DECISION OF THE CHAIRMAN OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

29 July 2011

Request for confidential treatment of certain information

(Compliance check of a registration – Confidential information – Substance identity – Substance tonnage data – Substance uses – Studies relating to substance – Protection of personal data)

Case number	A-005-2011
Language of the case	English
Appellant	Honeywell Belgium N.V. Belgium
Representative	Messrs. Herbert Estreicher and Marcus Navin-Jones Keller and Heckman LLP Avenue Louise 523 B – 1050 Brussels Belgium
Contested decision	CCH-D-0000001396-72-03/F of 22 March 2011 adopted by the European Chemicals Agency (hereinafter 'the Agency') pursuant to Article 41 of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p.1; corrected by OJ L 136, 29.5.2007, p. 3) (hereinafter 'the REACH Regulation')

THE CHAIRMAN OF THE BOARD OF APPEAL

gives the following

Decision

SUMMARY OF THE FACTS

1. On 21 June 2011, the appellant filed an appeal at the Registry of the Board of Appeal of the European Chemicals Agency (hereinafter 'the Registry') against the Agency's decision of 22 March 2011, by which the appellant's dossier was found non-compliant with the applicable information requirements of the REACH Regulation, and which required the appellant to submit, *inter alia*, further information following the conduct of a 90-day repeated dose toxicity study (sub-chronic toxicity study) in the rabbit by inhalation (hereinafter 'the 90-day study in rabbits'). The appellant has contested only that part of the Agency's decision by which the appellant has been requested to conduct the 90-day study in rabbits (hereinafter 'the Contested Decision').

2. Pursuant to Article 6(1)(g) of Commission Regulation (EC) No 771/2001 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (hereinafter 'the Rules of Procedure') (OJ L 206, 2.8.2008, p. 5), the appellant's notice of appeal contained a request that the following information be considered as confidential and not be disclosed during or after the present appeal proceedings:

    1) The substance identity and identifier information, i.e., the IUPAC name, the EC and CAS numbers, the REACH registration number and the REACH dossier submission number (hereinafter together 'the substance identity information');

    2) The substance registration tonnage band;

    3) The [CONFIDENTIAL INFORMATION], and comment by, [CONFIDENTIAL INFORMATION]; and

    4) The name of three Clinical Research Organisations (hereinafter 'the CROs') together with the identities of the three experts at the respective organisations who provided statements in support of the appellant's claims (hereinafter 'the experts' identities').

3. On 29 June 2011, the Chairman of the Board of Appeal (hereinafter 'the Chairman') requested the appellant to provide clarifications for its request for confidential treatment (hereinafter 'the Chairman's request for clarifications'). More specifically, the Chairman transmitted a copy of a powerpoint presentation with the title "HFO-1234yf Industry Update February 6, 2009" (hereinafter 'the presentation'), and invited the appellant to:

    1) Substantiate its request for confidential treatment, in particular as regards the substance identity information. More specifically, the appellant was invited to provide further details of the alleged harm to its commercial interests that would ensue from disclosure of the substance identity information;

    2) Clarify whether it had requested confidentiality pursuant to Article 119(2) of the REACH Regulation for the substance identity information and the substance tonnage band in the course of the REACH registration process, and if so, whether the Agency had accepted such claim(s);

3) Clarify its commercial interests in protecting the confidentiality of the substance identity information and the substance tonnage band considering that such information was already in the public domain; and

4) State whether it requests the names of its external legal counsel to be kept confidential.

4. By a separate letter dated 7 July 2011, which was addressed to the Registry, the appellant provided additional information to the Board of Appeal (hereinafter 'the letter of 7 July 2011'). In this letter, the appellant clarified and amended its request for confidential treatment. The amendments followed the submission of the full, non-redacted version of the Contested Decision by the appellant. By the letter of 7 July 2011, the appellant requested that the following information should also be treated as confidential:

1) With respect to the request for confidential treatment of the substance identity information, also the substance's chemical and trade names;

2) Information on the substance's precise tonnage data;

3) Information on studies submitted to the Agency, including the title and name of the studies as well as the study reference numbers; and

4) Information on the uses of the substance.

5. On 11 July 2011, the Chairman transmitted a copy of a significant new use rule of the United States Environmental Protection Agency (hereinafter 'the EPA' and 'the EPA rule') relating to the substance in question, published in the United States Federal Register on 27 October 2010. The Chairman invited the appellant to take that document into consideration in its reply to the Chairman's request for clarifications.

6. By a letter dated 15 July 2011, the appellant replied to the Chairman's request for clarifications and provided the following information (hereinafter 'the reply of 15 July 2011', together with the request for confidential treatment in the notice of appeal and the letter of July 7, 2011, 'the confidentiality request'):

1) The appellant provided further justifications and arguments for its claim for confidential treatment of the substance identity information;

2) The appellant clarified that its claim with respect to the substance tonnage information related to the precise substance tonnage data, and not to the tonnage band. Accordingly, the appellant withdrew its claim for confidential treatment of the substance tonnage band; and

3) The appellant clarified that it does not request the names of its external legal counsel to be treated as confidential.

7. In light of the appellant's clarifications in the reply of 15 July 2011, the Chairman notes that it is not necessary to consider further the appellant's request with respect to the substance tonnage band. Similarly, the confidential treatment of the appellant's external legal counsel shall not be considered further in this Decision. However, for the sake of clarity, the Chairman wishes to make known that names of appellants' representatives do not generally need to be published when appeals are announced in the Agency's website.

