EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

29 May 2018

(Biocidal products – Data sharing dispute – Every effort – Cost calculation method – Value of studies)

Case number	A-007-2016
Language of the case	English
Appellant	Sharda Europe B.V.B.A., Belgium
Representative	Claudio Mereu Fieldfisher (Belgium) LLP, Belgium
Intervener	BASF Agro B.V. Arnhem (NL) - Zürich Branch, Switzerland
Contested Decision	[Confidential] adopted by the European Chemicals Agency pursuant to Article 63(3) of Regulation (EU) No 528/2012 of the European Parliament and the Council regarding the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1; the 'BPR')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. By the Contested Decision, the European Chemicals Agency (the 'Agency') denied the Appellant permission to refer to studies owned by the Intervener for the biocidal active substance alpha-cypermethrin (EC No 614-054-3; CAS number 67375-30-8; the 'active substance').

2. The Appellant was seeking access to studies owned by the Intervener so that they could be used in an application to be included in the list of suppliers of biocidal products and substances which have not yet been approved (the 'Article 95 list'). Suppliers of biocidal products who have not been included in the Article 95 list published by the Agency can no longer place substances on the market after 1 September 2015.

3. On 29 October 2014, the Agency provided to the Appellant the name and contact details of the Intervener in response to the Appellant's enquiry under Article 62(2) of the BPR (all references to Articles concern the BPR unless stated otherwise).

4. On 1 December 2014, the Appellant asked the Intervener for the price of '*regulatory access [to] the set of evaluated vertebrate studies owned by [the Intervener and] an additional set of non-vertebrate toxicology, ecotoxicology and environmental fate studies owned by [the Intervener]*' on the active substance.

5. On 13 February 2015, the Intervener made an offer to the Appellant for access to the sets of studies referred to in the previous paragraph. On the same day, the Appellant requested the Intervener to itemise the costs of its offer '*study by study*'. The Appellant also asked whether this offer included all the studies on toxicology, ecotoxicology and environmental fate required under Article 95 (the 'full data package').

6. On 4 March 2015, the Intervener and the Appellant discussed the 13 February 2015 offer in a teleconference. The Appellant explained during the teleconference that it sought access to the full data package. The Intervener explained that its offer consisted of the right of access to the full data package through a letter of access to be used by the Appellant in the European Union for the purposes of the BPR. Under the terms of the offer, the Appellant was also allowed to sublicense to its '*affiliates*' its right of access to the studies. The Intervener outlined how the price in the offer had been calculated (the 'cost calculation method'). This included, the value of the studies as a baseline, a regulatory management fee, a risk fee and a profit element. The Appellant explained that it could not agree to the Intervener's cost calculation method. The Appellant asked the Intervener to provide an itemised breakdown of the value of the studies. The Appellant and the Intervener agreed that the next step would be for the Intervener to itemise its offer with costs presented '*study by study*' by 12 March 2015 and that the Appellant would then make a counter offer.

7. On 13 March 2015, the Intervener sent the Appellant a new offer for the full data package. The Intervener attached two tables to its offer. The first table showed the value of each study. The second table showed the result of the addition of the individual values of each individual study included in the Intervener's offer of 13 March 2015. The tables also showed the price to be paid by the Intervener after the application of the cost calculation method.

8. On 27 July 2015, the Appellant made a counter offer, contested the different elements of the cost calculation method, especially the claim of a risk fee and the mark-up for profit, and asked the Intervener to '*deliver itemised pricing by study*'. The Appellant also stated that the value of the studies outlined in the Intervener's different offers differed from industry practice and was rather based on the Intervener's internal budgeting practices. The Appellant claimed to have obtained lower quotes to conduct the studies from laboratories.

9. On 11 August 2015, the Intervener informed the Appellant that it had already sent it a list of the value of the studies on a study by study basis on 13 March 2015. The Intervener also justified the different elements of the cost calculation method. In particular, it argued that the risk fee and the regulatory management fee were appropriate due to the uncertainty about '*the outcome in the absence of clear guidance documents for the Biocidal products e.g. on the data requirements and risk assessments*'. It acknowledged that the profit element was '*unusual*' but stated that '*a company is not expected to invoice only its own costs'.* The Intervener asked the Appellant to provide the quotes from the laboratories mentioned in its counter offer of 27 July 2015.

