

Décision dans l'affaire 3143/2007/(CD)(WP)VL - Absence alléguée de garantie de l'indépendance d'experts scientifiques

Décision

Affaire 3143/2007/(CD)(WP)VL - Ouvert le 04/02/2008 - Décision le 04/05/2010

Le plaignant est une association allemande de patients souffrant de problèmes de santé, provoqués selon eux par le mercure contenu dans des amalgames dentaires. L'association a appris que la Commission avait demandé au Comité scientifique des risques sanitaires et environnementaux (CSRSE) de rendre un avis scientifique sur les risques du mercure contenu dans les amalgames dentaires. Le plaignant a estimé que les membres allemands du CSRSE agissaient dans les intérêts de l'industrie. Il a dès lors demandé que ces derniers soient remplacés par des experts indépendants. Pour ce faire, il a déposé plusieurs conclusions auprès de la Commission et du CSRSE. Après avoir examiné les informations fournies, la Commission a réfuté les arguments du plaignant. Par conséquent, le plaignant s'est adressé au Médiateur.

Le plaignant a allégué que la Commission n'a pas réagi correctement à ses préoccupations concernant le manque d'indépendance des experts. Il a en outre allégué que la Commission n'avait pas accordé une attention appropriée à ses conclusions relatives aux dangers du mercure contenu dans les amalgames dentaires, notamment à son courrier du 11 août 2007.

En réponse, la Commission a expliqué que les allégations du plaignant à l'encontre des membres allemands du CSRSE ne reposaient pas sur des preuves objectives et vérifiables. Elle a également souligné qu'un autre comité était chargé de préparer un avis scientifique sur les risques sanitaires potentiels du mercure contenu dans les amalgames dentaires. Les travaux du CSRSE étaient uniquement axés sur les effets du mercure sur l'environnement et, indirectement, sur la santé. La Commission a reconnu avoir eu tort de ne pas répondre à la lettre du plaignant du 11 août 2007 et a présenté ses excuses à cet égard. Cependant, elle a souligné avoir reçu un document identique de la part du plaignant à une occasion précédente et lui avoir accordé l'attention qu'il méritait.

Le Médiateur a conclu que le plaignant n'avait pas apporté de preuves concluantes permettant d'établir ses accusations selon lesquelles (i) les membres allemands du CSRSE manquaient de l'indépendance professionnelle nécessaire et (ii) la réaction de la Commission face aux critiques du plaignant était inappropriée. Par conséquent, aucun cas de mauvaise administration n'a été constaté au regard des principales allégations et revendications.



En ce qui concerne le reste de l'affaire, le Médiateur a estimé qu'il n'était pas justifié d'approfondir les enquêtes, étant donné que (i) la Commission a présenté une explication détaillée de l'approche qu'elle a adoptée, (ii) le plaignant s'est abstenu de toute observation sur ces commentaires et (iii) le plaignant n'a pas fourni au Médiateur les éléments nécessaires, notamment une copie de ladite lettre, lui permettant de se forger une opinion sur le traitement de ses conclusions du 11 août 2007.

THE BACKGROUND TO THE COMPLAINT

1. The complainant is a German association of patients suffering from health damage which they consider to have been caused by dental amalgam. At the time the present complaint was submitted, the European Commission was analysing the effects of mercury in dental amalgam. The Commission asked the Scientific Committee on Health and Environmental Risks (SCHER) and the Scientific Committee on Emerging and Newly Identified Health Risks (SCENIHR) for their opinions on the matter. More precisely, the Commission asked SCHER for an opinion on "*the environmental risks and indirect health effects of mercury in dental amalgam*" and SCENIHR for an opinion on "*the safety of dental amalgam and alternative dental restoration materials for patients and users*".

