Social and environmental organisations' demand radical overhaul of our food and environmental safety system and of the European Food Safety Authority (EFSA)

Working document

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Context

The European Commission is expected to launch a proposal to revise the EFSA Founding regulation[1] in the beginning of 2013. The EU institutions bear great responsibility for the way EFSA functions and the flaws that have been reported over the last ten years.

Beyond the founding regulation, that establishes EFSA's building blocks, EU laws dictate that the studies carried out to support the authorisation of risky products like pesticides, food additives and genetically modified foods are done by industry. But EFSA has the power – and in the case of pesticides, the legal obligation – to balance the risk assessment by considering data generated by independent scientists too. However, such data may or may not be available.

Also, EFSA itself is responsible for its policy on how to deal with conflicts of interest among experts, staff and management. This policy has been highly flawed for many years and still is far from perfect.

The revision of the founding regulation – that touches on EFSA's governance, independence, transparency and scientific quality – is a major opportunity to initiate radical change at the agency that is responsible for objective scientific advice on food and environmental safety at EU level.

The undersigned organisations make the following urgent demands for change upon the EU institutions and EFSA, to ensure that EFSA fulfils its intended role of providing unbiased and up-to-date scientific advice to protect public health. Many of these demands can be addressed through the founding regulation revision, though not all.

1) Prevent conflicts of interest

EFSA's independence policy should effectively exclude people with conflicts of interest from its scientific panels, working groups, scientific committee and staff.
EFSA should proactively seek out independent experts and push the EU institutions to grant the agency the means to pay them for their work. Any collaboration with industry and industry-affiliated bodies such as the International Life Sciences Institute (ILSI) should be ended. Declarations of interest should be better scrutinised and DoIs of senior staff members should be available online. The EFSA founding regulation should be revised so as to exclude industry-liaised affiliated people from the Management Board.

Independent scientists should be invited to peer review EFSA's guidance documents

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[1] The current Founding Regulation (EC) No 178/2002 is at:

and opinions and their comments should be made public. This is especially important in cases where conflicts of interest have been exposed in EFSA panel members who have generated guidance documents and opinions in the past. In these cases, even when the conflicted individual has gone, their work remains behind them, and may put public and environmental health at risk.

The 'revolving doors' should be effectively closed. EFSA staff moving from their position in EFSA to a position in industry or an industry lobby group, or vice versa, should be avoided by a minimum cooling off period of 2 years. Even if formally ended, affiliations with industry related bodies have to be taken into account by assessing conflicts of interest.

2. EU laws should be overhauled so that independent bodies test substances, not industry itself

Revise EU laws to mandate that risk assessments be based on studies carried out independently and paid for through a publicly managed fund. Industry should bear the costs – while ensuring that a strict barrier is maintained between industry and EFSA. This will ensure that EFSA has the capacity to protect food and environmental safety.

Either independent laboratories could be commissioned to do the testing, or an independent testing commission could be set up. The independent commission could take the company's data on the physical and chemical and/or genetic properties of the substance, confirm it, and do dose-ranging tests independently.

In the case of chemicals and pesticides, this would end the current reliance on high, unrealistic dose testing and enable low, realistic doses to be tested over a long period and during vulnerable periods of the organism. This reflects real-life human exposures, which current risk assessment practices often fail to test.

3. A code of scientific practice should be established for EFSA

Decisions affecting public health and environment are not only scientific in nature. They should include societal/ethical/economic considerations and involve a wide range of expertise. But insofar as EFSA is tasked with making decisions on the basis of scientific evidence, there should be systems in place to ensure that the evidence is selected and evaluated according to transparent and rigorous scientific procedures.

Currently it is often not clear how EFSA arrives at certain opinions and conclusions: for example, which scientific evidence it has taken into account and why; and which evidence it has discounted, and why.

This problem was highlighted in the divergence of EFSA's opinion on the safety of bisphenol A from that of the French food safety authority Anses.

EFSA's aim should be to develop policy in the public interest, based on the best available evidence. The objective should be objectivity. Objectivity in science is ensured by transparency and reproducibility. Adherence to these principles can help to minimize bias and to ensure that when controversy arises, it is possible to identify the origins of

diverging opinions.

EFSA's Founding Regulation should establish a commitment to embracing the best practices to achieve objectivity. This means the establishment of scientifically rigorous, transparent, and replicable methodologies for EFSA's risk assessment work. As well as building public confidence in the risk assessment process, this will also help to minimize the controversy around conflicts of interest that surrounds EFSA.

