

Emily O'Reilly European Ombudsman

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Strasbourg, 10/12/2013

Decision of the European Ombudsman closing his inquiry into complaint 622/2012/ANA against the European Food Safety Authority (EFSA)

Dear Dr Then,

On 23 March 2012, acting on behalf of Testbiotech e.V., you submitted a complaint to the European Ombudsman against EFSA concerning the latter's handling of an alleged conflict of interest concerning the Chair of one of EFSA's Scientific Panels.

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

No further inquiries are justified.

I have also made the following further remark:

In line with the accountability culture which the Ombudsman aims to instil in EU institutions in their relations with citizens and civil society, EFSA could consider informing its services that when an error is made, in addition to taking remedial action to correct it, it would be appropriate to acknowledge this error and to apologise for it.

Please find enclosed my decision on your complaint.

Yours sincerely,

Emily O'Reilly

Enclosure:

Decision on complaint 622/2012/ANA



Decision

of the European Ombudsman closing her inquiry into complaint 622/2012/ANA against the European Food Safety Authority (EFSA)

The background to the complaint

- **1.** The present complaint is about EFSA's handling of an alleged conflict of interest concerning the Chair of one of EFSA's Scientific Panels (hereinafter, 'the Chair'). The complainant is Testbiotech, a non-profit organisation that promotes independent research and public debate on the impact of biotechnology¹.
- **2.** By way of background, in December 2010, the complainant forwarded a report that it had prepared to EFSA. The report was entitled 'European Food Safety Authority: A level playing field for the biotech industry: standards for risk assessment massively influenced by industry' (hereinafter, the 'Level-playing field Report')².
- **3.** The Level-playing field Report claims that the International Life Sciences Institute ('ILSI')³, through scientists that have worked for both it and EFSA, has contributed to the shaping of EFSA's practices and procedures, interfering thereby with EFSA's independence.
- **4.** The Level-playing field Report notes that the Chair worked for ILSI since 2000 and had been a Chair of an EFSA Scientific Panel since 2003. The Report observes that, in 2004, the ILSI Task Force published a study which endorsed the concept of 'comparative assessment' for the purposes of assessing the risk of genetically engineered plants. This concept is based on the assumption that genetically engineered plants and conventionally-bred plants are equivalent. In 2004, under the responsibility of the Chair, EFSA adopted the EFSA Guidance Document for the risk assessment of food and feed derived from genetically engineered plants. EFSA's Guidance Document also endorsed the 'comparative assessment' concept⁴. Because of this, the Level-playing field Report contends that EFSA investigates genetically engineered plants less rigorously than if it were assumed that genetic engineering and conventional breeding are basically different. In the complainant's view, the latter assumption is much more plausible from a scientific point of view⁵.

¹ http://www.testbiotech.org/en

² http://www.testbiotech.de/sites/default/files/EFSA_Playing_Field_of_ILSI.pdf

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

Level playing field Report, p. 6.

⁵ Level playing field Report, p. 2.