2. On 25 May 2007, the complainant wrote to the Commission's Directorate-General for Health and Consumer Protection (DG SANCO) in relation to the request for a scientific opinion addressed to SCHER. The complainant expressed serious doubts regarding the independence of the German members of SCHER (Professor D., Dr M. and, in particular, Professor G.) and attached voluminous documentation in order to support its position. It submitted that the German members of this committee acted in the interest of the industries concerned and were known for issuing incorrect advisory opinions playing down the health risks of dangerous substances. It further alleged that the *Deutsche Gesellschaft für klinische und experimentelle Pharmakologie und Toxikologie* ('DGPT'), a German medical association to which the experts concerned belonged, had falsified scientific findings and academic publications in favour of the chemical and the pharmaceutical industries. The complainant referred to a calculation on half-life values of mercury in dental amalgams published in a DGPT newsletter article in 1990. It argued that DGPT's scientific results and methods were of questionable quality. It further argued that the German members of SCHER had attempted to conceal their membership of the DGPT in their curricula vitae. The complainant claimed that all German members should be excluded from SCHER.

3. In an e-mail to DG SANCO dated 4 June 2007, the complainant repeated its allegations concerning the German members of SCHER, and included three attachments concerning the effects of mercury.

4. On 27 July 2007, the complainant sent a further letter to DG SANCO, in which it pointed out that it had not yet received a reply to its letter of 25 May 2007. The complainant inquired



whether any action had been taken to exclude Dr D. and Professor G. from SCHER.

5. On 11 August 2007, the complainant sent its submission to the Commission's Directorate-General for Enterprise and Industry (DG ENTR).

6. On 25 September 2007, the complainant informed the President of the Commission by letter that it had not yet received replies to its letters dated 25 May and 27 July 2007. It therefore asked him to intervene.

7. On 8 October 2007, Mr B., a Head of Unit at DG SANCO, replied to the complainant, referring to its letter of 27 July 2007. He pointed out that, in accordance with Articles 14 and 15 of Commission Decision 2004/210/EC [1] ('Decision 2004/210'), the Commission laid great emphasis on issues of independence and transparency. The members of the scientific committees were nominated following an open call for expressions of interest and appointed in their individual capacity. They had to sign declarations on the absence of conflicts of interest in relation to each point on the agenda, as well as make an annual declaration to that effect. These declarations were published on DG SANCO's website. The individual membership of national scientific associations was considered as part of the individual choice and network of any active scientists. In addition, DGPT appeared to be a well-recognised German scientific organisation. Mr B. went on to state that any scientific information was welcome and would be considered if peer-reviewed. He also noted that various of the scientific committees' preliminary opinions had been made available for public consultation with a view to enhancing the quality of their work. Furthermore, a call for information " *on mercury in dental amalgam and alternatives* " [2] had been published and the complainant had provided a contribution thereto. Finally, Mr B. added that the information provided had been submitted to SCENIHR.

8. On 31 October 2007, Mr B sent a further reply to the complainant, in light of his letter to the President of the Commission. Mr B. referred to his reply of 8 October 2007 and indicated that the complainant could consider this letter as a reply to his letters of 27 July and 25 September 2007.

9. In a letter sent to DG SANCO on 13 November 2007, the complainant argued that the DGPT was well-known in Germany for its bias towards the chemical and pharmaceutical industries. The complainant further submitted that Professor G. and Dr D., acting in leading positions within the association, had been involved in playing down toxicological risks for many years. In this context, it drew attention to DGPT's article of 1990 (attached to its letter of 25 May 2007), containing a calculation on half-life values of mercury, which it considered to have been manipulated. The complainant invited the Commission to contact various German patient initiatives and associations to verify its allegations. Furthermore, it put forward a number of questions concerning the independence of various German members of the DGPT and another medical association who were also members of the Commission's scientific committees. The complainant enclosed a recording of a radio interview with a former German state prosecutor concerning a German court case on timber preservatives, and a compact disc that it had sent to DG ENTR on 11 August 2007.