GROUNDS OF THE REQUEST

8. The appellant provided justifications in its notice of appeal for keeping confidential the information identified in paragraph 2 above. The appellant provided supplemental justifications in its letter of 7 July 2011 and the reply of 15 July 2011. The appellant's justifications for the confidentiality request can be summarised as follows:

- With respect to *the substance identity information*, the appellant states, firstly, that this information has been kept confidential by the Agency during the decision-making process. Secondly, the appellant claims that the substance to which the dispute relates is of no direct relevance to the present proceedings, and thirdly that the appellant has taken measures to keep confidential the fact that the present proceedings relate to the substance in question. According to the appellant, disclosure of this information would harm the appellant's or a third party's commercial interests, including as regards the development of commercial applications, the return on investment, the possible negative publicity and unfounded rumours among downstream users.
- As regards the appellant's request relating to *information on the substance's uses*, the appellant relies on the arguments raised with respect to the substance identity information.
- With respect to information on the *precise substance tonnage data*, the appellant relies on Article 118(2) of the REACH Regulation. In support of its argument, the appellant claims [CONFIDENTIAL INFORMATION].
- With respect to the [CONFIDENTIAL INFORMATION]*, and comment by* [CONFIDENTIAL INFORMATION].
- As regards *the CROs' names and the experts' identities*, the appellant claims that this information has been provided to the appellant on the understanding that it is private and confidential. As regards the experts' identities, the appellant invokes also Directive 95/45/EC of the European Parliament and of the Council of 24 October 1995 on the protection of individuals with regard to the processing of personal data and on the free movement of such data (OJ L 281, 23.11.1995, p.31, hereinafter 'Directive 95/45/EC'). According to the appellant, the disclosure of this information could affect the CROs' commercial interests and [CONFIDENTIAL INFORMATION]. Furthermore, the appellant claims that the Agency does not disseminate the CROs' names pursuant to Article 119 of the REACH Regulation for similar reasons.
- Finally, as regards the appellant's request for confidential treatment of *information on the studies*, the appellant relies on the arguments raised with respect to the substance identity information.

REASONS

9. Article 6(1)(g) of the Rules of Procedure provides that an appellant may request that information contained in a notice of appeal be treated as confidential.

10. In accordance with the second subparagraph of Article 6(6) of the Rules of Procedure, the Chairman shall decide on requests for confidential treatment for information contained in notices of appeal.

11. The issue to be decided by the Chairman in this Decision is whether or not to treat as confidential the information covered by the confidentiality request. This requires, as a first step, an assessment of whether the private interest opposing disclosure is legitimate, including an assessment of whether information covered by a request for confidential treatment is secret (see, by analogy, Order of the President of the Sixth Chamber of the General Court of 8 October 2009 in Case T-314/06 *Whirlpool Europe Srl v. Council of the European Union*, paragraphs 26-28). As a second step, if the private interest is found to be legitimate, it must be balanced against the public interest in transparency. To the extent that a request for confidential treatment relates to personal data of a natural person, the request falls to be assessed pursuant to Regulation (EC) No 45/2001 of the European Parliament and of the Council of 18 December 2000 on the protection of individuals with regard to the processing of personal data by the Community institutions and bodies and on the free movement of such data (OJ L 8, 12.1.2001, p.1, hereinafter 'Regulation (EC) No 45/2001'). This assessment calls for an analysis of whether the conditions, as defined in Regulation (EC) No 45/2001, for the legitimate processing of personal data are fulfilled, without it being necessary to consider separately any public interest in disclosure.

The scope of the Decision

12. By way of a preliminary remark, the Chairman wishes to clarify the scope of the present Decision.

13. Pursuant to Article 6(6) of the Rules of Procedure, the Chairman shall decide, upon request, whether information indicated by an appellant as confidential in a notice of appeal should be regarded as such. The Chairman shall ensure that confidential information is not published when an appeal is announced on the Agency's website. The same obligation to protect confidential information also applies to any final decision of the Board of Appeal by virtue of Article 21(5) of the Rules of Procedure, which provides that decisions of the Board of Appeal shall be published in full form, unless the Chairman decides otherwise upon a reasoned request of a party.

14. Thus, Articles 6(6) and 21(5) of the Rules of Procedure define the scope of the Chairman's decisions with respect to requests for confidential treatment. The Chairman's decision on confidentiality applies to the announcement of an appeal (hereinafter 'the announcement') and to any final decision by the Board of Appeal in an appeal case.

15. For the sake of clarity, it should be noted that the Chairman's decision taken pursuant to Articles 6(6) and 21(5) of the Rules of Procedure is distinct from the general right to access documents pursuant to Regulation (EC) No 1049/2001

of the European Parliament and of the Council of 30 May 2001 regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p.43, hereinafter 'Regulation (EC) No 1049/2001'). The assessment of confidentiality pursuant to Articles 6(6) and 21(5) of the Rules of Procedure pursues a different objective as it is conducted in the context of specific appeal proceedings before the Board of Appeal. Therefore, the interests to be considered, including the manner in which they are balanced, may be different from any assessment pursuant to Regulation (EC) No 1049/2001. Furthermore, the procedure for seeking access to documents pursuant to Regulation (EC) No 1049/2001 is distinct and unconnected to any appeal proceedings before the Board of Appeal.

16. Accordingly, the Chairman must determine in this Decision whether information covered by the appellant's confidentiality request can be disclosed in the announcement and in any final decision to be taken by the Board of Appeal in the present case.

17. For the sake of completeness, it should be added that in the event a third party applies to intervene in the present proceedings pursuant to Article 8 of the Rules of Procedure, and such an application were accepted by the Board of Appeal, the Chairman may need to reconsider the findings in this Decision . In those circumstances, the assessment would be limited to analysing what information needs to be disclosed to the intervening party.

