Corporate Europe Observatory

Submission to the European Food Safety Authority's public consultation : "Draft EFSA's policy on independence. How the European Food Safety Authority assures the impartiality of professionals contributing to its operations"

May 12 2017

1. Independence at EFSA – What are we discussing?

This section, and the title of the Consultation, seem to narrow the definition of "independence" to the notion of "impartiality". This is not incorrect: EFSA's draft points to the existing EU legal framework which refers to the duty of all EU administrations to act in an impartial manner. But it is insufficient: EFSA is not any EU administration but a very specific one, in charge of providing scientific assessments to the other EU institutions about the toxicity of food products put on the EU market.

The European Food Safety Authority's Founding Regulation 178/2002 stipulates, in the way it defines "Independence", that "The members of the Scientific Committee and the Scientific Panels shall undertake to act independently of any external influence".

This is repeated in the EFSA 2020 Strategy document quoted in the draft:, where EFSA' commits to achieve "the independence of its experts, methods and data from any undue external influence".

This is of course well meaning, but in practice is too optimistic. Such absolute independence from the outside world simply is not possible. EFSA's draft policy should make clearer, already in this section, what independence in the context of EFSA's remit means.

EFS's draft correctly acknowledges that "independence is a multi-faceted concept, covering, inter alia, aspects such as legal independence, financial independence, regulatory autonomy, personal independence and perception thereof".

But things are not so complicated either. EFSA's Founding Regulation stipulates that EFSA's remit is not only to be absolutely independent from any external influence but to "contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market."

Therefore, EFSA's independence policy should make sure that EFSA is firstly independent from the main threats to its mission.

EFSA's draft policy correctly acknowledges later in the draft (lines 180-183) that "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".

The overwhelming majority of EFSA's workload currently consists in evaluating the safety of regulated products before their possible authorisation on the EU market. Companies whose products are evaluated by EFSA have by far the largest interest in EFSA's activities, which means that EFSA's independence should be defined, firstly even if not exclusively, as its independence from the companies whose products it is evaluating.

This was rightly and repeatedly pointed by the European Parliament for the past four years.

We entirely support in principle the Parliament's demand, made again in its budget discharge this year, to

"incorporate into its new independence policy a two-year cooling-off period for all material interests related to the companies whose products are assessed by the Authority and to any organisations funded by them"

We urge EFSA to make this clear policy principle the cornerstone of its independence policy, with a cooling-off period of five years. And we urge the Authority to remove the exceptions to this principle it has introduced in this draft.

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

As stated in the previous section ("Independence at EFSA – What are we discussing?), the aim of EFSA's Independence policy should not only be that EFSA's actors are impartial but that EFSA is specifically made independent from interests that threaten EFSA's remit to "contribute to a high level of protection of human life and health, and in this respect take account of animal health and welfare, plant health and the environment, in the context of the operation of the internal market."

(There is a probable mistake in line 80, which should read "the independence assured" rather than "the transparency assured".)

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

Line 100: suggestion of addition: "...contributing to EFSA's mission ***and differentiate them from interests that do create a risk for EFSA's independence***."

Lines 102-109 (and related text box): comments on EFSA's proposed definition of a conflict of interest.

EFSA's proposed new definition of COI contains important elements which we support and others which undermine its effectiveness.

- EFSA's identification of COIs being situations and not cases of individual bias or dishonesty is very important and must be kept: at the end of the day, cases of COIs among its external experts indicate errors of recruitment by EFSA, and are not a judgement passed over these persons' integrity.

- "be reasonably perceived" (line 105): this is a delicate issue and we think EFSA dealt with it well here. Perceptions of conflict of interest do matter, therefore it is important that COI perception is included in the definition. At the same time, the assessment of a COI must be based on tangible evidence, otherwise this risks undermining EFSA experts' capacity to defend themselves against unfair accusations of COI and endangering their political rights (accusations of COI made simply because they would have expressed an opinion or defended a position simply disliked by the accuser). We think that the addition of "reasonably" here should help EFSA defend itself against baseless accusations.