10. On 7 December 2007, the complainant turned to the European Ombudsman.

11. On 8 January 2008, Mr B replied to the complainant, referring to its letters of 25 May, 25 September and 13 November 2007. He stated that he did not wish to comment on its criticisms concerning the qualifications and scientific opinions of Professor G. and other German members of SCHER. However, he pointed out that SCHER, of which Professor G. was Chairman, consisted of 19 highly qualified members from nine countries. They examine every detail before adopting an opinion, and allow for the possible issuance of minority opinions. No such minority opinions were expressed under the chairmanship of Professor G. and none of his colleagues complained about his competence or his work or expressed criticisms in that respect. The complainant's statements concerning Professor G. and other German members of SCHER were not based on verifiable evidence and could thus not be considered. Furthermore, the health effects of mercury in dental amalgams, which appeared to be the main concern of the complainant, were being examined by SCENIHR, which was presided by a British toxicologist, Dr B. SCHER was given responsibility for examining the environmental effects of dental amalgam, and its working group dealing with that topic was led by Professor T, a Spanish toxicologist, and not Professor G. or any other of the German scientists mentioned by the complainant. Therefore, the complainant's reservations and suspicions concerning the possible bias of persons involved in the assessment process were clearly unfounded.

THE SUBJECT MATTER OF THE INQUIRY

12. In its complaint to the Ombudsman, the complainant essentially put forward the following allegations:

- The Commission failed properly to react to the complainant's concerns as regards the independence of the German members of SCHER.
- The Commission failed properly to involve the complainant in its investigation into the risks of mercury. Doing so was contrary (a) to its own statement that it would involve stakeholders, and (b) to the European Parliament's resolution on the Community strategy concerning mercury of 14 March 2006.
- The Commission failed properly to handle the complainant's submissions of 25 May, 4 June, 11 August and 13 November 2007.

13. The complainant claimed that:

- the current German members of SCHER should be replaced by independent experts; and
- the Commission should give the complainant's submission of 11 August 2007 its proper weight. In particular, the central document of this submission should at least be translated into English and French in order to enable those responsible to take it into account.

THE INQUIRY

14. On 7 December 2007, the complainant submitted the present complaint to the Ombudsman. It provided additional materials by letters dated 8 and 19 January 2008.



15. On 4 February 2008, the Ombudsman opened an inquiry into the present case.
16. On 21 February 2008, the complainant sent a letter in which it reported on new developments.
17. On 18 March 2008, the Ombudsman forwarded the complainant's letter of 21 February 2008 to the Commission to allow the latter to take it into account in its opinion.
18. On 23 July 2008, the Commission transmitted the English original of its opinion on the present complaint. However, due to an informatics problem, the translation of the opinion into German was only sent to the Ombudsman on 10 September 2008. On 11 September 2008, the Ombudsman transmitted the opinion to the complainant for its observations.
19. The complainant did not send any observations.
20. On 2 December 2008, the Ombudsman asked the Commission to reply to a number of questions. On 7 April 2009, the Commission provided its reply.
21. On 18 May 2009, the Ombudsman forwarded the Commission's reply to the complainant for its observations.
22. No observations were received from the complainant.

THE OMBUDSMAN'S ANALYSIS AND CONCLUSIONS

A. The Commission's alleged failure properly to react to the complainant's concerns as regards the independence of the German members of SCHER and related first claim

Arguments presented to the Ombudsman

23. In its complaint, the complainant alleged that the Commission did not properly react to its submissions concerning the independence of SCHER's German members. In its letter of 25 May 2007, the complainant had drawn the Commission's attention to the fact that, in its view, the experts concerned had attempted to conceal their membership in the DGPT, which demonstrated a lack of integrity. However, the Commission failed to address the substance of this letter. The complainant further argued that its letter of 4 June 2007, in which it raised serious allegations regarding the composition of SCHER, and its letter of 13 November 2007 were not addressed by the Commission either.

24. The complainant attached a newspaper article, published in the German daily newspaper *die tageszeitung* on 6 August 2004, which it claimed to have sent to the Commission. In that



article, the Head of the Toxicology Department of Kiel University expressed his astonishment at the nomination of Professor G. to SCHER and stated that the latter had a "*conservative view of contamination*" and "*lacked sensitivity for low-level contamination*". In the same article, a senior public prosecutor was quoted as describing Professor G. as a "*submarine*" who, in a famous court case concerning timber preservatives, had stated that a certain chemical substance was harmless, whereas it could be demonstrated to cause cancer. In addition, the President of the German association for environmental medicine was quoted as saying that Professor G. "*played down the risk of dioxin*" in the context of procedures concerning the licensing of waste incineration plants.

