EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

17 December 2014

(Data sharing dispute – Every effort – Discrimination)

Case number	A-017-2013
Language of the case	English
Appellant	Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein Austria
Representative	Darren Abrahams and Indiana de Seze Steptoe & Johnson LLP Brussels Belgium
Intervener	FW Hempel Metallurgical GmbH Germany
Representative	Scott Megregian, Vanessa Edwards and Raminta Dereskeviciute K&L Gates LLP London United Kingdom
Contested Decision	DSH-30-3-D-0018-2013 of 12 July 2013 adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to Article 30(3) 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 BOARD OF APPEAL

composed of Mercedes ORTUÑO (Chairman), Rafael Antonio LÓPEZ PARADA (Legally Qualified Member), and Andrew FASEY (Technically Qualified Member and Rapporteur)

Registrar: Sari HAUKKA

gives the following

Decision

SUMMARY OF THE FACTS

Background to the dispute

1. According to the Contested Decision, on 18 January 2013, a representative of FW Hempel Metallurgical GmbH, who is also the Intervener in the present proceedings (hereinafter the 'Data Claimant' or 'Intervener'), contacted the Appellant regarding the formers intention to register vanadium at the 100 to 1 000 tonnes per annum tonnage band. The Appellant was asked by the Data Claimant, inter alia, whether the price of the letter of access of € 44 000 indicated on the Appellant's website was accurate.

2. The Appellant responded to the Data Claimant on 24 January 2013, and offered to send to it the updated substance information exchange forum (hereinafter the 'SIEF') agreement. The Appellant explained further that the price of the letter of access for the 100 to 1 000 tonnes per annum tonnage band was, in total, € 54 166.67. In that communication the Appellant informed the Data Claimant that a 10 % cost increase per year (hereinafter the '10 % annual cost increase'), as well as a € 1 000 administrative charge (also referred to during the data sharing proceedings as a 'handling fee'), applies to any purchase of a letter of access after 2010.

3. The Appellant and the Data Claimant subsequently exchanged correspondence on a number of occasions in which they discussed the cost of the letter of access. In particular, the discussions focused on the nature of the 10 % annual cost increase and the € 1 000 administrative charge.

4. On 24 April 2013, the Data Claimant submitted a claim to the Agency with a view to obtaining permission to refer to data involving testing on vertebrate animals contained in the joint registration dossier for vanadium. In that claim the Data Claimant included a 'note describing all the steps in the negotiations'. This claim followed the alleged failure of the negotiations with the Appellant to share data in accordance with the requirement set out in Article 30(1) of the REACH Regulation (all references to Articles hereinafter concern the REACH Regulation unless stated otherwise) requiring that the costs of sharing information resulting from tests on vertebrate animals are determined in a fair, transparent and non-discriminatory way (hereinafter 'every effort').

5. On 29 April 2013, the Agency sent a letter to the Data Claimant informing it that its submission of 24 April 2013 was incomplete. The Data Claimant was requested to provide, inter alia, the exact list of vertebrate animal studies that are subject to the dispute. In this respect, the letter stated that:

   '*… [following] a preliminary assessment of your claim and the related supporting documentation … [the Agency] considers the information provided to be insufficient and invites you to provide the following additional information:*

   (a) The exact list of vertebrate animal studies that are subject to the dispute:

   Indeed in the dispute claim submitted via web form, you indicate that the scope of the dispute is the total set of data contained in the joint submission and that your tonnage band is 100 - 1 000 [tonnes per annum]. We remind you that the scope of the data sharing disputes falling under the Article 30(3) provision is limited to vertebrate animal tests exclusively. Hence, we cannot proceed with your claim unless that list is clearly defined.

   […]'.

6. On 6 May 2013, in response to the request for further information, the Data Claimant provided the Agency with a list of the vertebrate animal studies that are subject to the data sharing dispute. The Agency confirmed receipt of this information in a letter of 8 May 2013. In that letter the Agency also, inter alia, informed the Data Claimant that the Agency considered that it had provided a complete set of documentary evidence fulfilling the requirements for a data sharing claim under Article 30(3) and that the Agency would process the claim further.

7. On 8 May 2013, the Agency requested the Appellant to provide a note setting out the record and the order of the efforts made by the parties to the data sharing dispute to reach an agreement and a copy of any correspondence demonstrating the efforts made to reach an agreement. The Appellant was also requested to provide a list of the endpoints involving vertebrate animal studies requested by the Data Claimant.

8. On 23 and 24 May 2013, the Appellant provided information to the Agency regarding the efforts made to reach an agreement. According to the cover letter accompanying the response, the Appellant provided, in particular, an indication of the list of endpoints involving vertebrate animal studies requested by the Data Claimant, a note setting out the record and the order of the efforts made by the parties to reach an agreement and a copy of correspondence up to 24 April 2013 demonstrating the efforts made by the parties to reach an agreement.

9. On 12 July 2014, following an assessment of the information provided by the Appellant and the Data Claimant, the Agency notified the Contested Decision to the Data Claimant, with the Appellant in copy. In particular, the Contested Decision stated that the Agency had decided to grant the Data Claimant:

   '*… permission to refer to the information involving testing on vertebrate animals you requested from the existing registrants of vanadium, represented by [the Appellant].*

   Based on the information provided by you and [the Appellant], [the Agency] has concluded that you have made every effort, whereas the existing registrants, represented by [the Appellant], did not make every effort to reach a fair, transparent and non-discriminatory agreement on the sharing of information you requested under Article 30(1) …'.

10. In the Conclusion to the Contested Decision the Agency stated that:

    '*By making an agreement to share data conditional upon a 10 % increase, which discriminated against all registrants, who are obliged to register after 2010, the existing registrants, represented by [the Appellant], did not contribute to finding a non-discriminatory agreement on data sharing.*

    The existing registrants, represented by [the Appellant], have therefore not made every effort to reach an agreement on the sharing of data and their costs in a fair, transparent and non-discriminatory way, as required by Article 30(1) ….

    Consequently, [the Agency] provides [the Data Claimant] the permission to refer to the requested data in accordance with Article 30(3).'

Procedure before the Board of Appeal

11. On 14 October 2013, the Appellant lodged the present appeal at the Registry of the Board of Appeal in which it requested the Board of Appeal to:

    - Confirm the suspensive effect of the appeal upon the Contested Decision, pending the decision of the Board of Appeal;
    - Annul the Contested Decision;

- Adopt a decision rejecting the claim made by the Data Claimant to refer to information on certain tests on vertebrate animals contained in the Appellant's registration dossier; and
- Order the refund of the appeal fee paid by the Appellant.

12. On 12 December 2013, since a member of the Board of Appeal was precluded from participating in the proceedings, the Chairman, pursuant to the first subparagraph of Article 3(2) of Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5; hereinafter the 'Rules of Procedure'), designated an alternate member, Rafael Antonio López Parada, to act in the present case as the legally qualified member of the Board of Appeal.

