

20 April 2011

Reply to letter from Catherine Geslain-Lanéelle, executive director of EFSA, regarding our report: *Europe's pesticide and food safety regulators: Who do they work for?*

We find Ms Geslain-Lanéelle's response¹ to our report² inadequate. It only makes a series of general statements that fail to address our substantive points.

Is EFSA a regulatory body?

Ms Geslain-Lanéelle says that EFSA is not a regulatory body.

We say: We can only assume that this claim is intended to distract from the substantive points of our report. It is contradicted by statements from EFSA itself, from the European Union official website, and from a European Commission document:

- EFSA admits in its own documentation that it is part of the regulatory framework.³
- The European Commission, in a document on EU agencies, explicitly and clearly defines EFSA as one of the “different types of [European] regulatory agencies”. It names EFSA as one of four regulatory agencies that provide “direct assistance to the Commission and, where necessary, to the Member States, in the form of technical or scientific advice and/or inspection reports”.⁴
- Europa.eu, the official website of the European Union, categorizes EFSA in the site menu and web address as a “regulatory agency and body”.⁵ The website explains EFSA's role in the regulatory process: “EFSA's risk assessments provide risk managers (EU institutions with political accountability, i.e. the European Commission, European Parliament and Council) with a sound scientific basis for defining policy-driven legislative or regulatory measures required to ensure a high level of consumer protection with regards to food safety.”⁶
- An official Europa document, “The Agencies of the European Community”, lists EFSA as one of seven agencies that “exercise regulatory functions”. Interestingly, it describes the main activity of EFSA not as protecting consumer health and safety but as “facilitating the operation of the internal market”.⁷

It is important to clarify that regulatory bodies are not just those that make final decisions and take votes on policy issues. Some bodies that are part of the regulatory framework, like EFSA, feed into that decision-making process. EFSA calls itself “the keystone of European Union (EU) risk assessment regarding food and feed safety... EFSA provides independent scientific advice ... on existing and emerging risks.”⁸ EFSA does not make the final decision or take the vote on a pesticide or GM food – but it provides the advice that forms the basis for EU institutions to take those decisions and votes. It is an agency with far-reaching influence on regulation of food in Europe. EFSA's conclusions are almost always accepted by the Commission.

We find it inexplicable that Ms Geslain-Lanéelle should choose to quibble over the definition of EFSA's status rather than address the substantive public interest issues raised by our report. We can only speculate over her motives for doing so. Perhaps, by dissociating EFSA from the description of regulatory body, she wishes to absolve it of accountability to the public and responsibility for decisions that are taken on pesticides and food safety. Or perhaps she aims to suggest that if EFSA cannot be defined as a regulatory body, the conflicts of interest in its ranks are not important. We find both possibilities destructive of public confidence.

EFSA's influence on GMO approvals

The case of GMO approvals shows EFSA's influential role in the decision-making process. When the comitology route is used in the decision-making process (which has been the case for all GMOs approved in Europe to date), the Commission goes with the EFSA opinion in opposition to that of the majority of ministers. If the Commission's decision departs from the EFSA opinion, the law says that it has to explain its reasons: "Where the draft decision is not in accordance with the opinion of the Authority [EFSA], the Commission shall provide an explanation for the differences." Evidently the Commission is not expected to form its own opinion if its advisory body is EFSA.

In practice, in most cases when a GMO is submitted for approval for use in food and feed, EFSA gives a positive opinion of safety and then the decision goes to the EU member states' ministers for a decision. Typically, a majority of the ministers, but not the qualified majority, will reject the GMO. At that point, there is a waiting period. If during that period no decision is made, the decision regarding that GMO's approval reverts to the European Commission. The Commission consistently goes along with EFSA's positive opinion of safety and approves it, when it could equally go with the view of the majority of ministers and reject it.

Thus, in the case of GMOs, the EFSA safety decision serves as the key hurdle that a GMO must pass. To date the EFSA has not rejected a single GMO on safety grounds.

