European Ombudsman

2522-2011-(VIK)CK-S2014-189739

Emily O'Reilly
European Ombudsman

Hans Muilerman
Pesticide Action Network Europe
Rue de la pépinière 1
Bruxelles
BELGIQUE

hans@pan-europe.info

Strasbourg, 27/03/2014

Decision of the European Ombudsman closing the inquiry into complaint 2522/2011/(VIK)CK against the European Food Safety Authority (EFSA)

Dear Mr Muilerman,

On 19 December 2011, acting on behalf of Pesticide Action Network Europe (PAN Europe), you submitted a complaint to the European Ombudsman against the European Food Safety Authority (EFSA).

After a careful analysis of all the information submitted to me, I have decided to close the inquiry with the following conclusion and critical remark:

It is important not only that there is good administration but also that, in the eyes of the citizens, good administration is seen to be done. By failing adequately to respond to the complainant's allegations that (i) some members of the WG were in a conflict of interest because of their links with industry and (ii) a balanced stakeholder representation in external meetings was not ensured, EFSA did not dispel the citizens' impression that there was a potential conflict of interest. This constitutes an instance of maladministration.

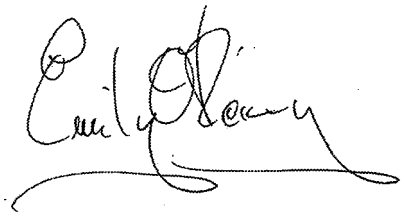
No further inquiries are justified with regard to the remainder of the complaint.

Please also note that in your observations on EFSA's opinion, you submitted a new claim, namely that EFSA should establish a fully independent working group in order to carry out a fresh review of the TTC. As this request had not been brought to the attention of EFSA beforehand, I did not to include it in the inquiry on the basis of Article 2(4) of the Statute of the European Ombudsman.

I apologise for the length of time it has taken to complete this inquiry.

Please find enclosed my decision on the complaint.

Yours sincerely,



Emily O'Reilly

Enclosure:

- Decision on complaint 2522/2011/(VIK)CK

Decision

of the European Ombudsman closing the inquiry into complaint 2522/2011/(VIK)CK against the European Food Safety Authority

The background to the complaint

1. The present case concerned the way the European Food Safety Authority (EFSA) handled an alleged conflict of interest concerning one of its Working Groups.

2. In 2008, EFSA established a Working Group (WG) with a view to exploring the possible use of a science-based tool for measuring the safety of chemical substances for human health, the Threshold of Toxicological Concern (TTC). The Chair of the WG was appointed by the Scientific Committee of EFSA[1] from among its members in July 2008. The WG worked from January 2009 until May 2011, when it submitted its draft opinion on the TTC to the Scientific Committee. The Scientific Committee endorsed the draft opinion and launched a public consultation on the opinion in July 2011.

3. The complainant, a non-profit organisation, submitted its comments in the course of the public consultation. It argued that EFSA failed to protect the interests of the public and promoted the interests of industry. On various occasions[2], it reiterated that through scientists that had worked for both the International Life Sciences Institute (ILSI)[3] and EFSA, ILSI contributed to the shaping of EFSA's decisions, thereby interfering with EFSA's independence. According to the complainant, ILSI is an industry lobby group.

4. On 19 December 2011, the complainant published the report entitled: *"A toxic mixture? Industry bias found in EFSA working group on risk assessment for toxic chemicals"*[4], in which it analysed the scientific and professional background of all the members of the WG and argued that the composition of the group was

[1] The Scientific Committee is competent for multisectoral issues and for those matters that do not fall under the precise competence of one of EFSA's Scientific Panels.
[2] On 30 January 2011, the complainant sent a letter to EFSA's Director urging EFSA to strengthen its independence. On 17-18 November 2011, it participated in the EFSA stakeholder forum where it made critical comments regarding the TTC.
[3] According to its website, ILSI is a non-profit organisation whose mission is to provide science that improves public health and well-being. See: http://www.ilsi.org/Pages/HomePage.aspx
[4] http://www.pan-europe.info/Resources/Reports/PANE%20-%202011%20-%20A%20Toxic%20Mixture%20-%20Industry%20bias%20found%20in%20EFSA%20working%20group%20on%20risk%20assessment%20for%20toxic%20chemicals..pdf

1 avenue du Président Robert Schuman
CS 30403
F-67001 Strasbourg Cedex

T. + 33 (0)3 88 17 23 13
F. + 33 (0)3 88 17 90 62

www.ombudsman.europa.eu
eo@ombudsman.europa.eu

heavily biased. On the same day, it sent the report to EFSA[5] and complained to the European Ombudsman.

