

Cinneadh i gcás 1830/2017/SRS maidir leis an gcaoi a roghnaíonn Coiste Eolaíoch an Choimisiúin Eorpaigh um Rioscaí Sláinte agus Comhshaoil agus Rioscaí atá ag Teacht chun cinn (SCHEER) saineolaithe seachtracha chun comhairle eolaíoch a chur ar fáil

Cinneadh

Cás 1830/2017/SRS - **Tosaithe an** 23/04/2018 - **Cinneadh an** 08/02/2019 - **Na hinstiúidí lena mbaineann** An Coimisiún Eorpach (Ní bhfuarthas drochriarachán) | An Coimisiún Eorpach |

Bhain an cás seo leis an gcaoi a ndearna Coiste Eolaíoch an Choimisiúin Eorpaigh um Rioscaí Sláinte agus Comhshaoil agus Rioscaí atá ag Teacht chun cinn (SCHEER) saineolaithe a roghnú chun páirt a ghlacadh i meitheal, a dhréachtaigh tuairim faoin úsáid a bhaintear as príomhaigh neamhdhaonna i dtaighde.

D'áitigh an gearánach nach raibh an nós imeachta chun na saineolaithe a roghnú trédhearcach agus nach raibh iolracht tuairimí laistigh den mheitheal á háirithiú ag an gCoimisiún. D'áitigh sé, go háirithe, nach raibh líon suntasach saineolaithe ar na roghanna malartacha do phríomhaigh neamhdhaonna i dtaighde páirteach sa mheitheal.

Chinn an tOmbudsman nár sháraigh SCHEER an rogha leathan a bhí aige maidir le saineolaithe a roghnú sa chás seo agus go raibh an próiseas sách trédhearcach. Chinn an tOmbudsman, dá bhrí sin, nach raibh aon drochriarachán i gceist.

Background to the complaint

1. The complaint, submitted by a UK organisation that campaigns for the abolition of all animal experiments, is about how the European Commission ensures that experts for working groups of the Scientific Committee on Health and Environmental and Emerging Risks (SCHEER) are selected in an impartial and transparent manner.

2. SCHEER is a 'scientific committee' [1] that provides independent scientific advice to the Commission on questions concerning health, environmental and emerging risks. [2]

3. In 2008, the Commission asked SCHEER for an opinion on the use of non-human primates



(NHPs) in research. The opinion, issued in 2009, concluded that, from a scientific point of view, the use of NHPs was essential for scientific progress in a number of important areas of disease research and safety testing.

4. Following a complaint [3] , the Ombudsman made a recommendation that the Commission should modify its rules concerning scientific committees. The Commission agreed to require the publication of a call inviting experts to express their interest with the aim of identifying the best possible candidates for working groups of its scientific committees.

5. In 2016, the Commission asked SCHEER to update the 2009 opinion [4] , following the adoption of new EU rules on animal testing [5] . On 8 June 2016, SCHEER launched the process to seek applications from external experts (the call for experts) to take part in a working group on NHP testing (the NHP Working Group). [6]

6. On 18 May 2017, SCHEER adopted the final opinion on the need for NHPs in biomedical research, production and testing of products and devices. [7]

7. On 13 October 2017, the complainant turned to the European Ombudsman.

The inquiry

8. The Ombudsman opened an inquiry into: how the members of the NHP Working Group were selected; the alleged failure to ensure a plurality of views in the NHP Working Group; and the alleged lack of transparency concerning the assessment of candidates.

9. In the course of the inquiry, the Ombudsman received the Commission's reply to her request for information and, subsequently, the complainant's comments on the Commission's reply.

How the members of the NHP Working Group were selected

Arguments presented to the Ombudsman

10. The complainant claimed that the selection criteria applied by the Commission [8] did not correspond to the criteria set out in the call for experts in two ways. The criteria applied by the Commission (a) imposed an additional requirement that experts should be "*currently working with NHPs*", and (b) did not reflect a criterion in the call for experts on the need for expertise in the field of ethics relating to the use of NHPs.

11. By requiring that experts be *currently* working with NHPs, the Commission excluded all experts who no longer work with NHPs, and those who had never worked with NHPs. The complainant argued that experts who are currently working with NHPs may be more inclined to



take the view that NHP research is necessary and should continue. It argued that, as a result, they are biased in favour of research using NHPs. In addition, selecting only experts currently working with NHPs could also breach the requirement that the working group must be balanced.

12. In its reply, the Commission stated that the external experts were selected, first, from the SCHEER reserve list and, then, based on the call for experts. According to the applicable rules [9], the European Medicines Agency nominated one external expert, and the Commission nominated two experts from the reserve list and five from the call for experts. Those selected were chosen above other candidates on the list because they had more experience or because preference was given to other candidates with equivalent expertise in order to achieve geographical or gender balance, in line with the applicable rules.

13. The Commission stated that it had received 42 applications. In order to keep the size of the working group manageable, priority was given to applicants with expertise in three main areas: (a) fundamental research involving NHPs and pre-clinical studies using NHPs; (b) alternative methods in biomedical research and testing products and devices aiming to replace, reduce and refine methods using NHPs; and (c) animal welfare/animal protection, especially in relation to NHPs. In the Commission's view, this combination prevented any bias.

14. The Commission also stated that, contrary to the complainant's assertion, one of the seven appointed experts had expertise in ethics.

15. In its comments on the Commission's reply, the complainant stated that the Commission failed to address the differences between criteria used for assessment and those in the call for experts, notably as regards "*current*" expertise. It had also not explained the specific expertise of each candidate, but merely referred to their online CVs.

16. According to the complainant, the call for experts implied that expertise in animal welfare was a criterion that should be independent of any current expertise in NHP research. The complainant restated its view that none of the experts selected had any expertise in animal welfare and ethics.

The Ombudsman's assessment

17. Scientific committees, such as SCHEER, play an important role in ensuring that the Commission obtains the necessary scientific advice to carry out its duties correctly. [10]

18. In the context of a previous inquiry [11], the Ombudsman found that committees have a broad margin of discretion in identifying (i) their needs in relation to assistance from external experts and (ii) the most appropriate experts to provide that assistance. In deciding to consult and select external experts, SCHEER has to make scientific assessments of its needs, and of whether experts who apply meet those needs. [12] It should not be influenced by a desire to obtain a pre-determined outcome. [13] These findings also apply to this case.



19. Specifically, SCHEER had a broad margin of discretion in determining whether the expertise of applicants corresponded to the criteria in the call. SCHEER's decision is open to review only if it made a manifest error in how it exercised its discretion. The terms of the call constitute the assessment framework for the evaluation of applicants.

20. In this case, the complainant takes issue with two alleged discrepancies between the criteria for assessing the applications, listed in the 'note to the file', and those set out in the call for experts.

21. The Ombudsman finds that the fact that the criteria used to assess the applicants clarified that experts should have "*current*" experience did not result in SCHEER exceeding its broad margin of discretion. The Ombudsman finds it reasonable that, *to update* an opinion from 2009, SCHEER would favour experts not just with knowledge of the use of NHPs in research, but also with "*current*" experience and knowledge of the latest scientific advances in the use of NHPs.

22. The Commission explained that, in order to keep the NHP Working Group to a manageable size, SCHEER prioritised applicants with expertise in multiple areas. Thus, it did not only select those with current work experience with NHPs, but also with expertise in alternative methods and animal welfare, especially in relation to NHPs. The Ombudsman considers that, in doing so, SCHEER adopted a reasonable approach, reconciling the need for the NHP Working Group to work efficiently with the requirement that it should be balanced.

23. Furthermore, as the Commission stated, one of the researchers selected as an external expert includes *expertise in ethics* on his CV.

24. Therefore, the Ombudsman finds no maladministration concerning this issue.

Failure to ensure a plurality of views in the NHP Working Group

Arguments presented to the Ombudsman

25. The complainant argued that the overriding purpose of asking SCHEER for an opinion was to determine when research involving NHPs could be replaced with alternative approaches (*replacement*), and not how to ensure that it causes less suffering to NHPs (*refinement*). [14] The complainant claimed that only one expert has any experience in the 'replacement' of NHPs in research, while three others have experience in 'refinement'. Moreover, since the selection process focused only on experts with current expertise in NHP research, SCHEER was failing to ensure a plurality of views, as it was obliged to do. Finally, none of the members of the NHP Working Group appears to work or have links to animal protection organisations.

26. The Commission contended that SCHEER's work is of a strictly scientific nature and should not be confused with stakeholders' consultations, where different views are represented. To



inform the NHP Working Group's assessment, SCHEER had organised a 'call for information', a public hearing and a public consultation to which any scientist or organisation could have submitted scientific evidence. The NHP Working Group had taken this evidence into account, and several scientific articles submitted by the complainant through these procedures were included in the final opinion.

27. The Commission acknowledged, on the other hand, that the composition of the working group needed to be balanced in that SCHEER had to ensure that all fields of expertise relevant to the mandate of a working group are covered. It was also required to avoid any conflicts of interest, and, as far as possible, guarantee gender and geographical balance.

28. In this case, the external experts were selected based on their scientific excellence in the fields of expertise needed to produce the requested scientific opinion. The Commission stated that three out of seven members of the working group had specific expertise on the replacement of NHPs in research. The names and affiliations of the members of the NHP Working Group were published online, together with their declarations of interests, when the opinion was adopted.

29. In its comments on the Commission's reply, the complainant also took issue with SCHEER's decision to accept the external expert nominated by the European Medicines Agency (EMA), while it had not asked the European Centre for the Validation of Alternative Methods (EURL ECVAM) to nominate an expert.

The Ombudsman's assessment

30. The complainant contends that since only one expert appears to have specific experience of alternative methods concerning the 'replacement' of NHPs, the composition of the NHP Working Group was not balanced.

31. In the Ombudsman's view, the composition of a particular expert group is balanced if it accurately reflects the different types of expertise necessary to enable the group fully to carry out the mandate conferred on it. 'Balance' does not therefore refer to, or require, a situation of arithmetic equilibrium or parity of the different interests represented in an expert group. [15]

32. In this case, the complainant contested the Commission's statement that three of the seven selected experts had specific expertise in the replacement of NHPs. The complainant argued that only one member of the NHP Working Group has such expertise, while three others had expertise in refinement.

33. The CVs published online seem to indicate, as the Commission stated, that three experts had experience in "replacement". In any case, the complainant seems to imply that 'replacement', 'reduction' and 'refinement' of research methods using NHPs were autonomous, self-standing criteria for selecting the experts. However, the relevant criterion used to select the experts referred to experience in 'alternative methods' that aimed at replacement, reduction and



refinement [16] . Therefore, even if - as the complainant contends - only one expert had expertise in replacement and at least three others had expertise in “refinement”, this does not imply that the group lacked expertise in ‘alternative methods’.

34. Regarding the fact that SCHEER did not also ask the EURL ECVAM to nominate experts, as it did with EMA [17] , this does not appear to be possible, according to the applicable rules [18] .

35. Therefore, the Ombudsman finds no maladministration regarding this matter.

Transparency of the selection process

Arguments presented to the Ombudsman

36. The complainant argued that, under the applicable rules [19] and in line with a previous recommendation of the Ombudsman [20] , when selecting experts, the Commission and SCHEER should prioritise technical excellence, independence, impartiality and transparency, and conduct a “*comparative assessment of the applicants*” on this basis. It claimed that, since no individual assessment of candidates was available, there was also no record of a comparative assessment having taken place, which meant the process lacked transparency.

37. In its reply to the Ombudsman, the Commission pointed out that the note to the file sets out the selection criteria and describes how the applicants were assessed. It lists the names of the selected applicants and how their independence was verified, and indicates the number of unsuccessful candidates. In the Commission’s view, it has already complied with the Ombudsman’s previous recommendation regarding the selection of external experts by adopting a decision on expert groups [21] in 2016. Neither that decision, the decision establishing SCHEER, nor the rules governing SCHEER [22] , require SCHEER to draw up an individual assessment of each application.

The Ombudsman's assessment

38. As the complainant mentioned, the Ombudsman has previously found that a comparative assessment of candidates should be carried out. [23] This comparative assessment should be properly documented and be publicly accessible, whilst paying due regard to the need to comply with data protection rules. [24]

39. While it is true that there was no specific document for the individual assessment of each expert, and that the ‘note to the file’ is succinct, this does not mean that a comparative assessment was not performed. The ‘note to the file’ that was provided to the complainant and to the Ombudsman: (i) describes the selection criteria applied and the methodology followed; (ii) lists the names of the selected applicants; (iii) explains that the unsuccessful candidates did not



meet the selection criteria; and (iv) includes an assessment of the declarations of interest of the selected experts. Moreover, the names, CVs and declarations of interests of the selected experts were published online in order to ensure the transparency of the process. [25]

40. The Ombudsman considers that the note to the file and the subsequent publication of the names and CVs of the selected experts ensured a sufficiently transparent process.

41. Therefore, the Ombudsman finds no maladministration regarding this matter.

Conclusion

Based on the inquiry, the Ombudsman closes this case with the following conclusion :

There was no maladministration by the European Commission.

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

Emily O'Reilly

European Ombudsman

Strasbourg, 08/02/2019

[1] Commission decision of 7.8.2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment, C(2015) 5383 final, Brussels, 7.8.2015 available at https://ec.europa.eu/health/scientific_committees/docs/call_2015_5383_decision_with_annexes_en.pdf [Nasc].

[2] For more information on SCHEER, see https://ec.europa.eu/health/scientific_committees/scheer_en [Nasc].

[3] Case 2558/2009/DK, available at: <https://www.ombudsman.europa.eu/cases/decision.faces/en/49159/html.bookmark> [Nasc].

[4] The request can be found at: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_q_001.pdf [Nasc].



[5] Directive 2010/63/EU on the protection of animals used for scientific purposes, <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=celex%3A32010L0063> [Nasc].

[6] The 'call for experts' can be found at: https://ec.europa.eu/health/scientific_committees/call_experts/call_experts_primates_2016_en [Nasc].

[7] Available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/scheer/docs/scheer_q_001.pdf [Nasc].

[8] The criteria applied in selecting the experts were set out in the 'note to the file'.

[9] As set out in the Rules of Procedure of the Scientific Committees on Consumer Safety (SCCS) and Health, Environment and Consumer Risks (SCHEER) of April 2016, available at: https://ec.europa.eu/health/sites/health/files/scientific_committees/docs/rules_procedure_2016_en.pdf [Nasc].

[10] Recital 7 and Article 12 of Commission Decision of 7.8.2015 on establishing Scientific Committees in the field of public health, consumer safety and the environment, C(2015) 5383 final; Rules of Procedure of the Scientific Committees on Consumer Safety (SCCS) and Health, Environment and Consumer Risks (SCHEER) of April 2016.

[11] Decision of the European Ombudsman in Case 2558/2009/DK, paragraph 25, available at <https://www.ombudsman.europa.eu/cases/decision.faces/en/49159/html.bookmark> [Nasc].

[12] Decision of the European Ombudsman in Case 2558/2009/DK, paragraph 26.

[13] Decision of the European Ombudsman in Case 2558/2009/DK, paragraph 27.

[14] Replacement and refinement are two elements of the 'Three Rs principle'. The 'Three Rs principle' refers to avoiding the use of animals in testing as far as possible ('replacement'), using fewer animals ('reduction'), and causing less suffering to animals ('refinement'). Alternative test methods include not only those methods that avoid the use of animals, but also those that reduce both the number of animals used and their suffering.

[15] Decision of the European Ombudsman in her strategic inquiry OI/6/2014/NF concerning the composition and transparency of European Commission expert groups, paragraph 21, available at <https://www.ombudsman.europa.eu/en/decision/en/86030> [Nasc].

[16] The criteria applied in selecting the experts were set out in the 'note to the file'. The relevant criterion concerns experience with “ *alternative methods in biomedical research, production and testing of products and devices aiming at replacement, reduction and refinement of methods using non-human primates* ”.



[17] According to the Commission, an expert from EMA was invited under paragraph 137 of the Rules of Procedure of the Scientific Committees.

[18] The EURL ECVAM is part of the Commission's Joint Research Centre. Paragraph 137 of the Rules of Procedure of the Scientific Committees does not provide for the participation of staff from the Commission.

[19] Rules of Procedure of the Scientific Committees on Consumer Safety (SCCS) and Health, Environment and Consumer Risks (SCHEER) of April 2016.

[20] Decision of the European Ombudsman in Case 2558/2009/DK, paragraph 33.

[21] Commission Decision C(2016)3301 on establishing horizontal rules on the creation and operation of Commission expert groups.

[22] Rules of Procedure of the Scientific Committees on Consumer Safety (SCCS) and Health, Environment and Consumer Risks (SCHEER) of April 2016.

[23] Decision of the European Ombudsman in Case 2558/2009/DK, paragraph 33 and 47.

[24] Rules of Procedure of SCHEER, paragraph 95; Decision of the European Ombudsman in Case 2558/2009/DK, paragraph 34.

[25] Available at:

https://ec.europa.eu/health/scientific_committees/experts/declarations/scheer_wg_en [Nasc].