- "in relation to the subject of the work performed" (lines 108-109): we request that this section is deleted as it unduly narrows the scope of the assessment. The consequence of doing so would fail to take into account the transversal way lobbying works, in particular as far as "horizontal" issues such as experimental guidelines and risk assessment methodologies are concerned. **This old loophole must be closed for EFSA's independence policy to become meaningful.**

As a consequence, the new definition for a COI at EFSA should become: "any situation where an individual has an interest that may compromise or be reasonably perceived as compromising his or her capacity to act independently in the public interest at EFSA".

Line 114: The expression "potential COI" is not helpful and should be avoided throughout the text: as EFSA's proposed definition recognises, a COI is a specific situation. Therefore, either there is a situation of CoI, or there isn't; but "potential COI" does not really make sense. See a very helpful critique on this, "Why There Are No "Potential" Conflicts of Interest", in a newly published JAMA special issue on COIs
http://jamanetwork.com/journals/jama/fullarticle/2623620

Lines 129-131: we are concerned that “creations of the mind” are listed as a “main pattern of COI”, on par with “economic or financial” interests and “affiliations”. This risks being used to restrict experts’ rights to be on a panel simply because they would have a stated position on any topic vaguely related to the issue being discussed, and undermine the quality of the scientific discussions within the agency. The existing clause, restricting experts from reviewing their own work, should be kept as it is, and, **unlike financial interests conflicting with EFSA’s remit which should not be allowed at all among EFSA staff and appointed experts, we demand that the risk of bias created by non-financial interests is dealt through collegiality, by securing a diversity of views in panels.** The distinction between the two is well argued by Pr. Lisa Bero in her recent contribution to the above-mentioned special issue of JAMA, “Addressing Bias and Conflict of Interest Among Biomedical Researchers”, http://jamanetwork.com/journals/jama/fullarticle/2623632

Lines 143-157: we support the current obligations of declarations listed.

Lines 159-165: Attempting to perpetuate the main loophole in EFSA’s existing independence policy, as does this section, will only perpetuate EFSA’s exposure to COI scandals. Interests must be assessed in the light of EFSA’s mission to protect human health and its duty to be independent from companies whose products it is evaluating.

Lines 165-170: The principle of scientific excellence implies, among other things, that EFSA’s opinions are independent from regulated companies in order to not be discredited by conflicts of interests. The availability of expertise is an important issue but cannot legitimate the undermining of EFSA’s independence policy. As we repeatedly pointed out, EFSA can use the hearing expert system to access any expertise it desires without undermining its independence.

Lines 180-183: It is very good that the document acknowledges this, but it would benefit from this being mentioned much earlier (see comments in section 1).

Line 185: Declaring the proportion of annual earnings is not sufficient; the amounts must be declared, if need be in brackets as is the case in the EU’s Lobbying Transparency Register.

Lines 212-214: EFSA’s independence policy should also apply to its Management Board. Currently, the Board is excluded. At the very least, the “preventive measures” mentioned should be detailed, and rules defined for their application.

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

We support the approach outlined in this section. We ask for this approach to be extended to all financial interests in companies whose products are evaluated by EFSA.

Crucially, we also ask for this approach to be extended to organisations funded by such companies. **The current draft does not exclude the main channel for industry influence: industry-funded organisations such as ILSI, ECETOC, CEFIC's LRI etc. These should be given absolute priority.**

The exclusion should also apply to large public research organisations who provide research services to industry and obtain a very significant proportion of their resources from such commercial activities, such as Germany's Fraunhofer.

It would be therefore important that a separate category is introduced, in line with the European Parliament's requirements: financial links and decision-making responsibilities in "companies whose products are evaluated by EFSA, and organisations funded by them."