This is because with proper methodologies in place, the identity, interests and biases of an individual or group who carries out the assessment work become less important. The most important factor instead becomes whether the methodology was followed correctly. If it was, then the same verdict would be reached, whoever carried out the assessment. Correct adherence to a rigorous methodology can be easily verified and any mistakes remediated.

A code of scientific practice should be established for EFSA reviews, covering:

a. how evidence is located and selected, including search parameters, inclusion and exclusion criteria for studies, and strategies for ensuring full capture of relevant evidence, including grey literature;
b. how evidence is weighted/de-weighted and evaluated, including a priori and clearly-stated criteria for evaluating the quality of individual studies and overall body of evidence, to ensure maximum use of all available literature.
c. Acknowledge scientific uncertainty where it exists, possibly in the same way that IPCC does.

EFSA's method of selecting and evaluating data for risk assessment must be systematized.

On pesticides and chemicals, EFSA should respect existing EU laws (e.g. the REACH law on chemicals and the pesticides regulation) that give due weight in the risk assessment to studies from the open peer-reviewed scientific literature, rather than favouring industry studies conducted according to OECD/Good Laboratory Practice (GLP) protocols. EFSA's Opinions and Guidance documents show that it often fails to fulfil these requirements.

EFSA should develop detailed protocols for the testing of genetically modified organisms (GMOs). Especially, detailed protocols for long-term testing of the food safety of GMOs need to be devised.

Where EFSA has the ability to request further (long-term) studies, it must do so on the basis of any uncertainties presented by the data available. EFSA has so far not requested any such studies for GM crops, although phrases acknowledging uncertainties, such as "unlikely to be of biological significance", pervade EFSA's assessments of GM crops.

While industry studies must continue to be conducted according to OECD protocols and GLP rules, lack of OECD/GLP compliance must not be used as a reason to dismiss or de-weight studies from the mainstream scientific literature, where the peer review process ensures research is of sufficient quality.

EFSA must give rigorous scientific arguments for dismissing or de-weighting studies,

especially those finding adverse effects, from the open peer-reviewed scientific literature in the risk assessment. If doubt exists, then the funds available to EFSA could be used to repeat such studies (if necessary, according to agreed protocols) to determine whether the effects are real or artefacts.

In the case of GMOs, there is a lack of scientific research carried out independently of industry. Therefore companies seeking authorization of GMOs should pay a fee into a publicly administered fund, which would be used to commission independent risk research on their products.

4. Improve transparency and accountability

EFSA must make accessible all data and information on which it bases risk assessments. All industry data, and EFSA's decision-making processes on the data, must be available on the internet. Currently, industry data on pesticides is not publicly available: for example, on glyphosate. While most industry data on GMOs is available from EFSA on request, this information should automatically be published on a website.

Independent, systematic auditing of EFSA's Opinions and Guidance documents should be carried out to ensure due process is followed.[2] It is not enough for EFSA expert opinions to be evaluated by other EFSA experts; this is an internal and non-independent process.

Rules are only effective insofar as they are implemented. Therefore there is a need for an auditing process to ensure due process is followed. The auditing process should be capable of responding to complaints and queries and, like all auditors, should be financially and governmentally independent of the organisation it is auditing.

The audits should check that EFSA's decisions are accountable and functioning in the public interest, in order to ensure the public is not exposed to potential harm.

5. Ensure wider participation

EFSA must broaden the area of scientific expertise of its experts. EFSA expert panels have come under criticism for having too narrow a range of expertise. We recommend that at a minimum, the following types of experts should be actively sought out and invited to serve on EFSA expert panels:

- to assess human health risks: embryologists, endocrinologists, neurologists, neurodevelopment specialists, reproductive biologists, human geneticists, paediatricians and other clinicians;
- to assess environmental risks: ecologists, biologists, soil biologists, entomologists, animal welfare and wildlife experts.

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[2] This type of audit is *not* the same as the audit finalised in 2012 by the European Court of Auditors, which focused on EFSA's independence policy in the past. Nor did the evaluation of EFSA's work by accountancy firm Ernst&Young independently verify the quality of EFSA's outputs.

EFSA experts should be paid. The current practice of using unpaid volunteer experts who must do their EFSA work in their spare time may favour experts who receive consulting fees or other payment from industry.

EFSA experts should be paid out of public funds for their safety assessment work, but industry must cover the cost. However, the money must not go directly from industry to EFSA; a distance must be maintained between industry and EFSA. This could be achieved by setting up a publicly administered fund, which collects fees from industry and then commissions EFSA to carry out or commission the task.

A system must be established to include different types of input into the risk assessment, including societal, economic, ethical and environmental factors – though this should not be the task of EFSA.

While the existing Founding Regulation stipulates that such factors should be taken into account, there is no evidence that this aspect is implemented.