- **5.** The Level-playing field Report reached the conclusion that there is evidence that the work of EFSA's Scientific Panels "has, to an alarming degree, been impacted by the vested interests of industry".
- **6.** By letter dated 17 December 2010, EFSA disputed the accuracy of the Level-playing field Report with regard to both (a) EFSA's scientific approach in assessing the safety of genetically modified plants and (b) the processes in place to ensure the independence of its scientific advice.
- 7. Specifically, as regards (a), EFSA argued that its scientific approach in the risk assessment of genetically modified plants is widely accepted by international organisations such as the Food and Agriculture Organisation, the World Health Organisation, the Codex Alimentarius Commission and the Organisation for Economic Co-operation and Development. EFSA informed the complainant about a consultative workshop it was planning on the choice of comparators for genetically modified risk assessment and invited it "to join us on this occasion and participate in this important scientific discussion and opportunity to further your own understanding of how EFSA carries out its risk assessment work in this area".
- **8.** As regards (b), EFSA drew the complainant's attention to "the rigorous procedures and processes in place at EFSA to ensure the high quality and independence of its scientific advice. EFSA has very stringent policies in place to allow it to anticipate, prevent and proactively manage any potential conflicts of interest in relation to its scientific work. However, the Authority is never complacent in this area and is currently working on an overall policy on independence-building on the key pillars which support our independence today including our existing policy on declarations of interest, our current rules on the selection of experts and the legally prescribed collective decision making of panels."
- **9.** In February 2012, the complainant forwarded to EFSA another report entitled 'Conflicts on the menu: A decade of industry influence at the European Food Safety Authority (EFSA)' by Corporate Europe Observatory and earthopensource, February 2012 (hereinafter, the 'Conflicts on the menu Report')⁶.
- **10.** The Conflicts on the menu Report identifies a number of alleged flaws in the manner in which EFSA has been set up and which, in the opinion of the authors, hinder it from achieving its main objective, namely, to ensure that Europe's food is safe⁷.
- **11.** Besides concerns of a general nature, the Conflicts on the menu Report suggests that EFSA's relations with the industry and industry-sponsored bodies have affected EFSA's independence on two levels:
- (1) <u>Science</u>: when carrying out the risk assessment of potentially hazardous products, EFSA follows industry-sponsored protocols and methodology, notably the Good Laboratory Practice ('GLP'), while disregarding independent peer-reviewed research. According to the study, ILSI plays a central role in promoting this "grey literature".
- (2) <u>Conflicts of interest and revolving doors</u>: the Report observes that members of EFSA's Management Board and of its Scientific Panels work for EFSA on a

⁶ http://www.corporateeurope.org/sites/default/files/publications/Conflicts_%20on_the_menu_final_0.pdf

⁷ http://www.efsa.europa.eu/



voluntary basis. When not working for EFSA, they work either for the industry or for industry-sponsored bodies. This, in the authors' view, creates a conflict of interest which EFSA failed adequately to address. The authors took the view that EFSA's revised rules are inadequate to address such conflicts of interest⁸. As regards EFSA's staff members, the Conflicts on the menu Report refers to instances of 'revolving doors' at EFSA, one of which has been the subject of a complaint to the Ombudsman⁹.

- **12.** In its reply of 15 February 2012 that was posted on its website¹⁰, EFSA resolutely rejected the contents of the Conflicts on the menu Report in relation to both the scientific approach it follows and its independence.
- **13.** On 21 March 2012, the complainant lodged the present complaint with the Ombudsman. The complainant enclosed both Reports and, focusing on the Chair of EFSA's scientific panel here concerned, stated that, although it was expected that the Chair's term at EFSA was going to end in the coming weeks¹¹, it was necessary that a proper analysis of the case be carried out so as to find out whether EFSA failed to act properly and, if so, what kind of actions needed to be taken to avoid similar conflicts of interest in the future.

The subject matter of the inquiry

14. The Ombudsman opened an inquiry into the following allegation and claims:

Allegation:

EFSA failed to address the conflict of interest concerning the Chair of one of its scientific panels.

Claims:

- (1) EFSA should acknowledge that it failed to address the conflict of interest concerning the Chair of one of its scientific panels.
- (2) EFSA should implement effective measures to prevent similar conflicts of interest in the future.

^{8 (}a) Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority, 15 March 2012, available at

http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf, (b) Decision of the Executive Director implementing EFSA's Policy on Independence and Scientific Decision-Making Processes regarding Declarations of Interests, 21 February 2012, available at

http://www.efsa.europa.eu/en/keydocs/docs/independencerules.pdf. It should be noted that the new policy builds upon (c) EFSA's Policy On Declarations Of Interests, September 2007, available at http://www.efsa.europa.eu/en/keydocs/docs/doipolicy.pdf, (d) the Implementing Act to the Policy on Declaration of Interests Guidance Document on Declarations of Interest, September 2009, available at http://www.efsa.europa.eu/en/keydocs/docs/doiguidance.pdf, and (e) the Implementing Act to the Policy on Declaration of Interests Procedure for Identifying and Handling Potential Conflicts of Interest, September 2009, available at http://www.efsa.europa.eu/en/keydocs/docs/doiconflicts.pdf.