25. In its letter of 21 February 2008, the complainant pointed out that the Commission had not attempted to contact the patient organisations listed in its letter dated 13 November 2007. It further argued that the DGPT 1990 publication on mercury in dental amalgams was offensive to persons suffering from sickness caused by chemicals, and that the association had manipulated academic books on toxicology. The complainant expressed its disappointment with the fact that the Commission did not find it worthy to comment on these issues. In this regard, it added that Professor G.'s lack of expertise had been commented upon in a ruling by a German court that would have been easily accessible to the Commission. It further argued that, contrary to Mr B.'s statement, it had in fact submitted sufficient evidence to call into question the independence of the German members of SCHER. The complainant finally pointed out that the Commission received three other complaints concerning the same issue. These were from (i) the European Academy for Environmental Medicine, (ii) a group of scientists and (iii) patient organisations.

26. In its opinion, the Commission pointed out that, since 25 May 2007, the complainant had sent it several letters accusing Professor G., the chairman of SCHER, of falsifying scientific findings. The complainant also referred to Dr M. and Professor D, members of SCHER, as falsifiers of science in view of their membership in the DGPT, which the complainant felt had falsified science in matters relating to amalgam.

27. The Commission stressed that it had carefully considered the letters and documents sent by the complainant on 25 May, 4 June and 13 November 2007. Contrary to what the complainant appeared to imply, these letters had been translated into English in order to facilitate examination by the responsible service. The Commission's unit dealing with the scientific committees replied to these letters on 8 and 31 October 2007 and 8 January 2008.

28. The Commission emphasised that it had examined the complainant's allegations concerning the independence of the German members of SCHER. However, it concluded that the critical articles and the expressions of views on the scientific positions of Professor G that the complainant had submitted as well as the DGPT membership of the experts concerned did not constitute evidence of a specific interest that might be considered as prejudicial to the independence of these experts in relation to the risk assessment of dental amalgam performed by SCHER. In particular, membership of DGPT – a scientific association comprising experts from academia, industry, medical professions and other circles in the areas of toxicology and pharmacology – which promotes scientific knowledge in those disciplines, could not be considered as a specific interest prejudicial to the independence of the experts, which would



have to be declared according to Article 14 of Decision 2004/210. The complainant's allegations against the DGPT were not supported by facts and the allegation that Professor G. and the other scientists mentioned had represented the interests of the industry in the DGPT was based on mere statements, such as " *they have faithfully played down all the dangers to suit the industry* " and " *falsified scientific facts* " on amalgam tooth fillings. More specifically, the criticism concerning the calculation of the mercury half-life values appeared to have been based on a misunderstanding of the scientific approach used by the DGPT to evaluate the toxicity of amalgam fillings.

29. The complainant argued that SCHER's risk assessment of mercury in dental amalgams could be biased due to the influence of the German members and that, as a result, patients' health might suffer. The Commission pointed out that SCHER was not assessing potential risks to human health caused by dental amalgam, but rather the environmental aspects. Human health aspects were being dealt with by SCENIHR. The concern that the position of the German members of SCHER could compromise the conclusions on human health of the ongoing risk assessment of dental amalgam was thus not relevant. Moreover, SCHER comprises 17 members from 9 countries and its decisions are made by majority voting. The Commission underlined that the work on the environmental aspects of dental amalgam had been assigned to an *ad hoc* SCHER working group led by a Belgian scientist, Professor J. Therefore, all guarantees were in place to ensure that SCHER's opinion on the environmental aspects of dental amalgam would in any event be balanced. The Commission thus took the view that the complainant's submissions did not provide acceptable, objective and verifiable reasons and justifications for the request to replace the German members of SCHER.

30. Having examined the Commission's opinion, the Ombudsman concluded that he needed further information in order to deal with the matter. Therefore, he asked the Commission to explain how it evaluated the statements quoted in the article that was published in the *tageszeitung* .