Are experts independent of industry to be found?

Ms Geslain-Lanéelle says: "It is an inescapable fact that many scientific experts working in the public sector are involved to varying degrees in projects funded by, or involving, industry."

We say: Ms Geslain-Lanéelle's use of the word "many" implies that she agrees with the contention in our report, that experts who are genuinely independent of industry interests are indeed to be found. We understand that it is still possible to get an education in toxicology and related disciplines and to do research in these fields without receiving relevant industry funding.

EFSA roles should be filled with such independent experts. People who should be excluded from these roles include experts who actively work with industry in redesigning risk assessment, as ILSI affiliates do.

Is EFSA effective in rooting out conflicts of interest?

Ms Geslain-Lanéelle says: "EFSA has put in place a robust and comprehensive system to register interests, identify any potential conflicts and take appropriate actions where needed." She cites the case of Angelo Moretto, who resigned from the EFSA Plant Protection Products and their Residues (PPR) Panel after it emerged that he had a conflict of interest, as an example of how well the system is working.

We say: We applaud EFSA's actions over Moretto – but they do not go far enough, both with regard to Moretto and with relation to other EFSA experts. We deal with this subject in detail in our report and it

would be redundant to go over the same ground here. But it can be said, in short, that if the EFSA's internal process were robust and transparent, Moretto would not have been appointed at all. It appears that someone with conflicts of interest was appointed and then, when objections were raised by unknown parties, he was persuaded to resign.

Most importantly, EFSA overlooks the involvement of its experts with the pesticide, chemical, and food industry-funded group ILSI.

ILSI meetings and workshops in collaboration with government regulators are held behind closed doors. They are not open to the public, NGOs, or any stakeholders beyond the small but powerful group of corporations that fund ILSI and their invited guests, such as key EFSA appointees. It would appear that these invitees are brought into the ILSI circle of confidential discussions to influence their thinking in favour of the pesticide, chemical, and food corporations that fund ILSI.

We conclude that ILSI operates in the manner of a private lobby club. To repeat a main point of our report: it is unacceptable for government regulators and expert advisers to collude with ILSI in such non-transparent forums.

Does EFSA consider the totality of scientific evidence?

Ms Geslain-Lanéelle says: “EFSA’s scientific advice considers the totality of scientific evidence, regardless of source.”

We say: Whatever evidence EFSA considers, its output (in the form of Opinions and Guidances) does not reflect the totality of scientific evidence. Rather, there is an overall trend of favourably citing industry-linked sources and redefining risk assessment in the direction of decreased rigour and decreased expense for industry. Again, it would be redundant to repeat the contents of our report. We simply urge people to read it and reach their own conclusions based on the evidence.

Does EFSA accept industry-generated suggestions on risk assessment?

Ms Geslain-Lanéelle says that EFSA does not merely accept data or methodologies but defines the data requirements with which industry applicant dossiers for pesticides and GMOs must comply. Then its Scientific Committee and Panels provide direction on risk assessment approaches.

We say: Our report demonstrates that EFSA inappropriately allows industry, often via ILSI recommendations, to define data and methodological requirements for pesticide and GMO safety assessment. Opinions issued by EFSA expert panels uncritically recommend ILSI suggestions on data and methodologies, and treat these recommendations as if they had the weight of independent scientific evidence.

Our report also explains why we are concerned about EFSA’s attempts to define data requirements and to direct risk assessment approaches. Its advice on these issues shows a distinct trend in the direction of decreased rigour.

We are aware that the data requirements of the new pesticide regulation will be debated this year, and that many civil society observers are concerned about EFSA’s influence on the process.

We would like to place on record our broad satisfaction with the new democratically established pesticide regulation, which has the potential to bring the pesticide assessment process into line with the public interest. But we share other independent observers’ concerns about the extent to which EFSA, in collaboration with ILSI and other industry lobby groups, is already attempting to water down the requirements of the legislation

through its Guidances and Opinions.