⁹ Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA against the European Food Safety Authority (EFSA), available at

http://www.ombudsman.europa.eu/cases/decision.faces/en/50246/html.bookmark

http://www.efsa.europa.eu/en/edinterviews/docs/corporateceoearthopensource120215.pdf

¹¹ See, Article 1(3) of EFSA's Management Board Decision of 17 December 2009 concerning the establishment and operations of the Scientific Committee, Scientific Panels and of their Working Groups.



- 15. When opening the inquiry, the Ombudsman drew EFSA's attention to the fact that the present complaint spans almost 9 years and that the complainant argued that EFSA had failed to address the question of conflict of interest at different stages. The Ombudsman considered that it would not be useful to extend the inquiry to the entire 9-year period for the following reasons: (a) although the EFSA Regulation¹² and the principles of good administration apply throughout, EFSA's internal rules which are currently in place and which govern the independence of scientific panel members apply since 2009; (b) the complainant drew EFSA's attention to the alleged maladministration concerned in December 2010; and (c) focusing the inquiry is in the interest of the efficient handling of the matter by the Ombudsman. In light of the above, the Ombudsman decided that the present inquiry should be limited to the manner in which EFSA handled the alleged conflict of interest in relation to the Chair's last term from 2009 to 2012.
- **16.** On a further point, the Ombudsman noted that, although the present inquiry only concerned the complainant's allegation and claims against EFSA, the interests of a third party, the Chair, were also involved. Although the complainant requested that its complaint be dealt with publicly, the Ombudsman has the power to declare a complaint confidential on her own initiative, in order to protect the interests of a third party¹³. However, the Ombudsman decided not to exercise this power in the present case, because it is in the public interest that the complaint should be dealt with transparently and, in any event, the complainant had already given publicity to the complaint. To address the issue of protecting the interests of the Chair, the Ombudsman asked EFSA to ensure that its opinion on the complaint takes account of any views that the Chair may wish to express regarding the complaint.

The inquiry

- 17. On 19 April 2012, the Ombudsman asked EFSA for an opinion on the complainant's allegation and claims. On 27 July 2012, EFSA sent its opinion, which was forwarded to the complainant for observations. On 17 August 2012, the complainant submitted its observations.
- **18.** On 27 February 2013, the Ombudsman informed EFSA and the complainant that it was necessary to inspect all relevant documents held by EFSA. On 16 May 2013, the Ombudsman's services inspected EFSA's file on the complaint. On 31 May 2013, the Ombudsman forwarded a copy of the report on the inspection to the complainant with an invitation to submit observations by 30 June 2013. The complainant did not submit any observations on the inspection report.

Regulation (EC) No 178/2002 of the European Parliament and of the Council of 28 January 2002 laying down the general principles and requirements of food law, establishing the European Food Safety Authority and laying down procedures in matters of food safety, OJ 2002, L 31, p. 1. ¹³ Article 10.1 of the European Ombudsman's Implementing Provisions, available at:

http://www.ombudsman.europa.eu/resources/provisions.faces.



The Ombudsman's analysis and conclusions

Preliminary remarks

Admissibility

- **19.** In its opinion, EFSA argued that the information about the Chair's relations with ILSI were declared in his Declarations of Interest ('DoIs') since 2003 and were available on EFSA's website since 2008. The complainant lodged the present complaint with the Ombudsman in 2012. Consequently, EFSA argued that the complaint is inadmissible in accordance with Article 2(4) of the Ombudsman's Statute which provides that "a complaint shall be made within two years of the date on which the facts on which it is based came to the attention of the person lodging the complaint" and should, therefore, be rejected.
- **20.** Moreover, EFSA also argued that the allegation is generic and, therefore, does not allow EFSA to defend itself.
- **21.** In its complaint, the complainant argued that it only became aware of the issue in 2010 within the context of the research that it carried out for the purposes of the 'Level-playing field Report'.
- **22.** In determining the point in time when the 2-year time-limit enshrined in her Statute starts to run, the Ombudsman considers that the relevant provision places emphasis on when the person lodging the complaint became aware of the facts on which it is based rather than from when the facts were publicly available. According to its statement, the complainant became aware of the facts underpinning the complaint in December 2010. There is nothing to suggest that this statement is incorrect. It follows that the complaint is admissible. In the letter of 27 February 2013 informing EFSA about the inspection and addressing its inadmissibility objection, the Ombudsman explained that, even if EFSA's objections had been accepted, the present inquiry would have been continued on the Ombudsman's own initiative, since it is in the public interest to clarify the issues that have been raised.
- **23.** As regards EFSA's argument that the allegation is generic, the Ombudsman understands the complainant's grievances to concern EFSA's handling of the alleged conflict of interest of the Chair and the latter's relations with ILSI. She considers the complainant's allegation to be sufficiently precise to enable EFSA to defend itself and the Ombudsman to carry out an examination of the complaint.

