

Απόφαση στην υπόθεση 437/2015/ZA - Απόφαση της Ευρωπαϊκής Διαμεσολαβήτριας επί της αναφοράς 437/2015/ZA σχετικά με εικαζόμενη σύγκρουση συμφερόντων στο πλαίσιο έργου για την εκτίμηση των κινδύνων γενετικά τροποποιημένων οργανισμών, χρηματοδοτούμενου από την Ευρωπαϊκή Επιτροπή

Απόφαση

Υπόθεση 437/2015/ZA - Εκκίνηση έρευνας στις 15/04/2015 - Απόφαση στις 28/07/2016 - Εμπλεκόμενο θεσμικό όργανο Ευρωπαϊκή Επιτροπή (Μη διαπίστωση κακοδιοίκησης) |

Η Διαμεσολαβήτρια διερεύνησε την υπόθεση και τάχθηκε υπέρ της στάσης της Επιτροπής να μην επεμβαίνει στην επιστημονική ερμηνεία ούτε στη διαδικασία δημοσίευσης των επιστημονικών μελετών που χρηματοδοτεί. Η Διαμεσολαβήτρια κατέληξε επίσης στο συμπέρασμα ότι η ύπαρξη σχέσεων μεταξύ των επιστημόνων που συμμετέχουν στο έργο και του συναφούς κλάδου δεν συνιστά από μόνη της απόδειξη σύγκρουσης συμφερόντων. Η Διαμεσολαβήτρια επεσήμανε ότι η Επιτροπή συχνά χρηματοδοτεί έργα που υλοποιούνται είτε από τον κλάδο είτε από ομάδες που διατηρούν στενούς δεσμούς με αυτόν. Παρόλα αυτά, η Διαμεσολαβήτρια εισηγήθηκε στην Επιτροπή να αποστείλει στον ενδιαφερόμενο μια πιο ολοκληρωμένη και διεξοδική επεξήγηση των λόγων για τους οποίους εκτιμά ότι η ύπαρξη σχέσεων μεταξύ του κλάδου και των επιστημόνων που συμμετέχουν στο έργο GRACE δεν συνιστά περίπτωση σύγκρουσης συμφερόντων.

Η Διαμεσολαβήτρια διαπίστωσε επίσης ότι η Επιτροπή είχε τηρήσει όλες τις νόμιμες διατάξεις όσον αφορά τη δημοσίευση των ονομάτων των εμπειρογνομόνων που συμμετείχαν στην αξιολόγηση και επιλογή των έργων προς χρηματοδότηση από το έβδομο πρόγραμμα-πλαίσιο. Με γνώμονα την περαιτέρω ενίσχυση της διαφάνειας και τη διευκόλυνση της άσκησης δημοσίου ελέγχου, η Διαμεσολαβήτρια συνέστησε στην Επιτροπή να δημοσιεύει στο εξής τα ονόματα των εμπειρογνομόνων που αναλαμβάνουν καθήκοντα αξιολόγησης ανά θεματική ή/και τομέα του εβδόμου προγράμματος-πλαισίου. Η Διαμεσολαβήτρια εισηγήθηκε επίσης τη δημοσίευση των δηλώσεων σύγκρουσης συμφερόντων των αξιολογητών.

The background to the complaint

1. The complaint concerns alleged conflicts of interest and alleged failures to assess scientific information properly in the context of the financing of a project chosen for EU funding under the



European Commission's Seventh Framework Programme (FP7).

2. The project, known as GRACE (Genetically Modified Organisms Risk Assessment and Communication of Evidence), concerned GMO risk assessment [1] . It was chosen for EU funding following a Call launched in 2011.

3. The complainant, a research institute based in Germany, published a report [2] in 2013 pointing to what it considered to be a number of scientific weaknesses in the GRACE project. It also argued that there were possible conflicts of interest involving the GRACE project coordinator and participating scientists.

4. In 2014, the complainant wrote to the Commission complaining about the fact that the Commission had not taken a position on the complainant's 2013 report. Later, it asked the Commission to disclose the names of the experts who had selected the GRACE project for funding.