This watering down process has led to a lawsuit being brought against EFSA by ClientEarth and Pesticides Action Network Europe. They claim that EFSA has not been transparent about decisions that led to its industry-friendly Guidance on the interpretation of the new pesticide regulation.¹⁰

Are there conflicts of interest on EFSA's management board?

Ms Geslain-Lanéelle refers to the founding regulation of EFSA which says that the management board should include four members from “organisations representing consumers and other interests in the food chain”. Therefore, she writes, “It is by design that members of the Management Board have links with a particular food sector; they are selected for that very experience and expertise.”

We say: In a letter to Corporate Europe Observatory, Ms Geslain-Lanéelle names the four EFSA management board members from organisations representing consumers and other interests in the food chain as Matthias Horst (industry), Pieter Vanthemsche (farmers), Sue Davies (consumers) and Sinikka Turunen (consumers).¹¹

Our report named two members of the EFSA management board as having current or recent links with ILSI: Diana Banati and Milan Kovac. Neither is among the four EFSA board members “representing consumers and other interests in the foodchain” named by Ms Geslain-Lanéelle. So who do Banati and Kovac represent? The public? Or ILSI and its industry funders?

In fact, Ms Geslain-Lanéelle's mention of these four board members reinforces our argument. She has pointed out that not only does EFSA have on its board an overtly industry-affiliated board member (Horst), whose presence on the board is justified by the founding regulation, but it also has the two industry-affiliated members (Banati and Kovac) that we complained about, whose presence on the board is not justified by any regulation. The EFSA management board cannot claim any credibility while Banati and Kovac are still on it.

As the EFSA founding regulation cited by Ms Geslain-Lanéelle does not justify the presence of Banati and Kovac on the board, it is unclear why she invokes it here or introduces the four other board members into the argument.

While EFSA says that its board members “do not, in any way, represent a government, organisation or sector”,¹² it is disingenuous to suggest that a member will not represent the interests of an organisation or sector with which he or she is affiliated. Presumably it is in acknowledgement of this fact that EFSA invites its board members to fill out declaration of interest forms.

What power does the EFSA management board have over EFSA's scientific output?

Ms Geslain-Lanéelle says: “The Board has no power to review EFSA's scientific outputs nor to influence their adoption procedure”.

We say: The board nevertheless has considerable power in that it appoints members of the scientific committee and scientific panels that give advice on pesticides and food safety. Appointment of ILSI-linked people (such as long-time former PPR Panel member and present CONTAM Panel member Alan Boobis; and current PPR Panel member Theodorus Brock) opens up the possibility of a pro-industry bias in EFSA Opinions and Guidances issued by such panels.

Given the conflicts of interest that have existed within EFSA for many years, its scientific outputs must be subjected to independent review. We are not concerned about who does this as long as:

- The reviewers are genuinely independent
- The process is transparent
- Evaluations are based on up-to-date, independent, and complete scientific knowledge.

How much power does the EFSA have over who sits on its management board?

Ms Geslain-Lanéelle says: “EFSA plays no role in the appointment of Board members; they are appointed by the Council of EU Ministers in consultation with the European Parliament and based on a short-list drawn up by the European Commission after an open call for interest.”

We say: While EFSA does not have the power to appoint its own board members, it has the power to screen them for conflicts of interest and to suggest that they resign, as appears to have happened in the case of Moretto (but only after his conflicts of interest were exposed by unknown parties). This would be a useful first step to take with ILSI- and other industry-affiliated people, if done thoroughly and transparently. In addition, the Council of Ministers and the Commission must ensure that people with conflicts of interest are not appointed to the EFSA management board in the first place.

Conclusion

We note that Ms Geslain-Lanéelle affirms EFSA’s commitment to scientific excellence in the service of the public good. We look forward to seeing EFSA take decisive action to align its activities with this aim, which we wholeheartedly support. However, this aim cannot be achieved as long as EFSA experts collude with ILSI and other industry affiliates in behind-closed-door meetings funded and controlled by the industries that EFSA is charged with helping to regulate.

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