EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

10 March 2020

(Biocidal Products Regulation – Data-sharing – Decision granting permission to refer – Intention to perform tests on vertebrate animals – Deadline for adopting a decision – Time of payment – Every effort)

Case number	A-007-2018
Language of the case	English
Appellants	Sumitomo Chemical (UK) plc, United Kingdom Sumitomo Chemical Company Ltd, Japan
Representatives	Koen Van Maldegem and Gerard McElwee Fieldfisher (Belgium) LLP, Belgium
Intervener	Endura S.p.A., Italy Represented by: Peter Kugel VVGB Advocaten/Avocats, Belgium and Marco Bronckers Belgium
Contested Decision	DSH-63-3-D-0022-2017 of 1 March 2018, adopted by the European Chemicals Agency (the '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; the 'BPR')

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. This appeal concerns a data-sharing dispute regarding eight studies on vertebrate animals required for the approval of prallethrin (EC No 245-387-9) as an active substance (the 'eight studies at issue').

2. The data-sharing dispute was between the Appellants (Sumitomo Chemical (UK) plc and Sumitomo Chemical Company Ltd) on the one hand, and the Intervener (Endura S.p.A.) on the other. Sumitomo Chemical (UK) and the Intervener are suppliers of prallethrin on the European Union market. Sumitomo Chemical Company is the data owner of the eight studies at issue.

Events preceding the entry into force of the BPR

3. Prallethrin was notified as an existing active substance for the purposes of the work programme established under Article 16(2) of Directive 98/8/EC concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1; the 'Review Programme').

4. The Hellenic Republic was appointed rapporteur Member State for the assessment of prallethrin with a view to its possible inclusion in Annex I, IA or IB to Directive 98/8/EC.

5. In 2003, the Appellants and the Intervener began to discuss the sharing of data on prallethrin and other active substances. These discussions led to the Intervener obtaining letters of access from the Appellants for studies on several active substances but not on prallethrin.

6. In 2006, Sumitomo Chemical (UK) and the Intervener submitted their respective dossiers on prallethrin to the relevant competent authority of the Hellenic Republic.

7. The dossier submitted by Sumitomo Chemical (UK) included the eight studies at issue. The competent authority of the Hellenic Republic found the dossier submitted by Sumitomo Chemical (UK) to be complete, in accordance with Article 9 of Commission Regulation (EC) No 2032/2003 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC (OJ L 307, 24.11.2003, p. 1).

8. The dossier submitted by the Intervener referred to the eight studies at issue. The competent authority of the Hellenic Republic considered the Intervener's dossier to be '*sufficiently complete*' to allow it to carry out its evaluation of prallethrin with a view to its possible inclusion in Annex I, IA or IB to Directive 98/8/EC.

9. Both Sumitomo Chemical (UK) and the Intervener were consequently included as participants in the Review Programme in support of prallethrin for product type 18 (insecticides, acaricides and products to control other arthropods).

Events following the entry into force of the BPR

10. On 17 July 2012, the BPR entered into force (all references to Chapters and Articles hereinafter concern the BPR unless stated otherwise). In accordance with the second subparagraph of Article 97, the BPR applied from 1 September 2013.

11. Sumitomo Chemical (UK) and the Intervener were included in the list of active substance suppliers established under Article 95 due to their participation in the Review Programme. Both could consequently continue to supply prallethrin on the EU market beyond 1 September 2015.

12. After 1 September 2013, the Appellants and the Intervener had numerous exchanges concerning the sharing of data, and costs, on prallethrin.

13. On 22 September 2014 and 6 June 2016, the Appellants and the Intervener concluded two data-sharing agreements on prallethrin. The entry into force of each of these agreements was conditional on (i) the competent authority of the Hellenic Republic confirming that the eight studies at issue could be used for the assessment of prallethrin from the Intervener's source, or alternatively (ii) the Intervener waiving the first condition and paying an agreed amount (EUR [CONFIDENTIAL] in cash and USD [CONFIDENTIAL] in kind) in instalments. These agreements expired without entering into force on 1 September 2015 and 1 September 2016 respectively.

14. Between September 2016 and September 2017, the Intervener repeatedly requested the Appellants to renew the expired data-sharing agreement of 6 June 2016. The Appellants repeatedly refused, stating that they would be willing to issue the Intervener with a letter of access only on the basis of a '*straightforward*' data-sharing agreement without conditionality clauses and with the total payment to be made at once rather than in instalments.