5. The Commission replied stating that the experts participating in the GRACE project had been selected on the basis of high standards and it saw no reason to question the scientific independence and scientific credibility of the project. The complainant was not satisfied with the Commission's reaction and lodged the present complaint with the Ombudsman on 10 March 2015.

The inquiry

6. The Ombudsman opened an inquiry into the complaint focusing on the following matters: (i) the Commission's alleged failure to address the complainant's concerns about the scientific soundness of the project's results and the independence of the related publication in the journal *Archives of Toxicology* and (ii) the Commission's alleged failures to ensure the objectivity and independence of the GRACE project, in particular full transparency with respect to the experts involved in the selection of the project.

7. In the course of the inquiry, the Ombudsman received the opinion of the European Commission on the complaint and, subsequently, the comments of the complainant in response to the Commission's opinion. In conducting the inquiry, the Ombudsman has taken into account the arguments and opinions put forward by the parties.

(i) Alleged failure to address the complainant's concerns about the scientific soundness of the project's results and the independence of the related publication in the journal

Archives of Toxicology

Arguments presented to the Ombudsman



8. The complainant was not satisfied with the Commission's reply to the points it made concerning the integrity and independence of the peer review process carried out prior to the publication of the GRACE results in a scientific journal, the *Archives of Toxicology*. The complainant argued that the journal's editor had close links to some of the authors of the article and to industry. Thus, it argued, the independence and scientific soundness of the publication was not ensured. In its second letter to the Commission, the complainant insisted that the publication should be withdrawn and that re-publication be considered only after a rigorous peer review process. The complainant also stated that the Commission should ensure that the paper is published in a journal 'not stigmatised' by its questionable cooperation with the biotech industry.

9. The Commission responded that the design and implementation of the GRACE study, as well as the interpretation of the results of the 90-day feeding trials, were put under extensive and open consultation with civil society organisations (including the complainant), industry and other relevant stakeholders. The results had been made publicly available and discussed before publication.

10. Regarding the objectivity of the scientific findings, the Commission maintained that it is for the scientific community to discuss different findings in an open debate. It insisted that it was not for the Commission to interfere in the scientific interpretation or the publication process by questioning or comparing different scientific findings. Any intervention in that respect could be interpreted as a political intervention in a scientific process and would be against the principle of scientific freedom. The same applies to the peer review process preceding the publication in the journal *Archives of Toxicology*. The Commission argued that the publication process is in the hands of the scientists responsible for drafting and publishing the report and that it is not part of its function to take a view on the content of a scientific publication or on the review process prior to publication.

11. The Commission stated that it was aware that, in a letter addressed to the complainant and published on the project's website, the coordinator of the study had addressed point by point the alleged scientific shortcomings identified by the complainant. Moreover, the Commission argued that the scientific debate should be pursued through an appropriate scientific platform, such as the one made available by the journal *Archives of Toxicology* to encourage and facilitate open scientific discussion and appraisal of the GRACE results.

12. The Commission finally argued that the complainant had failed to demonstrate any conflict of interest in the process of publication. It noted that the Chief Editor of the journal had rejected the accusations on his alleged conflict of interest in a letter published in the *Archives of Toxicology*.

13. In its observations, the complainant was not satisfied with the Commission's additional explanation provided in the opinion.



The Ombudsman's assessment

14. The Ombudsman considers that the Commission's opinion has dealt properly with the complainant's concerns. She agrees with the Commission's own view that it is not for it to interfere in the publication, by third parties, of scientific studies which it funds. She also notes that, in any event, the Commission checked whether the GRACE project scientists reacted to the complainant's 2013 Report. The GRACE coordinator had replied point by point to the complainant's scientific criticism while the journal's editor responded to the complainant's allegations concerning lack of independence of the review prior to publication. Moreover, both replies were published on GRACE's webpage.

(ii) Alleged failures to ensure the objectivity and independence of the GRACE project, in particular through ensuring full transparency with respect to the experts involved in the selection of the project

Arguments presented to the Ombudsman

15. The complainant argued that a number of scientists involved in the GRACE project, as well as the project's scientific coordinator, had strong affiliations to entities funded entirely or partly by the biotech industry [3] .