Scope of the inquiry

- **24.** As mentioned above, in the letter opening the present inquiry, the Ombudsman decided to examine the complainant's allegation only in relation to the last term of the Chair from 2009 to 2012.
- **25.** In response, by letter dated 4 May 2012, the complainant informed the Ombudsman that the reason for its complaint was the Chair's ties with ILSI in 2003-2004, when he was first appointed as Chair whilst still working as part of

¹⁴ Available on the Ombudsman's website at http://www.ombudsman.europa.eu/resources/statute.faces#hl1



the ILSI Task Force. Consequently, the complainant also wanted to know how EFSA dealt with the alleged conflict of interest during that period of time.

- **26.** On 29 May 2012, the Ombudsman replied to this letter, reiterating that it was appropriate to examine the alleged conflict of interest in this case with reference to the most recent term of the scientific panel and in light of the internal rules currently in place, rather than the rules dating back to 2003 which were no longer in force. This approach also took into account that the alleged conflict of interest was only brought to EFSA's attention in December 2010.
- 27. In its observations on EFSA's opinion, the complainant argued that EFSA's risk assessment of genetically engineered plants was still based on a concept developed under the responsibility of the Chair. The complainant argued that the decisions taken by the scientific panel in question from 2003 to 2012, including its basic concept of risk assessment, should be re-evaluated. A proper evaluation of the role of the Chair over the whole period from 2003 to 2012 was also of crucial importance for EFSA's new internal rules on independence. The case involving the Chair should be investigated fully to make it possible to draw informed conclusions regarding other potential conflicts of interests, now and in future. In light of this, the complainant urged the Ombudsman to examine the case in full depth and not to limit the investigation only to the period from 2009 to 2012.
- **28.** In the letters in which the Ombudsman informed EFSA and the complainant of the decision to inspect EFSA's file, the Ombudsman also pointed out that the question whether it was necessary to extend the scope of the inquiry would be addressed after the documents on EFSA's file had been inspected.
- **29.** Having carefully examined both the Level-playing field Report and the Conflicts on the menu Report as well as the complainant's submissions, the Ombudsman understands that the complainant invited her to extend the temporal scope of her inquiry on the ground that a finding of maladministration concerning EFSA's handling of the alleged conflict of interest in 2003-2004 would: (a) establish that EFSA's guidelines for risk assessment for genetically modified organisms were flawed and, hence, all decisions of the scientific panel in question were also flawed and needed to be re-evaluated, and (b) help draw useful lessons about handling potential conflicts of interest in the future. In this context, the complainant mentioned EFSA's decision to extend the contract of another Scientific Panel member, which would be assessed under the new rules.
- **30.** Before addressing the relevant issue, the Ombudsman considers it necessary to reiterate 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 in cases where EFSA's approach could give rise to the impression that it failed properly to identify and assess a possible conflict of interest in helping EFSA 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, 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

¹⁵ http://www.efsa.europa.eu/

¹⁶ Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA, at paragraph 60 (see footnote 9 above).



the rules and procedures in place so that any such instances of maladministration do not occur again in the future.