13. On 5 December 2013, the European Coalition to End Animal Experiments (hereinafter 'ECEAE') applied to intervene in the proceedings before the Board of Appeal opposing the remedy sought by the Appellant. On 30 January 2014, the Board of Appeal rejected the application to intervene on the grounds that ECEAE did not establish an interest in the result of the present appeal as required by Article 8(1) of the Rules of Procedure.

14. On 6 December 2013, the Data Claimant applied to intervene in the proceedings before the Board of Appeal opposing the remedy sought by the Appellant. By Decision dated 24 January 2014, the Board of Appeal granted the Data Claimant's application to intervene.

15. On 16 December 2013, the Agency submitted its Defence. On 24 January 2014, the Appellant lodged its observations on the Defence.

16. On 24 February 2014, the Intervener submitted its observations on the procedural documents submitted in the case. On 25 and 26 March 2014 respectively, the Agency and the Appellant submitted their observations on the Intervener's observations.

17. On 28 May 2014, the Agency and the Intervener lodged their observations on the Appellant's observations on the Defence.

18. On 12 June 2014, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 23 June 2014, the Agency informed the Board of Appeal that it did not request a hearing to be held. On the same date, the Appellant requested a hearing to be held. As a result, in accordance with Article 13 of the Rules of Procedure, the Parties were summoned to a hearing which was held on 18 September 2014. At the hearing, the Parties and the Intervener made oral presentations and also responded to questions from the Board of Appeal.

REASONS

Claims under examination

19. The Appellant requests the Board of Appeal to annul the Contested Decision, which granted the Data Claimant permission to refer to information resulting from testing on vertebrate animals for the registration of vanadium, and to adopt a decision not to grant the Data Claimant permission to refer to that information. In support of its claim the Appellant presents five pleas.

20. By its first plea, the Appellant claims that the Agency made a manifest error of law by accepting the data sharing dispute as admissible under Article 30(3). By its second plea, the Appellant claims that its right to be heard and its right of defence had been breached by the Agency. By its third plea, the Appellant claims that, in its analysis of the data sharing dispute, the Agency relied on evidence incapable of substantiating its conclusion that the Data Claimant had made every effort to reach an agreement and

that the Appellant had not. By its fourth plea, the Appellant claims that the Agency in reaching its decision had failed to take into account all the necessary and available information. By its fifth plea, the Appellant claims that the Agency had exceeded its powers by considering the data sharing conditions themselves rather than whether every effort to reach an agreement had been made.

21. The Board of Appeal will firstly address the Appellant's fifth plea.

Appellant's fifth plea alleging that the Agency exceeded its competence in considering the data sharing terms themselves rather than whether every effort to reach an agreement had been made

Arguments of the Parties and Intervener

22. The Appellant argues that, rather than assessing whether the Appellant and the Data Claimant had made every effort to reach an agreement in a fair, transparent and non-discriminatory way, the Agency considered and allowed its judgment to be vitiated by considerations of the actual sums requested in the negotiations between the parties. The Appellant claims that this is contrary to the Agency's role in a data sharing dispute as set out in the Questions and Answers on data sharing and related disputes which provides inter alia that '… [the Agency] will not assess whether the claim (cost or conditions under which sharing is proposed) is justified' (ECHA-10-QA-04-EN, published on 30 July 2010, question 1.2).

23. The Appellant argues that in stating in the Contested Decision that the '… amount of 1 000 EUR for the administrative cost of issuing a [letter of access] may be justifiable', the Agency exceeded its competence. The Appellant adds that the only aspect which is potentially relevant for the assessment of whether every effort was made is the Appellant's efforts to articulate the rationale for the administrative cost.

24. The Appellant also argues that in assessing the € 1 000 handling fee the Agency made an error of fact by failing to consider that the Appellant did not argue that the handling fee only related to the work of a specific person, namely the 'REACH manager'.

25. The Appellant argues that the legal flaw of evaluating the data sharing terms themselves, rather than the efforts to achieve agreement on them, was also made in respect to the 10 % annual cost increase. The Appellant claims that the Contested Decision focuses on the actual cost formula and seeks to characterise it as discriminatory. The Appellant claims that this goes beyond an assessment of whether every effort was made.

26. The Appellant claims that it had conceived the 10 % annual cost increase in order '…to remedy a financial imbalance stemming from the obligation for the lead registrant – with the support of the Appellant – to pre-finance the whole dossier, for companies which can remain on the market without sharing in the costs, whatever their number'. The Appellant claimed during the proceedings that the 10 % annual cost increase '… was not constructed as a penalty but rather as a reward to "early bird" registrants'. The Appellant claims that the objective justification in support of the 10 % annual cost increase – namely, securing a critical mass of early bird registrants to pre-finance the registration efforts – should have been properly assessed by the Agency.

27. The Appellant claims that the conclusion in the Contested Decision that the '… 10 % increase … discriminated against all registrants' is incorrect. In particular, the Appellant claims that in the correspondence between it and the Data Claimant, which was submitted to the Agency during the data sharing dispute, the Appellant consistently indicated that the sums received as data access compensation would be subject to a reconciliation process. The Appellant claims that, in effect, the Data Claimant was

asked to make a deposit that was subject to reconciliation and, as a result, there are no grounds to argue that the terms of the letter of access are discriminatory. The Appellant claims that the Agency did not sufficiently take into consideration the reconciliation system or the Appellant's considerable efforts to justify the 10 % annual cost increase. The Appellant argues further that, in any event, the Agency incorrectly conducted its assessment of whether the agreement was discriminatory.

28. The Agency claims that it did not exceed its competence in the adoption of the Contested Decision and that it did not assess whether the actual price of the letter of access itself is justified or not.

29. The Agency claims that its competence in assessing a data sharing dispute is limited to verifying whether the parties to that dispute have correctly executed their obligation to make every effort. The Agency claims that it does not assess whether an offer is reasonable or justifiable. The Agency states that, in its factual assessment of the efforts made, it evaluates inter alia whether the parties answer each other's questions and make proposals or suggestions to overcome any disagreements. The Agency also states that in assessing whether the parties made every effort to reach an agreement it only takes into consideration arguments exchanged between the parties during the negotiations.

30. In relation to the Appellant's specific claims the Agency argues that it did not make an assessment of the € 1 000 administrative charge in the Contested Decision. The Agency states rather that it concluded that the Appellant had not made every effort in relation to the administrative charge.

31. The Agency claims that, in relation to the 10 % annual cost increase, it reached the conclusion that the Appellant's offer was manifestly discriminatory exclusively on the basis of the statements of the Appellant itself and on the basis of the repeated claims made by the Data Claimant which were not addressed by the Appellant. The Agency claims that this was sufficient to demonstrate the violation by the Appellant of its obligation to make every effort.

32. The Agency also claims that the negotiations regarding the reconciliation of payments concerned the adjustment of the share of data costs to the number of registrants and that this reconciliation process was independent from the 10 % annual cost increase and the € 1 000 administrative charge.

Findings of the Board of Appeal

33. In its appeal the Appellant essentially disputes the Agency's findings in relation to both the € 1 000 administrative charge and the 10 % annual cost increase related to the purchasing of the proposed letter of access. The Board of Appeal will address these issues in turn.