The procedure for claiming confidential treatment for information in a notice of appeal

18. Before analysing the substance of the appellant's confidentiality request, the Chairman considers it opportune to address certain procedural issues raised by the appellant's correspondence, in particular the letter of 7 July 2011 and the reply of 15 July 2011.

19. Firstly, the Chairman notes that the Registry requested the appellant to submit the full, non-redacted version of the Agency's decision, a part of which has been contested by the appellant in the present proceedings. The appellant is correct in observing that pursuant to Article 6(1)(d) of the Rules of Procedure, an appellant is only required to submit the reference of the decision which is being contested, not a copy of the contested decision.

20. In the present case, the Registry requested a courtesy copy from the appellant in the interest of ensuring that a full, non-redacted version of the Contested Decision had been notified to the appellant. Had the appellant declined to submit the full, non-redacted version of the Contested Decision, it would have been open for the Registry to request that version directly from the Agency.

21. By way of a more general remark, the Chairman wishes to observe that redacted documents should not be submitted to the Board of Appeal. This applies also to documents for which a party has requested confidential treatment. This is implicit, first, from Article 6(6) of the Rules of Procedure, which requires the Chairman to decide whether information in a notice of appeal is to be regarded as confidential. To this effect, point 39 of the Practice Directions to parties to appeal proceedings before the Board of Appeal of the European Chemicals Agency (hereinafter 'the Practice Directions') requires that any request for confidential treatment shall "indicate the relevant words, figures

or passages for which confidentiality is claimed". In other words, a party must indicate in the original version of a document information for which confidential treatment is requested. Furthermore, point 40 of the Practice Directions clarifies that whether "any particular information is to be regarded as confidential is a matter for the Chairman of the Board of Appeal to decide". Such an assessment necessarily requires that the Chairman has full access to all information in documents submitted to the Board of Appeal. Moreover, the process outlined in points 42 *et seq.* of the Practice Directions for confidentiality requests clarifies that redacted versions of documents should be submitted to the Board of Appeal only after the Chairman has decided on a request for confidential treatment.

22. Secondly, for reasons explained in detail below, the Chairman disagrees with the appellant's contention that the substance identity and the Agency's decision, to the extent that it has not been contested by the appellant, are irrelevant for the purposes of the present proceedings. By way of a preliminary observation, the Chairman notes that the non-contested parts of the decision contain information are relevant for the purposes of assessing the appellant's request for confidential treatment. With regard to the substance identity, the Chairman considers it to be intrinsically linked with the present proceedings, including the assessment of the appellant's confidentiality request.

23. By way of a more general observation, in cases where only a part of the Agency's decision has been contested, the Board of Appeal must be able to satisfy itself whether the non-contested part includes information that is relevant for its decision-making. This may include an assessment of whether the contested part can be separated from the non-contested part, and whether any remedies to be granted by the Board of Appeal may have effects beyond the contested part.

24. Moreover, while it is for appellants to define the scope of their claims in each individual case, including the factual allegations and any evidence offered in support thereof, it is for the Board of Appeal to decide what information is necessary for its decision-making. This applies equally to the Chairman when called upon to decide on requests for confidential treatment.

25. Thirdly, as regards the appellant's remark that the Contested Decision is marked "confidential" and [CONFIDENTIAL INFORMATION], the Chairman is not bound, when assessing a request for confidential treatment contained in a notice of appeal, by any finding on confidentiality by the Agency or any of the committees working under the auspices of the Agency (see, by analogy, Order of the President of the Sixth Chamber of the General Court of 8 October 2009 in Case T-314/06 *Whirlpool Europe Srl v. Council of the European Union*, paragraphs 26-28). The assessment of confidentiality in proceedings before the Board of Appeal pursues a distinct objective. More specifically, requests for confidential treatment before the Board of Appeal are raised in connection with public proceedings that serve, in addition to an appellant's private interest, also a wider public interest. This is reflected by the fact that information on appeals and the final decisions of the Board of Appeal in appeal cases must be made public. Accordingly, the Chairman, when called upon to decide on a request for confidential treatment, must have regard not only to the appellant's private interest in protecting confidential information but also to the public interest in transparency, and more specifically the public's right to know about proceedings that take place before the Board of Appeal. This balancing of potentially conflicting and opposing interests sets apart the process before the

Board of Appeal; the Chairman's decisions cannot be contingent upon any prior findings on confidential treatment by the Agency.

26. Fourthly, as regards the appellant's argument raised in the reply of 15 July 2011 that certain types of information have been treated as confidential in appeal announcements published on the Agency's website in prior cases, the Chairman wishes to stress that requests for confidential treatment are analysed on a case-by-case basis. To the extent that information is not public by reason of the first subparagraph of Article 6(6) of the Rules of Procedure and the Decision of the Board of Appeal of 30 September 2009 on Implementing the Rules on Publication of an Announcement of the Notice of Appeal on the website of the Agency (hereinafter 'Decision on the publication of the announcement'), it is the Chairman's duty to assess in each individual case what information is necessary for the purposes of the announcement and any final decision, having due regard to appellants' legitimate interests in protecting confidential information.

27. Finally, the Chairman wishes to clarify that when a decision has been adopted with respect to a request for confidential treatment, information which is not considered confidential can be made public in the announcement and any final decision without the Board of Appeal, including its Chairman and the Registry, seeking an appellant's prior consent.

28. Furthermore, the Chairman observes, with respect to the appellant's request for information submitted in its notice of appeal to be returned and/or destroyed, that the Board of Appeal is required, pursuant to Article 24 of the European Code of Good Administrative Practice, to keep adequate records of, *inter alia*, documents it receives. To this effect, a document retention policy applicable to the Board of Appeal stipulates that no document submitted to the Board of Appeal in connection with appeal proceedings can be returned or destroyed.