- **31.** It is on this basis that the complainant's additional arguments in support of extending the scope of the inquiry must be examined. As regards point (a), it is useful to point out that the material scope of the inquiry is limited, on the basis of the contents of the complaint that the complainant had submitted, to examining how EFSA handled an alleged conflict of interest in the present case. The Ombudsman's inquiry does not extend to any assessment of the scientific advice emanating from the Scientific Panel in question. This would not be otherwise if the Ombudsman were to include the period prior to 2009 in the inquiry. If the complainant considered that EFSA's guidelines for risk assessment for genetically modified organisms and, as a consequence, all decisions of the Scientific Panel in question were flawed, it would therefore have had to submit a separate complaint to the Ombudsman within a period of two years upon learning of these guidelines and decisions.
- **32.** As regards (b), it is important to recall that it was only in 2010 that EFSA's attention was drawn to the conflict of interest that allegedly occurred in 2003-2004, that is, 7 years later. It should be noted that EFSA's rules on independence had changed three times in the meantime¹⁷. The currently applicable legal framework concerning the monitoring and evaluation of conflicts of interest is significantly different from the one applicable in 2003 and, as the Ombudsman had already the opportunity to note, sufficiently robust¹⁸. The Ombudsman is therefore not convinced, in light of the new framework, that useful lessons could be learnt by examining the allegation under the old rules.
- **33.** It should also be pointed out that, in its observations, the complainant argued that the manner in which the Chair's DoIs had been screened by EFSA might have been influenced by the allegedly close relations between the Chair of EFSA's scientific panel and the Head of the corresponding Unit. While the complainant admitted that this was "only speculative", it nonetheless encouraged the Ombudsman to examine the documents held be EFSA that might shed some light on how the issue had been discussed internally.
- **34.** The Ombudsman underlines that her services carried out an inspection of EFSA's file that covered all documents on EFSA's handling of the alleged conflict of interest in question, that is, not only documents from the period between 2009 and 2012 but also documents from the period from 2003 to 2009. The inspection revealed that EFSA had carried out an assessment of the Chair's DoIs and kept a detailed record of that assessment. Without going into the details of EFSA's assessment, it should be noted that there was no indication that EFSA did not comply with the rules in force at the time.
- **35.** In light of these considerations, the Ombudsman confirms that it would not be useful to extend the present inquiry beyond the last term of the Chair's mandate, that is, from 2009 to 2012.

¹⁷ In 2004, EFSA adopted a Code of Conduct and a Guidance document on declarations of interest. In 2007, EFSA adopted a new policy on Independence and its Implementing Acts, the latter having been amended in 2009. In 2012, these policies were replaced by the currently applicable rules. For more detail and links to the texts available on EFSA's website, see above at footnote 6.

¹⁸ Decision of the European Ombudsman closing his inquiry into complaint 775/2010/ANA, cited above.



A. Allegation that EFSA failed to address the conflict of interest concerning the Chair of one of its scientific panels and the related claims

Arguments presented to the Ombudsman

- **36.** In its complaint, the complainant alleged that EFSA failed to take appropriate steps to avoid the conflicts of interest resulting from the Chair's appointment to one of EFSA's scientific panels.
- **37.** As regards the applicable legal framework, the complainant referred to EFSA's policy on the handling of conflicts of interest¹⁹ and the OECD definition of 'conflict of interest'²⁰. It argued that, on the basis of the OECD's definition, the Chair's involvement in ILSI constituted a conflict of interest and he should have refrained from being a candidate for this role. Given that the alleged conflict of interest involved the Chair of a scientific panel, the complainant argued that, in accordance with EFSA's rules, a separate assessment was required.
- **38.** Moreover, the complainant expressed its dissatisfaction with the fact that EFSA did not take any steps when the Level-playing field Report was published. It noted that the only thing that happened was a change in the Chair's Annual DoI. While in October 2010 the Chair's DoI reported that his affiliation with ILSI was ongoing from 2000 "till now", the DoI that was made available in March 2012 reported that the affiliation with ILSI had stopped in 2005. The complainant enclosed both DoIs and stated that, in its view, even if the information provided in the second DoI were to be correct (which the complainant considered doubtful), it remained evident that "there was a conflict of interest in his first years at EFSA and that this should have been acted upon by the EFSA management."
- **39.** In its opinion, EFSA first outlined the role and functions of the Scientific Panel in question. It then identified as applicable rules the EFSA Policy on Declarations of Interests of 2007 and the Implementing Act of September 2009. EFSA pointed out that, before the adoption of the new legal framework in 2012, the definition of conflict of interest endorsed by the OECD did not apply to its administrative processes. It argued that its conduct should be assessed exclusively with reference to its own rules and applicable framework.

