EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

4 April 2017

(Biocidal products – Data sharing costs – Revenues received under the Biocidal Products Directive – Permission to refer)

Case number	A-001-2016
Language of the case	English
Appellant	Troy Chemical Company B.V., The Netherlands
Representatives	Darren Abrahams and Eléonore Mullier Steptoe & Johnson LLP, Belgium
Intervener	Thor GmbH, Germany
Contested Decision	DSH-63-3-D-0017-2015 of 8 January 2016 adopted by the European Chemicals Agency pursuant to Article 63(3) of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1; hereinafter the 'BPR')

THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman), Andrew Fasey (Technically Qualified Member) and Sari Haukka (Legally Qualified Member and Rapporteur)

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the dispute

1. On 13 January 2016, the Appellant lodged the present appeal at the Registry of the Board of Appeal against the Contested Decision. By the Contested Decision, the European Chemicals Agency (hereinafter the 'Agency') granted permission to the Intervener to refer to studies owned by the Appellant concerning the biocidal active substance 3-iodo-2-propynylbutyl carbamate (hereinafter the 'active substance'). The Intervener had notified the Agency on 7 October 2015 of a failure to reach an agreement with the Appellant with respect to the sharing of the data contained in those studies, in accordance with Article 63(3) of the BPR (all references to Recitals and Articles hereinafter concern the BPR unless stated otherwise).
2. The Intervener was seeking access to the studies owned by the Appellant in order to apply for inclusion in the list of suppliers of biocidal products and substances which have not yet been approved, which is published by the Agency pursuant to Article 95 (hereinafter the 'Article 95 list').

Background of the dispute

3. Between 2004 and 2008, a task force comprising of four companies, including the Appellant (hereinafter the 'Task Force'), submitted studies to the authorities of the relevant rapporteur Member State for the active substance pursuant to Commission Regulation (EC) No 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3) and in the framework of the second review programme referred to in Article 16(2) of this Directive (OJ L 123, 24.4.1998, p. 1; hereinafter the 'BPD').
4. Article 96 of the BPR repealed the BPD with effect from 1 September 2013.
5. On 24 September 2014, the Appellant was included in the Article 95 list as a review programme participant for the active substance for six product types.
6. On 7 July 2015, the Intervener contacted the Appellant to enquire about the price of a letter of access to the studies submitted by the Appellant in support of its application for the approval of the active substance for the long-term repeated dose toxicity and carcinogenicity endpoints. In the same enquiry, the Intervener requested the Appellant to '*also send […] the related cost calculation model for this price.*'
7. On 10 July 2015, the Appellant informed the Intervener that '*before starting negotiations and in order to assure the confidential exchange of information between competitors, [the Intervener and the Appellant] need to establish an "Every Effort and Secrecy Agreement"*' (hereinafter the 'EESA'). The Appellant provided a draft of the EESA and indicated that it '*[had] to be signed before [the Appellant could] provide [the Intervener] with further information.*'
8. On 13 July 2015, the Intervener responded to the Appellant by providing comments on, and amendments to, the EESA. In addition, the Intervener enquired as to why '*the price for the [letter of access] and the amount of studies which would be covered by the [letter of access] are not provided before an EESA is concluded.*' The Intervener further explained that '*[f]ollowing the "Fast-Track" approach of the Practical Guide [on BPR: Special Series on Data Sharing of April 2015] an over-the-counter scenario could be possible, especially to comply with the tight regulatory timeframe given by [the Agency]*' (hereinafter the 'Practical Guide'). The Intervener requested the Appellant to '*provide [to it] the [letter of access] price for the studies the Task Force has submitted*

under the BPD/BPR for the following endpoints at short notice: [l]ong-term repeated dose toxicity (≥12 months)[…] [and] [c]arcinogenicity.'

9. On 16 July 2015, the Appellant replied to the Intervener and provided, along with a version of the EESA bearing amendments and comments, a list of the studies submitted by the Appellant for the active substance for the purpose of complying with the BPD and the BPR for the long-term repeated dose toxicity and carcinogenicity endpoints. The Appellant requested the Intervener to '*review and indicate for which information/studies [the Intervener sought] a [letter of access].*'

10. On 17 July 2015, the Intervener sent a scanned signed copy of the EESA to the Appellant and requested it to provide a draft data sharing agreement for the Intervener's review. In reply to the Appellant's question concerning the list of studies, the Intervener stated that it would revert to the Appellant as soon as it '*[had] decided to which study/ies [it was] intending to buy [the letter of access].*'

11. On 20 July 2015, the Appellant informed the Intervener that it was '*currently preparing a draft data sharing agreement which [would] be sent to [the Intervener] for review [as soon as possible].*'

12. On 21 July 2015, the Intervener emphasised to the Appellant '*the utmost urgency [it faced] to meet the regulatory obligations and deadlines given by the Agency*' and added that *'[i]n order to comply with the deadlines, we have to reach an agreement on data sharing until next week at the latest, otherwise we would be forced to inform [the Agency] that we are not able to reach an agreement.'* The Intervener also requested the Appellant to '*provide [it] with a cost model with a detailed cost breakdown for all the studies listed on the list [the Appellant] provided on 16 July*' and to give an indication of the timeline for the draft data sharing agreement to be provided.

13. On 23 July 2015, the Appellant sent the Intervener a table with a list of prices for the studies listed by the Appellant on 16 July 2015 as well as details of the calculation of these prices. This list set out the total '*compensable value'* for the studies as well as the share of the price to be paid by a single company. The share of the price for a single company corresponded to half of the total '*compensable value'* indicated by the Appellant for the studies. On 24 July 2015, the Appellant sent the Intervener a draft data sharing agreement for its review.

14. On 31 July 2015, the Intervener responded to the Appellant's letter of 23 July 2015 stating, inter alia, that '*the division of the costs [of the studies] by 2 [as between the Intervener and the Appellant] is inappropriate'* considering that *'the studies are used by more than one participant (respectively all the members of [the Task Force])*'. The Intervener added that '*[n]ot considering the members of the Task Force which have access rights, [the Appellant] would be acting in an unfair and discriminatory manner.*' The Intervener also added that '*one of the intentions of [data sharing under the BPR] is to give Data Owners a chance to "recover part of their investment by receiving equitable compensation".*' The Intervener added that it expected feedback from the Appellant on its comments or a revised price quotation by 6 August 2015.

