of willful 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 21 June 2017.

²³ If you are interested in facts and figures related to the implementation of this policy, have a look at EFSA's Annual

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 20 June 2024

For EFSA's Management Board

[NOT SIGNED]

Aivars Bērziņš

Chair of the Management Board

DRAFT