Assessment of the appellant's confidentiality request

1. Substance identity information, information on the uses of the substance and the studies relating to the substance

29. The appellant has requested confidential treatment for the substance identity information. As explained above, the appellant has requested the substance's chemical and trade names, name in the IUPAC nomenclature, the EC and CAS numbers, as well as the REACH registration and dossier submission numbers to be treated as confidential.

30. The appellant has also requested that information on the uses of the substance and information on studies relating to the substance should not be disclosed. As regards the substance's uses and the studies, the appellant claims that this information, if coupled with information on the appellant's identity, would disclose the substance identity. In view of the link between the appellant's claims as regards the substance identity, the uses of the substance and the studies, the Chairman considers it opportune to assess these claims under the same heading.

31. However, it is implicit from the appellant's request that the principal claim relates to the substance identity information. If information on the substance

identity were not treated as confidential, and thus disclosed in the announcement and any final decision, the appellant's request with respect to the uses of the substance and the studies would be rendered superfluous as a link between the substance, its uses and the studies could be made based on publicly available information. For these reasons, the appellant's request relating to information on the uses of the substance and the studies is, by definition, corollary to its request regarding the substance identity information.

32. By way of a further preliminary remark, and contrary to what the appellant has claimed, the Chairman considers information on the specific substance to be directly and highly relevant for assessing the present case, including the appellant's request for confidential treatment. In the Chairman's opinion, it is not possible to separate the present proceedings from the specific substance. The subject-matter of the dispute concerns, *inter alia*, the scientific need to carry out a 90-day study in rabbits for the specific substance. Accordingly, and without prejudice to the any findings by the Board of Appeal on the substance of the case, the Chairman considers the substance identity to be intrinsically linked with the present proceedings. Therefore, it is necessary for the Chairman to assess whether the appellant has a legitimate interest in keeping information on the substance confidential, and if so, whether there is any overriding public interest that would call for that information to be made public.

Substance identity information

33. First, the Chairman observes that substance identity information is not automatically confidential pursuant to Articles 118 and 119 of the REACH Regulation.

34. By the Chairman's request for clarifications, the Chairman invited the appellant to clarify whether it had claimed confidential treatment for the substance identity information in the course of the REACH registration process. This clarification was aimed at ascertaining, first, whether confidential treatment pursuant to Article 119 of the REACH Regulation was possible by reason of the substance's properties (in particular, whether it fell within Article 119 of the REACH Regulation as a dangerous substance within the meaning of Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substance (as amended, hereinafter 'Directive 67/548/EEC'), and as a corollary, whether the appellant had an interest in keeping confidential this information.

35. In response to the Chairman's request for clarifications, the appellant informed the Chairman by the reply of 15 July 2011 that its registration is [CONFIDENTIAL INFORMATION]. The reply of 15 July 2011 seems to imply that no claim for confidential treatment pursuant to Article 119 of the REACH Regulation has been made. In fact, as explained above, the appellant relies in support of its claim on the fact that the Agency [CONFIDENTIAL INFORMATION] treated the substance identity information as confidential in the course of the REACH evaluation process.

36. Whilst taking note of the Agency's stance on the confidentiality of the substance identity information in the course of the REACH evaluation process, the Chairman underlines that the Agency's position is not binding on the Chairman (see paragraph 25 to this Decision). As a matter of fact, the Chairman must assess the appellant's confidentiality request in the context of

the present appeal proceedings, in accordance with the general framework for analysing requests for confidential treatment contained in notices of appeal (see paragraph 11 to this Decision).

37. In the present case, the Chairman deems the following considerations to be relevant for assessing the appellant's private interest in keeping confidential the substance identity information.

38. First, based on documents that are publicly available and which have been notified to the appellant, it is clear that information on the substance identity is in the public domain. In fact, as is clear from the presentation which was sent as an annex to the Chairman's request for clarifications, information on the substance's name, chemical and trade names as well as CAS and EC numbers are publicly available. Similarly, information on the appellant's REACH registration number is in the public domain.

39. In accordance with settled case-law of the European Courts, a precondition for the confidential treatment of information is that it be known only to a limited number of persons (see, by analogy, Cases T-474/04, *Pergan Hilfsstoffe für Industrielle Prozesse v. Commissio*n, [2007] ECR II-4225, paragraph 65 and T-198/03, *Bank Austria Creditanstalt AG v. Commission*, [2006] ECR II-1429, paragraph 71). Information can lose its confidential nature when the public at large or specialist circles have access to it (see, by analogy, Order of the President of the Third Chamber of the General Court of 5 July 2010 in Case T-304/08 *Smurfit Kappa Group v. Commission*, paragraph 13 and the cases cited therein).

40. However, the fact that information on the appellant's substance is already in the public domain does not signify *per se* that the appellant's interest in keeping confidential the substance identity information could not be legitimate in proceedings before the Board of Appeal. In fact, the appellant is seeking to keep confidential the fact that the particular substance is the subject of the present proceedings before the Board of Appeal rather than the substance identity *per se*.

41. Whether the appellant's request can be considered legitimate depends on whether the appellant's interest is legitimate and substantiated, and whether disclosure could result in harm to those interests.

42. The appellant has explained in an extensive manner its interest in keeping confidential the substance identity information. In essence, the appellant's stated private interest is to avoid any unfounded and unjustified concerns coming into being as regards the safety of the substance, the substance's regulatory status, and the process being followed by the Agency. According to the appellant, such unfounded and unjustified concerns could be deployed by its competitors to the detriment of the appellant and third parties.