15. On 6 August 2015, the Appellant responded that '*you [i.e. the Intervener] refer to data sharing which occurred under the BPD. In effect, you are asking us to apply the BPR retroactively. There is no legal obligation to do so. Data sharing under the BPR need only take into account sharing which has occurred from 1 September 2013. Accordingly, we do not propose to modify this two way split'* (hereinafter 'the division of costs by two'). The Appellant also included in this communication a reduced price quotation that included a reduction of the management fee and took into account the limited territorial scope of the data access rights.

16. On 1 September 2015, the Intervener responded that:

'*Pursuant to [the Appellant's] reply […], it can be assumed that the studies were already shared with the Task Force (TF) members. Given that according to Article 62 BPR, data sharing applies to studies which were submitted either under [the BPD] or the BPR, we believe that data sharing occurred under the BPD should also be considered, especially if the data is used by the other participants also for BPR purposes now.*'

17. The Intervener indicated a price which it was prepared to pay for each study and which corresponded to less than a third of the price proposed by the Appellant in its communication of 6 August 2015.

18. On 23 September 2015, the Appellant replied to the Intervener's communication of 1 September 2015 stating that '*[d]ata sharing under the BPR need only take into account sharing which has occurred from 1 September 2013 and there is no obligation under the BPR to reduce compensation to take into account pre-BPR data sharing agreements.*' The Appellant added that the BPR did not apply retroactively and that it could not in this context accept the Intervener's counter-offer. It added that it hoped that the Intervener would '*reconsider [its] position in order to reach a prompt conclusion of these negotiations.*' In the same communication, the Appellant also updated the quotation table for the different costs of the studies requested by the Intervener.

19. On 28 September 2015, the Intervener answered that it did not believe it was possible to reach an agreement and that it was '*unfair and discriminatory vis-à-vis the prospective applicants to ignore the participants which are using the same data under the BPR, just because they obtained access rights earlier under the BPD'.* The Intervener added that the Appellant's approach did not take into account access rights granted to use the data under the BPD and led prospective applicants to contribute to a larger share of the costs incurred by the data owner than the other participants in the Task Force. The Intervener also considered that data owners would, following the Appellant's approach, make a profit '*which is clearly not the intention of the mandatory data sharing under the BPR*' and that '*under this circumstances [sic] the creation of a level playing field, which is sought by the BPR, would be impossible.*' The Intervener asked the Appellant to reconsider its approach by 30 September 2015 and added that in the alternative '*[the Intervener] would be forced to regard the negotiations as failed and to submit a dispute to [the Agency].*'

20. On 30 September 2015, the Appellant replied to the Intervener by quoting the chapter on data sharing in the Practical Guide on Biocidal Products Regulation which in its view '*emphasises that pre-1 September 2013 activities are not material [to the Appellant's and the Intervener's data sharing negotiations]'.* According to the section of the BPR Practical Guide Chapter on Data Sharing quoted by the Appellant:

'*Where the negotiations started before 1 September 2013 […] [and as] under the previous legislation (Directive 98/8/EC) there was no mandatory data sharing obligation per se, the new obligation under the BPR cannot have retroactive effect, and [the Agency] cannot take into consideration what was achieved or negotiated prior to 1 September 2013 in a data sharing dispute. Where negotiations started before the entry into application of the BPR, parties should identify the remaining points of disagreement and the points on which they have reached an agreement as of 1 September 2013. This can serve as a basis for the negotiations that must take place after 1 September 2013*.'

21. The Appellant added that '*[t]he BPD has been repealed and what happened under the BPD is similarly immaterial in the BPR context. We reject the suggestion that we are profiteering by applying the mandatory BPR rules. The objective of Article 95 is to correct a long-standing free-rider problem which has enabled companies who chose not to be Review Programme Participants to benefit from the expenses incurred by those who were Participants. We consider that our reasonable offer to you is in line with that principle and fair and non-discriminatory cost sharing, applying the new legal framework established by the BPR since 1 September 2013. We remain open to discussing these issues and consider that recourse to the Data Sharing Dispute mechanism would be premature and not be in the parties' best interests. We urge you to reconsider your declared intentions.*'

22. On 7 October 2015, the Intervener submitted a data sharing dispute to the Agency pursuant to Article 63(3), including details of all communications between the Appellant and the Intervener.

23. On 14 October 2015, the Agency requested the Appellant to provide documentation of the data sharing negotiations with the Intervener including any correspondence, minutes from telephone calls and meetings demonstrating the efforts made by all the parties to reach an agreement up to 7 October 2015.

24. On 28 October 2015, the Appellant provided the Agency with the communications between the Appellant and the Intervener up to the date of submission of the data sharing dispute by the Intervener.

25. The Appellant added that it was apparent that every effort to reach an agreement had not been exhausted and the negotiations had not reached a standstill. The Appellant argued that the Intervener had, at the time of the submission of the data sharing dispute, not yet reacted to the draft data sharing agreement submitted to the Intervener on 24 July 2015. It had also not indicated which studies it intended to purchase a letter of access for despite having received the list of studies from the Appellant on 16 July 2015. The Appellant stated that the Intervener had failed to respond to the Appellant's offer and justifications of 23 September 2015 and that it threatened instead, in its communication of 28 September 2015, to initiate a data sharing dispute. The Appellant further argued that '*[t]he BPR's data sharing dispute mechanism is not intended to be used as a threat or an "ultimatum" to force a party to accept the other's unreasonable view*' and that for the Intervener to give the Appellant a period of two working days to change its position was unreasonably short. The Appellant added that the Intervener had interrupted negotiations during a three week period preceding the deadline provided in Article 95(2). The Appellant also indicated that there had been further exchanges between itself and the Intervener after 7 October 2015, the date on which the Intervener submitted the data sharing dispute.

26. On 21 December 2015, the Agency notified to the Intervener a communication entitled '*request for proof of payment relating to [the Intervener's] data sharing dispute under Article 63(3)*' (hereinafter the 'request for proof of payment') which indicated that the Agency intended to grant the Intervener permission to refer to certain studies requested from the Appellant on the condition that the Intervener provide proof to the Agency that it paid the Appellant a share of the cost incurred pursuant to Article 63(3). A draft decision on the data sharing dispute was attached to the request for proof of payment. Copies of the request for proof of payment and the draft decision were also sent to the Appellant.

27. On 22 December 2015, the Appellant informed the Agency by email that no payment had been received from the Intervener on the date that the data sharing dispute was lodged with the Agency or since the dispute was lodged. The Appellant added that Article 63(3) requires the Agency to assess whether every effort has been made and whether the prospective applicant has paid a share of the costs. The Appellant

therefore considered that the Agency must assess whether the conditions of Article 63(3) have been met by the Intervener prior to initiating the dispute.