16. The complainant further maintained that, following the publication of its report in April 2013, the Commission failed to carry out sufficient verifications as regards possible conflicts of interest. Therefore, it had not ensured the independence and scientific credibility of the GRACE project. The complainant maintained that, contrary to the interpretation put forward by the GRACE scientists, the complainant's data did indicate some negative health impact in rats fed with genetically engineered maize.

17. The complainant also argued that the Commission's existing practice in this area, regarding publication of the names of expert evaluators, is inadequate from a transparency perspective. In order to ensure full transparency, the Commission should, in the complainant's view, publicly disclose which experts were assigned to evaluate which individual project proposals. Thus, for example, the Commission should publish the names of the expert evaluators who dealt with the GRACE project.

18. In its opinion, the Commission restated its determination to ensure the highest standards possible in all projects it funds. To that end, it selects experts based on international peer reviews. It also ensures regular monitoring of the progress of projects and evaluates their results.

19. On the question of the GRACE project's links to industry, the Commission pointed out that the Call specifically required that applicant projects should have links with existing related



activities and stakeholders, including with industry.

20. The Commission further argued that, as with all FP7 projects, the GRACE project was selected based on international peer review standards, using independent highly qualified experts. It maintained that by using independent external experts, the Commission ensures that the proposals selected for funding are judged impartially and fairly. The experts used to evaluate projects are selected from a database following open calls addressed to both individuals and relevant organisations, such as national research agencies, research institutions and enterprises. Rules provide for the specific selection criteria and abilities to be considered in setting up a pool of experts and assigning them to individual proposals. The experts work in their personal capacity and independently from any organisation [4] .

21. Furthermore, the Commission listed the evaluation and selection criteria that guided the evaluation of the GRACE project [5] . It stated that all legal rules in place, aimed at ensuring the highest standards of independence and excellence, were observed. It stressed that, when appointing an independent expert, the Commission takes all necessary steps to ensure that the expert is not faced with a conflict of interest situation concerning the matter on which the expert is required to provide an opinion [6] .

22. The Commission noted that, according to the relevant rules, a complete list of all experts involved in the evaluation process of each specific programme of the FP7 is published annually [7] . The Commission further noted that there is no obligation to publish the names of experts for each call relating to a project covered by the programme, as this would affect "*their impartiality and integrity, influence their opinion and /or undermine the decision making process*". Based on the aforementioned rules, and in order to respect data protection requirements, the Commission stated that it was not in a position to disclose the names of the experts who had chosen the GRACE project.

23. In its observations, the complainant insisted that the Commission did not give any reassurance as regards the independence of the individual experts who were involved in the evaluation and selection of the GRACE project. It insisted that the experts' names should be disclosed.

24. Furthermore, the complainant maintained that the Commission had failed to address the substance of its allegations on the apparent and hidden conflicts of interest of leading scientists involved in the GRACE project, despite the clear evidence the complainant had provided in its reports and in other written communications with the Commission.

The Ombudsman's assessment

25. The complainant raises two separate issues of alleged conflicts of interest. It argues, *first* , that the persons who selected the GRACE project had conflicts of interest. *Second* , it argues that the scientists involved in the GRACE project had links to industry.



26. The *first* question is whether there was a conflict of interest as regards the experts who chose the GRACE project. The Ombudsman points out that conflicts of interest arise where a **public official** , or a person assisting a public authority in its tasks (such as an independent expert who is providing advice to a public institution), has private interests which conflict with the interests of the public authority concerned. The reason such conflicts of interest must be avoided is because they undermine the independence of the public authority and call into question the objectivity of the decisions the public authority takes.

27. Against this background, the Ombudsman points out that a conflict of interests in relation to the GRACE project could have arisen if, for instance, the particular experts who chose the GRACE project had a connection with an interested party, such as with the biotech industry or with scientists involved in the GRACE project.

28. However there is no evidence in the file that the experts who chose the GRACE project were in a conflict of interest. The complainant's view appears to be that the GRACE project should not have been chosen for funding and that, accordingly, the persons who chose it for funding must have been in a conflict of interest situation. This appears to be no more than an assertion which does not constitute evidence of a conflict of interest.