One additional observation: this currently excludes EFSA's Board. EFSA's founding regulation talks about the need to have "interests representing the food chain"; the unclarity has so far enabled the food industry to manage to have employees appointed on the Board, which is a permanent issue for EFSA's reputation.

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

Line 269: the word "perception" should be replaced by "risk".

Lines 263-282: The first paragraph (263-273) correctly describes professional involvement with the food industry, whose regulation is EFSA's core business, as a source of risk of regulatory capture which needs to be tackled with a cooling-off period.

But the second paragraph (275-282) bizarrely broadens the scope of the interests to which the cooling-off period should be applied by extending it to "private" interests "in EFSA's sphere", which means, as footnote 13 tells us, that these interests can be "of a commercial nature or an association of activists pursuing a common interest or objective."

This conflation of financial and nonfinancial interests is not consistent with the description of the problem which EFSA aims to solve with its policy (risk of regulatory capture). As argued above and in EFSA's own previous paragraph, the cooling-off period should be

applied to financial interests in regulated companies and organisations funded by them. The risk of bias created by non-financial interests, on the other hand, should be tackled with maximising the diversity of views in the panels and working groups (again, see Bero L., “Addressing Bias and Conflict of Interest Among Biomedical Researchers”, JAMA 2017 http://jamanetwork.com/journals/jama/fullarticle/2623632).

Line 281: **We demand that the cooling-off period is of five years.**

Lines 285-286: **We support the inclusion of occasional consultancy contracts in the scope of the cooling-off period, as it is the main improvement in the draft compared to the existing independence policy.**

Line 286: **The non-listing/exclusion of research funding is self-defeating, since research funding is by far the largest source of financial conflicts of interests among EFSA’s experts (about 40% in our 2013 assessment).**

Research funding should be included in the cooling off period, as the European Parliament specifically requested in its 2015 Budget Discharge resolution: “*regrets that the Authority has not included research funding in the list of interests to be covered by the two-year cooling-off period, as the discharge authority already identified in the latest discharge decisions; calls on the Authority to swiftly implement the measure in line with the discharge authority's repeated requests.*”

Lines 286-288: Again, keeping the scope of interests’ assessment only to the panel’s mandate will only perpetuate EFSA’s exposure to COI scandals.

Lines 288-292: This is too loosely defined and reads as an attempt to perpetuate the loophole introduced in the June 2016 draft, which had been strongly criticised by EFSA’s Board (and by us) for this reason. Most scientific advisory activities are collegial, including in industry-funded organisations. **As it is worded, the exclusion of “scientific advisory activities” would exclude industry lobby groups such as ILSI from the scope of the assessment, which is inacceptable. Again, the cooling-off period should be applied across the board the way the European Parliament has been requesting it: “for all material interests related to the companies whose products are assessed by the Authority and to any organisations funded by them”.**

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

The approach described here, delegating to Member States organisations the responsibility to ensure their experts' independence, is politically understandable (need to avoid entering into conflicts with these institutions) but will prove self-defeating in practice, because there is a huge discrepancy among national agencies. For instance, the German BfR allows industry employees on its scientific panels while the French ANSES clearly bans them. EFSA should not pay the price of national institutions' weaknesses, as is too often the case in the EU.

Also, this means that EFSA basically gives up making sure its work is independent from governmental and political interference. This cannot be a good idea.

Therefore, we urge EFSA to request that Member States representatives fill a DOI, that this DOI is always published (this is not currently the case) and that these experts respect EFSA's independence policy.

3.4 Managing conflicting interest in research funding – A balanced approach

Lines 346-351: Yes, but the purpose of research PPPs, including those encouraged by EU policies, is mainly product development and innovation, not risk assessment (and existing cases of EU-funded PPPs in this domain are problematic). EFSA's core business being the risk assessment of industry products, PPPs cannot be considered in the same way here. Since EFSA suffers from policy choices made by DG Research and national research administrations which narrow the pool of available expertise, it should not take these policies as granted but point at the fact that, precisely, they do undermine its work and should be changed to at least stop endangering the agency' operational needs.