43. In this respect, the Chairman takes notice of the appellant's claimed private interest in not disclosing the substance identity information. However, at the same time, the Chairman observes that information on possible regulatory concerns is already in the public domain. In the United States, the EPA has issued a significant new use rule for the substance following a risk assessment of potential hazards and exposures, including consumer uses. The imposition of the EPA rule signifies, *inter alia*, that any manufacturing, importation or processing of the chemical for any activity that is designated as a significant new use must be notified to the EPA before such activity can begin.

44. While these concerns have been raised in the context of the United States' regulatory process, the human health concerns, including the recommendation for further testing, identified in the EPA rule could be in the Chairman's assessment sufficient in themselves to give rise to the potential harm to commercial interests, as claimed by the appellant. In fact, the appellant concedes in its reply of 15 July 2011 that competitors monitor issues such as the regulatory status of competing products and chemical substances. Such monitoring, even if geographically limited, would be unlikely to exclude the United States, a market of considerable size and importance.

45. Moreover, it is relevant to note that the downstream users of the specific substance include, for instance, automotive producers. These are multinational companies that operate globally. In the opinion of the Chairman, they could not be expected to be insulated from regulatory concerns raised in the United States. Thus, the potential for harm, which according to the appellant could ensue from the disclosure of regulatory concerns raised by the Agency with respect to the specific substance, may already exist.

46. The Chairman considers that the appellant's reply of 15 July 2011 does not alter this assessment. Without taking a position on the appellant's claim as regards companies' acquaintance with the EPA's significant new use rules and conversely the lack of familiarity with the REACH evaluation process, the fact remains that information on human health concerns and the need for further testing exists, and these can already be deployed to the appellant's detriment. In this respect, the Chairman also wishes to note that it is for companies to assess the need, and the most appropriate manner, to communicate with their customers and downstream users regarding regulatory issues.

47. It follows from the foregoing that the appellant has failed to establish a link between the disclosure of the substance identity information and the claimed harm to its private interest given that information on regulatory concerns is already in the public domain. The appellant's claim is general and abstract in nature (see, by analogy, Case T-380/04, *Terezakis v. Commission* [2008] ECR II-11 (Summ.pub.), paragraph 93). Consequently, the harm claimed is not reasonably foreseeable, but hypothetical (see, by analogy, Case T-211/00, *Kuijer v. Council of the European Union*, [2002] ECR II-485, paragraph 56).

48. For the above reasons, the Chairman concludes that the private interest to keep confidential the substance identity information has not been clearly established in the present case.

49. However, in the interest of completeness, the Chairman will nevertheless analyse whether there is an overriding public interest, which would require the disclosure of the substance identity information in the appeal announcement and any final decision by the Board of Appeal (see paragraphs 59 *et seq.* below).

Information on the uses of the substance

50. As regards the request for confidential treatment of information on the uses of the substance, the appellant argues, in essence, that disclosure of information on the substance's uses would reveal, if coupled with the appellant's identity, the identity of the substance.

51. By way of a preliminary remark, the Chairman observes that in accordance with Article 118(2)(b) of the REACH Regulation, disclosure of information on a

substance's precise use, function or application is deemed, as a general rule, to undermine the protection of a registrant's commercial interests. However, it is implicit that Article 118(2)(b) of the REACH Regulation would not apply if information, for which confidential treatment is requested, were already in the public domain.

52. As in the case of the substance identity information, the Chairman observes that information on the uses of the appellant's substance is in the public domain. In fact, the appellant concedes that it is common knowledge in the industry that the appellant supplies the substance as a refrigerant [CONFIDENTIAL INFORMATION].

53. As information on the substance's uses is in the public domain and recalling the observations made at paragraph 31 to this Decision, the legitimacy of the appellant's interest regarding the substance's uses depends on whether the appellant's request with respect to the substance identity information succeeds (see paragraph 59 below).

Information on studies relating to the substance

54. By the letter of 7 July 2011, the appellant requested that information on studies specified in the Contested Decision be treated as confidential. As this request was raised in the context of the submission of the full, non-redacted version of the Contested Decision, the Chairman understands the request to relate to studies detailed in the part of the Contested Decision which has not been appealed (i.e., Section II.1 of the Contested Decision).

55. For the sake of clarity, the Chairman observes that the assessment with respect to the studies does not apply to the 90-day study in rabbits, which is the subject of the present appeal. In accordance with Article 6(6) of the Rules of Procedure, this information relates to the subject matter of the present proceedings, and it is, as such, public information.

56. The request for the confidential treatment of the studies is based on the appellant's claim that disclosure of this information would reveal, if coupled with the appellant's identity, the identity of the substance.

57. The Chairman observes that information on studies is contained in the part of the Contested Decision that does not form part of the appeal before the Board of Appeal.

58. For this reason, the Chairman rejects as irrelevant the appellant's confidentiality request with respect to the studies. However, in the interest of clarity, the Chairman observes that this information will not be disclosed in the announcement or any final decision by the Board of Appeal.

The public interest with respect to the substance identity information

59. In accordance with the general framework for assessing requests for confidential treatment (see paragraph 11 to this Decision), even if an applicant has established that it has, *a priori*, a legitimate interest to be protected, that interest must be balanced against the public interest (see Case T-198/03, *Bank of Austria Creditanstalt AG v. Commission*, [2006] ECR II-1429, paragraph 71).

60. The public interest refers generally to the activities of the EU institutions, including the Agency and the Board of Appeal, taking place as openly as

possible. Thus, on a general level, the public interest equates with the general public's right to information.