29. The Ombudsman points out that the Commission publishes the names of all the experts, used by the Commission to evaluate projects, by programme, by theme and by year [8] .The Commission does so proactively since Article 17(5) of Regulation 1906/2006 requires the Commission to publish, once a year, the list of the independent experts who have assisted it in the FP7, organised by programme [9] . The complainant has not suggested however that any person on the relevant annual list [10] had a link to interests which would have excluded him or her from evaluating the GRACE project.

30. In this context, the Ombudsman observes that transparency is the best means of preventing conflict of interest. The more transparent the Commission is as regards naming experts who choose projects, the less likely it will be that conflicts of interest will go undetected. The Ombudsman appreciates that the Commission already publishes the list of experts involved in FP7 projects by theme. The Ombudsman believes that, **for the future**, the Commission could consider publishing the names of those experts who are involved in the evaluation of specific projects by breakdowns that would correspond to FP7's area and/or topic categories. The Ombudsman considers that such a breakdown would still achieve the required balanced mix between transparency and protecting the decision making process as well as the evaluators.

31. The Ombudsman notes that the published FP7 lists include the names of the experts, their title, nationality, their institution, and domain of activity [11] . She suggests that, **for the future and for similar programmes** [12] , the Commission publishes their declarations of interest, too. Such declarations of interests should be sufficiently detailed to allow interested parties to take a view as regards whether a conflict of interest exists in relation to the evaluation of any specific project. In order to avoid any possible difficulties with the need to protect personal data, the experts in question should be alerted in advance that the Commission intends to publish their names and their conflict of interest declarations in the context of the specific Call on which they



will be working.

32. As to whether the Commission should **now** release further information relating to the specific experts who examined the GRACE proposal, the Ombudsman notes that, if it so wishes, the complainant may make a request for public access to the relevant documents, under the access to documents Regulation, that is under Regulation 1049/2001 [13] .

33. As regards the *second* issue, the Ombudsman notes that the Commission frequently funds projects which are carried out by industry or by groups with close links to industry. Indeed such links with industry were required by the Call in question [14] . It follows that in its design, the GRACE project accepts the value of links with industry and that there could, therefore, be a perception of a conflict of interest. Whether there was an unacceptable conflict of interest would depend however on the particular case and on the precise nature of the activity of the industry organisation in question and on the extent of the links between that organisation and one or more of the scientists involved.

34. The Ombudsman notes that most of the research bodies involved in the GRACE project were universities and public research entities [15] . In the Ombudsman's view, the complainant did not provide substantiated evidence to show that any unacceptable conflict of interest existed.

35. However, the Ombudsman believes that whenever any suspicion is voiced regarding the independence of the scientists involved in an EU funded project, the Commission needs to be proactive in its response. Its response in such a situation should be thorough, complete and based on all the facts. Any failure to respond in this way could have the effect of undermining the legitimacy of the Commission, as the funder of the project, as well as undermining the scientific output itself. This is even more the case where, as in the GRACE project, scientific results are expected " *to support EU risk assessors and EU policy makers by providing scientific evidence and scientific recommendations regarding the EU risk assessment process and generally on the outcome of research on the biosafety of GMOs*" [16] . In the present case, the Commission failed to respond to the complainant's concerns as thoroughly and as comprehensively as would be desirable.

Conclusion

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

The Ombudsman finds no maladministration by the Commission.

The complainant and the Commission will be informed of this decision.

Suggestions for improvement



1. In the light of the Ombudsman's findings in paragraph 35 the Commission should consider sending the complainant a fuller and more thorough explanation of why it takes the view that the links between industry and the GRACE scientists do not create conflict of interest situation.

2. Subject to relevant provisions on the processing of personal data and commercial confidentiality, the Commission should consider, in order to better fulfil the transparency objective prescribed by the legislature, publishing the names of experts evaluating projects by breakdowns that would correspond to the topic and/or area categories of the FP7. Moreover, the publication of the lists of experts should be accompanied by their declarations of interests.