The subject matter of the inquiry

5. The Ombudsman opened an inquiry into the following allegations and claims:

Allegations:

1. EFSA failed to guarantee the independence of the members of its working groups and scientific panels, in particular of the TTC working group.

2. EFSA failed to ensure a balanced stakeholder representation in its external meetings, in particular as regards the TTC.

Claims:

1. EFSA should put an end to the TTC working group or change its composition by removing all its members that have links with the industry.

2. EFSA should develop a strict policy on conflicts of interest applying to the experts taking part in its working groups and scientific panels.

3. EFSA should ensure a balanced stakeholder representation in its external meetings, in particular as regards the TTC.

The inquiry

6. On 4 April 2012, the Ombudsman asked EFSA for an opinion on the complainant's allegations and claims. On 25 June 2012, EFSA submitted its opinion, which was forwarded to the complainant for observations. The complainant sent its observations on 24 July 2012.

The Ombudsman's analysis and conclusions

Preliminary remarks

7. Given that the relevant WG ceased to exist in May 2012, the complainant's first claim, according to which EFSA should put an end to this working group, has become devoid of purpose. Furthermore, the Ombudsman notes that although the complainant's first allegation appears to refer in general terms to the independence of EFSA's working groups, its submissions only concerned the TTC WG. The Ombudsman's inquiry has therefore focused only on this working group.

[5] The complainant also made a request for access to documents pursuant to Regulation 1049/2001 with a view to obtaining documents relating to the Terms of Reference of the WG and to the procedure by which the WG's members had been selected, as well as all the documents prepared by the WG. The complainant was granted partial access to a number of the requested documents, including the documents concerning the composition of the WG.

A. Alleged failure to guarantee the independence of the TTC working group and related claim

Arguments presented to the Ombudsman

8. The complainant argued that EFSA failed to maintain the appropriate distance from industry-sponsored groups, thus undermining its credibility and independence. In this context, the complainant referred to the report it had published in 2011 and in which it had noted that 10 out of 13 members of the WG had been involved in promoting the TTC approach and had affiliations with industry or ILSI, either on a contractual basis or by means of joint academic publications. The complainant added that, in 2005, the Chair of the WG had published a monograph on the TTC approach with the support of ILSI's Threshold of Toxicological Concern Task Force[6]. The complainant argued in this context that EFSA's internal rules and procedures did not ensure that industry-linked persons were prevented from being members of the TTC working group, given that the majority of members of the group were closely linked with industry, such as ILSI. Moreover, EFSA did not have in place an adequate policy on conflicts of interest.

9. The complainant expressed its dissatisfaction with the way the Chair and the members of the WG were selected. It argued that the selection of the members of the WG in particular had been left entirely to the discretion of the Chair of the WG. The procedure for appointing members did not involve any supervision by EFSA or by its external evaluators. The complainant further submitted that the WG had functioned for over three years as a scientific panel, without having undergone the full selection procedure required for members of the Scientific Committee.

10. In its opinion, EFSA explained that the WG was established in close consultation between the Chair of the WG, EFSA's Scientific Committee and the Head of the latter Committee. In particular, the expertise required for such a working group was discussed and agreed on between the Chair of the WG and the head of the unit in charge of the Scientific Committee. Because the mandate required the assessment of the possible use of the TTC approach in EFSA's remit, it was necessary to involve panel members that had a background or at least some understanding of the TTC approach. Potential candidates were contacted by EFSA and those who expressed an interest submitted an annual Declaration of Interest, which EFSA reviewed, and only those who passed the screening were further assessed. EFSA also noted that the WG worked in close cooperation with the Scientific Committee and that its work did not constitute a final assessment but only a preparatory stage. Having fulfilled its mandate, the WG ceased to exist after it had completed its work. On 22 May 2012, the Scientific Committee, the only body responsible for adopting EFSA's scientific opinions, adopted its final opinion on the TTC tool[7].