10. On 13 August 2015, the Appellant informed the Intervener that it had obtained '*a quote from a well reputed EU-[B]ased GLP laboratory*' for the full data package which '*was three times lower than the quote provided by the Intervener*' in its offer of 13 March 2015. The Appellant attached a table '*with the detailed list of studies […] and the itemized cost for them against those claimed by [the Intervener]*'.

11. On 14 August 2015, the Intervener replied to the Appellant that it was still waiting for a precise list of the studies to which the Appellant wanted to refer and asked the Appellant for the identity of the laboratory behind the Appellant's quote. The Intervener observed that the values outlined by the Appellant for the studies in its communication of 13 August 2015 were lower than the values described in the 2007 Fleischer list[1] (the 'Fleischer list'). The Intervener attached a draft data sharing agreement for the Appellant's review.

12. On 21 August 2015, the Appellant provided a list of 35 studies that it was '*actually seeking access to'* (the '35 studies'). It indicated that it considered the Fleischer list to be neither official nor binding and that it did not have pre-eminence over an actual quote.

13. On 24 August 2015, the Intervener replied that the list of 35 studies differed significantly from the studies covered by the full data package requested by the Appellant on 4 March 2015 and the list of studies shared by the Intervener on 13 March 2015. The Intervener stated that it would make an offer for access to the 35 studies as soon as possible.

14. On 26 August 2015, the Appellant commented on the draft data sharing agreement referred to in paragraph 11 above. The Appellant indicated that as it had been negotiating with the Intervener for about a year without reaching an agreement, the Appellant did not believe that it was possible to reach an agreement on data sharing in the near future. It gave the Intervener notice that it would lodge a data sharing dispute with the Agency under Article 63(3). The Appellant stated that it nevertheless expected the Intervener's feedback on its comments on the draft data sharing agreement. It also requested an offer from the Intervener for access to the 35 studies. The Appellant withdrew its 28 July 2015 counter offer. On the same day, the Intervener made an offer to grant the Appellant access to the 35 studies.

15. On 28 August 2015, the Intervener sent the Appellant an annotated and updated version of the draft data sharing agreement.

16. On 3 September 2015, the Appellant stated that it disagreed with the valuation of the studies given in the Intervener's offer of 26 August 2015. It also disagreed with the cost calculation method and in particular the profit element. The Appellant suggested that to get around the disagreements they should '*move the discussions towards a more straight forward business deal*'. It described a business deal as '*a figure that is deemed*

[1] Manfred Fleischer, *Testing Costs and Testing Capacity According to the REACH Requirements – Results of a Survey of Independent and Corporate GLP Laboratories in the EU and Switzerland*, Journal of Business Chemistry (2007), 4(3).

acceptable having regards to the circumstances of the case'. The Appellant suggested to the Intervener that they meet and discuss a business deal.

17. On 7 September 2015, the Intervener acknowledged the '*opportunity to explore a compromise*' and stated that '*after discussion with relevant stakeholders including [its] business colleagues and [its] legal department'* it was willing to '*proceed in this direction*'. It asked the Appellant for '*more specifics on what [the Appellant] meant with [a business deal]*.'

18. On 22 October 2015, the Appellant and Intervener met to discuss a business deal. The minutes of that meeting, drafted by the Appellant on 2 November 2015 and commented by the Intervener on 10 November 2015, state that:

    - the Appellant requested access to the 35 studies and no longer to the full data package,
    - the Appellant could nevertheless consider a business deal offer for the full data package,
    - the Appellant and the Intervener both made new offers for the full data package and for the 35 studies. They continued to disagree on their respective approaches. The Appellant's offer used as a baseline 50% of the value of the studies that the Intervener used in its previous offer. To that amount a 5% regulatory management fee was added. The resulting amount was decreased by 50% to reflect that the data was to be used solely for BPR purposes. The Appellant's counter offer did not include a profit element nor a risk fee,
    - the Appellant stated that the value of the studies outlined in the list shared by the Intervener on 13 March 2015 '*appeared to be […] replacement costs and [were] not based upon [the Intervener's] invoices.*' The Appellant asked for '*proof of these costs by way of original invoices, itemised costs and study development*',
    - as they could not agree on the value of the studies, the Intervener told the Appellant that it would discuss a business deal internally and make an offer by 12 November 2015, and
    - the Intervener suggested that the Appellant and the Intervener could appoint a third party to calculate the value of the studies.