28. On 23 December 2015, the Agency replied to the Appellant's email that a response would be prepared within fifteen working days in line with good administrative practice.

29. On 7 January 2016, the Intervener made a payment to the Appellant and provided the proof of payment to the Agency.

30. On 8 January 2016, the Agency informed the Appellant that it would receive shortly the final decision on the data sharing dispute. Later on the same day, the Agency notified the Contested Decision to the Intervener and sent a copy to the Appellant. In the Contested Decision, the Agency found that the Appellant had failed to make every effort in the data sharing negotiations. The Agency granted permission to the Intervener, in accordance with Article 63(3), to refer to studies owned by the Appellant concerning the active substance for the long-term repeated dose toxicity and carcinogenicity endpoints.

Procedure before the Board of Appeal

31. On 13 January 2016, the Appellant lodged the present appeal.

32. The Appellant requests the Board of Appeal to declare the appeal admissible, annul the Contested Decision and order the refund of the appeal fee.

33. On 3 March 2016, Thor GmbH applied to intervene in the proceedings before the Board of Appeal in support of the Agency. By decision of 6 April 2016, the Board of Appeal, having heard the Parties, granted the Intervener's application to intervene.

34. On 21 March 2016, the Agency lodged its Defence requesting the Board of Appeal to dismiss the appeal as unfounded.

35. On 17 May 2016, the Appellant lodged its observations on the Defence and responded to certain questions of the Board of Appeal.

36. On 20 May 2016, the Intervener submitted its statement in intervention.

37. On 23 June 2016, the Agency submitted its observations on the Appellant's observations on the Defence.

38. On 23 and 27 June 2016 respectively, the Agency and the Appellant submitted their observations on the statement in intervention.

39. On 7 July 2016, the Parties and the Intervener were notified of the Board of Appeal's decision to close the written procedure. On 19 July 2016, the Appellant requested a hearing to be held. As a result, in accordance with Article 13 of Commission Regulation (EC) No 771/2008 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, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.5.2016, p. 4), the Parties were summoned to a hearing which was held on 16 November 2016. At the hearing the Parties and the Intervener made oral presentations and responded to questions from the Board of Appeal.

Reasons

40. The Appellant puts forward five pleas in law in support of its appeal, alleging (i) a breach of the admissibility requirement in Article 63(3) as the Agency decided on a data sharing dispute despite the fact that the Intervener had not made a payment before initiating the dispute, (ii) a breach of the substantive criterion in Article 63(3) in

granting the Intervener permission to refer to the requested studies in the absence of a payment before initiating the dispute, (iii) a breach of the Agency's Guidance on data sharing, (iv) an error by the Agency in the assessment of whether the intervener had made every effort and (v) a breach of Article 95 in ruling that pre-BPR cost sharing has to be taken into consideration in the calculation of the price to be paid for the studies.

41. The Board of Appeal will examine jointly the Appellant's first, second and third pleas, which all concern whether the payment of a share of the costs incurred by data owner should have been made by the prospective applicant, pursuant to Article 63(3), before lodging the data sharing dispute.

42. The Board of Appeal will then address together the Appellant's fourth and fifth pleas, both of which concern the substantive part of the Agency's assessment leading to the Contested Decision.

The first, second and third pleas, alleging a breach of Article 63(3)

Arguments of the Parties

43. By its first plea, the Appellant claims that the Contested Decision breaches an admissibility '*standard*' in Article 63(3) in that the Agency decided on a data sharing dispute even though the Intervener had not made a payment to the Appellant before it initiated the dispute on 7 October 2015.

44. The Appellant argues that '*the use of the past tense in Article 63(3) establishes that the payment must have been made by the prospective applicant on the date on which it submits a data sharing dispute.*' The Appellant concludes that the Agency should have rejected the Intervener's data sharing claim as inadmissible considering that the Intervener had paid nothing by the time it lodged the data sharing dispute with the Agency.

45. By its second plea, the Appellant claims that the Contested Decision breaches Article 63(3) and that this argument is supported by a literal, systemic and purposive interpretation of Article 63(3) as well as by the Agency's guidance.

46. First, the Appellant argues that, according to a literal interpretation, the use of contrasting tenses in Article 63(3) establishes the payment by a prospective applicant as a condition which must have been met in the past in order for the Agency to grant the permission to refer. The Appellant concludes that the Agency therefore breached the plain terms of Article 63(3), which require a prospective applicant to have paid a share of the costs prior to initiating the data sharing dispute.

47. Second, the Appellant argues that, according to a systemic interpretation, the condition of a payment having been made must be given the same temporal application as the other criterion in Article 63(3), i.e. that every effort has been made to reach an agreement. The Appellant explains that the Agency applies the every effort criterion on the basis of events up to the date of submission of the dispute claim which it uses as a cut-off date. The Appellant considers that this cut-off date must therefore also be applied to the payment criterion in Article 63(3) and that the Agency cannot allow prospective applicants to make a payment on a later date. In the Appellant's view, a consistent temporal application of both the every effort criterion and of the payment criterion allows the Agency to assess whether, at the time the dispute was initiated, the two criteria for it to grant permission to refer were met.

48. Third, the Appellant argues that, according to a purposive interpretation, the requirement in Article 63(3) that a payment has to be made prior to the lodging of a dispute is supported by the objective of the BPR data sharing provisions of creating of

a level playing field on the market for existing substances spelled out in Recital 58. The Appellant adds that Article 95 has the objective of correcting a long-standing '*free-rider*' problem. The Appellant refers to the past situation which enabled companies who chose not to be review programme participants under the BPD to benefit from the expenses incurred by the participants to these review programmes. The Appellant is of the opinion that it was not the legislator's intention to further prolong the existence of the '*free-riding*' problem by allowing a delay in payment being made to a data owner.

49. The Appellant submits that its reading of Article 63(3) is also consistent with Section 4.2(b)(iv) of the Practical Guide, entitled '*Proof of Payment*', which provides that '*[t]he Agency does not require proof of payment to be submitted at the time of lodging a dispute*' and only addresses the timing of the proof of payment but not the timing of the payment itself. The Appellant adds further that the Agency's Guidance on Data Sharing refers consistently to payment as '*having been made'* and that this wording is consistent with a reading according to which, although the proof of payment may be provided after the initiation of the dispute, the payment itself must have been made before its initiation.