31. In its reply, the Commission outlined that it had carefully considered the said article, which contained criticisms of the scientific positions expressed by Professor G. in relation to certain controversial court cases in Germany. The Commission pointed out, however, that the article did not include any scientific argument or any potential evidence as regards interests which could have influenced Professor G's position. In particular, there was no element demonstrating any undisclosed interest which could be prejudicial to Professor G's independence in his role as member of SCHER.

The Ombudsman's assessment

32. In its correspondence with the Commission and in its complaint to the Ombudsman, the complainant raised serious allegations as to the independence of certain members of the SCHER and demanded that they be replaced by other, independent experts. In the complainant's opinion, the Commission failed properly to react to its concerns. The central issue to be examined here is thus whether the Commission adequately responded to the complainant's allegations.



33. Having carefully evaluated the materials put forward by the complainant, the Ombudsman notes that they contain allegations against, or criticisms of, Professor G. and other German members of SCHER. However, as the Commission correctly observed, these materials do not provide any conclusive evidence that could call into question the independence of the experts concerned. The only tangible fact that the complainant has put forward concerns the experts' membership of the DGPT. However, the Ombudsman is not convinced that the mere fact of being a member of a scientific organisation – or of not mentioning this membership in one's curriculum vitae – could give rise to doubts regarding an expert's independence. This could be otherwise if the relevant organisation was itself clearly serving the interests of a certain industry. However, the complainant has not established that this was the case with the DGPT. In this context, the complainant's submissions concerning the DGPT appear to be based to a large extent on a subjective interpretation of the association's actions and publications. Furthermore, the complainant has not disputed the Commission's statement that the other members of SCHER never expressed any doubts as to Professor G.'s independence or found it necessary to publish a dissenting opinion under his leadership of the Committee. Whilst not conclusive in itself, this fact adds further weight to the Commission's view that the complainant has not established its allegations against Professor G. and the other German members of SCHER.

34. As mentioned earlier, the complainant is an organisation of patients suffering from health damage that they consider to have been caused by mercury in dental amalgam. In its complaint, the complainant explicitly stated that it did not contest the composition of SCENIHR. In this context, it appears useful to note that, as explained by the Commission, SCHER dealt with environmental effects and indirect health effects of the use of mercury in dental amalgam, whereas SCENIHR dealt with the effects it has on patients and users [3] . Even if any of the members of SCHER had been biased, it is unclear how this could have affected SCENIHR's conclusions.

35. In view of the above considerations, and on the basis of the available information, the Ombudsman takes the view that the Commission reacted adequately to the complainant's allegations concerning the German members of SCHER. Therefore, no maladministration has been found as regards the complainant's first allegation and the first claim.

B. The Commission's alleged failure properly to involve the complainant in its investigation into the risks of mercury

Arguments presented to the Ombudsman

36. The complainant argued that the Commission failed to comply with its own commitment to involve stakeholders and with point 41 of the European Parliament resolution on the Community strategy concerning mercury of 14 March 2006, which it understood to call on the Commission to involve patient associations, such as itself, in consultation procedures concerning the risks of mercury in dental amalgam.



37. In its opinion, the Commission explained that, in January and February 2008, it launched a public consultation as regards the opinions to be adopted by SCENIHR and SCHER. The complainant sent a contribution which included two scientific articles and a copy of a letter dated 23 January 1997 from Dr A. and Mr B. to Dr W. The body of the message and the letter had been translated from German and provided to the SCHER working group members for their consideration.

38. The Commission pointed out that the procedures concerning the scientific committees did not foresee the participation of representatives of stakeholders. Only scientists and experts, in their personal capacity, who were chosen on the basis of their scientific expertise, are members of the committees and their working groups. The European Parliament resolution mentioned by the complainant referred to the Medical Devices Experts Group (MDEG), a group of experts assisting the Commission with regard to the transposition of Council Directive 90/385/EEC [4] . This was a separate entity, acting under the responsibility of DG ENTR, which had a role, composition and working procedures that are different from the scientific committees involved in the present case. As regards the complainant's e-mail of 4 June 2007, which was a reply to a public call for information, the Commission submitted that it had been dealt with in accordance with the applicable procedure. According to point 4 of the Commission's applicable Pilot Dialogue Procedures [5] , no individual reply was foreseen in such cases.