19. On 30 October 2015, the Appellant lodged a data sharing dispute with the Agency pursuant to Article 63(3) (the 'first data sharing dispute').

20. On 16 November 2015, the Appellant asked the Intervener for '*a revised offer*'.

21. On 17 November 2015, the Intervener stated that it was prepared to revise its offer of 26 August 2015 in the context of a business deal but that it was for the Appellant to make a proposal and to give more information on the '*parameters for a business deal*'. It requested the Appellant to propose a business deal by 30 November 2015. The Intervener also suggested again appointing a third party to calculate the value of the studies.

22. On 12 December 2015, the Appellant proposed a business deal consisting of a 20% increase in the value of the counter offer it had made on 22 October 2015 for access to the full data package.

23. On 16 December 2015, the Intervener asked the Appellant to clarify by 18 December 2015 the scope of a business deal and how many studies it requested. On the same day, the Appellant answered that the proposed business deal was for the full data package. It also explained that it was prepared to limit the possibility it had under Article 95(4) to allow its customers to make reference to the studies and to waive a share of any reimbursement for data sharing costs paid by third parties in the future. It also explained that the proposed business deal was '*no longer based on a study by study discussion*'. The Appellant asked the Intervener to make a counter offer to the proposed business deal by 18 December 2015.

24. On 18 December 2015, the Intervener stated that it would make a business deal counter offer by 10 January 2016.

25. On 11 January 2016, the Intervener made business deal counter offers to the Appellant for the full data package and for the 35 studies. The Intervener stated that these counter offers did not allow sublicensing of the rights of access to the studies to the Appellant's customers. The terms of these counter offers meant that the Appellant would only have a right of access to the studies through letters of access, meaning that the Appellant would not have access to copies of the full study reports but only to available summaries. The Intervener stated that its business deal counter offer for the full data package represented a 55% reduction compared to its offer of 13 February 2015.

26. On 18 January 2016, the Appellant stated that as the gap between the Appellant's and the Intervener's offers was still so great, even after the Intervener's business deal counter offer, the negotiations had '*reached an impasse'*. The Appellant explained that it saw '*no further ways to unlock the current situation*'. The Appellant also explained that the Intervener had still not provided an itemised breakdown of the value given to each of the requested studies. Although it had already lodged a data sharing dispute on 30 October 2015, the Appellant stated that it *'[would] proceed with the lodging of [a second data sharing dispute with the Agency]'*.

27. On 19 January 2016, the Agency adopted decision [confidential] on the first data sharing dispute (see paragraph 19 above). The Agency did not grant the Appellant permission to refer to the Intervener's studies because the Appellant had not submitted the data sharing dispute as a measure of last resort. The Agency considered that the negotiations had not reached a standstill. According to the Agency, the negotiations had moved to a new phase because the Appellant and the Intervener had abandoned the attempt to find an agreement based on a study by study approach and instead were focussing their efforts on reaching a business deal.

28. On 22 January 2016, the Intervener sent an email to the Appellant in which it explained that it did not consider the negotiations to have reached an impasse. This was because the two companies had made significant progress towards an agreement between October 2015 and January 2016. The Intervener suggested again asking a third party to calculate the value of the studies. The Intervener also stated that it was prepared to submit the calculation of the value of the studies to an arbitration body and that it committed to accept an arbitration order '*within the financial frame already discussed between [the Appellant and the Intervener]*'.

29. On 6 February 2016, the Appellant responded that the business deal counter offers made by the Intervener on 11 January 2016 for the full data package and for the 35 studies were still too high. The Appellant explained that the Intervener's suggestion to ask a third party to calculate the value of the studies was '*another attempt to regress negotiations and bring them back to a stage that was already abandoned in October 2015 in favour of a "business deal"'.*

30. On 27 February 2016, the Appellant notified the Agency of a failure to reach an agreement on data sharing with the Intervener. In accordance with Article 63(3), the Appellant lodged a second data sharing dispute and requested the Agency to grant it access to the '*studies that it needs to supplement its own dossier in order to fulfil its obligations towards entry [into the Article 95 list]*'. In this communication, the Appellant summarised the negotiations between it and the Intervener since 1 December 2014.

