

How can EFSA independence be strengthened?

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1. EFSA independence – What is the issue?

Industry currently has the upper hand in risk research relevant to the food, agrochemical and biotech sectors. This has huge implications for the actual data used in risk assessment¹ and for the general landscape of risk research. It also means that political decision-makers need to take responsibility for strengthening independent risk research as requested by EU regulation. Regrettably, as yet, effective mechanisms for ensuring such independent risk research are largely missing.

Further, the food, agrochemical and biotech sectors are intensely engaged in lobbying activities. Indeed, the food industry is one of the largest industries in the EU with an annual turnover of billions of euros. This plainly creates strong incentives for industry to influence regulatory authorities and political decision-making on the basis that lower regulatory standards can save money, sell even more products and continue to increase profits.

The influence and activities of industry in this direction have been established on several levels: Direct communication from industry, indirect communications via networks, organisations and institutions, such as the International Life Sciences Institute (ILSI), and also deliberately hidden influence. Many of these activities are organised in a strategic and systematic way. To make one comparison, there is overwhelming evidence to suggest that for many years the tobacco industry kept its influence on research and the authorities well hidden from public view. Currently, an increasing amount of evidence is emerging from the agrochemical and biotech-sectors that points in same direction.

As far as EFSA is concerned, this setting shaped by industry is very relevant for their work in the risk assessment of regulated products. There is frequently no data available that has been generated independently of industry.

The above also has major consequences for the independence of EFSA experts as many experts in the field will have received funding from industry, and will generally have several reasons of their own for cooperating with industry.

In short, effective mechanisms need to be established to strengthen EFSA independence from regulated industries.

¹Guillemaud, T., Lombaert, E., Bourguet D. (2016) Conflicts of Interest in GM Bt Crop Efficacy and Durability Studies, PLoS ONE 11(12): e0167777, <https://doi.org/10.1371/journal.pone.0167777>

2. Aims and general principles

In regard to its independence, EFSA should adopt guiding principles that encompass a definition of its primary interests, which is the protection of health and the environment. According to EFSA's own website, "Food is essential to life. EFSA's scientific advice helps to protect consumers, animals and the environment from food-related risks".²

Further, clear objectives should be developed. Most relevant in this context is the goal to avoid - as far as possible - influence from the regulated industries. These objectives should be added to the aim to ensure "impartiality": EFSA should explicitly state that priority must be given to safeguarding its independence from the food and agrochemical industry.

In the end, the benchmark for EFSA rules is set by the priority given to strengthening EFSA independence from regulated industry. EFSA methods and rules need to be developed accordingly.

3. A comprehensive approach to prevent the occurrence of conflicts of interest

Conflicts of interest are a problem for those who need to make expert judgements on behalf of others; thus, their primary interest is the well-being of those who rely upon these judgements. For EFSA and their experts, the protection of health and the environment should be their primary concern. Therefore, EFSA should define COI as follows (adopted from IOM, Institute of Medicine of National Academies, US, 2009)³: "*A conflict of interest is a set of circumstances that creates a risk that professional judgement or actions regarding the primary interest of EFSA can be unduly influenced by a secondary interest*"

Although this definition is similar to the OECD definition from 2003 it has some advantages: The IOM definition invites the authority to apply a broader framing, which can help to assess the complexity of the underlying problem and to avoid an approach that is too formalistic.

Since the food industry and agrochemical and biotech industry substantially overlap in their interests, the whole range of EFSA activities must be taken into account in assessing the DOI, and not only the specific sector in which the expert supposedly works. However, EFSA's approach to identifying CoIs as outlined in the draft is too narrow, since it is only related to activities that overlap with matters discussed in the relevant EFSA group(s) where the individual is serving or is expected to serve.

While financial interests in many cases are the most relevant entry point, the analysis must be sufficiently broad and not just target the individual person. The analysis also needs to encompass relevant organisations pushing for, or driven by commercial interests of regulated industries. This is in line with the Ombudsman's ruling from 2015 asking for disclosure of arrangements between academia and business.⁴ This broader analysis of potential COIs should take into account organisations no matter whether advisory, academic, or commercial, that are (partially) paid, organised, or affiliated with regulated industries.