50. By its third plea, the Appellant claims that the Practical Guide gave it the legitimate expectation that in the absence of a payment from the Intervener, the Agency would not adjudicate the data sharing dispute and not grant the Intervener permission to refer.

51. The Appellant also submits that the obligation for prospective applicants to pay a share of the costs is not a '*down payment*' on a positive decision by the Agency following a data sharing dispute. The Appellant further observes in that regard that if the Agency does not grant a permission to refer at the end of a data sharing dispute procedure, this does not automatically mean that a prospective applicant should be refunded. It only means, in the Appellant's view, that the conditions in Article 63(3) were not met and negotiations to reach an agreement would have to resume, during which time a prospective applicant can ask for the payment made under Article 63(3) to be deducted from the final payment of the price for the letter of access.

52. The Agency argues that the wording of Article 63(3) indicates that the payment of a share of the costs must be made before the permission to refer is given. The Agency adds that Article 63(3) separates as two distinct criteria the payment of a share of the costs from the assessment of the efforts of the parties. The Agency claims that this is demonstrated by the use of the word '*and*' in Article 63(3) between the two listed criteria, i.e. that a prospective applicant demonstrates that every effort has been made to reach an agreement and that a prospective applicant has paid the data owner a share of the costs incurred.

53. The Agency further argues that, given that Article 63(3) gives competence to the national courts to determine the amount of a proportionate share of the cost that a prospective applicant pays a data owner, the condition to have paid a share of the costs cannot be an element of the Agency's assessment of every effort of the parties to the data sharing dispute.

54. The Agency also argues that it would be disproportionate to require a prospective applicant to make a payment to a data owner in a situation where they have not agreed on a share of the cost and when a prospective applicant does not know whether its data sharing dispute will be successful. Were a prospective applicant to lose the data sharing dispute, it would be forced, in the Agency's view, to re-claim its payment from the data owner and have missed interest on that amount and bear the risk of a possible insolvency of the data owner.

55. The Agency contests that the Appellant's argument is supported by a literal, systemic, historical and teleological, or in other words purposive, interpretation of Article 63(3). The Agency explains its view that, according to a literal interpretation, the wording of Article 63(3) indicates that payment must be made before the permission to refer is given. The Agency adds that if the legislature had meant to make the payment an admissibility criterion or a substantive condition, it would have mentioned the proof of payment in the first subparagraph of Article 63(1) describing how a prospective applicant submits a data sharing dispute.

56. The Agency states that it was already its practice under Article 27(5) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, 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') to assess the parties' efforts upon submission of a dispute and then to ask a potential registrant to provide a proof of payment if that was the only condition missing for it to receive a permission to refer. Payment before submission of the dispute was not required. The Agency explains that this practice precedes the BPR and is reflected amongst other in the REACH Guidance on Data Sharing, which does not mention that the payment of a share of the costs by a prospective applicant is part of the assessment of its every efforts. The Agency further observes that the footnote to Article 63(4) refers to the '*Guidance on Data Sharing established in accordance with [the REACH Regulation]*' (hereinafter 'the REACH Guidance on Data Sharing') and that data sharing under the BPR is built on the data sharing model of the REACH Regulation.

Findings of the Board of Appeal

57. The Board of Appeal observes that, under these pleas, the main point of disagreement between the Appellant and the Agency concerns the interpretation of the second subparagraph of Article 63(3). More precisely, by its first, second and third pleas, the Appellant claims that the payment of a share of the costs incurred by the data owner should have been made by the prospective applicant before lodging the data sharing dispute.

58. The Board of Appeal observes that the examination of the first, second and third pleas requires it to interpret Article 63 and in particular the second subparagraph of its third paragraph.

59. As a preliminary point, it should be recalled that, in determining the scope of a provision of European Union law, its wording, context and objectives must all be taken into account (see, for example, judgments of 25 January 2017, *Vilkas*, C-640/15, EU:C:2017:39, paragraph 30, of 21 January 2016, *Knauer*, C-453/14, EU:C:2016:37, paragraph 27, and of 16 December 2015, *Sweden* v *Commission*, T-521/14, EU:T:2015:976, paragraph 57). However, there is in principle no need for interpretation of a provision, particularly in the light of its context and purpose, when its scope can be determined with precision on the basis of its wording alone, the clear text being sufficient in itself (see *Sweden* v *Commission*, cited previously in this paragraph, paragraph 59; see also, to that effect, judgment of 3 September 2015, *Sodiaal International*, C-383/14, EU:C:2015:541, paragraphs 20 and 24).

60. The Board of Appeal will therefore proceed to examine the wording and, if necessary, the context and objectives of Article 63.

61. The second subparagraph of Article 63(3) provides that '*[w]ithin 60 days of being informed, the Agency shall give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred'*.

62. The Board of Appeal notes that this provision establishes, first, a temporal condition for the Agency to give a permission to refer to the requested tests or studies after having been informed by a prospective applicant of a failure to reach an agreement in a data sharing negotiation. Second, the second subparagraph of Article 63(3) lays down two conditions for the permission to refer to be granted: the demonstration by a prospective applicant that every effort has been made to reach an agreement, and the payment of a share of the costs incurred has been made to the data owner. It is therefore clear that the permission to refer shall be given within 60 days of the data sharing dispute being notified to the Agency '*provided that*' these two separate conditions have been met. There is nothing in Article 63(3) specifically indicating that the payment must be made before the submission of the data sharing dispute.

63. The Board of Appeal notes that the connecting terms '*provided that*' and '*and*' ('*pour autant que*' and '*et*' in the French version, '*wenn*' and '*und*' in the German version) must be understood, according to their generally accepted meaning as prescribing two cumulative conditions without necessarily indicating the sequence in which the two conditions must be fulfilled.

64. It is therefore apparent that the wording of Article 63(3) does not suffice, on its own, to determine with precision whether the two conditions need to be fulfilled at the time the data sharing dispute is introduced. Therefore, the Board of Appeal will examine the context and objectives of this provision.

65. With regard to the context of the second subparagraph of Article 63(3), the Board of Appeal observes that Article 63 is part of Chapter XIV of the BPR. This chapter concerns data protection and data sharing. As regards data sharing, Article 62(1) states that, in order to avoid animal testing, testing on vertebrates should be undertaken only as a last resort. The same provision adds that testing on vertebrates shall not be repeated for the purposes of the BPR.

66. It is in this context that the Agency gives permission to a prospective applicant, in accordance with the second subparagraph of Article 63(3), to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that it has paid the data owner a share of the costs incurred. The context of the second subparagraph of Article 63(3) does not therefore clarify at which moment in time the payment of a share of the costs incurred should take place.