The Agency's assessment of the € 1 000 administrative charge

34. The Appellant argues in particular that in the Contested Decision the Agency exceeded its competence by assessing the € 1 000 administrative charge itself and that, in any case, in that assessment the Agency made an error of fact.

35. The relevant part of the Contested Decision related to the € 1 000 administrative charge reads as follows:

'*[The Data Claimant] had explicitly requested information on the hourly rate of [the Appellant's] REACH manager in the context of the negotiations on the administrative charge. Although the amount of 1 000 EUR for the administrative cost of issuing a [letter of access] may be justifiable, the [Data Claimant] could reasonably make this request, because a discussion of the administrative workload involved in the issuance of a [letter of access] and the related costs would have helped the parties reach a*

common understanding on the appropriate administrative charge. However, [the Appellant] did not reply to this request. It thereby showed a lack of efforts'.

36. The Board of Appeal finds that it is clear from this part of the Contested Decision that the Agency did not conclude on whether the € 1 000 administrative charge itself was justifiable. The Board of Appeal considers that on this aspect of the cost of the letter of access the Agency concluded only that the Appellant did not adequately explain to the Data Claimant, following its request for further information in this regard, the justification for the € 1 000 administrative charge and that this lead to a finding that the Appellant had not satisfied the requirement to make every effort.

37. As the Board of Appeal finds that that the Agency did not enter into an assessment of the amount of the administrative charge itself the Appellant's claim in this respect must be dismissed.

The Agency's assessment of the 10 % annual cost increase

38. The Appellant claims that, in deciding that the 10 % annual cost increase was discriminatory, the Agency exceeded its competence. The Appellant adds that in any event the 10 % annual cost increase was not discriminatory, in particular because the costs would be reconciled after the 2013 registration deadline.

39. For the purposes of the claim related to the 10 % annual cost increase the relevant part of the Contested Decision reads as follows:

'*… the existing registrants, represented by [the Appellant] made the sharing of the data subject to the payment of a 10 % annual increase of the price of the [letter of access] calculated from 2010, which was obviously discriminatory.*'

40. In the Conclusion to the Contested Decision the Agency also states that:

'*By making an agreement to share data conditional upon a 10 % increase, which discriminated against all registrants, who are obliged to register after 2010, the existing registrants, represented by [the Appellant], did not contribute to finding a non-discriminatory agreement on data sharing.*

The existing registrants, represented by [the Appellant], have therefore not made every effort to reach an agreement on the sharing of data and their costs in a fair, transparent and non-discriminatory way, as required by Article 30(1) …'.

41. As a preliminary observation, the Board of Appeal considers that the Agency should not, during its assessment of a data sharing dispute, examine whether the actual and precise cost of a letter of access is reasonable or justified. In this regard, the scope of the Agency's review is correctly set out in the Agency's Questions and Answers on data sharing (see paragraph 22 above) and was confirmed by the Agency itself during the present proceedings.

42. The Board of Appeal considers that the Agency is entitled however to make an assessment of whether each of the parties to the data sharing dispute made, pursuant to Article 30(1), '… every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way'. Furthermore, the Board of Appeal observes that this requirement should be read as a whole. In other words, the test for the Agency to apply is whether every effort was made bearing in mind the need for the cost sharing to be determined in a fair, transparent and non-discriminatory way.

43. The Board of Appeal also highlights that the Agency's analysis of a data sharing dispute is case-specific and context driven. In the present case, the Board of Appeal considers that the Agency was obliged to examine the annual cost increase as this was repeatedly raised by the Data Claimant during the negotiations as a cause of concern

and was the principle issue preventing an agreement from being reached. In this respect, it should also be noted that the Data Claimant indicated that it would be prepared to pay the € 44 000 for the letter of access on the condition that it was subject to subsequent reconciliation.

44. The Board of Appeal considers that, in the Contested Decision, the Agency did not examine whether the 10 % annual cost increase, as opposed for example to a 5 % or 2 % annual cost increase, was justifiable. The Agency rather only examined whether an increase payable by future registrants based on the applicable registrant deadline, irrespective of the specific amount, was justifiable based on the arguments presented during the data sharing negotiations between the parties.

45. In light of the above, the Board of Appeal finds that the Agency did not exceed its competence in this regard.

46. With regards to the Appellant's claim that the 10 % annual cost increase was not discriminatory, the Board of Appeal observes that the cost of the letter of access offered by the Appellant would be different depending on when it was purchased by the registrant. Additionally, the deadlines for registering phase-in substances are set out in Article 23 and there is no obligation to register before these deadlines. As a result, any additional charge based solely on the time of registration means that later registrants are required to pay more. In this respect, the Board of Appeal considers that an additional charge which is to be paid only by registrants who purchase the letter of access after 2010 is de facto discriminatory unless there are legitimate and justifiable reasons for charging additional amounts to later registrants.

47. The Board of Appeal will next examine therefore whether the Appellant had justified the apparent discriminatory nature of the 10 % annual cost increase during the data sharing negotiations. As a preliminary observation in this regard, the Board of Appeal observes that any cost sharing arrangements must ensure that costs are shared fairly amongst all registrants of the same substance.

48. The Board of Appeal notes in particular that the Appellant's responses to the Data Claimant's enquiries on this issue indicate that the 10 % annual cost increase was designed to act as an incentive to encourage companies to purchase the letter of access early. As highlighted in the Contested Decision, in its email of 28 February 2013, the Appellant explained that:

'*As incentive for companies that intend to REACH register a substance ≤ 1000, 100 or 10 tonnes in 2013 or 2018 but to purchase a [letter of access] in 2010, a 10 % cost increase per year applies for any purchase after 2010. This 10 % cost increase p.a. is the compensation for costs that active consortium members have been bearing (including funding and coordinating dossier preparation, SIEF management and participation in meetings). Thus, an equivalent of 0,83 % per month needs to be added to the [letter of access] deposit starting in January 2011 until the respective [letter of access] purchase.*'

49. The Appellant provided similar explanations for example in its emails of 5, 21 and 28 March 2013 to the Appellant. For example, in an email to the Data Claimant of 21 March 2013 the Appellant states that:

'Early and timely contributions (when work began in 2010) would … - in case of [the Data Claimant] – have led to a proportional avoidance of that adequate portion of capital costs and risk, borne by the [Appellant]. This missing part of coverage of capital cost can only be allocated to [the Data Claimant] and to nobody else, [especially] to no other Consortium member and to no other [letter of access] Buyer ….

[…]

This 10 % cost increase per year applies for any purchase after 2010, reflecting the burden of financing and risk for the contributing parties in advance. This 10 % cost increase p.a. is the compensation for in-advance-pay-in of the active Vanadium Consortium members and the early buyers of [letters of access] who have been bearing funding of coordinated dossier preparation since then. […]

In addition, we have been comparing our cost model with models of other trades and noted that similar penalties (also called "early bird specials") are in place …'.