15. On 7 September 2017, the competent authority of the Hellenic Republic informed the Intervener orally that the eight studies at issue could be used for the assessment of prallethrin from the Intervener's source.

16. On 18 September 2017, the competent authority of the Hellenic Republic informed Sumitomo Chemical (UK) that the Intervener, as part of its dossier, had submitted an *in vitro* test with different results to those from a similar *in vitro* test submitted by Sumitomo Chemical (UK).

17. On 28 September 2017, the Agency confirmed in writing that the eight studies at issue could be used for the assessment of prallethrin from the Intervener's source.

18. On the same day, the Intervener requested the Appellants to issue a letter of access under the conditions set out in the expired data-sharing agreement of 6 June 2016 (see paragraph 13 above). The Intervener consequently proposed amending the agreement to make it enter into force immediately. At the same time, the Intervener made a payment to Sumitomo Chemical Company for one half of the amount set out in the 6 June 2016 data-sharing agreement (i.e. EUR [CONFIDENTIAL]) as a first instalment.

19. On 9 October 2017, the Appellants informed the Intervener that Sumitomo Chemical Company refused to accept the payment, and would return it, on the grounds that it was not made under a valid data-sharing agreement. The Appellants reiterated that they would be willing to issue the Intervener with a letter of access only on the basis of a '*straightforward*' data-sharing agreement without conditionality clauses and with the total payment to be made at once rather than in instalments.

20. On 17 October 2017, the competent authority of the Hellenic Republic informed the Intervener that it was required to submit a letter of access showing that it had permission to refer to the eight studies at issue by 30 November 2017. It further stated that '*[f]ailing to submit the aforementioned letter of access by the specified deadline would result your [sic] immediate withdrawal from the review program [sic] as participant since your application dossier will be eventually considered as incomplete*'. Sumitomo Chemical (UK) received a copy of this communication.

21. On 31 October 2017, the Intervener informed the Appellants that it agreed to the terms and conditions of the data-sharing agreement proposed by the Appellants on 9 October 2017.

22. On 13 November 2017, the Appellants stated, in essence, that the Intervener should not have been allowed to participate in the Review Programme because its dossier was incomplete and prallethrin from its source may have a different hazard profile than that of Sumitomo Chemical (UK). Consequently, the Appellants did not wish to conclude a data-sharing agreement.

23. At 09:04 CET on 23 November 2017, the Intervener submitted a data-sharing dispute to the Agency.

Events following the submission of the data-sharing dispute to the Agency

24. At 09:09 CET on 23 November 2017, the Intervener informed the Appellants that it had submitted the data-sharing dispute to the Agency.

25. At 10:31 CET on 23 November 2017, the Appellants responded to the Intervener, mainly re-stating the arguments they had previously made on 13 November 2017. The Appellants also stated that they had filed a complaint with the European Ombudsman against the Agency, and that they would take action in the Hellenic courts.

26. On 18 December 2017, following the Agency's request, the Appellants submitted to the Agency a copy of their correspondence with the Intervener concerning the sharing of data, and costs, on prallethrin.

27. On 9 February 2018, the Agency informed the Intervener that, following its assessment of the data-sharing dispute, the Agency had concluded that the Intervener had made every effort to reach an agreement with the Appellants. The Agency therefore requested the Intervener to submit proof of payment of a share of the costs for the eight studies at issue in accordance with Article 63(3).

28. On 28 February 2018, the Intervener submitted to the Agency proof of a payment of EUR [CONFIDENTIAL] in favour of Sumitomo Chemical Company.

29. On 1 March 2018, the Agency adopted the Contested Decision.

Contested Decision

30. The Contested Decision finds, first, that the Intervener made every effort to reach a data-sharing agreement with the Appellants. This finding is based on an assessment of the negotiations that took place between the parties from the entry into application of the BPR (1 September 2013) to the moment of submission of the data-sharing dispute (09:04 CET on 23 November 2017).

31. The Contested Decision finds, second, that the Intervener paid Sumitomo Chemical Company a share of the costs for the eight studies at issue.

32. The Contested Decision consequently grants the Intervener permission to refer to the eight studies at issue pursuant to the second subparagraph of Article 63(3).

Procedure before the Board of Appeal

33. On 27 April 2018, the Appellants filed this appeal.

34. On 6 August 2018, the Agency submitted its Defence.

35. On 15 November 2018, Endura S.p.A. (the Intervener) was granted leave to intervene in these proceedings in support of the Agency.