39. Since the Commission's opinion focused on the role of DG SANCO, whereas the complainant had also referred to the involvement of DG ENTR, the Ombudsman asked the Commission to provide him with additional explanations regarding the latter's involvement. In addition, the Ombudsman asked the Commission to explain the distribution of responsibilities between DG SANCO and DG ENTR in the investigation concerning the risks of mercury and the role, composition and rules governing the functioning of the MDEG.

40. In its reply, the Commission explained that DG ENTR was responsible for the development and implementation of the regulatory framework concerning medical devices and for the control of its application. According to the definition of Article 1(2)(a) of Directive 93/42/EEC [6] , dental amalgam is a medical device. When carrying out its tasks, DG ENTR was assisted by the MDEG.

41. The MDEG is a consultative body composed of Member State and stakeholder representatives. It is consulted on issues relating to the implementation of the directives regulating medical devices. The Commission requested the MDEG to consider the use of mercury in dental amalgam, with a view to forming an opinion as to whether additional regulatory measures were appropriate under Action 6 of its Communication to the Council and the European Parliament on a Community Strategy concerning Mercury [7] . Following this consultation, and in agreement with the MDEG, DG ENTR requested, in January 2007, an opinion from SCENIHR on the safety of dental amalgam and alternative dental restoration materials for patients and users. In addition, the Commission asked SCHER for an opinion on the environmental risks and indirect health effects of mercury in dental amalgam.

42. SCENIHR and SCHER are two of the three independent non-food scientific committees of



the Commission. The Commission pointed out that the scientific committees provide it with sound scientific advice needed for preparing policy and proposals relating to consumer safety, public health and the environment. The committees perform their tasks in compliance with the principles of excellence, independence and transparency, which are ensured by the Rules of Procedure of the Scientific Committees [8] . With regard to the division of tasks between DG ENTR, DG SANCO, and the scientific committees, the Commission explained that DG ENTR is in charge of the risk management of medical devices and that where it identified a potential risk, it could decide to ask for a risk assessment. DG ENTR usually did so by soliciting the expertise of the scientific committees.

43. The Commission pointed out that, with the aim of preparing the opinions, and acting together with SCENIHR and SCHER, it had launched calls for information and public consultations. These calls were published on DG SANCO's website. All interested parties had had the opportunity to provide their comments and/or any further relevant information. No comments were received from the complainant during the public consultation on the SCENIHR opinion, which took place from 14 January to 22 February 2008. The Commission pointed out that members of the complainant submitted comments on an individual basis, which were then examined by SCENIHR in line with the applicable procedure. Similarly, the comments received from the complainant during the parallel public consultation on the SCHER opinion were assessed by that committee. DG ENTR and DG SANCO had thus adequately considered the concerns raised by the complainant and ensured that all information it had submitted was properly assessed. Subsequent to the adoption and publication of the SCENIHR opinion of 6 May 2008, the issue came again within the responsibility of DG ENTR in its risk-management role. Whilst being fully aware of the submissions calling for a ban on dental amalgam, including that of the complainant, DG ENTR took the view that, in light of the scientific opinions adopted by SCHER and SCENIHR, there was no legitimate basis for such a ban.

44. Although this was not the subject of the inquiry, the Commission nonetheless considered it useful to explain the reasons for the above position. According to SCENIHR, there was no scientific evidence that mercury in dental amalgam was a cause of diseases besides occasional local adverse effects (such as allergic reactions). In addition, it remained the material of choice for certain dental restorations in posterior teeth. Banning mercury in dental amalgam would, therefore, deprive patients of a relevant treatment option for certain tooth restorations. DG ENTR shared its views with stakeholders on the occasion of the MDEG meeting on 6 June 2008. The Commission noted that several groups had loudly called for a ban on dental amalgam. However, none of the experts had opposed the risk-management approach proposed by DG ENTR.