50. The Board of Appeal considers that the use of wording such as 'incentives for companies', 'compensation', and 'early bird specials' clearly demonstrated the Appellant's reasons for applying the 10 % annual cost increase. The use of terms such as 'compensation', and the implication of a discount (the effect of an 'early bird special') are not consistent with costs being shared fairly amongst all registrants regardless of the time of registration. Furthermore, in the communications between the parties during the data sharing negotiations there is no evidence of a process to ensure that all costs are ultimately shared fairly between registrants.

51. During the present appeal proceedings the Appellant argued that, with regards to the differences in prices charged to early and later registrants, the Agency made an error of fact in its assessment by assuming that the 10 % annual cost increase and the € 1 000 administrative charge were excluded from the reconciliation process due to take place after the 2013 registration deadline. The Appellant argues in essence that the existence of the reconciliation clause meant that there was no discrimination in practice as the costs would subsequently be fairly shared amongst all registrants.

52. The Appellant claims in particular that it was clear from its communications of 14 and 28 February 2013, and 5 and 21 March 2013 that the 10 % annual cost increase was included in the planned reconciliation. The Appellant referred, in particular, to the following:

'The cost structure for the letter of access *is based on the funding principles of [the Appellant], and these costs are to be covered in the following:*

(a) by deposit payment which depends on the Substance(s) and the Tonnage Band(s).

(b) *by adjustment of account (noting that there is a possibility for refunds as well as extra costs).*'

53. As a preliminary observation, the Board of Appeal considers that a system whereby the costs borne by each registrant of a particular substance are subsequently adjusted to take into account the eventual number and level of registrations may, in certain circumstances, be considered to be an important point in assessing whether every effort had been made.

54. However, the Board of Appeal considers that, whilst it is clear from the negotiations that a reconciliation of costs to take into account the registrations of vanadium would take place after the 2013 registration deadline, the Board of Appeal does not consider that it was made clear from the communications during the data sharing negotiations that the 10 % annual cost increase would be included in that reconciliation.

55. The Board of Appeal considers that the Appellant's use of wording such as 'incentives for companies', 'compensation', and 'early bird specials' during the data sharing negotiations clearly demonstrated the Appellant's reasons for applying the 10 % annual cost increase and created the impression that that increase was not included in the reconciliation process. For example, as indicated above, a later reconciliation is incompatible with the promise of 'compensation' or a discount (the effect of an 'early bird special').

56. The Board of Appeal notes that the Appellant clearly explained at the hearing that the reconciliation of costs after the 2013 registration deadline would include the € 1 000 administrative charge and the 10 % annual cost increase. The Board of Appeal considers that the Appellant's explanation at the hearing of the reconciliation process may have had a significant impact on any conclusion on whether the 10 % annual cost increase was in fact discriminatory. However, the Board of Appeal considers that, whilst this may have been the Appellant's intention from the beginning of the negotiations, the Appellant did not make this fact known to the Data Claimant during the negotiations despite the Data Claimant's repeated requests for information on the terms of the letter of access. As a result, the Appellant's explanation of the reconciliation process given at the oral hearing was not available to the Agency during its assessment of those negotiations. The Board of Appeal notes that, in its assessment of whether every effort had been made, the Agency cannot take into consideration arguments or justifications that were not made during those negotiations.

57. The fact that the scope of the reconciliation process only became clear at the oral hearing demonstrates that the Appellant failed to make every effort to explain those terms during the data sharing negotiations. In particular, if the reconciliation clause was intended to encompass the 10 % annual cost increase, the Appellant should have explained this clearly to the Data Claimant by, for example, providing it with the formula that it intended to apply to the reconciliation.

58. In light of the above, the Board of Appeal finds that the Agency did not make an error of fact in assuming that the reconciliation excluded the 10 % annual cost increase and the € 1 000 administrative charge.

59. Furthermore, in the absence of evidence during the data sharing negotiations regarding a system to ensure that costs were shared fairly between all registrants, the Board of Appeal finds that the Agency was justified in concluding that the Appellant '… did not contribute to finding a non-discriminatory agreement on data sharing'.

60. The Board of Appeal observes further that, even following the explanation provided at the oral hearing by the Appellant regarding the reconciliation, it is not in a position to assess whether the 10 % annual cost increase is in fact discriminatory. In particular, the Appellant has not provided clear evidence of the formula that will be applied to the reconciliation process.

61. In view of the above, the Appellant's fifth plea must be dismissed.

Appellant's first plea alleging that the Agency made a manifest error of law by accepting the data sharing dispute as admissible under Article 30(3)

Arguments of the Parties and Intervener

62. The Appellant claims that, pursuant to Article 30(1) and (3), a request for data sharing must identify the individual studies to which access is sought. The Appellant adds that as this condition had not been satisfied by the Data Claimant in the present case the Agency made a manifest error of law by accepting the data sharing dispute as admissible under Article 30(3).

63. The Appellant adds that this essential procedural requirement is repeated in the Agency's public guidance documents. In particular, the Appellant refers to the Agency's Questions and Answers on data sharing and related disputes (cited in paragraph 22 above) which states that the 'potential registrant making every effort to share the data contained in the registration (joint submission) dossier can contact [the Agency], using the web form available on [the Agency's] website …'. The document continues that the 'potential registrant will have to specify the vertebrate animal studies they requested

from the previous registrant(s) or their representative'. The Appellant points out that this is repeated in Section 3.4.2.2 of the Agency's Guidance on data sharing (Version 2.0, dated April 2012). The Appellant states that the Agency has provided no reasons for departing from these public guidance documents.

64. The Appellant claims that, in its Decision of 10 October 2011 in Case A-001-2010 (paragraphs 58 to 60), the Board of Appeal confirmed that such administrative procedures bind the Agency. The Appellant also claims that it had legitimate expectations as a result of the abovementioned guidance documents that no data sharing dispute would be accepted by the Agency before the Data Claimant had expressly defined its list of requested endpoints involving vertebrate animal testing.

65. In support of its claim, the Appellant points to the Agency's letter of 29 April 2013 to the Data Claimant in which it is stated that, in its dispute claim, the Data Claimant had only indicated that 'the scope of the dispute is the total set of data contained in the joint submission and that your tonnage band is 100 to 1 000 [tonnes per annum]. We remind you that the scope of the data sharing disputes falling under the Article 30(3) provision is limited to vertebrate animal tests exclusively. Hence, we cannot proceed with your claim unless that list is clearly defined'. The Data Claimant was therefore requested to provide the missing information by 7 May 2013.

66. The Appellant claims that the Data Claimant referred to a list of endpoints for the first time on 1 May 2013 in an email to the Appellant. The Appellant claims further that by letter of 6 May 2013 the Data Claimant provided the Agency with the requested information. The Appellant also referred to a letter of 8 May 2013 sent to the Data Claimant in which the Agency states that it:

'*… considers that [the Data Claimant] has provided a complete set of documentary evidence fulfilling the requirements for a data sharing dispute claim under Article 30(3) …. Therefore, [the Agency] will process your claim further. However, in the phone conversation of 7 May 2013 concerning the list of studies covering vertebrate animal testing, [the Agency] has informed you that this information still needs to be completed. The list of endpoints you have provided contains endpoints, which are not required for your tonnage band. [The Agency] has noted that you agreed to provide a corrected list before [the Agency] will issue its final decision*.'