11. With regard to the issue of conflicts of interest, EFSA observed that the rules applicable to the members of the WG were its Policy on Declaration of Interests, adopted in September 2007, and its two implementing decisions: the Procedure for identifying and handling potential conflicts of interest; and the Guidance Document on declarations of interest. In applying these rules, EFSA did not

[6] The Threshold of Toxicological Concern, ILSI Europe Monograph Series 2005, available at: http://www.ilsi.org/Europe/Publications/C2005Thres_Tox.pdf
[7] http://www.efsa.europa.eu/en/efsajournal/doc/2750.pdf

identify any conflict of interest. Moreover, EFSA did not consider that prior publications on a certain issue gave rise to a conflict of interest, but on the contrary, could be regarded as a positive aspect enhancing the level of expertise of the scientist concerned. Likewise, EFSA did not consider the simple participation in a workshop to be a conflict of interest.

12. EFSA also described the steps it undertook in order to strengthen its rules and procedures regarding conflicts of interest. It particular, EFSA had adopted a comprehensive new "Policy on Independence and Scientific Decision-Making Processes" and implementing rules applicable as of 1 July 2012[8]. EFSA also explained the way in which the new Policy and its Implementing Rules strengthened its independence and improved its assessment of possible conflicts of interest.

13. In its observations, the complainant pointed out that EFSA failed to rebut its findings that 10 out of 13 WG members had conflicts of interest and were favourable to a more general use of the TTC approach. The complainant also stressed that EFSA did not explain how it appointed the Chair of the WG. With regard to the new policy on conflict of interest, the complainant noted that, by adopting such a new policy, EFSA itself acknowledged that the policy applicable at the time that the facts of the present complaint arose could not prevent potential conflict of interest.

The Ombudsman's assessment

14. The Ombudsman recognises that EFSA's mandate to "ensure that Europe's food is safe" is of special interest to EU citizens. The fulfilment of this mission would be endangered if EFSA's approach could give rise to the impression that it failed properly to identify and assess a possible conflict of interest[9]. In helping EFSA to achieve its mission, the Ombudsman understands her own role as being to identify any failures in relation to the handling of potential conflicts of interest and, in so far as they constitute instances of maladministration, to help EFSA to eliminate them. Importantly, in order to promote good administration, the Ombudsman's role is to provide EFSA with guidance and advice to improve the rules and procedures in place so that any such instances of maladministration do not occur again in the future[10].

15. In this context, the Ombudsman will seek to examine whether, in the present case, EFSA failed to identify and to properly handle potential conflicts of interest, thus undermining the independence of the WG. In this respect, the Ombudsman attaches particular importance to the report which the complainant sent to EFSA in December 2011 and which also formed part of its complaint to the Ombudsman.

16. The Ombudsman notes that the complainant contested the WG's independence arguing that (i) the selection procedure followed was arbitrary; (ii) the vast majority of its members had links with industry; and (iii) the rules in force at that time were inadequate to guarantee the WG's independence. In response, EFSA's main line of defence was that its decisions and actions regarding the WG were in compliance with the rules in force at the relevant time.

[8] http://www.efsa.europa.eu/en/topics/topic/independence.htm
[9] Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA, paragraph 60.
[10] Decision of the European Ombudsman closing his inquiry into complaint 622/2012/ANA, paragraph 30.

17. The Ombudsman agrees with EFSA's view that the way it established the WG and the way it assessed its members' interests need to be examined in light of the rules applicable at the time when the WG was set up. The rules that applied to the establishment of the WG were (i) the Decision of EFSA's Management Board concerning the establishment and operations of the Scientific Committee and Panels, September 2007, and (ii) the Decision of EFSA's Executive Director concerning the selection of members of the scientific committee, scientific panels and external experts to assist EFSA with its scientific work, May 2008. It is clear from EFSA's submissions that the WG was indeed established in accordance with (i) Article 6 of the Decision of the Management Board, which provides that the members of a working group shall be designated by its Chair in consultation with the Scientific Committee, and (ii) Article 14 of the Decision of the Executive Director, which designated the procedure to be followed.