Line 353: As explained above, what EFSA proposes here is not "in line with EU wide approach to research funding".

Line 356: suggestion for addition: "research directly **or indirectly** funded by the private sector" to take into account funding coming from organisations representing industry interests. The more general wording used in the textbox ("Research funding from the private sector benefiting EFSA's experts…") is better from that perspective.

Line 357, "25% of the total budget": As stated above, 25% is too high and the proportion approach is not good for individual experts. What should be disclosed is both the proportion and the amounts, with a ceiling of 10.000€/year, and if need be the amounts should be declared in 2000€ brackets.

Line 357, “of the expert’s research’s team”: using the level of the “research team” for disclosure is good but risks leaving out important details if used alone. We suggest keeping the existing approach of looking at the funds « directly managed by the expert » and to introduce, in line with the European Ombudsman’s recommendations and EFSA’s draft, an additional disclosure of the funding sources (with corresponding amounts) of the expert’s research “team”.

Line 359, “for the sector of relevance”: Again, this unduly narrows the scope of the assessment and should be removed. For instance, an expert whose research would be funded at 90% by Bayer would still be allowed on the NDA panel with such a restriction.

Lines 359-353: “Private contributions to projects funded by public actors, such as those financed under EU Framework Programme 71 or Horizon 2020, do not count for this purpose”:

This exclusion, as currently worded, removes all public-private partnerships from the scope of the assessment. This cannot be a serious policy: many PPPs, including EU-funded ones, are largely driven by the funding and research priorities of companies whose products are evaluated by EFSA. Assessing PPPs from an independence perspective is not easy and needs to be done mainly on a case-by case basis, but this shouldn’t be a reason to remove all of them.

We suggest that research PPPs are assessed according to the following criteria:

- the quality of the information disclosed, in particular the respective financial contributions of the parties and the identity of the project leader (this is the case for most EU-funded PPP research projects but more rarely for the others)

- whenever the project leader of a research PPP is a company whose products are evaluated by EFSA (or an organisation funded by such a company), being involved in this PPP should not be allowed for an external expert at EFSA.

- a low maximum threshold, such as 20%, for industry’s contribution should be defined by EFSA.

4. Transparency and communication on competing interests management

General comments on transparency

DoIs are still not filled consistently. Amounts are missing, and very often, in particular for research funding, the nature of the work being funded is not detailed. This should be made systematically.

It should be made sure that the identity and interests of national experts contributing to EFSA's work, in particular on pesticides, are also published. This is currently not the case.

EFSA should commit to publish the results of its assessment of DOIs (focussing on the organisations assessed more than the experts themselves). This would make its independence policy easier to understand for all (in particular for applying experts), as well as be very useful for other food safety agencies and the media.

Line 394: The names of the experts undergoing a breach of trust procedure should be published. This is currently not the case.

Line 406 (Management Board): Such a register is good, but will make more sense once Board members are covered by EFSA's independence policy at the same level as the rest of its staff and experts. This is currently not the case, and explains why employees of industry-funded organisations are allowed to sit on the Management Board (with a voting power over such important decisions as EFSA's Independence policy…). Of course, since EFSA's Board Members are appointed by Member States after a proposal from the European Commission, this is beyond EFSA's power to change alone and should be taken on board by the Commission when it selects potential candidates to the Board.

5. Policy implementation and enforcement

Lines 418-423: How true. In 2013, we documented and published (in our "Unhappy Meal" report) multiple cases of panel chairs and vice-chairs being appointed in breach of EFSA's own rules. No corrective action was ever undertaken, and several of the experts are still on EFSA's panels today, sometimes in similar positions.

Lines 425-439: It would be important that at least an idea of the nature of the sanctions discussed here are included in EFSA's independence policy, and not all of them delegated to the implementing rules.

It is important that there is transparency on EFSA's decisions in this regard too in order for the public to see that the enforcement actually exists. Decisions should all be published.