36. On 31 January 2019, the Intervener submitted its statement in intervention.

37. On 4 March 2019, the Appellants submitted observations on the Defence.

38. On 12 March 2019, the Appellants and the Agency filed their respective observations on the statement in intervention.

39. On 13 May 2019, the Agency submitted observations on the Appellants' observations on the Defence.

40. On 9 October 2019, a hearing was held at the Appellants' request. At the hearing, the Appellants, the Agency and the Intervener made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

41. The Appellants request the Board of Appeal to declare the appeal admissible and well-founded, annul the Contested Decision, and order the Agency to pay the costs of these proceedings.

42. The Agency, supported by the Intervener, requests the Board of Appeal to dismiss the appeal.

Reasons

1. Relevant provisions

43. Chapter XIV, which consists of Articles 59 to 64, sets out rules concerning the protection, and sharing, of data under the BPR, and the sharing of costs related to those data.

44. Article 59(1) provides:

'*Without prejudice to Articles 62 and 63, data submitted for the purposes of Directive 98/8/EC or of [the BPR] shall not be used by competent authorities or the Agency for the benefit of a subsequent applicant, except where:*

(a) the subsequent applicant submits a letter of access; or

(b) the relevant time limit for data protection has expired.'

45. Article 60(2) provides:

'*The protection period for data submitted with a view to the approval of an existing active substance shall end 10 years from the first day of the month following the date of adoption of a decision in accordance with Article 9 on the approval of the relevant active substance for the particular product-type*.'

46. Article 62(1) provides:

'*In order to avoid animal testing, testing on vertebrates for the purposes of this Regulation shall be undertaken only as a last resort. Testing on vertebrates shall not be repeated for the purposes of this Regulation.*'

47. Article 62(2) provides that, during the protection period established under Article 60(2), any person intending to perform studies involving tests on vertebrate animals must inquire with the Agency whether such studies have already been submitted to the Agency or to the competent authority of a Member State. If so, the person in

question must request a letter of access concerning those studies from the data owner.

48. Article 63(1) to (4) provide:

'*1. Where a request has been made in accordance with Article 62(2), the prospective applicant and the data owner shall make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant. Such an agreement may be replaced by submission of the matter to an arbitration body and a commitment to accept the arbitration order.*

[…]

3. Where no agreement is reached with respect to data involving tests or studies on vertebrates, the prospective applicant shall inform the Agency and the data owner thereof, at the earliest one month after the prospective applicant receives the name and address of the data submitter from the Agency.

Within 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. Where the prospective applicant and data owner cannot agree, national courts shall decide on the proportionate share of the cost that the prospective applicant is to pay to the data owner.

The data owner shall not refuse to accept any payment offered pursuant to the second subparagraph. Any acceptance is without prejudice, however, to his right to have the proportionate share of the cost determined by a national court, in accordance with the second subparagraph.

4. Compensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner […].'

2. Assessment of the Appellants' pleas

49. The Appellants put forward seven pleas in support of their appeal. They allege:

- a breach of Article 62,
- breaches of Article 63(3),
- breaches of the right to be heard,
- errors of assessment,
- a breach of the precautionary principle,
- a breach of the principle of good administration, and
- a breach of the principle of '*non-discrimination*'.

50. The Board of Appeal will address these pleas in the order in which they were put forward. The second, third and fourth pleas, and later the sixth and seventh pleas, will be addressed together.

2.1. First plea: breach of Article 62

Arguments of the Appellants

51. The Appellants argue that the Intervener requires the eight studies at issue for a purpose which is not recognised by the BPR, namely to remain a participant in the Review Programme for prallethrin and to be included in the list of active substance suppliers of prallethrin established under Article 95.

52. At the hearing, the Appellants argued that the Intervener failed to inquire whether the eight studies at issue had already been submitted to a competent authority or to the Agency, as required by Article 62(2), before submitting the present dispute to the Agency. The Intervener made a first inquiry on 17 September 2013 and submitted a first (unsuccessful) data-sharing dispute to the Agency in 2015. After the rejection of the first dispute by the Agency, the Intervener should have made a new inquiry before submitting the present dispute.

Arguments of the Agency and the Intervener

53. The Agency, supported by the Intervener, argues that the Intervener is obliged to provide the eight studies at issue. As Article 62(1) prevents the Intervener from repeating those studies, it had to seek permission to refer to them.