18. The complainant did not contest this fact, but considered that the selection of the WG should have followed the procedure designated for the members of the Scientific Committee, since the latter offered more guarantees. However, this claim does not appear to have a basis in the legal framework applicable at the time. In fact, EFSA was not obliged to follow the procedure for the selection of members of the Scientific Committee when appointing the members of the WG.

19. Regarding the rules for handling conflicts of interest, the legal framework applicable to the present case included EFSA's Policy on Declaration of Interests adopted in September 2007, and two implementing decisions, that is to say, the Guidance Document on declarations of interest, and the Procedure for identifying and handling of conflict of interest. EFSA argued that it complied with the above rules in deciding to appoint the Chair and the members of the WG. In that regard the Ombudsman notes that even though EFSA may, when deciding on the composition of the WG, have acted in accordance with the applicable legal framework, new elements were later brought to its attention that could cast serious doubts upon the WG's independence and the soundness of EFSA's initial decision. In fact, in its report and subsequent correspondence to EFSA, the complainant put forward what appear, at first sight, to constitute significant evidence suggesting potential conflicts of interest and lack of impartiality in relation to the composition and functioning of the WG.

20. Public trust in the EU public administration can be severely undermined if members of staff, external experts that assist in the decision-making of the EU public administration or members of management boards are affected or are perceived to be affected by conflicts of interest[11]. In such cases, it is essential that the institutions must be perceived to act properly and to be in a position to defend their decisions vis-à-vis EU citizens, when asked to do so. This approach is instrumental in building public trust and confidence in the EU institutions' activities[12].

21. Consequently, following the publication of the report and upon receiving the complainant's further submissions, one would have expected EFSA to start a thorough investigation into the issues raised by the complainant and then inform the complainant of its findings in a timely manner, thus demonstrating

[11] See Decision of the European Ombudsman closing the inquiry into complaint 642/2012/TN against the European Medicines Agency (EMA), paragraph 43.
[12] Draft recommendations of the European Ombudsman in his inquiry into complaint 775/2010/ANA against the European Food Safety Authority (EFSA), paragraph 62.

its intention to maintain public trust in the WG, and/or, if necessary, to put right any possible wrongdoings. The Ombudsman will, therefore, examine whether EFSA responded adequately to the complainant's allegations which, on the face of it, appeared to have been serious.

22. EFSA does not appear to have formally replied to the complainant's report or to any other communication in which the latter raised concerns about the WG's independence. It was not until the Ombudsman opened the present inquiry that EFSA presented its views on the matter. The Ombudsman further notes that, while the complainant's submissions were detailed and contained concrete allegations regarding the Chair and some members of the WG, EFSA's reply did not address these issues in a thorough and specific manner. On the contrary, EFSA limited itself to some general observations.

23. For instance, in response to the complainant's argument that the Chair had published a monograph on the TTC approach with the support of ILSI, EFSA merely replied that prior publications could not be considered as evidence of a possible conflict of interest, without explaining why the specific publication to which the complainant had referred did not raise any questions regarding the Chair's independence. Likewise, EFSA rejected the possibility that participation in a workshop could give rise to a conflict of interest without providing any further clarifications regarding the organisation and the purpose of the specific workshop to which the complainant had referred. Moreover, the Ombudsman also finds it remarkable that, despite the obvious importance that the complainant attached to certain persons' alleged links to ILSI, EFSA did not address this issue in any detail. In fact, EFSA's opinion mentions the body concerned only once and only in passing.

24. In light of the above, the Ombudsman does not consider EFSA's response to have been adequate. The Ombudsman understands that EFSA was bound by the rules applicable at the time. However, it was not the case that these rules prevented it from assessing fully whether or not there were conflicts of interest as regards the members of the WG. It was open to EFSA to undertake such an assessment once the complainant had brought to its attention information that could cast doubt upon the soundness of its initial decision. What is more, it would clearly have been good administration to do so. Thus, by failing adequately to respond to the complainant's allegations that some members of the WG had close links with industry, EFSA failed to dispel the impression that there was indeed a conflict of interest. This constitutes an instance of maladministration. The Ombudsman will therefore make a corresponding critical remark.