67. Similarly, the first subparagraph of Article 63(3) states that '*where no agreement is reached in respect to data involving tests or studies on vertebrates, the prospective applicant shall inform the Agency and the data owner thereof*'. The word '*thereof*' clearly refers to a situation where no agreement is reached. It does not refer to the other condition set in the second subparagraph of Article 63(3) namely that a prospective applicant has paid a share of the costs incurred by a data owner.

68. The Board of Appeal recalls in addition that the third subparagraph of Article 63(3) provides that data owners shall not refuse to accept any payment offered pursuant to the second subparagraph. This provision does not indicate that the payment should be made before the data sharing dispute is lodged.

69. For the reasons laid out in paragraphs 65 to 68 above, the Board of Appeal considers that the context of the second subparagraph of Article 63(3) does not indicate whether the payment of a share of the costs incurred by the data owner needs to made before lodging a data sharing dispute.

70. The Board of Appeal will next interpret the second subparagraph of Article 63(3) in light of its objectives.

71. It is apparent from the wording of Article 62(1) that one of the main objectives of data sharing is to avoid animal testing. This objective is recalled in Recital 57, which states

that '*it is essential to minimise the number of tests on animals and for testing with biocidal products, or active substances contained in biocidal products, to be carried out only when the purpose and use of a product so requires. Applicants should share, and not duplicate, studies on vertebrates in exchange for equitable compensation*'.

72. The achievement of this objective does not depend on the timing of the payment of a share of the costs incurred by a data owner. This objective is more likely to be achieved if the payment can take place once a prospective applicant knows that it will be granted the right to refer to all or some of the data in question.

73. The Board of Appeal notes that another objective of data sharing is stated in Recital 58, which provides that '*a level playing field should be established as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of avoiding the establishment of monopolies, of sustaining free competition between economics operators and of equitable compensation of the costs borne by data owners*'.

74. Pursuant to Article 95(2), as of 1 September 2015 a biocidal product consisting of, containing or generating a relevant substance included in the Article 95 list shall not be made available on the market unless either the substance supplier or the product supplier is included in the Article 95 list for the product-type(s) to which the product belongs. Furthermore, in accordance with the second subparagraph of Article 95(1) '*a person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products ("the substance supplier") or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance ("the product supplier"), may at any time submit to the Agency either a complete substance dossier for that relevant substance, a letter of access to a complete substance dossier, or a reference to a complete substance dossier for which all data protection periods have expired*'.

75. It follows that, in accordance with Article 95(3), the Intervener was required to contact the Appellant, who is the data owner for toxicological, ecotoxicological and environmental fate and behaviour studies related to the active substance in question, and to negotiate access to those studies for the purpose of making a submission in accordance with the second subparagraph of Article 95(1).

76. It is in this light that the objective of establishing as quickly as possible a level playing field on the market of existing active substances should be examined. It follows from Articles 62 and 63 and the second subparagraph of Article 95(1) that a data owner is entitled to obtain a fair compensation for the use of its data inasmuch as these data are necessary to complete a prospective applicant's dossier. However, this right is not affected if the payment of a share of the costs incurred takes place after a data sharing dispute is lodged. On the contrary, requiring a prospective applicant to make the payment before the data sharing dispute is lodged, and before the Agency has assessed whether every effort has been made, would mean that the objective of establishing a level playing field could be endangered, as prospective applicants would refrain from making such a payment without any guarantee that they will get permission to refer to the data required in order to be included in the Article 95, list and therefore to stay on the market.

77. This conclusion does not however mean that the payment of a share of the costs plays no role in the assessment of whether every effort has been made. This question will be examined by the Board of Appeal in more detail under the fourth plea.

78. It follows from the above considerations that the Appellant's argument is not supported by a contextual interpretation. The Board of Appeal finds that the Appellant's interpretation of the second subparagraph of Article 63(3) is not consistent

with the objectives of the avoidance of unnecessary animal testing and establishing a level playing field between companies on the biocidal products market.

79. The Board of Appeal concludes that the context and the objectives of the BPR do not support the Appellant's interpretation of Article 63(3), which would require that the condition of a payment of a share of the costs incurred should have been made before the data sharing dispute was lodged by the Intervener.

80. As regards the Appellant's argument that the Practical Guide states that the Agency does not require a proof of payment to be submitted by prospective applicants at the time of lodging the dispute, the Board of Appeal considers that this statement does not demonstrate that the Agency should require that the actual payment is made before lodging the data sharing dispute. On the contrary, the Board of Appeal finds that in stating that the '*the Agency's draft decision becomes final only once the payment is proved to have been made*' the Practical Guide clearly opens the possibility for the Agency to finalise its decision once it has been proven that a payment has been made, be it before or after the data sharing dispute was lodged. The Appellant's argument relating to the alleged inconsistency of the Agency's practice with the Practical Guide must therefore be rejected.

81. Taking into account the fact that the Intervener paid a share of the costs incurred by the Appellant before the final decision was adopted by the Agency, the Board of Appeal concludes that the Agency correctly applied the second subparagraph of Article 63(3) and its own Practical Guide, when it assessed the data sharing dispute even though a payment was made by the Intervener to the Appellant only after the lodging of the data sharing dispute.

82. The first, second and third pleas are therefore dismissed as unfounded.

The fourth and fifth pleas, alleging an error in the assessment of the every effort criterion and a breach of Article 95

83. The Appellant alleges by its fourth plea that the Agency committed an error of assessment by ruling that the Intervener had made every effort to reach an agreement. By its fifth plea, the Appellant alleges that the Agency breached Article 95 by concluding in the Contested Decision that cost sharing that took place before the entry into force of the BPR had to be taken into consideration in the calculation of the cost of studies requested by the Intervener. Through these pleas, the Appellant is therefore arguing, in essence, that the Agency committed an error of assessment. The Board of Appeal therefore considers it appropriate to address the merits of the fourth and the fifth pleas together.

Arguments of the Parties

84. By its fourth plea in law the Appellant argues that the Agency committed an error of assessment in ruling that the Intervener has made every effort to reach an agreement.

85. Specifically, the Appellant claims that the Intervener failed to make every effort as it lodged the data sharing dispute prematurely even though the negotiations had not reached a standstill. The Appellant refers in particular to the offers and explanations it made to the Intervener in its communications of 23 and 30 September 2015 to which the Intervener, according to the Appellant, failed to reply.