31. On 18 May 2016, the Agency adopted the Contested Decision on the second data sharing dispute denying the Appellant permission to refer to the Intervener's studies on the active substance. The Contested Decision concludes that by rejecting the Intervener's proposal for a third party to calculate the value of the studies, the Appellant had blocked the negotiations from progressing and had failed to make every effort to reach an agreement.

Procedure before the Board of Appeal

32. On 11 August 2016, the Appellant filed this appeal.

33. On 17 October 2016, the Agency filed its Defence.

34. On 31 January 2017, BASF Agro B.V. Arnhem (NL) - Zürich Branch was granted leave to intervene in this case in support of the Agency.

35. On 2 March 2017, the Appellant submitted its observations on the Defence.

36. On 16 March 2017, the Intervener filed its statement in intervention.

37. On 5 April 2017, the Appellant submitted its observations on the statement in intervention.

38. On 7 April 2017, the Agency indicated that it did not have any comments on the statement in intervention.

39. On 13 April 2017, the Agency submitted its observations on the Appellant's observations on the Defence.

40. On 5 May 2017, the Board of Appeal requested the Agency to submit observations on the new arguments raised by the Appellant in its observations on the statement in intervention.

41. On 2 June 2017, the Agency submitted its observations on the Appellant's observations on the statement in intervention.

42. On 20 September 2017, a hearing was held at the Appellant's request. At the hearing, the Parties and the Intervener made oral submissions and answered questions from the Board of Appeal.

Form of order sought

43. The Appellant requests the Board of Appeal to annul the Contested Decision in its entirety, replace the Contested Decision with a decision granting the Appellant permission to refer to '*the requested tests or studies*', and order the Agency to pay the costs of these proceedings.

44. The Agency, supported by the Intervener, requests the Board of Appeal to dismiss the appeal in its entirety.

Reasons

45. In support of its appeal, the Appellant raises three pleas:

    1. The Agency acted beyond its powers by making the agreement to a third party valuation of the studies a necessary condition to demonstrate every effort under Article 63.

    2. The Agency committed a manifest error when assessing the '*every effort*' of the Appellant under Article 63(3).

    3. The Agency infringed the Appellant's right to be heard.

46. The Board of Appeal will first examine the Appellant's second plea.

1. The second plea: the Agency committed a manifest error of assessment of the Appellant's efforts under Article 63(3)

Arguments of the Appellant

47. The Appellant argues that the Agency committed a manifest error of assessment in concluding that:

- the Appellant blocked the negotiations from progressing,
- the Appellant did not make every effort as it rejected the Intervener's proposal for a third party to calculate the values of the studies, and
- the Intervener had made every effort.

48. In support of its first argument, the Appellant argues that the Intervener delayed the negotiations. The Appellant argues that after the Intervener's communication of 7 September 2015, the Intervener and the Appellant were '*aligned on the approach to pursuing a business deal*'. The Appellant argues that instead of following up on a possible business deal the Intervener sought to delay negotiations by suggesting, on 17 November 2016, the appointment of a third party to calculate the values of the studies. The Appellant argues further that with this suggestion the Intervener took the negotiations back to where they were on 22 October 2015, the date on which, according to the Appellant, the Appellant and the Intervener abandoned a study by study approach and agreed to pursue a business deal. Under a business deal, the Appellant and the Intervener no longer needed to discuss and agree the values of the individual studies. When the Intervener, in its communication of 17 November 2015, did not make a business deal offer, and asked for more information on the parameters of a business deal, it was disingenuously delaying the negotiations. The Appellant argues that it, on the other hand, increased its counter offer on 12 December 2015.

49. In support of its second argument, the Appellant states that the BPR does not oblige the parties to a data sharing negotiation to refer a dispute on study costs to a third party. Instead, the Practical Guide: Special Series on data sharing (version 1, April 2015, the 'Practical Guide') mentions the referral of a cost dispute to a third party as a mere possibility. In addition, the Appellant considers that the Practical Guide is not legally binding as it is not, unlike the REACH Guidance on Data Sharing, mentioned in the BPR. The Agency was therefore wrong in concluding in the Contested Decision that, based on the Practical Guide, the Appellant blocked negotiations by rejecting the Intervener's suggestion to refer calculation of the value of the studies to a third party.

