



Decision of the European Ombudsman closing the inquiry into complaint 346/2013/SID against the European Food Safety Authority ('EFSA')

The complainant is a UK NGO which monitors developments in the field of genetic technologies. It complained about EFSA's handling of alleged conflict of interest issues involving members of an EFSA working group on genetically modified insects.

The Ombudsman found that EFSA should have requested one member of the working group *to provide it with details of the financial relationship between his university employer and a biotechnology company which promotes genetically modified insects. The Ombudsman further suggested that EFSA should revise its conflict of interest rules and the related instructions and forms it uses for declarations of interests.*

The background to the complaint

1. The complaint made by a UK NGO which monitors developments in the field of genetic technologies, concerns an allegation that EFSA failed to address conflict of interest issues in relation to certain members of a Working Group dealing with the issue of genetically modified insects. It further complained about EFSA's alleged failure to include the ingestion of genetically modified insects within the scope of a public consultation on the Guidance on risk assessment of food and feed from genetically modified animals. The Working Group began its work in 2010 and completed its work in 2013.

The inquiry

2. The Ombudsman opened an inquiry into the complaint and identified the following allegations and claims:

Allegations:

1) EFSA failed adequately to address the conflict of interest issues raised with respect to certain members of the Working Group on genetically modified insects.

2) EFSA failed properly to address the issue of ingestion of genetically modified insects in its draft Guidance document for Environmental Risk Assessment on genetically modified Animals which it issued for consultation in June 2012.



Claims:

- 1) EFSA should reconstitute the Working Group on genetically modified insects and, in doing so, should ensure that no members are biased or have a conflict of interest.
- 2) EFSA should duly take into account the issue of ingestion of Genetically Modified Insects when drawing up its Guidance document for Environmental Risk Assessment on Genetically Modified Animals.
3. In the course of the inquiry, the Ombudsman received EFSA's opinion on the complaint and, subsequently, the comments of the complainant in response to EFSA's opinion. The Ombudsman's decision takes into account the arguments and opinions put forward by the parties.

Allegation of failure adequately to address the Conflict of Interest issues raised in respect of certain members of the Working Group on Genetically Modified Insects and the related claim

Arguments presented to the Ombudsman

4. The complainant argued that five out of fourteen [1] members of EFSA's Working Group on genetically modified insects had links to a UK biotechnology company that seeks to commercialise genetically modified insects, including genetically modified mosquitoes and agricultural pests. Specifically, the complainant stated that the University of Oxford, which is the employer of one of the members of the working group, invests in a biotechnology company (referred to hereafter as "the biotechnology company") that promotes genetically modified insects. The complainant also stated that this particular member of the working group, as well as some other members of the working group, worked on research projects in which the biotechnology company was a partner.
5. In its opinion, EFSA argued that employment by a university has never been considered a conflict of interest at EFSA. It said that the rationale for choosing university employees is obvious. An approach which would involve not using such persons would disqualify precisely those full-time researchers and professors who are the least directly engaged in commercial activities.
6. As regards the complainant's argument that various members of the working group worked on research projects in which the biotechnology company was also a partner, EFSA stated that the complainant's reasoning, if followed, would lead to the conclusion that EFSA's experts are obliged not only to declare, on the forms used to make Declarations of Interests, their own outside activities, but also to declare what activities have been carried out by



partners in projects they have worked on.

7. EFSA noted, in respect of the number of experts involved in projects in which the biotechnology company was a partner, that the only information about these experts provided in the background to the complaint relates to publications in which the names of the experts and the biotechnology company appear. EFSA stated the policy to allow such publications was aimed at ensuring the highest possible freedom of expression for its scientists.

8. In its observations, the complainant stated that the financial interests of a university which employs an expert are relevant to the assessment of conflicts of interest (relating to that expert). The complainant added that the relevant expert, as an employee of the University of Oxford, was effectively undertaking joint research with the biotechnology company which promotes genetically modified insects. It also maintained its arguments regarding the fact that members of the working group worked on research projects in which the biotechnology company was also a partner.

The Ombudsman's assessment

9. EFSA has an obligation to ensure that the outside experts who advise it are of the highest quality possible. It also has an obligation to ensure that these experts are, and are also seen to be, independent of any third party influence that might unduly affect their ability and willingness to give the best advice possible. The Ombudsman underlines that the independence of such advice, and the appearance of such independence in the eyes of EU citizens, are vital to building trust in the important work of EFSA. By extension, and cumulatively, the fact that all EU institutions ensure that the advice they choose to obtain is independent builds trust in the EU. If such trust is undermined, EFSA, and the EU, will cease to be legitimate in the eyes of citizens.

10. The complainant stated that one expert appointed to the Working Group on genetically modified insects was working for the University of Oxford, and that the University of Oxford has commercial links with the biotechnology company (according to the complainant, the University of Oxford owns some 12.5% of the shares in the biotechnology company). The complainant insists that this situation calls into question the capacity of that expert to give independent advice to EFSA.

11. The Ombudsman notes that the expert in question is, given the specialised academic position he holds at the University of Oxford, clearly capable of giving the highest quality scientific advice on the issue of genetically modified insects. However, while the Ombudsman agrees that it is good administration for EFSA to take such impressive academic credentials into account when choosing experts, it is also necessary to ensure that the expert concerned was free to provide advice without being unduly influenced by interested parties, particularly one with a clear and strong commercial interest in the conclusions of the Working Group on genetically modified insects. It is important to underline, as regards the vital issue of building trust in the work of EFSA, and as regards the issue of ensuring that EFSA retains its legitimacy



in the eyes of citizens, that any appearance of a lack of independence must also be avoided.

12. The Ombudsman notes that it is increasingly common for universities and other third-level bodies to work closely with companies to carry out research and to commercialise the results of research. The traditional understanding that academia is necessarily and automatically "independent" must evolve to reflect these developing deeper relationships between academia and business. The view that academia, academic institutions and individual academics are independent of business must be based not on any preconceived assumptions, but rather on an examination of the specific relevant facts.

13. EFSA does not contest the assertion that the University of Oxford will, as a shareholder, benefit indirectly from the commercialisation of the products of the biotechnology company. It deals with this uncontested assertion by stating that "*employment by a university has never been considered a conflict of interest at EFSA*". It adds that "*the rationale for this choice is obvious: such an approach would disqualify precisely those full time researchers and professors who are least directly engaged in commercial activities*". The Ombudsman does not agree with this approach, which reflects a traditional, and now outdated, understanding of universities. The Ombudsman considers that it may well be possible, and indeed likely, that many universities and university staff remain independent of third-party influences. However, the question of whether, in a given case, a university and its staff are independent of third-party influences will depend on the precise relationship the university has with such third parties, and the mechanisms by which that relationship is managed by the university.

14. As regards the relationship between the University of Oxford and the biotechnology company, the Ombudsman notes that the University of Oxford has a direct financial interest in the commercial success of that company. That interest is not insignificant; EFSA has also not contested the assertion of the complainant that the biotechnology company is a world leader in the field of genetically modified insects, a field with obvious enormous commercial potential. It would thus appear that the University of Oxford stands to gain considerably if the company is successful.

15. The success of that company would appear to be greatly dependent on overcoming scientific challenges, overcoming the challenges of obtaining regulatory approvals and overcoming the challenge of gaining the public's trust in its products. In this context, the company, and by extension, the University of Oxford, stand to gain if public bodies, such as EFSA, look favourably on the issue of genetically modified insects.

16. In this context, it would be appropriate for a university, if it wishes to invest in commercial ventures, and wishes to ensure, at the same time, that it and its staff remain independent of influences resulting from those investments, to establish mechanisms, such as "Chinese walls" [2], to prevent communication and instructions from the investment arm of the university influencing the academic arm.

17. It is the Ombudsman's view that EFSA should have requested the expert concerned to provide EFSA with details of the relationship the University of Oxford had with the biotechnology company, and the mechanisms that the University of Oxford had put in place



to ensure that this relationship did not compromise the independence of the expert, before appointing him to the Working Group on genetically modified insects. It should then have studied those details with a view to determining if they were sufficient to remove even the appearance of a conflict of interest. EFSA failed to do so. By failing to do so, it did not reassure itself that the necessary mechanisms were in place to ensure the independence of the expert. This was an instance of maladministration with respect to which the Ombudsman will make a critical remark.

18. In this context, the Ombudsman also notes that EFSA has failed to take adequate account of the changing nature of universities in its conflict of interest rules and its Declarations of Interests forms. In light of the above, the Ombudsman will make a corresponding further remark.

19. The complainant also argues that the expert in question worked on a specific project at the university in collaboration with the biotechnology company. The Ombudsman notes that EFSA did in fact obtain from the expert detailed explanations as regards the precise nature of this collaboration with the biotechnology company. It appears, from these explanations, that the projects in question were not funded or resourced by the biotechnology company. Rather they were funded by a public body, namely a UK national funding institution. The Ombudsman does not agree that this arrangement implied any loss of independence for the expert. She sees no mechanism resulting from this arrangement whereby the company would obtain any leverage or influence over the expert. The Ombudsman therefore considers that there is no maladministration in respect of this aspect of the complaint.