86. The Appellant asserts, moreover, that the Agency erred in its assessment by considering that elements in the negotiations that were not related to the division of costs by two were minor issues. The Appellant considers that these discussions, which

included the negotiation of the territorial scope of the EESA, the dossier management fee and the management fee, should have been examined by the Agency as part of the every effort assessment.

87. The Appellant argues that the Intervener failed to make every effort to reach an agreement by failing to make a payment of a share of costs incurred before the lodging of the dispute claim. The Appellant considers that the payment of a share of the costs forms an integral part of the Intervener's obligation to make every effort to reach an agreement.

88. Furthermore, according to the Appellant, the Agency erred in finding that the Appellant did not explain its position according to which the pre-BPR cost sharing should not be taken into consideration and that the Appellant therefore did not make every effort. The Appellant submits that, on the contrary, it did express its position on the non-retroactivity of the BPR provisions in a clear and constructive manner to the Intervener on 6 August 2015 and on 23 and 30 September 2015, and that it did more than just repeat its position. The Appellant adds that the Agency failed to provide reasons for dismissing this explanation and did not explain what further information would have been needed to satisfy the every effort requirement in this regard.

89. The Appellant adds that, in its email of 30 September 2015, it invited the Intervener to continue discussions, indicated that it remained open to negotiations and considered that recourse to the data sharing dispute mechanism would be premature. The Appellant further explains that it was willing to reconsider its price offer and its understanding of pre-BPR data sharing, but that the Intervener failed to challenge the Appellant's understanding in a compelling manner and instead lodged a data sharing dispute.

90. The Appellant claims that the Agency confused the assessment of whether every effort had been made with its own opinion on whether the Appellant's position was well-founded or not. The Appellant alleges that the Agency introduced into the assessment of every effort a notion of fairness which is not present in the BPR and therefore overstepped the role attributed to it in data sharing disputes.

91. The Appellant adds further that the Agency, in limiting its assessment to the negotiations of the parties up to the date of the submission of the data sharing claim, erred in its assessment of whether every effort had been made.

92. By its fifth plea in law the Appellant claims that the Agency breached Article 95 by concluding that pre-BPR revenues and cost sharing had to be taken into consideration when calculating the share of the cost to be paid by the prospective applicant.

93. Specifically, the Appellant argues that the Agency's findings in the Contested Decision that the BPR forbids data owners from generating a profit when applying Article 95 is incorrect. According to the Appellant, the application of Article 95 generates '*unavoidable revenue streams*' for data owners and the BPR does not compel data owners to share the compensation received under the BPR proportionately with companies that have supported the same active substance under the BPD. The Appellant adds that if a pre-BPR data sharing agreement did not contain a reimbursement mechanism, there is then no obligation for the data owner to reimburse companies that contributed to data costs under the BPD. The Appellant concludes that a data owner would receive a '*revenue stream*' as an inevitable result.

94. According to the Appellant, these '*revenue streams*' are justified by the fact that data sharing was introduced in the BPR in order to address a '*free-rider*' issue that arose under the BPD. The Appellant describes the '*free-rider*' issue as a problem which has enabled companies who chose not to be part of the review programme for active substances under the BPD to benefit from the expenses incurred by those who did. The Appellant considers that the '*free-rider*' issue and the need to address it under the

BPR were ignored by the Agency in the Contested Decision. The Appellant considers, in particular, that the Agency implemented the data sharing provisions of the BPR as if they had the same factual and legislative background and context as those in the REACH Regulation.

95. The Appellant also argues that the Agency made an error of in the assessment of the Appellant's and the Intervener's efforts as it was influenced by its own legal opinion on the pre-BPR data sharing revenues. The Appellant cites in support of this argument the decision of the Board of Appeal of 23 August 2016 in Case A-005-2015, *Thor,* in which the Board of Appeal found that the Agency did not consider all the relevant facts in a balanced manner as required by Article 63(3) '*by disregarding some of the Appellant's efforts and by letting its own legal opinion […] influence the outcome of the Contested Decision.'*

96. As regards to the assessment of every effort made by the Appellant and the Intervener, the Agency argues that there need not be a standstill in relation to all issues under discussion in order for data sharing negotiations to have reached an impasse. A prospective applicant can submit a data sharing dispute as a measure of last resort if there is an insurmountable difference of views between it and a data owner.

97. The Agency states that while the parties had been discussing the price calculation for the studies, they had also been discussing other issues such as the management fee, the dossier management fee and the territorial scope of the letter of access. The Agency considers however that these other issues were of minor importance compared to the Appellant's cost calculation method. The Agency also notes that neither party showed any willingness to depart from their views on the pre-BPR revenues. The Agency concludes that the data sharing negotiations had reached a standstill and the Intervener therefore submitted the data sharing dispute as a measure of last resort.

98. The Agency also argues that the Appellant did not make every effort in the negotiations because it failed to explain why the division of costs by two was fair. In the opinion of the Agency, the division of costs by two is '*de facto, or manifestly, unfair*'. Specifically, the Agency considers that the calculation method employed by the Appellant implies that the Appellant would make a profit from the price paid by the Intervener. In other words, the Appellant's calculation method would lead to it obtaining sums exceeding the mere reimbursement of the costs of the studies to be shared.

99. The Agency explains further that the calculation employed by the Appellant defies the purpose of Article 95, which, bearing also in mind Recitals 54, 57 and 58, allows participants in the review programme to recover part of the costs they have borne to support the approval of an active substance. According to the Agency, the purpose of Article 95 is not to exploit alternative suppliers of active substances in order to make a profit. The Agency also makes reference to Article 63 and submits that it '*[sets] out the avoidance of animal testing as an objective of data sharing and, talks of a "share of costs incurred"*'. The Agency also quotes Article 63(4) which lays down that compensation for data sharing '*shall be determined in a fair, transparent and non-discriminatory manner.'*

100. The Agency considers in this respect that the rationale and design of data sharing under the BPR is very similar to the data sharing regime under the REACH Regulation. This is illustrated by the similarities in the wording between Article 63 of the BPR and Articles 27 and 30 of the REACH Regulation as well as by the footnote to Article 63(4) of the BPR, which refers to the REACH Guidance on Data Sharing.

101. The Agency adds that while Article 95 ends the possibility enjoyed by alternative suppliers under the BPD to make biocidal products containing an active substance in

the review programme available on the market without owning, or having any access to, data on the active substance, mandatory cost and data sharing under the BPR is not an opportunity to impose punitive conditions on alternative suppliers or to make a profit.