50. In support of its third argument, and to demonstrate that the Intervener did not make every effort, the Appellant argues the following:

- The data sharing negotiations lasted fifteen months in total, which is a very long period to negotiate access to data, and in itself shows that the Intervener did not make every effort.
- The Intervener provided an itemised list of its valuation of the studies on a study by study basis only two and a half months after the negotiations had started.
- The Intervener was not transparent as to its valuation of the studies. The valuation of the studies should not be based exclusively on the Intervener's internal costing methods because only some of the studies had been performed in-house. Invoices or some form of paper trail should be available to the Intervener to justify the valuation given to the studies. The Intervener did not however provide any such evidence during the data sharing negotiations.
- By seeking to make a profit from the data sharing negotiations through the cost calculation method used in its different offers the Intervener failed to make every effort.

51. The Appellant argues that the Contested Decision, by stating that '*[the Appellant] did not provide evidence related to the price offers received from the independent laboratory nor did it disclose the identity of this laboratory*', incorrectly shifts the burden of providing the value of the studies onto the Appellant whereas this should be provided by the Intervener.

Arguments of the Agency

52. The Agency considers that the main disagreement between the Appellant and the Intervener concerns the value of the studies. The Agency argues that the Intervener made greater efforts than the Appellant to overcome the disagreement on the value of the studies for the following reasons:

    - The Appellant rejected the Intervener's suggestion of 22 October 2015 to ask a third party for an independent calculation of the value of the studies, but offered no other suggestion or method to resolve the difference of opinion.
    - The Appellant '*interrupted*' the negotiations between 20 March 2015 and 28 July 2015.
    - The Appellant delayed the negotiations by initially requesting access to the full data package but later limiting its request to 35 studies.
    - The Appellant did not disclose the identity of the laboratory that provided quotes for the studies.
    - The Appellant did not explain why the value of the studies in its 28 July 2015 counter-offer was lower than the prices in the Fleischer list.
    - The Intervener provided in a timely manner, in March 2015, a list of studies, and an itemised breakdown of their value study by study.

53. The Agency argues that the '*negotiations do not show that the parties had agreed to pursue a "business deal" approach that ignores the cost of the studies. [The Intervener] continued to refer to the cost of the studies and repeatedly asked the Appellant to specify which other elements of an agreement [it] would like to alter to reach a lower compensation*'.

Arguments of the Intervener

54. The Intervener claims that it made every effort in the negotiations for the following reasons:

    - It provided fair, transparent and non-discriminatory offers to the Appellant. It listed the value of the studies, explained how this value was established and referred to the Fleischer list. The Appellant, on the other hand, did not provide the quotes from, nor the identity of, the laboratory it consulted.
    - It provided information rapidly and proactively during the negotiations. The time the negotiations took is in itself not relevant to the consideration of whether the every effort obligation has been complied with.
    - It explained orally and in writing the rationale for its different offers, the value of the studies and the cost calculation method.
    - It agreed to consider the Appellant's business deal proposal whilst at the same time pursuing a study by study approach together with a proposal for a third party calculation of the value of the studies.
    - It took into consideration in its 11 January 2016 offers the Appellant's suggestion for limitations on the use of the data.

55. The Intervener argues that the Appellant did not make every effort in the negotiations because it was not transparent on the studies to which it sought access. The Appellant first sought access to the full data package, then requested access to 35 studies only, and later asked again for the full data package when it proposed a business deal.

Findings of the Board of Appeal

56. With its second plea, the Appellant alleges that the Agency erred in its assessment of

the efforts made by the Appellant and the Intervener during the negotiations.

57. When an appellant claims that the Agency has made an error of assessment, the Board of Appeal must examine whether the Agency has examined, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached. In assessing the Agency's decisions on data sharing disputes taken under Article 63, the Board of Appeal considers in particular the balance of efforts between the data owner and the prospective applicant and whether this balance is correctly reflected in the contested decision (see Case A-014-2016, *Solvay Solutions UK*, Decision of the Board of Appeal of 7 March 2018, paragraph 51).