67. The Appellant claims that the object of the requirement to identify the list of endpoints subject to the dispute for which permission to refer is requested is inter alia to identify the studies to which the Data Claimant had expressly and actively sought to negotiate access from the data owner. The Appellant claims that this is consistent with the fact that the Agency's assessments under Article 30(3) are entirely focused on whether every effort has been made by the parties during the data sharing negotiations.

68. The Agency, supported by the Intervener, argues that during the data sharing negotiations the studies being negotiated were never in doubt. The Agency states that, already in its first message of 18 January 2013 on the issue, the Data Claimant announced its intention to register vanadium at the 100 to 1 000 tonnes per annum tonnage band. According to the Agency, this was sufficient information for the Appellant to quote a price for the letter of access as it implied that the Data Claimant requested access to the studies contained in the lead dossier for that tonnage band, which includes the information specified in Annexes VII to IX to the REACH Regulation.

69. The Agency argues that providing a list of studies is not an admissibility criteria for data sharing disputes although it must be clear which studies are being negotiated. The Agency states that, during the negotiations, the Appellant never expressed any doubts as to the studies that the Data Claimant wanted to share and that if the Appellant was uncertain it should have asked for clarification from the Data Claimant.

70. The Agency adds that the initial negotiations between the Data Claimant and the Appellant in the present case concerned not only the vertebrate studies relevant for the information requirements at 100 to 1 000 tonnes but also the applicable non-vertebrate data, in other words the whole data package. According to the Agency, once the negotiations failed, the scope had to change as a data sharing dispute can only relate to data involving testing on vertebrate animals. As a result, the Agency requested in a letter of 29 April 2013 the exact specification of the vertebrate studies which are under dispute.

71. The Agency also claims that a list of the studies for which permission to refer is requested is only a security measure aimed at protecting the rights of data owners by ensuring that access, if granted, is only given to the data required to cover a claimant's registration requirements.

Findings of the Board of Appeal

72. The Appellant argues in essence that the data sharing dispute was inadmissible and should not have been accepted by the Agency under Article 30(3) on the grounds that the Data Claimant had not identified the relevant studies to which permission to refer was sought. The Appellant claims that the Contested Decision is therefore unlawful.

73. The Board of Appeal observes that the Section of the Contested Decision entitled 'Admissibility' states inter alia that:

'*The studies relating to the data sharing dispute were clearly identified. The parties negotiated the "letter of access" for the joint submission registration of vanadium at the tonnage band of 100 to 1 000 tonnes per year. The studies involving vertebrate animal testing that were the subject of the negotiations and, by extension, of the data sharing dispute before [the Agency], are thus all vertebrate animal studies required for Annexes VII - IX of the REACH Regulation and available in the lead dossier for vanadium….*'

74. The Board of Appeal considers that before permission to refer is actually granted it is the duty of the Agency to clarify the individual relevant studies to which access is sought. In particular, as stated by the Agency, a definitive list of the studies requested is necessary to ensure that access, if granted, is only given to the data required to cover a claimant's registration requirements. In this respect, it is also important to note that, pursuant to Article 30(3), permission to refer can only be granted to studies involving vertebrate animals and not other data that may have been part of the initial negotiations. In order to address the Appellant's plea, however, the Board of Appeal must examine whether a list of the studies for which permission to refer is sought is necessary before the Agency can begin to examine the data sharing dispute.

75. The Board of Appeal observes that Article 30(1) and (3) does not provide that the provision of a precise list of the studies involving testing on vertebrate animals requested during the data sharing dispute is an admissibility criterion that must be satisfied before the Agency can commence its assessment of the data sharing dispute.

76. The Appellant claims that it is necessary that the endpoints are identified in advance so that the Agency can assess whether every effort was made. In this respect the Appellant considers that in assessing whether every effort has been made it is necessary to demonstrate that the object of the negotiations was unambiguously communicated to the data owner before the data sharing dispute mechanism in Article 30(3) is triggered.

77. On this point, however, the Board of Appeal observes that the alleged lack of precision on the endpoints did not contribute to the problems encountered in the negotiations between the Appellant and the Data Claimant. The Board of Appeal considers that, as stated in the admissibility section of the Contested Decision (see paragraph 73 above),

there was a common understanding during the negotiations that the Data Claimant was seeking to obtain a letter of access for vanadium at the 100 to 1 000 tonnes per annum tonnage band. From the evidence submitted to the Agency for the purposes of the data sharing dispute, the Board of Appeal observes that this was made clear early in the negotiations, for example in emails of 18 January 2013 and 27 February 2013 to the Appellant from the Data Claimant and its representative. The Board of Appeal considers that it was clear that all studies required for the registration of vanadium pursuant to Annexes VII, VIII and IX that were available in the lead dossier were therefore subject to the negotiations. The Board of Appeal also notes that the Appellant was able to quote a price for the letter of access without requiring any additional information regarding the data to which the Data Claimant wished to purchase access. The negotiations were therefore conducted on that basis and it is those negotiations which are the subject of the Agency's analysis of whether every effort was made to reach an agreement.

78. The Board of Appeal also observes that when a potential registrant makes a data sharing inquiry within a SIEF it does not know exactly which studies are available. This information must be provided by the data owners through the SIEF. The potential registrant can ask for all the studies available, not only for those produced through testing on vertebrate animals. The potential registrant is free to negotiate access to all or some of the studies regardless of whether they involve testing on vertebrate animals. However, if no agreement is reached, and if the potential registrant has made every effort to reach that agreement, then it only has the right to obtain from the Agency permission to refer to the studies involving testing on vertebrate animals and which are required for its registration. It is therefore only at the point when the permission to refer is granted by the Agency that a precise identification of relevant studies becomes essential. In certain data sharing disputes it may be necessary for the Agency to have such information at an earlier stage in order for it to assess whether every effort has been made.

79. The Board of Appeal also considers that, although the Guidance referred to in paragraph 63 above states that a potential registrant should specify the vertebrate animal studies they requested from the previous registrant, the provision of a complete list of endpoints for which permission to refer is sought is not necessary for the Agency to commence its examination of the data sharing dispute. In this respect, the Board of Appeal observes that the Appellant has not contested the scope of the permission to refer granted by the Agency but rather the granting of the permission in itself.

80. The Appellant also claims that it had legitimate expectations as a result of the Guidance that no data sharing dispute would be accepted by the Agency before the Data Claimant had expressly defined the list of requested endpoints involving vertebrate animal testing. The Appellant, in particular, refers to the Agency's Questions and Answers on data sharing and related disputes (cited in paragraph 22 above) which states in Section 3.4. that:

'*The potential registrant making every effort to share the data contained in the registration (joint submission) dossier can contact [the Agency], using the web form available on [the Agency's] website ….*

The potential registrant will have to specify the vertebrate animal studies they requested from the previous registrant(s) (or their representative)'.

81. The Appellant points out that this is also repeated in Section 3.4.2.2 of the Agency's Guidance on data sharing (cited in paragraph 63 above). In support of its argument the Appellant also states that the web form for submitting a data sharing dispute includes the field 'List of endpoints subject to the dispute for which permission to refer is requested'.