61. When analysing the public interest in the present case, it is important to consider the specific context of the REACH Regulation, and the fundamental objectives and principles that underlie it. These include the generation and dissemination of information on chemicals that permeates many of the provisions of the REACH Regulation (see, for instance, Recitals 14, 19, 25, 56 and 117 to the REACH Regulation). In fact, the REACH Regulation foresees the dissemination of information in the context of the different REACH processes including, importantly, evaluation (see, for instance, Recitals 65 and 68 to the REACH Regulation).

62. In this context, the Chairman considers it relevant that the appellant's substance [CONFIDENTIAL INFORMATION]. [CONFIDENTIAL INFORMATION]. [CONFIDENTIAL INFORMATION] the Agency have identified potential consumer exposure to the substance. These findings indicate that the general public has an interest in the substance and possibly in the present proceedings that seek to contest the appropriateness of further testing, as required by the Agency.

63. Furthermore, in the context of appeal proceedings before the Board of Appeal, the public interest also includes the special interests of potential interveners, and more specifically, the right for third parties to participate in proceedings that may affect their legal interests. Thus, when assessing an appellant's request for confidential treatment, the Chairman must ensure that any announcement provide potential interveners with necessary information to allow them to exercise their rights (see, by analogy, Order of the President of the Seventh Chamber of the General Court of 8 September 2010 in Case T-421/08, *Performing Right Society Ltd v. Commission*, paragraph 18 and cases cited therein). Accordingly, in the present case the Chairman must have regard to the possible interests of users down the supply chain, including consumers.

64. Finally, by way of a more general remark, the Chairman notes that applicants for confidential treatment should foresee, given the adversarial and public nature of proceedings before the Board of Appeal, the possibility that some of the confidential documents and information forming part of the appeal may need to be made public (see, by analogy, Order of the President of the Fourth Chamber of the General Court of 22 February 2005 in Case T-383/03, *Hynix Semiconductor Inc. v Council of the European Union*, [2005] ECR II-621, paragraph 46). At the same time, it should be noted that exercising the right to appeal against the Agency's decisions is an essential element in the system for legal redress created pursuant to the REACH Regulation. As such, being a party to proceedings before the Board of Appeal does not imply *per se* a negative effect on an appellant's reputation.

65. For reasons explained above, and having balanced the relevant factors and interests involved, the Chairman rejects the appellant's request for confidential treatment of the substance identity information. This conclusion applies also to information on the uses of the substance.

66. However, the Chairman considers that for the purposes of the announcement and any final decision in the present case, it is sufficient to identify the substance by the name indicated in the Contested Decision, *i.e.,* 2,3,3,3-tetrafluoropropene. As regards information on the uses of the substance, the

Chairman considers it sufficient that the announcement and any final decision by the Board of Appeal identify the substance's use as a refrigerant.

2. Precise substance tonnage data

67. The appellant has invoked Article 118(2) of the REACH Regulation in support of its request for confidential treatment of the precise substance tonnage data. Pursuant to that provision, the disclosure of information on the precise tonnage of a substance is deemed, as a general rule, to undermine the protection of a registrant's commercial interests.

68. The Chairman observes, based on a review of documents submitted by the appellant to the Board of Appeal in connection with the present appeal, including the notice of appeal and its appendices, the Contested Decision, the letter of 7 July 2011, and the reply of 15 July 2011, that none of the documents in the case file contain information on the precise tonnage data. However, the Chairman wishes to note that some of the appendices to the notice of appeal have been redacted. Accordingly, the Chairman's findings with respect to the precise substance tonnage data are limited to information that has been made available to the Board of Appeal.

69. As the documents submitted to the Board of Appeal do not contain information for which the appellant has requested confidentiality, the Chairman rejects the appellant's confidentiality request in this respect as irrelevant.

70. For the sake of good order, the Chairman observes that even if the documents submitted to the Board of Appeal in connection with this appeal case did contain precise tonnage data, that information would not be disclosed in the announcement or any final decision by the Board of Appeal.

3. The [CONFIDENTIAL INFORMATION] *and comment* [CONFIDENTIAL INFORMATION]

71. An assessment of whether [CONFIDENTIAL INFORMATION], and comment [CONFIDENTIAL INFORMATION] is to be treated as confidential in the present proceedings calls for an assessment of whether the appellant's interest in treating this information confidential is legitimate. As [CONFIDENTIAL INFORMATION], on the one hand, and the related comment, on the other, raise different legal issues, the Chairman will consider these claims separately apart from the assessment below (see paragraph 72 to this Decision) of whether this information is already in the public domain.

On the confidential nature of the information

72. The Chairman observes, firstly, that information on [CONFIDENTIAL INFORMATION] and the related comment does not fall within the scope of Article 118 of the REACH Regulation (information that is protected, as a general rule, against disclosure) or Articles 119(1) and 119(2) of the REACH Regulation (information that is always disseminated and information for which confidential treatment can be requested, respectively). Accordingly, in practice, [CONFIDENTIAL INFORMATION], and comment by, [CONFIDENTIAL INFORMATION] is not information that is generally made public pursuant to the REACH Regulation.

73. Secondly, as the appellant has indicated, information on [CONFIDENTIAL INFORMATION] and the related comment is not in the public domain. [CONFIDENTIAL INFORMATION]. As regards the related comment, the MSC meeting minutes contain a record of a comment having been made without disclosing, however, the contents thereof.

74. For the above reasons, the Chairman considers [CONFIDENTIAL INFORMATION] and the related comment to be information that is not in the public domain.