Emily O'Reilly

European Ombudsman

Done in Strasbourg 28/07/2016

[1] For further details see: <http://www.grace-fp7.eu/en/content/grace-brief> [Σύνδεσμος]

[2] Link to the report:

http://www.testbiotech.org/sites/default/files/Testbiotech_Doubts_%20EU_Research_Project_GRACE_2.pdf

[3] The complainant referred particularly to the International Life Science Institute (ILSI) and the International Society for Biosafety Research (ISBR). See respective links:

<http://www.ilsa.org/Pages/HomePage.aspx> [Σύνδεσμος] and <http://isbr.info/> [Σύνδεσμος] The complainant also referred to a GRACE member working for Monsanto.

[4] Commission Decision 2011/161/EU

[5] "*Scientific and technological excellence and relevance to the objectives of the specific programme; the potential impact through the development, dissemination and use of project results; the quality and efficiency of the implementation and management*".

[6] The involvement of independent experts in the evaluation of FP7 proposals submitted to the Commission, such as the GRACE project, is governed by Regulation 1906/2006 and Commission Decision 2011/161/EU, Euratom. Article 17 of the Regulation and point 3 of the Commission Decision delineate the role of the external experts, the procedure for their selection, as well as the means for achieving a high level of expertise as well as avoiding conflict situations. In particular, Article 17(3) of the Regulation requires the Commission to "*take all necessary steps to ensure that the expert is not faced with a conflict of interests in relation to the matter on which the expert is required to provide an opinion*". To achieve that objective, the selection is based on prearranged objective criteria, while the selected experts are required to sign a declaration of no conflict of interest at the time of their appointment (a reconfirmation is



required at the end of each evaluation exercise) and to inform the Commission if such a conflict arises in the course of their duties

[7] Regulation (EC) No 1906/2006 of the European Parliament and of the Council of 18 December 2006 laying down the rules for the participation of undertakings, research centres and universities in actions under the Seventh Framework Programme and for the dissemination of research results (2007-2013), Article 17(5) " *The Commission shall publish once a year in any appropriate medium the list of the independent experts that have assisted it for the Seventh Framework Programme and each specific programme* ". See also paragraph 29 and footnote 8 below.

[8] http://ec.europa.eu/research/participants/portal/desktop/en/funding/reference_docs.html#fp7
[Σύνδεσμος]

The FP7 Cooperation programme under which GRACE project was funded comprised 11 themes (GRACE was funded under theme 2). For each theme there exist seven lists of experts, namely one per year (2007-2013). The annual lists setting out the names of the experts, their nationality, their institution, and domain of activity comprises, on average, 250 names.

[9] See footnote 7.

[10] [Cooperation Programme, Food, Agriculture and Fisheries, and Biotechnology Theme, Expert list KBBE 2012](#). [Σύνδεσμος]

[11] The Horizon 2020 experts' lists are more informative as they include information on: most recent employer, most recent employer's city, skills and competences.

[12] As is the on-going Horizon 2020.

[13] In the *Bavarian Lager* case the Court of Justice ruled that when a request for access to documents containing personal data is made, the Data Protection Regulation 45/2001 becomes fully applicable. Article 8(b) of Regulation 45/2001 lays down two cumulative conditions to which the transfer of personal data is subject. Personal data may be transferred only (a) if the recipient establishes the necessity of having the data transferred, and (b) if there is no reason to assume that that transfer might prejudice the legitimate interests of the data subject. The foregoing judgement requires the Commission to carry out the balancing test between the various interests of the parties concerned (including requiring the recipient of personal data to establish the need for their disclosure, so called 'necessity test').

[14] This was in fact a core objective of the research projects financed under theme 2 of the FP7. The Call itself clearly indicated that the involvement of industry in the projects it is strongly encouraged and " *linking up with ongoing/existing activities in the area of GMO research would be considered* ". In this context, the Call included a number of research institutions or organisations that were considered as important players in this research field and with which candidate consortiums could potentially collaborate or share expertise.



[15] The GRACE consortium comprises of eighteen participants (e.g. universities, public research institutes, one international non-profit research organisation, organisations for dissemination of knowledge; federal research institutes etc.) from thirteen countries.

[16] [Work Programme 2012, Cooperation, Theme 2, Food, Agriculture and Fisheries, and Biotechnology, page 62 \[Σύνδεσμος\]](#).