82. The Board of Appeal observes that in certain circumstances administrative guidance, such as the Guidance in the present case, can constitute a precise assurance by the administrative body as to the course of conduct that it follows and, as such, it can create legitimate expectations (see in that regard, the Decision of the Board of Appeal of 9 April 2014 in Case A-001-2013, paragraph 65).

83. The Board of Appeal finds, however, that the wording of the Questions and Answers, the Guidance and the web form does not state, or even imply, that the Agency would not proceed to the assessment of the data sharing dispute unless a precise list of endpoints is provided. In addition, the Board of Appeal observes that the assessment of the data sharing dispute does not necessarily require the availability of a precise list of endpoints for which permission to refer is sought. In the present case, it is clear that the absence of such a list had no bearing on the Agency's assessment.

84. In any event, the Board of Appeal considers that the rights of the Data Claimant must also be considered in this analysis and that Guidance cannot be interpreted to the detriment of the legitimate expectations of a third party, in this instance the Data Claimant. The Board of Appeal considers that in their efforts to reach an agreement data owners cannot be so formulaic; in some cases the discussions will cover a complete data set and in others a solitary endpoint. The Board of Appeal finds that in the present case it was totally clear what the issue at hand was and that specific endpoints were not at issue in the negotiations.

85. The Board of Appeal also considers that the lead registrant knows which studies involving testing on vertebrate animals are available within the SIEF and are needed for registration purposes for each tonnage band. The Board of Appeal considers that the Appellant could not simply remain silent on this issue and then subsequently seek to rely on technical requirements, which in this case the Board of Appeal has found did not in any case exist, as a means of contesting the Data Claimant's right to receive permission to refer; this would not be making every effort.

86. In view of the above, the Board of Appeal considers that the Appellant's arguments on legitimate expectations must be dismissed.

87. The Board of Appeal therefore considers that the Agency did not act unlawfully in proceeding with its assessment of the data sharing dispute despite the absence of a precise and accurate list of studies for which permission to refer was sought.

88. In view of the above, the Appellant's first plea must be dismissed.

Appellant's second plea alleging that the Agency breached its right to be heard and its rights of defence

Arguments of the Parties and Intervener

89. By its second plea, the Appellant claims that, during the procedure leading to the adoption of the Contested Decision, the Agency breached its right to be heard and its right of defence as the parties to the dispute were not provided with copies of their respective submissions regarding whether every effort had been made. The Appellant claims that this deprived it of the right to defend itself against, potentially unseen, claims of its failure to make every effort.

90. The Appellant states that if there is no exchange with the Agency concerning the records of the data sharing negotiations communicated to it in the context of the data sharing dispute, and if an element has been left out from the Agency's assessment, this may materially bias its findings, as has happened in the present case. The Appellant considers that it is therefore essential that the parties to a data sharing

dispute are permitted to see each other's submissions and comment on them during the assessment process.

91. The Agency argues that its competence in a data sharing dispute is limited to verifying whether the parties to that dispute have correctly executed their obligation to make every effort to reach an agreement in a fair, transparent and non-discriminatory way.

92. The Agency considers that the Appellant was duly heard when it was asked to submit its records of the data sharing negotiations as the Agency assesses only the efforts made by the parties, and not the legal arguments they subsequently make regarding those negotiations.

93. The Intervener argues that the Appellant and the Data Claimant submitted their records of the negotiations between them and since those negotiations were exclusively between them, they were by definition aware of them and thus the parties' right to be heard and right of defence were fully observed.

Findings of the Board of Appeal

94. The Board of Appeal observes that in order to assess the efforts made by the parties to the data sharing dispute those parties provided the Agency with, in particular, a copy of correspondence demonstrating the efforts made to reach an agreement. On 24 April 2014, the Data Claimant submitted to the Agency a 'note describing all the steps in the negotiation' including the email exchanges between the Data Claimant and Appellant during the data sharing dispute and dated from 27 February 2013 to 10 April 2013.

95. In the letter of 8 May 2013 the Appellant was requested to provide the Agency with a note setting out the record and the order of the efforts made by the parties to the data sharing dispute to reach an agreement, as well as a copy of any correspondence demonstrating the efforts made to reach an agreement. The Appellant was also requested to provide a list of the endpoints involving vertebrate animal studies requested by the Data Claimant. In that letter the Appellant was also informed that '… [b]ased on the complete set of information received, [the Agency] will perform an objective and contradictory assessment of the parties' efforts to reach an agreement on the sharing of the data under fair, transparent and non-discriminatory conditions, in accordance with Article 30(1)…'.

96. On 23 and 24 May 2013, the Appellant provided information to the Agency regarding the efforts made to reach an agreement. According to the cover letter accompanying the response, the Appellant provided, in particular, an indication of the list of endpoints involving vertebrate animal studies requested by the Data Claimant, a note setting out the record and the order of the efforts made by the parties to reach an agreement, as well as a copy of correspondence up to 24 April 2013 demonstrating the efforts made by the parties to reach an agreement.

97. The Appellant claims in essence that the Agency's failure to cross-notify the submissions of the parties indicated above in paragraphs 94 and 96 deprived it of the ability to effectively defend itself against '… (unseen) claims of its failure to make every effort'.

98. The Board of Appeal finds that the procedure for the Agency's examination of a data sharing dispute, in particular the opportunity for the parties to such a dispute to receive copies of the respective submissions, is not specifically foreseen in the REACH Regulation. Nonetheless, pursuant to Article 41(2)(a) of the Charter of Fundamental Rights of the European Union, the right to good administration includes 'the right of every person to be heard, before any individual measure which would affect him or her adversely is taken'. The Board of Appeal considers however that this does not mean that there is an automatic requirement for submissions to be cross-notified to the

parties to a data sharing dispute for their observations or comments. The absence of such a step does not therefore automatically mean that there has been a breach of this right to be heard. The Agency must consider, on a case-by-case basis, what measures need to be taken in order to comply with the fundamental right to be heard.

99. The Board of Appeal observes that the task of the Agency in a data sharing dispute is to examine the efforts made by the parties to reach an agreement during data sharing negotiations. This entails examining the records of the negotiations, and the arguments presented therein, as provided by the parties to that dispute. The Board of Appeal further observes that the Agency's assessment of whether every effort is made is wholly based on the exchanges of information between the two parties and that this was made clear to the Appellant in the Agency's letter of 8 May 2013 (see paragraph 95 above).

100. Following a question from the Board of Appeal on the issue, the Agency informed the Board of Appeal that the Agency did not examine any document, or claim, from the Data Claimant during its evaluation of the dispute which was not known to the Appellant. The Board of Appeal observes that all claims examined by the Agency had been made in the correspondence between the parties. In fact the documents considered by the Agency referred to above only consisted of communications between the parties where the Appellant was either the sender or the recipient. As stated by the Agency, the Contested Decision contains a detailed report of the negotiations between the parties which quotes the messages on which the Contested Decision is based.