Findings of the Board of Appeal

102. The Board of Appeal observes that the main issue raised by the fourth and the fifth pleas is the method proposed by the Appellant to calculate the costs to be paid by the Intervener for the studies it requests. Under both pleas, the Appellant disputes in essence the Agency's conclusion in the Contested Decision that the cost calculation method proposed by the Appellant was unfair and therefore meant that it had not made every effort to reach an agreement. The Appellant thereby asserts that the Agency erred in its assessment of whether every effort was made.

103. The Appellant raises four additional arguments under the fourth plea. It asserts, first, that the Intervener failed to make every effort in the negotiations by lodging the data sharing dispute prematurely. Second, the Appellant claims that the Agency erred in considering the management fee, the dossier management fee and the territorial scope of the data access rights to be of minor importance. Third, the Appellant considers that the Agency made an error of assessment in considering that the two cumulative conditions in Article 63(3) do not need to be fulfilled at the same moment in time. Fourth, the Appellant argues that the Agency erred in the Contested Decision by limiting its assessment to the negotiations of the parties up to the date of the submission of the data sharing dispute.

104. The Board of Appeal will first address the main argument raised under the fourth plea regarding the Agency's assessment of the fairness of the Appellant's cost calculation method. It will then examine the three additional arguments raised under that plea and will lastly address the fifth plea.

105. As regards the Agency's assessment of the fairness of the cost calculation method proposed by the Appellant, the Board of Appeal notes that the Agency stated in the Contested Decision that it '*conducted an assessment serving to establish whether the parties have fulfilled their legal obligation to make every effort to share the studies and their related costs in a fair, transparent and non-discriminatory way*'. The Agency concluded that '*disregarding the context of data and cost sharing under the BPR, the compensation that [the Appellant] had already received under the BPD is de facto unfair and discriminatory'* and that *'the Appellant had not justified with legitimate arguments the apparent unfair and discriminatory nature of the proposed calculation mechanism.'*

106. It is therefore clear that the assessment, in the Contested Decision, of whether the Intervener had made every effort is based on the Agency's understanding that it is allowed, under the BPR, to assess the fairness, transparency and non-discriminatory nature of the cost calculation method employed by the parties to a BPR data sharing dispute.

107. To determine whether the Agency committed an error of assessment, it is necessary for the Board of Appeal to determine whether the fairness, transparency and non-discriminatory nature of the division of the costs by two were relevant factors for the Agency's assessment of whether every effort had been made.

108. In replacing the BPD with the BPR the legislator took into account the fact that companies already owning data on active substances obtained from vertebrate tests might be reluctant to provide this data to prospective applicants who would depend on this data in order to fulfil their obligations under the BPR. As observed in paragraph 73

above, one of the aims of the data sharing provisions in the BPR is to establish a level playing field between companies, to promote free competition between them and to avoid monopolies being created.

109. Article 63(3) enables the Agency to give prospective applicants permission to refer to data owners' studies in certain circumstances (see paragraph 61 above) to avoid unnecessary testing on vertebrate animals.

110. The second subparagraph of Article 63(3) states only that a prospective applicant has to demonstrate that every effort has been made to reach an agreement. Article 63(3) does not specify how a data owner should be compensated. The third subparagraph of Article 63(3) provides that '*the data owner shall not refuse to accept any payment offered pursuant to the second subparagraph*' and leaves it to national courts to decide on the proportionate share of the cost that a prospective applicant is to pay a data owner if no agreement on compensation for data sharing is reached. Article 63(4) states in that regard that '*[c]ompensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner'.* The Board of Appeal finds therefore that the every effort criterion under the BPR requires applicants to demonstrate their efforts to reach an agreement on sharing the results of studies but does not involve an assessment of the cost calculation method employed by data owners.

111. It follows that, when assessing the every effort criterion under the BPR, the Agency is not entitled to assess the fairness, transparency and non-discriminatory nature of cost calculation methods employed by the parties to a data sharing dispute.

112. Nevertheless, the Board of Appeal recognises that an assessment of the fair, transparent and non-discriminatory nature of data sharing negotiations cannot be completely separated from the assessment of the negotiations on the cost sharing. Therefore, whilst the Agency cannot examine whether the cost calculation method is in itself fair, transparent and non-discriminatory, the Board of Appeal considers that the Agency should consider whether the parties, when negotiating a calculation method did so in good faith, or in other words with a real intention to find an agreement. This assessment will necessarily include considerations on cost sharing but should be limited to analysing the parties' behaviour rather than the actual amounts involved. For example, a data owner's behaviour must not be such as to create a barrier for a prospective applicant to enter the biocidal products market. Equally, the condition of paying a share of the costs cannot be construed as a simple formal requirement whereby the Agency would automatically grant access to studies by virtue of proof of any kind of payment once it has established that every effort has been made in the negotiations.

113. It is appropriate, therefore, for the Board of Appeal to examine whether in the present case the parties made every effort when negotiating a data sharing agreement, having regard to whether they demonstrated a real intention to find an agreement.

114. The Board of Appeal notes that the documentary evidence provided shows that the Appellant made a first price proposal to the Intervener through a table of quotations on 23 July 2015. As described in paragraph 13 above, this price offer envisaged dividing the total cost of the requested studies by two. The Intervener indicated its opposition to the division of costs by two for the first time on 31 July 2015 on the grounds that a failure to take into account the amounts already paid by the other members of the Task Force would be unfair and discriminatory.

115. On 6 August 2015, the Appellant answered that the Intervener's approach would amount to applying the BPR retroactively and that it did not propose to modify the division of costs by two. On 1 September 2015, the Intervener reiterated its opposition and its view that data sharing under the BPR should take account of data sharing under the BPD. On 23 September 2015, the Appellant repeated that it did not

consider the BPR to apply retroactively and explained that this was in line with past negotiations and market practice. On 30 September 2015, the Intervener answered that the Appellant's approach resulted in the Intervener contributing a bigger share of the costs incurred by the data owner than the members of the Task Force. The Appellant answered on 30 September 2015 that it still considered that BPR data sharing rules did not apply retroactively.

116. The Board of Appeal notes from these exchanges that, whilst the Appellant insisted on its position that the costs should be divided by two and the BPR does not apply retroactively, the Intervener explained constructively why it considered the proposed cost calculation method to be unfair. The Intervener also provided an alternative cost calculation method based on a seemingly objective criterion, that is to say taking account of the number of members of the Task Force. This method would have enabled the data owner to recover more of its investment associated with supporting the active substance.