[CONFIDENTIAL INFORMATION]

75. By way of a preliminary remark, the Chairman observes that the appellant has not invoked Regulation (EC) No 45/2001 as grounds for its request for confidential treatment of [CONFIDENTIAL INFORMATION].

76. Notwithstanding this fact, the Chairman considers that the appellant's request must be assessed in light of Regulation (EC) No 45/2001. In accordance with Article 1 of Regulation (EC) No 45/2001, it falls on the EU institutions and bodies to protect the fundamental rights and freedoms of natural persons, in particular the right to privacy with respect to the processing of personal data. The provisions of Regulation (EC) No 45/2001 apply also to the Agency and the Board of Appeal.

77. Article 2(a) of Regulation (EC) No 45/2001 defines 'personal data' as any information relating to an identified or identifiable natural person. An identifiable person is one who can be identified, directly or indirectly, in particular by reference to an identification number or to one or more factors specific to his or her physical, physiological, mental, economic, cultural or social identity. Personal data includes also surnames and forenames (see Case C-28/08 P, *Commission v The Bavarian Lager Co. Ltd*, paragraph 68).

78. In accordance with Article 2(b) of Regulation (EC) No 45/2001, 'processing of personal data' means any operation or set of operations which is performed upon personal data, whether or not by automatic means, such as collection, recording, organisation, storage, adaptation or alteration, retrieval, consultation, use, disclosure by transmission, dissemination or otherwise making available, alignment or combination, blocking, erasure or destruction. Therefore, the communication of surnames and forenames constitutes 'processing' for the purposes of Regulation (EC) No 45/2001 (see to that effect, Case C-28/08 P, *Commission v The Bavarian Lager Co. Ltd*, paragraph 69).

79. Article 5 of Regulation (EC) No 45/2001 defines the circumstances in which personal data may be legitimately processed. It includes, pursuant to Article

5(a) of Regulation (EC) No 45/2001, circumstances where processing is necessary for the performance of a task carried out in the public interest further to the EU Treaties or other legal instruments adopted on the basis thereof, or where it is in the legitimate exercise of official authority vested in the EU institution or body or in a third party to whom the data are disclosed.

80. As regards the present case, the Chairman wishes to note that Appendix 3 to the notice of appeal does not contain, as such, [CONFIDENTIAL INFORMATION]. However, Appendix 3 to the notice of appeal reveals that [CONFIDENTIAL INFORMATION]. [CONFIDENTIAL INFORMATION].

81. Consequently, as the statement attached as Appendix 3 to the notice of appeal [CONFIDENTIAL INFORMATION] contains personal data for the purposes of Regulation (EC) No 45/2001.

82. As regards the processing of personal data, the Chairman observes that the conditions of Article 5 of Regulation (EC) No 45/2001 for legitimate processing are not fulfilled in the present case insofar as the appeal announcement is concerned. Article 6(6) of the Rules of Procedure and the Decision on the publication of the announcement identify information that must be included in any announcement. The identity of a person, on whose statement an appellant relies in support of its claims, does not fall within the scope of information that must be included in the announcement.

83. This conclusion applies *mutatis mutandis* to any final decision by the Board of Appeal.

84. Accordingly, the Chairman considers that [CONFIDENTIAL INFORMATION] is protected pursuant to Regulation (EC) No 45/2001 against disclosure in the announcement and any final decision by the Board of Appeal in the present case.

[CONFIDENTIAL INFORMATION]

85. As regards [CONFIDENTIAL INFORMATION]. [CONFIDENTIAL INFORMATION] contains a record of concerns [CONFIDENTIAL INFORMATION], it provides no details, including reasons, for those concerns. In fact, [CONFIDENTIAL INFORMATION]. It is clear from a comparison of the public version of the meeting minutes with Appendix 3 to the notice of appeal that the former lacks the detailed scientific information contained in Appendix 3 to the notice of appeal.

86. Article 11(3) of the Rules of Procedure for the Member State Committee (MB/50/2010 final of 30 September 2010, hereinafter 'the MSC Rules of Procedure') provide that statements by individual MSC members do not fall within documents that must be published on the Agency's website. Further, Article 11(4) of the MSC Rules of Procedure provides that, with the exception of so-called minority positions, individual views "shall not be ascribed to a particular individual unless this is explicitly requested by the individual".

87. As regards the present case, the minority position exception in the MSC Rules of Procedure would not seem to apply. The MSC accepted unanimously the Agency's proposed amendments, and as noted above, [CONFIDENTIAL INFORMATION] statement was explicitly claimed confidential.

88. Also, the publicly available Working Instructions for the Member State Committee (MSC) to process draft decisions under dossier evaluation (as

updated in February 2011) imply that there is no access to, *inter alia*, documents created during the compliance check process (see Working Instructions for the Member State Committee (MSC) to process draft decisions under dossier evaluation (update of February 2011, paragraph 4.6)).

89. [CONFIDENTIAL INFORMATION]

90. In light of the foregoing considerations, and the appellant's claims as to the [CONFIDENTIAL INFORMATION], the Chairman considers that the appellant has, *a priori*, a legitimate interest in keeping confidential [CONFIDENTIAL INFORMATION].

91. However, in accordance with the general framework for assessing requests for confidential treatment (see paragraph 11 to this Decision), it is necessary to consider whether any public interest considerations would call for [CONFIDENTIAL INFORMATION] to be disclosed.

The public interest with respect to [CONFIDENTIAL INFORMATION] *comment*

92. The concept of public interest has been considered in detail above (see paragraphs 59 *et seq.* to this Decision).

93. In the Chairman's opinion, there are no public interest considerations that would require [CONFIDENTIAL INFORMATION] to be published either in the announcement or in any final decision. The non-disclosure of this information would not call into question the interests of possible interveners. The interests of the general public to access this information are even more remote.