101. Furthermore, during the present appeal proceedings, the Appellant did not identify any documents, communications or claims concerning the data sharing negotiations between the parties that the Agency had considered as part of its assessment and of which it had not been aware during the negotiations.

102. The Appellant argues that some of the documents it submitted during the present appeal proceedings had only been obtained from the Agency following an access to documents request under Regulation (EC) No 1049/2001 of the European Parliament and the Council regarding public access to European Parliament, Council and Commission documents (OJ L 145, 31.5.2001, p. 43). These documents include for example the web form submitted by the Appellant on 24 April 2013 and an Agency letter to the Data Claimant on 8 May 2013. The Appellant has not however identified that any of those documents had an impact on the Agency's findings regarding the parties' efforts to reach an agreement. Furthermore, the Board of Appeal does not consider that any of these documents were relevant to the assessment carried out by the Agency regarding whether every effort had been made.

103. In light of the above, the Board of Appeal finds that, during the data sharing dispute, only communications between the parties during the data sharing negotiations, and the claims made therein, were considered by the Agency in its assessment of whether every effort had been made. In addition, all communications between the parties during the data sharing negotiations were considered by the Agency in their assessment of whether every effort had been made. As a consequence, the Board of Appeal considers that the Appellant's right to be heard was fully respected during the data sharing dispute in the Agency's assessment of whether every effort had been made during the data sharing negotiations.

104. The Board of Appeal further observes that even if the Board of Appeal had found that the Agency had infringed the Appellant's right to be heard, according to settled case-law, a procedural irregularity leads to annulment of all or part of a decision only if it is established that the content of that decision could have differed if that irregularity had not occurred (see by analogy, for example, Case C-194/99 P*, Thyssen Stahl* v *Commission*, ECLI:EU:C:2003:527, paragraph 31). The appeal proceedings offered the

Appellant the opportunity to identify any (unseen) claims of its failure to make every effort, and to effectively defend itself. As indicated in paragraph 101 above, the Appellant did not identify during these appeal proceedings any documents, communications or claims concerning the data sharing negotiations between the parties to the dispute that the Agency had considered as part of its assessment and of which it had not been aware during the negotiations. The Board of Appeal considers therefore that even if the Appellant had received a copy of the Data Claimant's submissions from the Agency this would not have led to a different result.

105. In light of the above, the Appellant's second plea must be dismissed.

Appellant's third plea alleging that the Agency relied on evidence incapable of substantiating the conclusion that every effort had or had not been made

106. By its third plea, the Appellant argues that the Contested Decision is premised upon several considerations which cannot legitimately be used as the basis for the conclusion that the Appellant did not make every effort to reach an agreement and that the Data Claimant did. In this respect, the Appellant raises three main arguments which the Board of Appeal will examine in turn.

(i) Crediting the Data Claimant for inaction

107. The Appellant contests, in practice, the statement in the Contested Decision that the Data Claimant:

'*… started the negotiations sufficiently early. [The Data Claimant] took contact with the [Appellant] through their consultant in January 2013. This was four months before the registration deadline of 31 May. It is fair to assume that the parties could have agreed within these four months, had they not encountered disagreement over elements of the [letter of access] pricing*'.

Arguments of the Parties and Intervener

108. According to the Appellant, the Agency overlooked the fact that the Data Claimant raised no objections to the cost formula for the letter of access for almost 6 weeks after its first contact in January 2013. According to the Appellant, the Contested Decision therefore erroneously credits the Data Claimant as having made efforts when it was in fact silent and thus inactive.

109. The Agency, supported by the Intervener, argues that the data sharing dispute had been submitted to the Agency at a time when comprehensive negotiations had already taken place. The Agency considers that the Data Claimant and the Appellant had time to exchange their views and the negotiations had clearly reached a standstill.

Findings of the Board of Appeal

110. The Board of Appeal notes that, by the time the data sharing claim was submitted to the Agency on 24 April 2013, the Data Claimant and the Appellant had reached an impasse in the data sharing negotiations. The Board of Appeal found in paragraphs 38 to 61 above that the 10 % annual cost increase and the scope of the reconciliation process, which was the main focus of the data sharing dispute, had not been adequately justified by the Appellant prior to the data sharing dispute being submitted to the Agency. The Board of Appeal considers that this was the principle reason for the impasse being reached. The Board of Appeal considers that any delay on the part of the Data Claimant in objecting to the cost of the letter of access had no role in that impasse being reached.

111. The Board of Appeal also observes that there was in fact some activity during the six week period in which the Appellant claims that the Data Claimant was inactive. As stated in the Contested Decision, on 24 January 2013 the Appellant explained the cost of the letter of access to the Data Claimant. On the same day, the Data Claimant requested the Appellant to send an updated copy of the SIEF agreement. The Contested Decision states that the Data Claimant sent a reminder of this request on 11 February 2013 and then received from the Appellant the template for the letter of access for the 100 to 1 000 tonnes per annum tonnage band on 14 February 2013. The Board of Appeal also observes that according to the Appellant's letter to the Agency of 24 May 2013, the Data Claimant contacted the Appellant by telephone during the week of 18 February 2013. The Data Claimant then raised their concerns regarding the 10 % annual cost increase and the € 1 000 administrative charge on 27 February 2013. The Board of Appeal therefore considers that the Appellant's claim that the Data Claimant remained inactive during the first six weeks of the negotiations is incorrect.

112. The Board of Appeal also considers that the amount of time prior to the registration deadline that the Data Claimant started the negotiations was not a decisive consideration in the Agency reaching a conclusion on whether every effort was made. The Board of Appeal considers that even if the Data Claimant had submitted the data sharing dispute closer to the registration deadline, or even after it, this would not have impacted on the overall conclusion of whether every effort had been made.

113. The Board of Appeal considers that in this analysis, and regarding issues of timing, the consideration of the state of negotiations at the time the data sharing dispute was submitted to the Agency is of far greater importance. Furthermore, the Board of Appeal considers that the time at which a data sharing dispute should be lodged with the Agency and the amount of time that parties should invest in negotiating the sharing of data is entirely dependent on the facts in the particular case.

114. In light of the above, the Board of Appeal finds that the Appellant's claim that the Agency credited the Data Claimant for inaction in reaching its conclusion regarding every effort must be dismissed.

(ii) Crediting the Data Claimant for mere repetition of its objections to the proposed terms of data access

Arguments of the Parties and Intervener

115. The Appellant contests in effect the finding in the Contested Decision that:

'*The submission of the dispute was also not premature, as the last e-mails show that the negotiations had reached a standstill, because the parties had exchanged their arguments on the 1,000 EUR administrative fee and the 10% annual increase and were not willing to move away from their positions.*'

116. The Appellant argues that this suggests that unless a data owner makes concessions to requests for discounted letters of access it will always be deemed to have failed to have made every effort to reach an agreement. The Appellant claims that the Agency was in fact crediting the Data Claimant for a mere repetition of its objections to the proposed terms of data access.

117. The Agency, supported by the Intervener, argues that the Agency concluded in the Contested Decision that the data sharing dispute had been submitted at a point in time when comprehensive negotiations had taken place, in which the parties had time to exchange their arguments, and the negotiations had reached a standstill. According to the Agency, the information submitted by both parties shows that they had taken the necessary time to exhaust the negotiations.

Findings of the Board of Appeal

118. The Board of Appeal observes that the Data Claimant was in effect obliged to repeat the same objection to the 10 % annual cost increase because the Appellant failed, as the Board of Appeal has found in paragraphs 38 to 61 above, to demonstrate that the 10 % annual cost increase was not potentially discriminatory. In other words, the Data Claimant could not move forward in the negotiations because its concerns were never adequately addressed by the Appellant. In particular, as highlighted above, the lack of clarity regarding the scope of the reconciliation process contributed to the standstill in the negotiations. The Board of Appeal considers that the fact that during the oral hearing the Appellant clearly explained for the first time that the reconciliation would include the 10 % annual cost increase supports the finding that the Appellant failed to clearly clarify the data sharing terms during the negotiations. This demonstrates that the Data Claimant was justified in repeating its objections to the 10 % annual cost increase.

119. The Board of Appeal finds therefore that the Appellant's claim that the Agency credited the Data Claimant for mere repetition of its objections to the proposed terms of data access in reaching its conclusion regarding every effort must be dismissed.

(iii) Crediting the Data Claimant with making every effort when it had failed to convey to the Appellant the exact list of vertebrate animal studies

Arguments of the Parties and Intervener

120. The Appellant argues that by failing to define a list of the studies subject to the data sharing negotiations the Data Claimant never established the object of those negotiations and as such could not be considered to have made every effort.

121. The Agency states that the parties negotiating access to data must clarify which studies are needed for the registration dossier in question and for which they are negotiating access. According to the Agency, this is an element of making every effort in data sharing negotiations. The Agency adds that the specification of the studies subject to the negotiation can be done in several ways. For example, as in the present case, the Data Claimant can specify the whole data set for a relevant tonnage band. The Agency adds that in the negotiations between the Appellant and the Data Claimant there was never any doubt as to the studies that were being negotiated.

Findings of the Board of Appeal

122. As stated above in the Board of Appeal's examination of the Appellant's first plea (see paragraphs 72 to 88 above), the alleged lack of precision on the endpoints did not create any problems in the negotiations between the Appellant and the Data Claimant. The Board of Appeal considers that there was a common understanding during the negotiations that the Data Claimant was seeking to obtain a letter of access for vanadium at the 100 to 1 000 tonnes per annum tonnage band. The Board of Appeal finds that the lack of an exact list of vertebrate animal studies had no bearing on the success or otherwise of the negotiations and was therefore not relevant in considering whether every effort had been made.

123. The Board of Appeal also observes that the Appellant did not identify the lack of an exact list of vertebrate animal studies as being an obstacle to an agreement during the data sharing negotiations. In fact, the Appellant stated in its submission of 24 May 2013 to the Agency, in other words after the data sharing dispute had been brought before the Agency, that '… the subject matter of dispute … does not bear on the list of endpoints or vertebrate animal data in the dossier and the cost thereof … the only point of contention on 24 April 2013 was the 10 % per annum cost sharing and the handling fee'.

124. The Board of Appeal finds therefore that the Appellant's claim that the Agency credited the Data Claimant with making every effort when it failed to convey to the Appellant the exact list of vertebrate animal studies must be dismissed.

125. In view of the above, the Appellant's third plea must be dismissed.

Appellant's fourth plea alleging that the Agency failed to consider all the available information necessary in order to evaluate whether every effort was made

Arguments of the Parties and Intervener

126. The Appellant argues that in concluding that the Data Claimant had made every effort to reach an agreement in a fair, transparent and non-discriminatory manner and the Appellant had not, the Agency failed to take into account the Appellant's efforts to engage with the Data Claimant several years in advance of the submission of its data sharing dispute. In particular, the Appellant argues that the fact that it circulated the draft SIEF agreement in 2010 is a clear indication of proactive engagement in a process designed to ensure that every effort is made. By notifying the SIEF members early of the SIEF agreement the Appellant enabled the members of the SIEF to raise their objections to the terms thereof at an early stage. The Appellant adds that at that time no objections were raised.

127. The Agency claims that it considered the fact that the Appellant circulated the draft SIEF agreement before the registration deadline of 2010. The Agency argues however that the mere circumstance that the first registrants (for example those registering at the 2010 registration deadline) have to find an agreement on the data and cost sharing earlier than later registrants (for example those registering at the 2013 and 2018 registration deadlines) in order to be able to fulfil their registration requirements, does not mean that they are free to agree on a cost sharing mechanism that discriminates against later registrants. According to the Agency, it also does not mean that later registrants are bound by such a discriminatory cost sharing mechanism, based only on their silence during the period when they had no obligation yet to share data and to submit a registration. According to the Agency, the early circulation of information on data sharing conditions is not therefore decisive in the assessment of efforts made by existing registrants.

Findings of the Board of Appeal

128. The Board of Appeal observes that companies which have pre-registered phase-in substances in accordance with Article 28 are obliged to participate in a SIEF pursuant to Article 29. However, there is no obligation for those pre-registrants to actually register the substance concerned. For example, if a pre-registrant decides to cease manufacture or import of the substance concerned before the applicable registration deadline set out in Article 23 it will not be required to register the substance.

129. The Board of Appeal notes that the data sharing obligations under Article 30 are only triggered when a registrant requires one or more studies for the purpose of registration and makes a request to other SIEF members pursuant to Article 30(1). Furthermore, there was no obligation for the Data Claimant to engage in data sharing negotiations three years in advance of the registration deadline applicable to it. Indeed, as stated in the previous paragraph, a pre-registrant does not necessarily know at that stage whether it is even going to register. It should be noted that for many potential registrants there could be eight or nine years between a SIEF being established and a registration being submitted.

130. In addition, regardless of what is in a SIEF agreement, the parties still have to make every effort and it is this that must be assessed by the Agency in a data sharing dispute. The Board of Appeal finds that, for the assessment of a data sharing dispute under Article 30(3), the actions taken from the moment the data sharing negotiations commence are the most relevant. Whilst the early circulation of a SIEF agreement is good practice, the lack of a response to this cannot be taken as agreement to the terms therein.

131. The Board of Appeal therefore considers that, in view of the above, the circulation of the SIEF agreement in 2010 is not a decisive element in assessing whether in the present case every effort had been made by the parties. In this respect the crucial element in assessing whether every effort had been made in this particular case was the actions taken by the parties after the data sharing negotiations commenced and especially the negotiations concerning the 10 % annual cost increase.

132. In view of the above, the Appellant's fourth plea, and therefore the appeal in its entirety, must be dismissed.

Other issues under examination

Refund of the appeal fee

133. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 107, 17.4.2008, p. 6), the appeal fee shall be refunded if the appeal is decided in favour of an appellant.

134. As the Board of Appeal has decided the appeal in favour of the Agency in the present case, the appeal fee shall not be refunded.

ORDER

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Decides that the appeal fee shall not be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Sari HAUKKA
Registrar of the Board of Appeal