117. The Board of Appeal considers that the Agency correctly concluded that the Intervener had made efforts in the negotiations in formulating counter-offers based on objective criteria. In particular, in its email to the Appellant of 1 September 2015, the Intervener made a priced counter-offer based on an alternate cost calculation method dividing the costs between the members of the Task Force and the Intervener. The Appellant, after being requested several times by the Intervener to react to this priced counter-offer, answered three weeks later on 23 September 2015 stating that it did not consider it to be fair.

118. It follows that the Intervener demonstrated a real intention to find an agreement.

119. The Board of Appeal finds that the Agency therefore correctly reached the conclusion in the Contested Decision according to which '*the [Intervener] has made efforts to engage in meaningful data sharing negotiations by asking constructive questions and bringing forward concise arguments, challenging the cost proposal made by [the Appellant], thereby acting in respect of their obligation to make every effort to come to a fair, transparent and non-discriminatory data sharing agreement.'* This is without prejudice to whether the Appellant made every effort or not or whether its legal position with regard to the retrospective nature of the BPR was correct or not.

120. The Board of Appeal therefore finds that the Agency, while it went beyond its scope of assessment in concluding that the division of costs by two was manifestly unfair, did not err in its assessment of the Intervener's behaviour. It follows that the Agency did not commit an error when assessing whether the Intervener had made every effort in accordance with Article 63(3).

121. The Board of Appeal will next examine the Appellant's four additional arguments under the fourth plea as described in paragraph 103 above.

122. As regards the Appellant's argument that the Intervener had not made every effort to reach an agreement and prematurely lodged the data sharing dispute, the Board of Appeal has already observed, at paragraphs 116 to 119 above, that the Agency made no error when finding that the Intervener had made every effort. With regard to whether the Intervener submitted the data sharing dispute prematurely the Board of Appeal notes that the Appellant repeatedly insisted on its position concerning the division of costs by two and the non-retroactivity of the BPR. In addition, the Board of Appeal observes that the communications from the Appellant to the Intervener of 23 and 30 September 2015, whilst providing additional context on the regulatory framework of the BPR, did not differ in substance as they both contained the same argument, namely that the BPR did not apply retroactively and that BPD cost sharing could therefore not be taken into account by the Appellant in its cost calculation method.

123. In this context, the Board of Appeal finds that the Intervener was justified in lodging a data sharing dispute claim with the Agency. The Board of Appeal concludes that the lodging of such claim was not premature and that the Agency did not err in its assessment in that regard.

124. As regards the Appellant's argument that the Agency was incorrect in finding that certain negotiation items, other than the cost calculation method, were of minor importance, the Board of Appeal observes that while the negotiation progressed on the management fee, the dossier management fee and on the territorial scope for the data's access rights, the issue of the division of costs by two remained. The Board of Appeal notes that the division of costs by two was a crucial element in any successful conclusion of the data sharing negotiations. This is clear given that, as mentioned in paragraph 16 above, the cost calculation method taking into account all Task Force members would have resulted in a cost to the Intervener of less than half of the price the Appellant asked for the letter of access. With such strongly diverging views on price, the questions of the management fee and of the territorial scope of the data access rights were therefore considerably less important. Whilst there was progress on the other negotiation items the Board of Appeal finds that the Agency did not err in considering that the other negotiation items were of a lesser importance than the division of costs by two.

125. As regards the Appellant's arguments that the Agency made an error in the assessment of whether every effort had been made by considering that the two cumulative conditions of Article 63(3) need not be fulfilled at the same moment in time, this argument was also raised by the Appellant in the context of its first, second and third plea. The Board of Appeal has already held, at paragraph 81 above, that the Agency correctly applied Article 63(3) in finding that the Intervener's payment of a share of the costs before a final decision was adopted by the Agency was sufficient to meet the payment condition.

126. As regards the Appellant's argument that the Agency erred in its assessment of whether every effort had been made by limiting its assessment to the negotiations of the parties up to the date of the submission of the data sharing dispute, the Board of Appeal has observed above (see paragraph 67) that the use of the word '*thereof*' in the first subparagraph of Article 63(3) refers to a situation in which no agreement has been reached. It follows that in the assessment of whether every effort has been made the Agency is required to examine the efforts made leading up to the moment of the submission of the data sharing dispute. It is not required, however, to assess events that may occur after the data sharing dispute was submitted. Therefore, the Board of Appeal finds that the Agency did not err in its assessment of whether every effort had been made in this regard.

127. By its fifth plea, the Appellant argues that the Agency breached Article 95 by finding that pre-BPR cost sharing had to be taken into account when calculating the share of the cost to be paid by a prospective applicant.

128. The Board of Appeal has already found, at paragraph 120 above, that, to the extent it assessed the proposed cost calculation method as '*de facto, or manifestly, unfair*', the Agency has overstepped its role in its assessment of the data sharing dispute.

129. However, the Board of Appeal has already found, at paragraph 119 above, that the Agency's conclusion that the Intervener had made every effort was not tainted by an error of assessment. As the fact that the Agency overstepped its role by assessing the fairness of the proposed cost calculation method did not affect the outcome of its assessment of whether every effort had been made, this error is not capable of resulting in the annulment of the Contested Decision.

130. The Board of Appeal observed in paragraph 62 above that the Agency's assessment in the context of data sharing dispute is two-fold and consists of determining whether the prospective applicant has, first, made every effort and, second, has paid a share of the costs incurred. In this respect, the Board of Appeal has found that the Intervener did make every effort and made a payment to the Appellant on 7 January 2016. The two criteria for the Agency's assessment under the second subparagraph of Article 63(3) being fulfilled, the question as to whether the Agency breached Article 95 is not decisive in determining whether the Contested Decision should be annulled. Consequently, the Board of Appeal finds that the Contested Decision does not need to be annulled on the grounds of the fifth plea.

131. In light of the above the fourth and the fifth pleas must be dismissed and the present appeal must therefore be rejected in its entirety.

Refund of the appeal fee

132. In accordance with Article 4(4) of Commission Implementing Regulation (EU) No 564/2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 19.6.2013, p. 17), the appeal fee shall be refunded if the decision is rectified in accordance with Article 93(1) of the REACH Regulation or if the appeal is decided in favour of the appellant.

133. As the appeal has been dismissed, the appeal fee shall not be refunded.

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

Marc GOODACRE
on behalf of Alen MOČILNIKAR
Registrar of the Board of Appeal