The Ombudsman's assessment

45. The complainant's second allegation consists of two aspects. The first concerns Parliament's resolution of 14 March 2006 on the Community strategy concerning mercury, and in particular its point 41, which the complainant considers the Commission not to have observed. It appears useful to note that, in the relevant passage of the resolution, Parliament calls upon the Commission to involve a wider range of stakeholders in the composition of the



MDEG. However, the complainant approached the Commission not the MDEG as regards the composition of SCHER. Furthermore, in its complaint and in its correspondence with the Commission, the complainant did not put forward any specific allegations as regards the MDEG. Therefore, no maladministration can be found as regards this aspect of the case.

46. The second aspect concerns the Commission's commitments to consulting stakeholders on the dangers of mercury. In this regard, however, the Commission explained that it had carried out public consultations concerning the opinions to be adopted by both SCHER and SCENIHR. The complainant reacted to these calls by submitting comments, which, along with the contributions of its members, were considered in accordance with the procedures published and applicable to calls for information and public consultation. The complainant has not specified in what precise way it considers that the Commission failed to observe its commitments in this area. In light of the information provided to the Ombudsman's request for further information, the Commission indeed appears to have complied with its general commitments. Against this background, no maladministration can be established with regard to the second aspect of the second allegation either.

C. The Commission's alleged failure properly to handle the complainant's submissions and the related second claim

Arguments presented to the Ombudsman

47. In its complaint, the complainant alleged that the Commission failed to consider its submissions of 25 May, 4 June, 11 August and 13 November 2007. It emphasised, however, that its main concern revolved around its 600-page submission of 11 August 2007, the core document of which comprised 70 pages. The complainant pointed out that it had contacted the Commission's services by telephone two months after sending this submission and discovered that nobody had read it by that time. According to the complainant, it was subsequently informed that someone able to understand German might eventually read the 70-page document, but the submission would not be translated into other languages. It was disappointed that the Commission had not given its contribution the proper consideration it deserved. In particular, the central part of its contribution ought to have been translated into French or English in its view.

48. In its opinion, the Commission referred to the explanations it provided in response to the first allegation. It also recalled that it had carefully considered the letters and documents sent by the complainant on 25 May, 4 June and 13 November 2007 which, contrary to what the complainant appeared to imply, had been translated into English in order to facilitate an examination by the responsible service. The Commission's unit dealing with the scientific committees replied to these letters on 8 and 31 October 2007 and 8 January 2008. The Commission confirmed that the complainant also wrote to DG ENTR on 11 August 2007. Given that the material provided to DG ENTR in this correspondence was identical to that in relation to which the complainant had already received the aforementioned replies from DG SANCO, the Commission's services did not formally reply to it. However, the Commission recognised that



this was a mistake and offered its apologies to the complainant for this omission.

49. In relation to the second claim, the Commission stated that it had carefully examined the complainant's submission of 11 August 2007, translated the reference documents into English, explained its position and invited the complainant to present comments on the draft opinions to be adopted by SCHER and SCENIHR within the framework of the public consultations.

50. The Ombudsman considered it useful to ask the Commission for additional comments on the role of DG ENTR with respect to the second claim. In its response, the Commission reiterated that the complainant's submission of 11 August 2007, which focused on the dangers of mercury and dental amalgam, was identical to the material received by DG SANCO at an earlier stage. Nevertheless, DG ENTR forwarded the submission to DG SANCO for information. It underlined that all the information received from the complainant during the calls for information mentioned above was assessed by SCENIHR and SCHER, in line with the applicable procedure for calls for information [9]. Contrary to what the complainant appeared to imply, a translation into English had been produced so as to facilitate the examination of these submissions by the responsible service and by the scientific committees. The Commission added that several members of SCENIHR and SCHER, as well as members of the two related working groups which prepared the draft opinions, spoke German.

The Ombudsman's assessment

51. The complainant's third allegation concerns the Commission's handling of its submissions of 25 May, 4 June, 11 August and 13 November 2007.