25. The complainant also argued that the rules regarding handling of conflicts of interest in force at the time of the facts were inadequate. The Ombudsman takes the view that it would serve no useful purpose if she were to examine, at this point in time, whether these rules were indeed adequate to guarantee the independence of experts. This conclusion is based on the following two considerations.

26. First, the Ombudsman[13] has already assessed EFSA's previous policy on ethics and integrity, including conflicts of interest, and reached the conclusion that these rules were not sufficient to ensure an adequate handling of conflict of interest. In addition to that, the Ombudsman notes that the European Court of

[13] Decision of the European Ombudsman in his inquiry into complaint 775/2010/ANA against the European Food Safety Authority (EFSA)

Auditors concluded, in its report "Management of conflict of interest in selected EU Agencies"[14], that EFSA, among other EU agencies, had failed adequately to manage situations of conflict of interest. Moreover, the European Parliament postponed its approval of EFSA's accounts for 2010 partly due to what it considered to be an unsatisfactory management of conflict of interest[15].

27. Second, those rules are no longer in force. In fact, in response to the above criticism, EFSA adopted a new Policy on Independence and Scientific Decision-Making Processes and Implementing Rules, applicable as of 1 July 2012[16]. In its opinion, EFSA described the specific measures it took with a view to enhancing its independence and transparency in decision-making. Its initiatives in the area of ethics and integrity include: (i) new rules on independence adopted after a thorough public consultation; (ii) investment in IT infrastructure (a new electronic Declaration of Interests tool was put in place); (iii) specific staff training and allocation of dedicated staff to the screening of declarations; and (iv) meetings with stakeholders on the implementation of the new rules and regular online publications on EFSA's website on independence-related matters.

28. The Ombudsman welcomes EFSA's willingness to strengthen its rules and procedures. It is particularly important for EFSA to have, and to be perceived as having, an irreproachable policy and practice as regards conflicts of interest, given its important societal role, namely food safety and protection of public health. The Ombudsman trusts that EFSA will demonstrate its readiness and determination effectively to deal with situations of alleged conflict of interest that may occur in the future. It is not, however, within the scope of the present inquiry to assess EFSA's new legal framework. The Ombudsman reserves the right to look again into this matter, in the context of a future complaint or an own-initiative inquiry. In light of the above, there is no reason further to pursue the complainant's claim that EFSA should adopt a robust policy on conflict of interest with regard to the scientific experts contributing to EFSA activities.

B. Alleged failure to ensure a balanced stakeholder representation in external meetings

Arguments presented to the Ombudsman

29. In support of this allegation, the complainant referred to two meetings which were co-organised with ILSI, on an invitation-only basis, and included exclusively or nearly exclusively industry-linked people and representatives. In the complainant's view, this cast doubts upon EFSA's independence and impartiality. The first meeting took place in 2005 and concerned genotoxic substances. The second meeting was a workshop on the TTC which took place in June 2011.

30. In its opinion, EFSA submitted that this part of the complaint was not sufficiently clear. It stated that it assumed that the complainant's second allegation and related claim referred to the composition of its working groups. It went on to explain in detail how it had endeavoured to comply with the

[14] Management of conflict of interest in selected EU Agencies, European Court of Auditors, Special Report No 15/2012, OJ 2012 C 368, p. 11, available at: http://eca.europa.eu/portal/pls/portal/docs/1/17190743.PDF

[15] http://www.europarl.europa.eu/sides/getDoc.do?pubRef=-//EP//TEXT+TA+P7-TA-2012-0173+0+DOC+XML+V0//EN&language=EN#BKMD-70

[16] http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf

requirements as to independence and scientific excellence, and how it was open to scientific comments from civil society. In relation to the 2011 workshop, EFSA pointed out that several of the WG's members attended the workshop with a view to explaining EFSA's approach on the matter. In EFSA's view, participation in conferences and seminars is an activity inherent to the practice of the scientific profession.

31. In its observations, the complainant observed that many persons who were later to become members of the WG, including its Chair, were present at the 2005 meeting, which was co-organised by EFSA, ILSI and a number of companies. In relation to the 2011 Workshop, it argued that EFSA's logo on the draft programme of the meeting and the presence of an EFSA staff member on the organising committee made it perfectly clear that EFSA participated in the organisation of that workshop, to which independent scientists and environmental NGO representatives were not invited.