¹⁹ Implementing Act to the Policy on Declaration of Interests Procedure for Identifying and Handling Potential Conflicts of Interest (see footnote 8).

²⁰ The complainant refers to the following definition of conflict of interest which was provided in 'Bribery in Public Procurement: Methods, Actors and Counter-Measures', (OECD, 2007), available at http://stats.oecd.org/glossary/detail.asp?ID=7206, and states: "Conflict of interest occurs when an individual or a corporation (either private or governmental) is in a position to exploit his or their own professional or official capacity in some way for personal or corporate benefit". Importantly, EFSA adopts the same definition of conflict of interest in its Policy on Independence and Scientific Decision-Making Processes of the European Food Safety Authority, 15 March 2012, available at http://www.efsa.europa.eu/en/keydocs/docs/independencepolicy.pdf, at p. 11. It should be pointed out, however, that the 'Recommendation of the Council on Guidelines for Managing Conflict of Interest in the Public Service' (OECD, 2003), available at http://www.oecd.org/dataoecd/13/22/2957360.pdf, offers the following definition: "A 'conflict of interest' involves a conflict between the public duty and private interests of a public official, in which the public official has private-capacity interests which could improperly influence the performance of their official duties and responsibilities".



- **40.** On the basis of the above-mentioned rules that were applicable at the time, EFSA argued that the Chair's involvement in "the past [in] a scientific activity as the one described in the Dol ... was not considered a potential conflict of interest". Moreover, according to EFSA, the Chair's involvement with ILSI ended in 2005. "This was indeed precisely the conclusion applied by EFSA to the interest regarding the Chair's scientific contribution to a publication coordinated by ILSI." On a more general level, EFSA dismissed the complainant's comments about the Chair's continuing contacts with ILSI as "generic, unfounded and unmotivated".
- **41.** As regards the requirement to carry out a separate assessment of the role of the Chair of a scientific panel, EFSA argued that it does not contest this and that it, in fact, performed a separate assessment of the Chair's DoI's in accordance with the applicable rules.
- **42.** In response to the complainant's argument that while in October 2010 the Chair's DoI stated that he had an affiliation with ILSI from 2000 "till now", in March 2012 it stated that affiliation had ended in 2005, EFSA argued that it was only in December 2010 that the Chair "updated his Dol regarding the time span of his scientific contribution to two publications drafted under the coordinating auspices of ILSI. In that respect, at EFSA there was never any doubt regarding the fact that the interest in question ended in 2005, as EFSA staff screening the Chair's Dol were familiar with the two scientific papers coordinated by ILSI that represented the outcome of those activities. Indeed, the two scientific papers in question were published by ILSI in 2004 and 2005 respectively. Finally, it should be underlined that the delayed update of [the Chair]'s Dol does not undermine or invalidate in any way the assessment of the interest discussed in this complaint".
- **43.** In the remainder of its opinion, EFSA analysed the new Implementing Rules on Declarations on Interest and summarised the changes these rules had brought about, with an emphasis on the significant investment of resources (IT and human capital) to facilitate the implementation, monitoring and enforcement of the system screening DoIs of its staff and experts. Moreover, EFSA argued that the effective implementation of its procedures for the screening of DoIs had been validated by independent and internal reviews that were performed from 2008 to 2011.
- **44.** In its observations, the complainant argued that it had no reason to believe that the information provided in the Chair's DoI in 2010 was wrong and that his contacts with ILSI stopped in 2005. The complainant therefore asked EFSA to list any contacts between the Chair and ILSI it was aware of.
- **45.** The complainant argued that there was maladministration on EFSA's part not only because of its failure to take action against the conflicts of interest of the Chair of one of its scientific panels from 2003 to 2005, but also because "in the period between 2009 and 2012 when strong criticism emerged about the role [the Chair] and his contacts with ILSI... EFSA simply waited until the end of [the Chair]'s term and did not engage in a detailed re-evaluation of the work of the [...] panel during the time [he] acted as Chair".