Further, it is not only necessary to develop adequate criteria, but also to define a process of how to assess the relevant circumstances case by case. Some cases will require more diligence than others. It should be taken into account that financial gains cannot always be identified. Furthermore, in some cases, there might be attempts to hide relevant interests. The EFSA needs to be aware that these circumstances have been shaped by industry and they should not take a naïve approach. If

²<https://www.efsa.europa.eu/>

³<https://www.ncbi.nlm.nih.gov/books/NBK22942/>

⁴<https://www.ombudsman.europa.eu/cases/decision.faces/en/58868/html.bookmark>

indications for potential COIs emerge, then they should follow the hypothesis that some specific experts are more likely than not to be influenced by the interests of industry. Hence, it would become necessary to establish the absence of COIs rather than the evidence for COIs.

4. Cooling off periods: An effective way of preventing conflicts of interest

Past activities, especially if they show a degree of continuity, can be highly relevant for the assessment of potential COIs, even if those activities were discontinued at the time when the expert became actively involved at the EFSA. Consequently, activities that were terminated before an expert was employed at EFSA should not be set aside without further assessment. Further assessment should not only take into account whether an expert has worked as a self-employed professional, but also whether he/she was an employee of a legal entity pursuing private or commercial interests in EFSA's sphere.

In general, the obligation for experts to declare all interests that touch on EFSA activities should also apply to the criteria for establishing a cooling-off period; this should not be restricted to specific activities. A cooling off period of two years should be established for both directions and for expert groups as well as for staff members. This period should apply to all material interests related to the commercial agri-food sector, including research funding, consultancy contracts or membership in industry-captured organisations.

5. Cooperation with national and international authorities, universities or research institutes

Current EFSA standards are based on a set of categories that are not very well defined. For example, "other membership or affiliation or other relevant interest, including professional organisations, regarding the relevant matter might be "allowed or not allowed" without defining clear objectives or criteria.

To improve the situation, EFSA should publish its list of the "Food Safety Organisations" with whom their experts can cooperate without triggering a COI. Further, EFSA should establish a list of other organisations actively engaged in these sectors, irrespective of whether these organisations are advisory, academic, or purely commercial. EFSA should qualify the role and describe the possible impact of these organisations on the work of EFSA. Staff members and experts need to organise contacts accordingly. This list should encompass, at the very least, all organisations in which EFSA experts are actively involved (membership, participation in workshops, presentations).

6. Research funding from industry

It has to be made clear that avoidance of COIs cannot be dealt with simply as an essentially formal exercise. For example, it is not sufficient to only rely on defined thresholds for industry funding of individual experts, since there are ways for industry to avoid such thresholds and to establish its influence by other means. Whatever the case, a threshold of 25 % for research funding is very high. We suggest applying a maximum of 10 %. In addition, as long as the expert is actively engaged at EFSA, he/she should not receive any research funding from regulated industries.

7. How can expertise from industry be involved?

If EFSA is not able to find an adequate number of experts who are sufficiently independent of industry, then other experts with specific expertise might be selected. However, the activities of these experts as 'hearing experts' have to be strictly framed in order to avoid them impacting the outcome of risk assessment.

8. Further suggestions: Beyond EFSA

The EU Commission should:

- require applicants to publicly report payments to physicians, researchers and research institutions, academic organisations, political parties, health care institutions, professional societies, patient advocacy and disease-specific groups, providers of continuing medical education and foundations created by any of these entities (see IOM recommendations).
- produce annual reports, describing industrial impact on research and lobby activities in the field of regulated industries.
- develop a program that gives sufficient incentives for risk research carried out independently of the interests of regulated industries. For example, DG research should be ready to fund more EFSA relevant research, while in parallel, improve its own guidance for safeguarding its independence from regulated industries.
- oblige EFSA to explicitly mention the source of data / evidence used in their risk assessment and, in this case, identify uncertainties that go along with the absence of independent research data.