The Ombudsman's assessment

32. The Ombudsman notes that, in its second allegation, the complainant argued that EFSA failed to ensure a balanced stakeholder representation in its external meetings. To support its allegation, it referred to two meetings, which, in its opinion, were co-organised by EFSA and did not sufficiently involve representatives of civil society.

33. Regarding the first meeting, the Ombudsman notes that it was an international conference that EFSA co-organised with the Word Health Organisation (WHO) with the support of the ILSI, in November 2005. The conference followed the publication of an Opinion of EFSA's Scientific Committee in October 2005[17], and its purpose was to discuss how regulatory and advisory bodies evaluate the potential risks of the presence in food of substances that are both genotoxic and carcinogenic. The TTC approach was also discussed, although it was not the main subject of interest. The participants represented EFSA, WHO, ILSI, academia and national food safety authorities. There were also industry representatives. The conference report and the presentations were published[18].

34. Regarding the second event, that is to say, the workshop entitled "Threshold of Toxicological Concern: Scientific challenges and approaches" held in June 2011, it can be inferred from the draft programme, as well as from information that the complainant received in the context of its subsequent access to documents request, that EFSA was among the organisers of the workshop along with companies, institutes and an NGO defending animal rights[19]. The objective of the workshop was to explore the scientific challenges to the application of the TTC as a tool to aid decision-making in chemical safety assessment. It was aimed at safety and regulatory scientists from industry, government agencies, animal welfare organisations and academia from all over the world. A report on its conclusions was also published in a scientific review.

[17] Opinion of EFSA's Scientific Committee on a request from EFSA related to a Harmonised Approach for Risk Assessment of Substances which are both Genotoxic and Carcinogenic, available at: http://www.efsa.europa.eu/en/efsajournal/doc/282.pdf

[18] http://bookshop.europa.eu/en/efsa-who-international-conference-with-support-of-ilsi-europe-on-risk-assessment-of-compounds-that-are-both-genotoxic-and-carcinogenic-pbTMXA06001/

[19] From the documents obtained by the complainant in the framework of the access to documents request pursuant to Regulation 1049/2001, it appeared that "*a joint workshop on TTC will be organised by EFSA-ILSI-EU to review the regulatory use of the TTC approach and to identify and overcome barriers to acceptance.*"

35. The Ombudsman notes that in the second of the above-mentioned meetings, participation of civil society organisations appears to have been rather limited, namely to one NGO, while in the first one, there was no civil society participation at all. Nevertheless, the Ombudsman considers that it is not possible, on that basis alone, to draw a general conclusion that EFSA systematically failed to ensure a balanced representation in external meetings.

36. The Ombudsman nevertheless regrets EFSA's unwillingness properly to address the complainant's second allegation. She considers that the complainant had put forward sufficiently clear arguments to suggest that EFSA failed to ensure appropriate civil society representation in at least some of the meetings it had organised. In this context, the complainant referred to two specific meetings in particular and provided documents regarding these meetings. The Ombudsman cannot therefore accept that EFSA could not have understood the complainant's grievances. In her view, by failing adequately to respond to this part of the complaint, EFSA gave the impression that it preferred to avoid addressing the issue, thus failing to dispel doubts as to its efforts to ensure a balanced stakeholder composition in external meetings. This constitutes an instance of maladministration, and the Ombudsman will address it in her critical remark to EFSA.

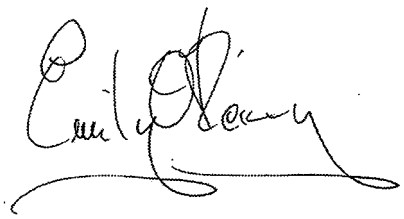
C. Conclusions

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

It is important not only that there is good administration but also that, in the eyes of the citizens, good administration is seen to be done. By failing adequately to respond to the complainant's allegations that (i) some members of the WG were in a conflict of interest because of their links with industry and (ii) a balanced stakeholder representation in external meetings was not ensured, EFSA did not dispel the citizens' impression that there was a potential conflict of interest. This constitutes an instance of maladministration.

No further inquiries are justified with regard to the remainder of the complaint.

The complainant and EFSA will be informed of this decision.



Emily O'Reilly

Done in Strasbourg on 27/03/2014