58. However, as paragraph 31 above shows, the Agency centred its assessment of the Appellant's and the Intervener's efforts on the proposal made by the Intervener on 22 January 2016, at a late stage of the negotiations, to use a third party to calculate the value of the studies. Concentrating the assessment on this aspect does not correctly reflect the balance of the Appellant's and the Intervener's efforts during the negotiations for the reasons set out below.

1.1. The assessment of the whole negotiations

59. The Agency's assessment of whether every effort has been made should consider the negotiations as a whole and the actions of the parties throughout those negotiations. In the context of the negotiations in the present case, the proposal for a third party calculation of the value of the studies referred to by the Agency in the Contested Decision was made by the Intervener on 22 January 2016, which is towards the end of the negotiations and in the context of a long running disagreement over the value of the studies (see paragraph 28 above). Discussions on the value of the studies started as early as 4 March 2015 when the Appellant asked the Intervener to itemise its 13 February 2015 offer with the values set out in a study by study basis (see paragraph 6 above). The Agency therefore gave disproportionate importance to one action and in so doing did not assess the whole negotiations and all the actions of the parties.

1.2. The lack of transparency on the value of the studies

60. As paragraphs 6 to 18 above show, the Appellant's and the Intervener's differences of opinions over the value of the studies remained a central source of disagreement and this disagreement cannot be ignored in the assessment of the efforts of the parties concerned.

61. The itemisation of the costs provided by the Intervener on 13 March 2015 (see paragraph 7 above) consisted of a list of studies with their associated values. It did not give precise details of how those values were derived nor did it include objective elements such as proof of costs or invoices, as requested by the Appellant, which could have enabled it to challenge those values. As stated in paragraphs 18 and 26 above, on 22 October 2015, the Appellant requested proof of the value of the studies included in the list provided by the Intervener on 13 March 2015, but did not receive this information from the Intervener. Without an objective basis for the value given by the Intervener to the studies, the Intervener did not make efforts to convey information on the value of the studies. This should have been the starting point for any negotiations on the cost ultimately to be paid for access to the studies. The Appellant did not have the information needed to effectively negotiate with the Intervener. The justification for the value given by the Intervener to the studies was not therefore explained by the Intervener in a transparent manner within the meaning of Article 63.

62. As a consequence of this lack of transparency, the Appellant made efforts to establish the value of the studies by requesting quotes from a laboratory (see paragraphs 8 and 10 above). As the owner of the studies, the Intervener could and should have used its own records to objectively justify the value of each of the studies. However, it failed to do so. The effect this failure had on the negotiations and the balance of efforts of the parties was not addressed in the Contested Decision.

1.3. The efforts in the negotiation of the cost calculation method

63. As observed in paragraph 59 above, the Agency should have considered the whole context of the negotiations in the Contested Decision.

64. In the negotiations leading to the present appeal, the Intervener and the Appellant disagreed not only on the value of the studies, which was the starting point of the negotiations, but also on the cost calculation method used by the Intervener in its different offers.

65. As paragraph 18 above shows, the Appellant after its initial reluctance (see paragraph 6 above), agreed in principle only with one component of the Intervener's cost calculation method, the regulatory management fee. However, the risk fee and the profit element also present in the different offers from the Intervener were consistently contested by the Appellant (see paragraph 8 above). The Appellant and the Intervener therefore remained far apart as regards the cost calculation method.

66. In the same way that the value of the studies was not transparently explained by the Intervener (see paragraph 61 above), the final price requested by the Intervener for access to the studies after the application of the additional fees equally lacked transparency. More importantly, even if such transparency had been ensured, the Appellant still disagreed in principle with two major components of the cost calculation method.

67. By focussing in the Contested Decision solely on the Intervener's proposal to get the value of the studies assessed by a third party, the Agency failed to consider that the parties' deadlock concerning the discussion on the cost calculation method also played a role in the negotiations. Even if the parties had followed a third party calculation of the value of the studies, it is not certain that they would have managed to find an agreement on the risk fee and the profit element, let alone on data sharing. The effort of the Intervener to suggest a third party assessment of the value of the studies only concerned one aspect of the Appellant's and the Intervener's negotiation and could not be separated from the issue of the cost calculation method.