The inspection of documents

46. The inspection carried out by the Ombudsman's services concerned documents falling within the following categories: (a) the Chair's Annual Declarations of Interest (ADoI), Specific Declarations of Interest (SDoI) and Oral Declarations of Interest (ODoI) from 2009 to 2012; (b) documents relating to the manner in which EFSA applied its internal rules to the screening of the Chair's



ADoIs, SDoIs, ODoIs from 2009 to 2012; and (c) any available documents concerning possible official contacts between the Chair and ILSI from 2009 to 2012. In addition, to help elucidate the Ombudsman's analysis of the procedures that EFSA had applied previously and to enable her to decide whether to extend the scope of the inquiry, the inspection also covered (d) all documents on issues (a) to (c) from 2003 to 2009. Furthermore, the Ombudsman asked EFSA to allow her services to inspect (e) any internal document or record, if available, of EFSA's assessment of the Chair's alleged potential conflict of interest, in particular, following the publication of the Level-playing field Report in December 2010.

47. The Ombudsman's representatives thoroughly examined the documents mentioned under (a), (b) and (d) above. The inspection revealed that the Chair's ADoI for 2010 was indeed amended in November 2010 to report that the scientific collaboration with ILSI had ended in 2005. In relation to (c), no documents were identified other than a letter from the Chair of 19 March 2013 confirming that he had not collaborated with ILSI since 2005. In relation to (e), there was no document other than EFSA's letter to the complainant of 17 December 2010 that is mentioned in paragraphs 6-8 above.

The Ombudsman's assessment

- **48.** The complainant's main contention is that, because of the Chair's affiliation with ILSI, there was a conflict of interest which EFSA failed to address. In its opinion, EFSA argued that there was no scientific collaboration between the Chair and ILSI since 2005, that the Chair had revised his ADoI for 2010 to reflect this and that, in any event, that collaboration was not considered as giving rise to a conflict of interest. In its observations, the complainant disputed EFSA's assessment of the existence of a conflict of interest and questioned which of the two 2010 ADoIs reflected the true state of affairs in the present case.
- **49.** At the outset, it should be pointed out that the Ombudsman understands that the allegation consists of a substantive and a procedural aspect. The substantive aspect concerns EFSA's conclusion that there was no conflict of interest while the procedural aspect concerns EFSA's handling of the matter of the alleged conflict of interest.
- **50.** In addressing the substantive aspect of the complainant's allegation, it must first be established whether there was scientific collaboration between the Chair and ILSI between 2009 and 2012. In essence, this requires that the complainant's question as to which of the two 2010 ADoIs was the correct one be addressed. The inspection of EFSA's file revealed that, on 29 November 2010, the Chair modified his 2010 ADoI as regards the information on the duration of his affiliation with ILSI. On the basis of the results of the inspection of EFSA's file, the Ombudsman is convinced that EFSA was entitled to rely on the revised ADoI of 2010 and was therefore entitled to take the view that there was no link between the Chair and ILSI during the period concerned that would have given rise to a conflict of interest. In this regard, it should also be noted that the complainant did not submit any specific elements which would call into doubt the contents of the revised ADoI of 2010. Taking into account the fact that the alleged scientific collaboration between the Chair and ILSI from 2009 to 2012 constitutes the thrust underlying the substantive aspect of the complainant's allegation, the Ombudsman considers that the substantive aspect of the complainant's allegation has not been established.