52. The complainant's submission of 4 June 2007 was sent in reply to the call for information concerning the opinion to be adopted by SCHER [10]. The relevant procedures indeed do not foresee an individual reply. The Commission pointed out, without being contradicted by the complainant, that its services took account of its letter of 4 June 2007. Given that the purpose of that procedure was to gather relevant scientific information for the consideration of the scientific committees, the Commission's approach cannot be considered unreasonable.

53. As regards the complainant's letters of 25 May and 13 November 2007, the Ombudsman notes that the Commission replied to them by letters dated 8 October 2007 and 8 January 2008. The complainant correctly pointed out that the letter of 8 October 2007 only referred to its letter of 27 July 2007. However, the letter of 27 July 2007 was, in essence, a reminder asking for a reply to the letter of 25 May 2007. The extent to which the Commission has taken the contents of these letters into account and replied to them has already been considered in the context of examining the complainant's first allegation above. Against this background, the Ombudsman considers that the Commission's handling of the complainant's letters of 25 May and 13 November 2007 was adequate.

54. As regards the submission of 11 August 2007, which the complainant considers to be the most important, the Commission provided a detailed account as to how it handled this submission. The complainant has not provided the Ombudsman with a copy of its letter of 11



August 2007, or of the documents it previously sent to DG SANCO. Nor has it made any observations on the Commission's explanations. In these circumstances, and on the basis of the information available to him, the Ombudsman thus takes the view that there are no grounds for further inquiries concerning this aspect of the case.

55. With its second claim, the complainant stated that the central document of its submission of 11 August 2007 should be translated into English or French. The Commission argued that (i) the complainant's submission of 11 August 2007 was identical to submissions that the complainant had already sent to DG SANCO in response to a call for information, and (ii) it had already translated those materials into English. In addition, the Commission pointed out that a number of members of SCHER and SCENIHR spoke German. The complainant has not submitted any comments on these explanations. Given these circumstances, the Ombudsman takes the view that there are no grounds for further inquiries into the complainant's second claim.

D. Conclusions

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

There are no grounds for further inquiries into the complainant's third allegation, as far as the letter of 11 August 2007 is concerned, and its second claim. No maladministration has been found with regard to the remainder of the complainant's allegations and claims.

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

P. Nikiforos DIAMANDOUROS

Done in Strasbourg on 4 May 2010

[1] Commission Decision No 2004/210/EC setting up Scientific Committees in the field of consumer safety, public health and the environment (OJ 2004 L 66, p. 45).

[2] It appears that Mr B. was referring to the SCENIHR call for information (see paragraph 52 below).

[3] As regards the use of mercury in dental amalgam and its effects on patients and users, SCENIHR published its opinion on 6 May 2008. It concluded that there was no scientific evidence demonstrating risks of adverse systemic effects and that the current use of dental amalgam does not pose a risk of systemic disease. The opinion is available under:

http://ec.europa.eu/health/ph_risk/committees/04_scenihr/docs/scenihr_o_016.pdf [Lien]



The SCHER opinion of 6 May 2008 on the environmental effects of mercury is available under:

http://ec.europa.eu/health/ph_risk/committees/04_scher/docs/scher_o_089.pdf [Lien]

[4] Council Directive 90/385/EEC of 20 June 1990 on the approximation of the laws of the Member States relating to active implantable medical devices (OJ 1990 L 189, p. 17).

[5] http://ec.europa.eu/health/ph_risk/documents/stakeholder_procedure_en.pdf [Lien]

[6] Council Directive 93/42/EEC of 14 June 1993 concerning medical devices (OJ 1993 L 169, p. 1).

[7] COM(2005)20 final.

[8] The Rules of Procedure of the Scientific Committees referred to by the Commission can be accessed at: http://ec.europa.eu/health/ph_risk/documents/ev_20040907_rd01_en.pdf [Lien]

[9] See footnote 5 above.

[10] The Ombudsman notes that the complainant appears to have sent two communications to the Commission on 4 June 2007, one to SCHER and another to SCENIHR. However, since the complainant provided the Ombudsman only with a copy of the e-mail sent to SCHER, he assumes that this is the communication it wished to complain about.