1.4. The business deal

68. A major step in the negotiations was when, on 3 September 2015, the Appellant proposed a business deal (see paragraph 16 above). Through this approach, the Appellant was seeking to circumvent the disagreements on the value of the studies and the cost calculation method applied to those values. This approach steered the negotiations towards a business deal that consisted of a global sum decoupled from the value of the individual studies. The significance of this approach was recognised by the Agency in its decision of 19 January 2016 on the first data sharing dispute (see paragraph 27 above).

69. However, despite initially backing the idea of a business deal, the Intervener, with its proposal of 22 January 2016 that a third party be asked to calculate the value of the studies, returned to a study by study approach (see paragraphs 28 and 29 above).

70. The Appellant therefore made a major effort, through its proposal for a business deal approach, to unblock the negotiations by moving them away from a study by study approach. The significance of this effort has not been adequately assessed by the Agency in the Contested Decision even though it had recognised the usefulness of this approach in its decision on the first data sharing dispute.

1.5. Conclusion on the Appellant's and the Intervener's 'every effort' assessment

71. In conclusion, in its assessment of the data sharing dispute, the Agency failed to take sufficiently into account the Appellant's efforts. In other words, it did not correctly consider all the facts of the case in arriving at its decision. In its assessment of the data sharing dispute under Article 63(3), the Agency gave too great a weight to the

Intervener's efforts, in particular its proposal to use a third party to calculate the value of the studies. In addition, the Agency failed to recognise that in the context of the case at hand, the value of the studies, which was the starting point of the negotiations, had not been objectively justified in a transparent manner. The Agency should also have considered the parties' efforts in their negotiations on the cost calculation method.

72. By not taking into account all the relevant facts the Agency did not correctly reflect the balance of the Appellant's and the Intervener's efforts in the negotiations.

73. It should also be noted that, while Article 63(1) states that '*an agreement [on data sharing] may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order*', the word '*may*' used in this provision indicates that submission of the matter to an arbitration body is only a possibility and not an obligation. It is only one means to find a solution to a data sharing negotiation. Using an arbitration body depends on the consent of both of the parties to a data sharing negotiation. A proposal to refer a data sharing negotiation to a third party cannot be construed as a substitute for the obligation to make every effort to reach a data sharing agreement.

74. The Appellant's second plea that the Agency committed a manifest error when assessing the '*every effort*' condition in Article 63(3) is therefore accepted and consequently the Contested Decision must be annulled.

75. Since the Contested Decision has been annulled, it is not necessary to examine the Appellant's other pleas.

76. In the Notice of Appeal, the Appellant requested the Board of Appeal to grant it permission to refer to '*the requested tests or studies*'. However, neither the Appellant nor the Agency has provided for the purposes of this appeal a precise list of the studies to which the Appellant was seeking access. Moreover, as shown for example in paragraphs 12 and 13 above, the number of studies requested by the Appellant was actually in question during the negotiations. It is therefore not clear to which studies the Appellant was seeking access during the data sharing negotiations.

77. The present case must therefore be remitted to the competent body of the Agency for re-examination.

Claim for reimbursement of costs

78. In its Notice of Appeal the Appellant requested the Board of Appeal to order the Agency to pay the costs of these proceedings.

79. 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, the 'Rules of Procedure'), as amended by Commission Implementing Regulation (EU) 2016/823 (OJ L 137, 26.5.2016, p. 4), does not provide for the reimbursement of costs that are not, as provided for in Articles 17 and 21(1)(h) thereof, related to the taking of evidence. Moreover, Article 17a of the Rules of Procedure provides that the parties shall bear their own costs.

80. Consequently, and as in the present case no costs arose in relation to the taking of evidence, the Appellant's request for reimbursement of costs is rejected.

Refund of the appeal fee

81. 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 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), or if the appeal is decided in favour of the appellant.

82. As the Board of Appeal has decided the appeal in favour of the Appellant, the appeal fee must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. Annuls decision [confidential] adopted by the Agency on [confidential].

2. Remits the case to the competent body of the Agency for re-examination.

3. Decides that the appeal fee shall be refunded.

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal