



Határozat az Európai Bizottság által a SCENIHR fogászati amalgámmal foglalkozó munkacsoportjában felmerülő esetleges összeférhetetlenségek kezeléséről szóló 1832/2014/TN ügyről - 1832/2014/TN. sz. ügyben hozott határozata

Határozat

Ügy 1832/2014/TN - **Vizsgálat megindítása** 02/12/2014 - **Határozat** 17/12/2015 - **Érintett intézmények** Európai Bizottság (Nem történt hivatali visszasság) |

Az ügy a Bizottság fogászati amalgámmal foglalkozó tudományos munkacsoportjában felmerülő állítólagos összeférhetetlenségeket vizsgálta. A munkacsoport a fogászati amalgám biztonságosságáról és teljesítményéről, illetve annak alternatíváiról készít véleményt. Az ombudsman megvizsgálta a kérdést, és azt állapította meg, hogy a szóban forgó ügyben a Bizottság nem követett el hivatali visszasságot, amikor értékelte a munkacsoport tagjainak függetlenségét és alkalmasságát.

Az ombudsman megragadta a lehetőséget, hogy az ügy általánosabb aspektusait is észrevételezze. Az ombudsman hangsúlyozta annak fontosságát, hogy a Bizottság tudományos bizottságaiban dolgozó szakemberek tudományos tanácsadói tevékenysége garantáltan független és objektív legyen. Még a látszata is nagyon káros lehet annak, hogy az ilyen tudományos tanácsadás esetleg nem független és objektív. A Bizottságnak ezért nemcsak azt kell biztosítania, hogy az effajta tudományos tanácsadás független és teljességgel objektív legyen, hanem azt is, hogy e tanácsadás függetlenségét és objektivitását illetően minden ésszerű kétséget eloszlasson.

Az ombudsman ezért fontosnak tartja, hogy a Bizottság nagyon megbízható eljárásokat vezessen be, amelyek garantálják, hogy a szakértők minden érdekeltégükről nyilatkozzanak. A Bizottságnak gondosan meg kell vizsgálnia az összes ilyen érdekeltéget. Ezeket az eljárásokat a lehető legátláthatóbb módon kell elvégeznie. Az ombudsman ezért örömmel látja, hogy a Bizottság dolgozik az „**Iránymutatások a tudományos bizottságok tevékenységeiben érintett tagok, külső szakértők és ad hoc szakértők érdekeltégi nyilatkozatainak kezeléséhez**” című dokumentum összeállításán, amelyben átlátható módon kívánja bemutatni, hogyan zajlik a szakértők érdekeltégeinek vizsgálata. Az ombudsman arra kérte a Bizottságot, hogy folyamatosan tájékoztassa az iránymutatások összeállításának folyamatáról és a végleges változatról.

The background to the complaint

1. The complainant, a citizen from Sweden, is concerned about possible conflicts of interest



in the Commission's scientific committee SCENIHR's [1] Working Group on Dental Amalgam. The Working Group in question drafted the 2014 Opinion on dental amalgam with the purpose of updating the previous opinion of 2008 on the safety and performance of both dental amalgam and possible alternatives.

2. In September 2014, the complainant set out his concerns in a detailed letter to the Commission. Among other things, the complainant stated that "*[t]he dental community is highly corporativistic [sic] where dental organizations and industry forms a tight group bonded together by mutual interests, organizational connections and financial dependence. ... A majority of the members of the SCENIHR 2014 Working Group Dental Amalgam (WGA) belong to the dental community. A number of the WGA members are heavily involved in or employed by organizations with strong connections to the industrial sector creating clear parallel loyalties to organizations other than the EU.*" The complainant listed a number of dental organisations, describing how he considers them to be interlinked and linked to industry. He then stated that "*[m]embers heavily involved with one of the stakeholders - dentistry - are dominating the WGA. Any ill effects from mercury fillings will [have] possible far reaching consequences for both dental organizations and the dental industry. By allowing a majority of members from the dental community to form the core of WGA a serious conflict of interest was created from the very beginning.*"

3. More specifically, the complainant named six members of the Working Group who he considered were in a conflict of interest situation and he asked the Commission to deal with these conflicts. He also asked the Commission whether it was appropriate to include, in the 2014 Working Group, persons who declared, in the 2008 Final Opinion on Dental Amalgam, that further scientific investigations on mercury fillings need not be performed. He asked whether such a statement is not evidence of a conflict of interest.

4. Not being satisfied with the Commission's response, the complainant turned to the Ombudsman in October 2014.

The inquiry

5. The Ombudsman opened an inquiry into the complaint and identified the following allegation and claim:

The Commission has failed to properly address the complainant's concerns about possible conflicts of interest among the members of the SCENIHR 2014 Working Group on Dental Amalgam and, more generally, about the suitability and objectivity of these members.

The Commission should not adopt the opinion produced by the SCENIHR 2014 Working Group on Dental Amalgam.

6. In her letter to the Commission opening the inquiry, the Ombudsman pointed out that the independence and objectivity of the EU public administration is vital in terms of building trust on the part of citizens. Accordingly, the Ombudsman pays great attention to any concerns about conflicts of interest. In this regard, also, the citizens' *perception* that such conflicts exist or that the persons concerned do not have the necessary suitability and objectivity is an issue that needs to be taken seriously and to be addressed. The Ombudsman therefore asked the Commission to address the following points:



1. The complainant listed, in his letter to the Commission, six of the members of the Working Group as possibly being in a conflict of interest situation, setting out the reasons why. In its response to the complainant, the Commission explained the methodology used for defining conflicts of interest situations in scientific committees and for mitigating unspecific and indirect conflicts of interest. The Commission did not, however, make an analysis, based on its methodology, of the information provided by the complainant about the six Working Group members, thereby explaining why it does not consider these Working Group members to be in a conflict of interest situation.

2. The Ombudsman asked the Commission to explain, in more detail, why most of the Working Group members have to be from the dental sector, given that the aim of the opinion is to evaluate " *scientific evidence on the potential association between amalgam and possible alternatives, and allergies, neurological disorders or other adverse health effects* ", which would seem to imply a need for medical expertise in the areas of, for instance, allergies and neurological disorders.

3. The Ombudsman also asked the Commission to address, more generally, the concern that some individuals who were involved in drafting the 2008 opinion on dental amalgam are involved in drafting the updated 2014 opinion, given that these individuals may be perceived as less inclined to question the conclusions made in the 2008 opinion, according to which further research into this area was unnecessary.

7. In the course of the inquiry, the Ombudsman received the opinion of the 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.

Allegation of failure to address concerns about possible conflicts of interest

Arguments presented to the Ombudsman

8. In its opinion, the Commission stated that SCENIHR adopted a preliminary opinion on " *The safety of dental amalgam and alternative dental restoration materials for patients and users* " in August 2014. A public consultation was then launched, with a view to gathering specific comments, suggestions, explanations or contributions on the scientific basis of the opinion, to enable SCENIHR to focus on issues which needed to be further investigated. Twenty five organisations and individuals participated in the public consultation, providing 101 comments. The Commission specifically invited the complainant to participate in the public consultation, but he chose not to submit any comments.

9. The Commission stated that the principles of excellence, transparency and division between risk assessment and risk management have guided the work of its three independent scientific committees since 1997. These principles ensure that EU citizens are granted the highest level of health protection possible. It is vital that experts of the scientific committees meet both the requirement of excellence and independence in order for them to be able to work in the public interest. To this aim, a robust set of Rules of Procedure were



adopted jointly by the scientific committees in 2009 [2] .

10. According to the Commission, conflicts of interest are often unjustifiably suspected when there is any interaction at all between science and industry. Yet, it argued, science thrives upon the exchange of knowledge between all researchers, including those from industry. In particular, when it comes to assessing the safety of consumer products or medical devices, clinical trials and testing of materials is essential and these trials are often funded by the industry. The financial crisis and the resulting decline in public funding allocated to research have led to an increasing number of partnerships between public and private actors to boost innovation and to serve the public interest. In order to mitigate the influence of industry, public bodies ensure that scientific research is designed, and that funds are managed, in an independent way. Professional associations of scientists often accept sponsorship from private companies to organise some of their corporate activities (conferences, awards, PHD sponsorship), but this does not imply undue influence from industry in the scientific activities of these associations.

11. If, as suggested by the complainant, membership in such societies were to be considered as a conflict of interest, the majority of scientists working for public institutions would be in a conflict of interest situation. If that was the case, the Commission would be able to rely only on retired scientists or scientists in public institutes who do not have any link to the private sector and who do not benefit from any partnership with the private sector.

12. In the Commission's view, professional affiliations, including those with partners from industry, enable scientists to network and to keep up to date (with scientific developments). This is not the same as a conflict of interest situation, which it has defined as "*a situation when an individual is in a position to exploit his or her own professional or official capacity in some way for personal or corporate benefit with regard to that person's function in the context of his or her cooperation with Scientific Committees*" [3] . The Commission screens this possibility very carefully, on the basis of the information provided by experts in their declarations of interest.

13. By providing the complainant with the methodology for assessing declarations of interest, rather than explaining individual assessments, the Commission aimed at striking a fair balance between transparency and the protection of the scientists' personal data. The Commission is of the view that sufficient transparency is provided through the publication of all documents concerning the activity of the Scientific Committees, including the experts' declarations of interest.

14. However, in its opinion to the Ombudsman, the Commission provided the SCENIHR Secretariat's individual analysis of the declarations of interest made by the six individuals referred to by the complainant, setting out why it does not consider these individuals to be in a conflict of interest situation.

15. In response to the question as to why most of the Working Group members had to be from the dental sector, the Commission stated that the experts were selected on the basis of the specific expertise needed to cover the mandate of the Working Group, which was on the



safety and performance of dental amalgam and alternative dental restoration materials. All experts in the Working Group are respected scientists who are well known in Europe and worldwide, who have published numerous scientific papers and who are working for international organisations, universities and public institutes in the Member States. None of them is employed by business operators. In total, there were four experts out of seven from the dental sector. The experts not coming from the dental sector were experts in (i) immunology and epidemiology; (ii) toxicology; and (iii) neurosciences including neurological disorders, methylmercury neurotoxicity and epidemiology. Two additional experts, one in epidemiology, occupational medicine and environmental health, and one in toxicology, also participated in the Working Group on an occasional basis. In addition, other members of SCENIHR participated during the finalisation of the draft opinion. The Commission thus considers that the Working Group was balanced and suited to prepare the draft opinion.

16. As regards whether it was appropriate to involve two experts who drafted the 2008 opinion in the drafting of the revised opinion, the Commission argued that it was indeed so. The Commission encourages assessments as to the usefulness of further research. The Commission needs this advice to prioritise further research on public health risks. Replying to such requests from the Commission cannot constitute a reason for being excluded from further work on risk assessment on the same subject. It is understood that such statements are based on current knowledge and therefore subject to change. The Commission underlined that SCENIHR does not carry out its own research in these different disciplines, but bases its work on the meta-analysis of primary scientific studies published in peer-reviewed journals. Moreover, the presence of other experts (peer review process), the input provided by external experts and the collegial nature of the decision making of SCENIHR, as well as its composition, are factors that mitigate against any potential conflict of interest.

17. The Commission thus concluded that it very carefully screened any potential conflict of interest of the relevant scientists. On this basis, the Commission found no reason to ask the SCENIHR to consider not adopting the 2014 opinion on the safety of dental amalgam and alternative restoration materials. The Commission considers that the comments received during the public consultation do not question the overall validity of the conclusions set out in the opinion or the independence of the members of the Working Group. However, due to the concerns expressed by the complainant, the SCENIHR Secretariat has decided to request a thorough and comprehensive review of the preliminary opinion on dental amalgam by SCENIHR members only, thus addressing citizens' perception of possible bias and conflicts of interest.

18. In addition, the Secretariat of the Scientific Committees is currently developing a set of "*Guidelines relating to the handling of declarations of interests of members, external experts and ad hoc experts involved in the activities of the Scientific Committees*", in particular regarding the assessment of the information provided in the declarations of interest. The aim of these Guidelines is to clarify the handling of declarations of interest from Scientific Committee experts (in terms of methods, responsibilities and procedures) in order to explain in a transparent manner how the assessment is made. The Commission hopes that this will reduce the number of questions received about conflicts of interest issues and clarify the



distinction between interaction with interested parties and conflicts of interest.

19. In his observations on the Commission's opinion, the complainant stated, in summary, that the Commission clearly does not understand the extent of industry involvement in the field of dentistry. According to the complainant, a majority of the members of the Working Group should not have been from the dental community. He added that the activities of dental organisations are financed, to a great extent, by industry. The dental organisations thus act as a voice for industry. This gives rise, in his view, to a clear conflict of interest.

20. The complainant argued that it was information from him about one of the experts having received funding from industry that made the SCENIHR Secretariat contact the expert in question to seek clarifications.

21. As regards that expert, the complainant argues, the Commission wrongly found that the expert was not in a conflict of interest situation. He added that the SCENIHR Secretariat tried to downplay the role of this expert in the Working Group.

22. According to the complainant, the Commission also chose not to comment at all on another expert's heavy involvement in the World Dental Federation.

23. The complainant also noted, with concern, that the preliminary opinion on dental amalgam was removed from the Internet, whereas preliminary opinions on other issues are still available.

The Ombudsman's assessment

24. SCENIHR, with the help of its working groups, provides opinions on emerging or newly-identified health and environmental risks. It is important to ensure that the scientific advice provided by the experts working for SCENIHR is of the highest quality and that it is fully independent and objective. Any factor which would undermine the independence and objectivity of that advice would cause great harm to the legitimacy of the EU. The **transparency** and **accountability** of SCENIHR and its working groups helps to ensure that the scientific advice provided by the experts working for SCENIHR is fully **independent** and **objective**.

25. The Rules of Procedure applicable to SCENIHR members and external experts expressly set out that SCENIHR members and external experts "*shall undertake to act independently from any external influence*".

26. The Ombudsman commends the Commission for this clear requirement. However, the Commission must ensure that this rule is made effective, by carefully examining the interests of each expert so as to ensure that they can provide advice free from undue influence.

27. It is also of vital importance that the Commission and the SCENIHR Secretariat are able reassure the citizens that such an examination has taken place in a correct manner.



28. The Commission states that the members of the working group in question were selected on the basis of the specific expertise needed to cover the working group's mandate. Given its mandate, the Ombudsman finds it entirely reasonable that a number of working group members come from the dentistry sector. The Ombudsman also notes that the members comprise specialists in other areas, such as immunology, epidemiology, toxicology and neurosciences.

29. The complainant is of the view that **the whole field of dentistry** is so influenced by industry that having **any** working group members from the field of dentistry is a problem. On the basis of the information provided to her, the Ombudsman does not agree, for the following reasons.

30. The complainant makes extensive reference to connections between dental science and industry. It seems that most dentists are a member of a dental representative organisations. Scientists working in the area of dentistry may also be members. It may also be true that companies working in the area of dentistry are members or partners of these dental organisations. It may even be the case that the dental industry partially funds some of these organisations. However, these facts would not mean that **every** dental practitioner and **every** scientist who joins these organisations is somehow controlled by industry. Such a broad conclusion has no basis in fact or logic. The complainant has put forward no argument to show how industry would use its membership of these organisations to exert control over all the members of the organisations.

31. The complainant also considers that it constitutes a conflict of interest for working group members to be closely involved in the work of the International Organization for Standardization (ISO). Apparently, at least two working group members are active in different ISO technical committees, one of them being the ISO Technical Committee on Dentistry. The complainant, in support of his view, argues that the aim of ISO is to help industry.

32. The Ombudsman notes that the ISO Technical Committee on Dentistry has as its aims the reduction of barriers to trade; the improvement in the quality of products on the market; the improvement in the quality of care provided to patients; the protection of the health and safety of dental patients and users; and the uniformity of the terminology used in dentistry. The business plan for the ISO Technical Committee on Dentistry also sets out that one of its objectives is to ensure that vested interests never dictate the development of dental standards. [4] The Ombudsman is of the view that working for or with a recognised standardisation body, governed by the above principles, cannot, on its own, constitute proof that a person is biased in favour of industry. Suffice to note that the complainant has put forward no mechanism by which industry could use an expert's work for the ISO as a means to undermine the expert's independence.

33. As regards the complainant's concern about working group members having an affiliation with NIOM (the Nordic Institute of Dental Materials), the complainant argues that "*NIOM's revenue stems from the dental material industry*". The Ombudsman notes that NIOM is a Nordic cooperative body for dental biomaterials. NIOM is owned partly by the University of



Oslo and by the Norwegian Ministry of Health. It works to promote patient safety. NIOM undertakes research, materials testing, standardisation [5] and research-based consulting directed towards health authorities and dental health services in the Nordic countries. Its research and consulting are required to be scientifically well-founded. [6] As in the case of the ISO, the Ombudsman is of the view that working for or with a recognised standardisation body, working to promote patient safety, cannot, as such, be considered to be biased in favour of industry. Even if NIOM's revenue stems (partly) from the dental material industry, such as in the form of accreditation fees, this does not mean that a person affiliated with NIOM is in a conflict of interest situation. Industry will have to pay fees for materials testing and accreditation regardless of which materials are considered safe and regardless of the outcome of the testing. There is thus no financial incentive for a person connected to NIOM to declare certain materials safer than others. Again, in sum, the complainant has put forward no mechanism by which industry could use an expert's work for NIOM as a means to undermine the expert's independence.

34. Having examined the SCENIHR Secretariat's individual analysis of the declarations of interest made by the six working group member that the complainant is concerned about, the Ombudsman finds four of them unproblematic without further comments. A fifth working group member was found to have an interest related to a product, Bisphenol A. However, appropriate mitigating measures were taken by the Commission: the relevant person did not contribute to the parts of the preliminary opinion concerning Bisphenol A.

35. The SCENIHR Secretariat contacted the sixth working group member about whom the complainant had concerns [7]. It found that the working group member in question did not declare all relevant interests before he was appointed as a working group member, namely his work in relation to two clinical studies. The working group member in question then explained why he did not think it was necessary to declare those clinical studies to the SCENIHR Secretariat. The SCENIHR Secretariat found that the studies should indeed have been declared. However, it added, after examining subsequently the details of the work carried out by the working group member, it found that they did not put the working group member in a conflict of interest situation.

36. The Ombudsman considers that the SCENIHR Secretariat acted correctly in relation to the undeclared interests. It contacted the working group member concerned and obtained the necessary information.

37. The Ombudsman also notes that this issue highlights again the importance of complying with the Ombudsman's recent suggestion that the Commission should clarify to experts that they need to make **complete declarations** of all relevant interests, and not only **those interests that the experts believe constitute conflicts of interests**. It is only when experts declare **all** relevant interest that the Commission can make thorough assessments of the independence of experts [8]. In the absence of such procedures, the Commission would effectively rely on experts to self-assess for conflicts of interest. This would not be sufficient or appropriate.

38. As regards the Commission's belated finding that the working group member was,



nevertheless, not in a conflict of interest situation, the Ombudsman notes that **the company** for which the person in question had made two clinical studies had a vested interest in the outcome of the work of the working group on dental amalgam. However, the question is whether the working group member had, by virtue of working on clinical studies for that company, a vested interest in the outcome of the work of the working group on dental amalgam. In the Ombudsman's view, the answer to that question depends on the extent and nature of his working relationship with that company. If the working group member had an extensive and long-term working relationship with that company, to an extent that his future financial interests might be intertwined with those of that company, his independence from that company might be questionable. In the present case, however, the Ombudsman finds that the nature and degree of dependence were not such as to create a conflict of interest situation. The SCENIHR Secretariat's conclusion in this regard is therefore correct.

39. Finally, as regards the working group members that previously provided the Commission with advice on dental amalgam, the Ombudsman notes that the complainant did not agree with the advice that was previously given by these experts, and deduces from this that the experts should not provide further advice to the Commission. The Ombudsman fails to see any logic in the complainant's arguments. The Ombudsman finds that the independence of such persons is not in any way compromised by the fact that they have advised the Commission previously.

40. On the basis of the above, the Ombudsman finds no maladministration by the Commission and the SCENIHR Secretariat as regards its evaluation of the independence and suitability of the members of the working group on dental amalgam.

41. The Ombudsman hopes that the above findings as regards the objectivity issue, together with the substantive review of the preliminary opinion on dental amalgam that the Commission has requested to be done by SCENIHR members only, should reassure the public that the work was carried out without undue influence from industry.

42. As regards the complainant's concern that the preliminary opinion on dental amalgam has been removed from the Internet, whereas other preliminary opinions are still available, the Ombudsman notes that older preliminary opinions are in fact not available on the Internet. This is true not only for the preliminary opinion on dental amalgam, but also for other older preliminary opinions. The Ombudsman thus does not find this fact to indicate any intention to be secretive about the work of the working group on dental amalgam. Nevertheless, the fact that, over the past year, the Ombudsman has received a number of complaints about possible conflicts of interest within SCENIHR and its working groups, shows that citizens are very concerned about the work carried out in this context. Even the citizens' *perception* that the work carried out in the context of SCENIHR is not done independently and objectively, and their concern that this is something that SCENIHR is trying to "cover up", is very damaging to the EU and needs to be taken seriously. In order to address this very serious question of perception, the Ombudsman considers that it is important for the Commission to put in place very robust procedures for the experts declaring their interests, and for the Commission assessing them, and to make these procedures as transparent as possible. As referred to above, the Ombudsman has already suggested to the Commission



that it improve its procedures for making sure that all interests that could conceivably give rise to a conflict are declared in the same way by all experts. [9]

43. The Ombudsman also views as a very positive step, towards greater transparency and accountability, the fact that the Secretariat of the Scientific Committees is in the process of developing a set of " *Guidelines relating to the handling of declarations of interests of members, external experts and ad hoc experts involved in the activities of the Scientific Committees* ", with a view to explain in a transparent manner how the assessment of interests is made. In this regard, the Ombudsman has already requested that the Commission keep her updated on the progress of drafting these Guidelines [10] . On 17 November 2015, the Commission informed the Ombudsman that the Guidelines on the handling of declarations of interest of the experts of the scientific committees exist as a draft which will be finalised and published online once the College of Commissioners has adopted the consolidated horizontal rules on expert groups including, for instance, provisions on conflicts of interest. According to the Commission, these consolidated rules on expert groups should be adopted shortly. [11] The Ombudsman thus repeats her request for the Commission to provide her with a copy of the final Guidelines once they have been finalised.

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.

Further remark

The Commission should provide the Ombudsman with a copy of the " *Guidelines relating to the handling of declarations of interests of members, external experts and ad hoc experts involved in the activities of the Scientific Committees* " once they have been finalised.

Emily O'Reilly

Strasbourg, 17/12/2015

[1] The Scientific Committee on Emerging and Newly Identified Health Risks. The Committee provides the Commission with opinions on emerging or newly-identified health and environmental risks and on broad, complex or multidisciplinary issues requiring a comprehensive assessment of risks to consumer safety or public health and related issues not covered by other Community risk assessment bodies.

http://ec.europa.eu/health/scientific_committees/emerging/index_en.htm

[2] http://ec.europa.eu/health/scientific_committees/docs/rules_procedure_en.pdf

[3] Rules of Procedure, footnote 12 on page 12.



[4]

http://isotc.iso.org/livelink/livelink/fetch/2000/2122/687806/ISO_TC_106__Dentistry_.pdf?nodeid=800823

[5] Accreditation according to ISO 17025 General requirements for the competence of testing and calibration laboratories with the Norwegian Accreditation:

<http://www.niom.no/content/accruited-testing> .

[6] <http://www.niom.no/content/about-niom-0>

[7] The complainant states that it was him alerting the Secretariat.

[8] The Ombudsman's decision in case 174/2015/FOR:

<http://www.ombudsman.europa.eu/cases/decision.faces/en/61195/html.bookmark>

[9] The Ombudsman's decision in case 174/2015/FOR:

<http://www.ombudsman.europa.eu/cases/decision.faces/en/61195/html.bookmark>

[10]

http://www.ombudsman.europa.eu/register/2015/OUT2015-005217/OUT2015-005217_M0.pdf

[11]

http://www.ombudsman.europa.eu/register/2015/INC2015-005454/INC2015-005454_M0.pdf