94. This finding is further supported by the fact that Article 6(6) of the Rules of Procedure and the Decision on the publication of the announcement do not require this information to be published.

95. Accordingly, the Chairman concludes that [CONFIDENTIAL INFORMATION] and the related comment are confidential information for the purposes of the announcement and any final decision. The Chairman recalls, however, the observations made at paragraph 17 to this Decision insofar as potential interveners are concerned.

4. The CROs' names and experts' identities

96. The appellant has invoked Directive 95/46/EC in support of its request for confidential treatment of the CROs' names and the experts' identities. As the CROs' names, on the one hand, and the experts' identities, on the other, raise different legal issues, the Chairman will consider these claims separately.

The experts' identities

97. As regards the appellant's request with respect to the experts' identities, the Chairman wishes to note, first, that the data protection rules applicable in the present case are those contained in Regulation (EC) No 45/2001. Directive 95/46/EC, which is invoked by the appellant, is addressed to the Member States of the European Union, which are bound by it through national implementing measures.

98. The provisions of Regulation (EC) No 45/2001 have been considered in detail above (see paragraphs 76 *et seq.* to this Decision). It suffices to note here that the experts' identities constitute personal data for the purposes of Regulation

(EC) No 45/2001, and that the communication of the experts' names in the announcement and any final decision would amount to processing of personal data within the meaning of Article 2(b) of Regulation (EC) No 45/2001. As in the case of [CONFIDENTIAL INFORMATION], the conditions for legitimate processing, as laid down in Article 5 of Regulation (EC) No 45/2001, are not met with respect to the appeal announcement and any final decision.

99. Accordingly, the Chairman concludes that the experts' identities are protected against disclosure in the announcement and any final decision pursuant to the data protection rules of Regulation (EC) No 45/2001. However, the Chairman recalls the observations made at paragraph 17 to this Decision as regards potential interveners.

The CROs' names

100. By way of a preliminary remark, it should be observed that the CROs' names fall outside the scope of application of Regulation (EC) No 45/2001. In accordance with Article 2(a) of Regulation (EC) No 45/2001, the provisions on the protection of personal data apply to information relating to an identified or identifiable natural person. Consequently, the request relating to CROs' names is analysed in accordance with the general framework for assessing requests for confidential treatment (see paragraph 11 to this Decision).

101. Regarding the substance of the claim, the Chairman observes that the appellant has not substantiated the claimed harm to the CROs' commercial interests. In accordance with point 39 of the Practice Directions, a request for confidential treatment must provide sufficiently detailed reasons for the request.

102. Where a request for confidential treatment has not been substantiated, it can be accepted only if the information and documents can be considered secret or confidential by their very nature (see, by analogy, Order of the President of the Sixth Chamber of the General Court of 18 November 2008 in Case T-274/07, *Zhejiang Harmonic Hardware Products Co. Ltd v. Council of the European Union*, paragraph 25 and Order of the President of the Fourth Chamber of the General Court of 22 February 2005 in Case T-383/03, *Hynix Semiconductor Inc. v. Council of the European Union*, [2005] ECR II-621, paragraph 34).

103. In the Chairman's assessment, this does not apply in the present case. The CROs' names constitute neither business secrets, nor are they confidential by reason of being information purely internal to the appellant or the CROs. In fact, the Chairman notes that information on the CROs' businesses is in the public domain. Thus, the appellant's request is in this respect purely hypothetical.

104. Secondly, as regards the appellant's claim regarding [CONFIDENTIAL INFORMATION], the Chairman observes that the appellant has not substantiated its claim. As with respect to the alleged harm to the CROs' commercial interests, the claim is purely hypothetical.

105. Consequently, the Chairman rejects the appellant's request not to disclose the CROs' names.

106. However, and notwithstanding the above considerations, the Chairman notes that the CROs' names is not information that is required to be published in the announcement pursuant to Article 6(6) of the Rules of Procedure and the Decision on the publication of the announcement.

107. This conclusion applies *mutatis mutandis* also to any final decision by the Board of Appeal.

108. In fact, in the Chairman's assessment, the publication of the CROs' names may allow the experts' identities to be deduced. As explained above, information on the experts' identities is confidential and will not be disclosed in the announcement or any final decision (see paragraph 97 *et seq.* to this Decision).

109. Accordingly, the Chairman concludes that the CROs' names do not constitute confidential information for the purposes of the present proceedings. However, this information will not be published in the announcement or any final decision by the Board of Appeal. Finally, the Chairman recalls the observations made at paragraph 17 to this Decision as regards potential interveners.

ORDER

On those grounds,

THE CHAIRMAN OF THE BOARD OF APPEAL

hereby:

1. Decides to accept the appellant's request for confidential treatment with respect to the following information
   - [CONFIDENTIAL INFORMATION] and the related comment; and
   - The experts' identities.

   This information will not be disclosed in the appeal announcement nor in any final decision by the Board of Appeal in the present case.

2. Decides to reject the appellant's request for confidential treatment with respect to the following information:
   - The substance identity information;
   - Information on the uses of the substance;
   - The precise substance tonnage data, and information on the studies relating to the substance, as irrelevant; and
   - The CROs' names.

   Information on the substance identity and the uses of the substance is not confidential for the purposes of the present proceedings and can be made public in the appeal announcement and any final decision by the Board of Appeal.

   However, information on the precise tonnage data, the studies relating to the substance and the CROs' names will not be published in the appeal announcement nor in any final decision by the Board of Appeal in the present case.

Mercedes ORTUÑO
Chairman of the Board of Appeal