- **51.** As regards the procedural aspect of the allegation, it emerges from the inspection that EFSA carried out a separate assessment of the Chair's DoIs in accordance with the applicable rules. That having been said, it appears clear that EFSA's assessment lacked diligence. Specifically, it should be pointed out that, by EFSA's own admission, it was well known within EFSA that the Chair's involvement in ILSI had ceased in 2005. However, those involved in the screening of the ADoIs in 2009 and 2010 apparently failed to detect that the statement that the Chair had an interest in ILSI was inaccurate on the basis of what, according to EFSA, was common knowledge in it.
- **52.** The Ombudsman considers that it is of cardinal importance to ensure that the Dols made by members of Scientific Panels²¹ and put in the public domain are trustworthy and correct. EFSA's policy on independence and the mechanisms in place, notably the screening of Dols, would be undermined if the screening of Dols is not as rigorous and effective as it could and should be. EFSA's failure to identify the error in the Chair's ADols in 2009 and 2010 demonstrates that the screening that was carried out in the present case did not comply with this requirement.
- **53.** Where the Ombudsman finds maladministration, she has the possibility of making a proposal for a friendly solution or addressing draft recommendations to the institution concerned, in accordance with her Statute, with a view to putting things right. As regards the present case, the Ombudsman notes, however, that the error in the Chair's ADoI for 2010 was already corrected in November 2010. She furthermore recalls that no maladministration could be found as regards EFSA's conclusion that there was no conflict of interest on the part of the Chair during the period under review. In these circumstances, the Ombudsman considers that no further inquiries are justified into the complainant's allegation and the related first claim.
- **54.** It appears useful to add, though, that, on 1 December 2010, the complainant forwarded to EFSA the Level-playing field Report, which suggested that, on the basis of the information available on EFSA's website, the Chair was still collaborating with ILSI. However, in its reply to the complainant of 17 December 2010, EFSA did not address this issue, even though the relevant ADoI had been screened only a couple of days beforehand, that is, on 29 November 2010. Even in the course of the present inquiry EFSA did not properly address this matter. It was only through the inspection carried out by her services that the Ombudsman obtained a better understanding of EFSA's handling of the error in the screening of the Chair's ADoIs and the follow-up action it had taken to remedy this error.
- **55.** It should be underlined that the Ombudsman assigns great importance to EU institutions dealing properly with any mistakes that may have occurred in their administrative practice. This culture of accountability, which the Ombudsman aims to instil in the EU institutions' relations with citizens and the civil society, implies that when an EU institution makes an error, the institution concerned should not only take action to correct it, but also acknowledge the error and apologise for it. In order to help EFSA improve its behaviour in this connection in the future, the Ombudsman will make a corresponding further remark below.

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²¹ Article 37 of the EFSA Regulation (see footnote 12 above).



56. Finally, the Ombudsman recalls that the complainant also claimed that EFSA should implement effective measures to prevent similar conflicts of interest in the future. It should be noted that the complainant's second claim is premised on the presence of a conflict of interest. However, and as explained above, no such conflict of interest was found to exist in the present case. It is true that the procedural handling of the matter by EFSA left room for improvement. The Ombudsman notes, however, that the complainant did not argue that there was a general problem as regards the screening of the DoIs of experts and members of Scientific Panels. In light of the results of the inspection that was carried out by her services, the Ombudsman is led to the conclusion that what happened in the present case should be attributed to a one-off error. It should further be noted that, in the course of the present inquiry, EFSA informed the Ombudsman that it had made considerable investments in terms of both IT and human resources to improve the system for the screening of DoIs in the recent years. In view of the above, the Ombudsman reaches the conclusion that there are no grounds for further inquiries into the complainant's second claim.

57. In light of the above considerations, the Ombudsman considers that there are no grounds for further inquiries into the present complaint. She, therefore, closes the case.

B. Conclusion

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

No further inquiries are justified.

The complainant and EFSA will be informed of this decision.

The Commission, which was informed at the opening of the present inquiry, should also be informed.

Further remark

In line with the accountability culture which the Ombudsman aims to instil in EU institutions in their relations with citizens and civil society, EFSA could consider informing its services that when an error is made, in addition to taking remedial action to correct it, it would be appropriate to acknowledge this error and to apologise for it.

Emily O'Reilly

Done in Strasbourg on 10/12/2013