20. The complainant also argues that other experts on the particular Working Group worked on projects alongside the biotechnology company, specifically on a World Health Organisation project in which the biotechnology company was also a partner. The Ombudsman notes, however, that the projects in question were not financed or otherwise resourced by the biotechnology company (they were organised and funded by the World Health Organisation) and the projects had no direct commercial aim. The fact that the biotechnology company also participated in that project could not as such reasonably imply that the company acquired any influence over the experts who were also called upon to take part in the project organised and funded by the World Health Organisation. The Ombudsman therefore considers that there is no maladministration in respect of this aspect of the complaint.

21. The complainant also appears to argue that certain members of the Working Group on genetically modified insects co-authored academic papers with persons working for the biotechnology company. The Ombudsman is of the view that the co-authorship of papers, in an academic journal, does not, in the absence of any commercial links between the various authors, imply that the biotechnology company acquired any influence or leverage over the experts. The Ombudsman therefore considers that no further inquiries are justified into this aspect of the complaint.

22. As regards the complainant's claim that the working group be reconstituted, the Ombudsman notes that the working group concluded its work in 2013. It is thus no longer



possible to remedy the maladministration noted in paragraph 17 above. However, in the future the Ombudsman urges EFSA to take a different approach so that, on an objective view, EFSA cannot be questioned on the experts it appoints to its groups. The Ombudsman wishes to recognise, in this context, the great efforts that EFSA has put into improving its conflicts of interest rules. However, in light of the above, it appears necessary that it makes additional efforts to ensure that its rules reflect the evolving nature of academia [3].

Allegation of failure properly to address the issue of ingestion of Genetically Modified Insects in its draft Guidance document for Environmental Risk Assessment on Genetically Modified Animals

Arguments presented to the Ombudsman

23. The complainant argues that the larvae of genetically modified insects that die inside fruit and vegetables may be eaten by humans. According to the complainant, reference to such larvae should thus have been included in its draft Guidance document for Environmental Risk Assessment on Genetically Modified *Animals*. The complainant argues that EFSA, however, failed to consider this fact when its draft Guidance document for Environmental Risk Assessment on Genetically Modified Animals was drawn up.

24. EFSA maintained that the complainant referred to a version of a *draft* guidance document that had not yet been finalised and which was issued prior to a public consultation. EFSA noted that the *final version* of the guidance document, issued after the public consultation, included a more elaborated and extensive paragraph on the issue complained about. EFSA noted that this paragraph reflected the outcome of the public consultation, to which the complainant contributed. The complainant in its observations argued, in essence, that there had been inadequate consultation in respect of the *final version* of the guidance document, and while advice was given in that version on what process (for applicants) to use, the final version was not comprehensive i.e. it still did not explicitly mention dead GM insect larvae in food.

The Ombudsman's assessment

25. The Ombudsman considers that EFSA has provided an adequate explanation of its position in relation to the allegation. The Ombudsman has also examined the final Scientific Opinion of EFSA and notes that EFSA has indeed addressed the issue in the final document, which states:

" GM insects placed on the EU market and released into the environment (as meant in the present document; see chapter 1) are generally not intended to be used as food or feed. Therefore, the present section of this Guidance Document considers primarily effects of GM insects on human health through routes of exposure other than ingestion or intake; these include ocular and nasal exposure as well as exposure through dermal contact and inhalation. However, applicants should assess the likelihood of oral exposure of humans to GM insects or their products which are not intended for food or feed uses. If such exposure is likely and ingestion or intake will occur at levels which could potentially place humans at risk, then applicants should apply the assessment



procedures described in the EFSA Guidance Document on the risk assessment of food and feed from GM animals and on animal health and welfare aspects (EFSA, 2012a). [4] "

26. The Ombudsman therefore considers EFSA has 'addressed' the issue and that no further inquiries are justified into this allegation. The Ombudsman stresses that she takes no view on the scientific merits of the position of EFSA.

Conclusion

On the basis of the inquiry into this complaint, the Ombudsman closes it with the following critical remark:

EFSA failed to ensure that those experts who work in academia declare all relevant information to EFSA.

The complainant and EFSA will be informed of this decision.

Further remark

EFSA should revise its conflict of interest rules, and the related instructions and forms it uses for declarations of interests.

Emily O'Reilly

European Ombudsman

Strasbourg 30/01/2015

[1] EFSA identifies 15 scientific experts and 2 hearing experts.

[2] A "Chinese wall" is a business term describing an information barrier within an organisation that is erected to prevent exchanges or communication that could lead to conflicts of interest.

[3] The Ombudsman is currently conducting an own-initiative inquiry (OI/6/2014/NF) into the composition of expert groups established by the European Commission. This inquiry is expected to be concluded later this year. While the inquiry is focusing on expert groups established by the Commission, its conclusions may also have some wider application to EU agencies more generally.

[4] See <http://www.efsa.europa.eu/en/efsajournal/doc/3200.pdf>