54. If the Intervener fails to obtain permission to refer to the eight studies at issue, it will be considered to have withdrawn from the Review Programme pursuant to Article 11(1)(d) of Commission Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in the BPR (OJ L 294, 10.10.2014, p. 1).

Findings of the Board of Appeal

55. The Appellants put forward two arguments in support of their first plea.

56. First, the Appellants argue that the Intervener requires the eight studies at issue for a purpose which is not recognised by the BPR.

57. Following the request made by the competent authority of the Hellenic Republic on 17 October 2017, in order to participate in the procedure for the approval of prallethrin as an active substance under Chapter II, the Intervener is required to provide a letter of access showing that it has permission to refer to the eight studies at issue.

58. The eight studies at issue involve tests on vertebrate animals, and Article 62(1) prohibits the repetition of such studies. The Intervener cannot therefore repeat the eight studies at issue but must refer to them.

59. However, the Intervener is not the data owner of the eight studies at issue, and those studies benefit from the protection period set out in Article 60(2). In order to refer to the eight studies at issue, the Intervener must therefore obtain a letter of access to those studies from Sumitomo Chemical Company in accordance with Articles 59(1)(a) and 62(2), or be granted permission to refer to them by the Agency in accordance with Article 63(3).

60. The Appellants' first argument must therefore be rejected.

61. Second, the Appellants argued at the hearing that the Intervener failed to make a new inquiry, as required by Article 62(2), before submitting the present dispute to the Agency.

62. According to the first subparagraph of Article 62(2), a prospective applicant must inquire with the Agency whether the studies they intend to perform using vertebrate animals have already been submitted to the Agency or to the competent authority of a Member State. If the studies have already been submitted to the Agency or the competent authority of a Member State, the Agency provides the prospective applicant with the name and contact details of the data submitter and the data owner. However, after a prospective applicant has made this inquiry once it has the necessary information to contact the data submitter and the data owner. Therefore there is no need for the prospective applicant to repeat the inquiry if it needs to submit a new data-sharing dispute with the Agency concerning the same studies.

63. In the present case, the Intervener submitted an inquiry to the Agency on 17 September 2013. Following that inquiry, the Agency informed the Intervener that the eight studies at issue had already been submitted by Sumitomo Chemical (UK) to the competent authority of the Hellenic Republic. There was therefore no need for the Intervener to repeat its inquiry before filing the data-sharing dispute that led to the Contested Decision.

64. The Appellants' second argument, which was raised only at the hearing, must therefore be rejected without the need to examine its admissibility.

65. The first plea must consequently be rejected.

2.2. Second, third and fourth pleas: breach of Article 63(3), breach of the right to be heard and errors of assessment concerning '*every effort*'

Arguments of the Appellants

66. By their second plea, the Appellants argue that the Agency breached the second subparagraph of Article 63(3) in the following three ways.

67. First, the Appellants argue that the Contested Decision was adopted after the expiry of the time-limit of 60 days set out in the second subparagraph of Article 63(3). According to the Appellants, that time-limit expired on 22 January 2018 (counting from the day of filing of the dispute) or, at the latest, on 16 February 2018 (counting from the day the Agency received documentary evidence from the Appellants). The Contested Decision however was adopted on 1 March 2018.

68. The Appellants add that the Contested Decision could have been substantively different if it had been adopted in time because '*to argue otherwise is to argue that, regardless of the length of a deadline, only one outcome is inevitable and possible*'.

69. Second, the Appellants argue that the Intervener paid the data owner (Sumitomo Chemical Company) a share of the costs on 27 February 2018. The Intervener therefore failed to pay a share of the costs of the eight studies at issue within the time-limit set out in the second subparagraph Article 63(3) (see paragraph 67 above).

70. Third, the Appellants argue that the amount of that payment was lower than the Intervener had previously accepted to pay. The Intervener paid EUR [CONFIDENTIAL] on 27 February 2018, whereas on 31 October 2017 it accepted to pay EUR [CONFIDENTIAL] in cash and USD [CONFIDENTIAL] in kind.

71. By their third and fourth pleas, the Appellants argue that the Agency committed the following four errors in assessing whether the Intervener made every effort to reach an agreement with the data owner (Sumitomo Chemical Company).

72. First, the Agency wrongfully excluded from its assessment correspondence from before the BPR applied (1 September 2013) and after the moment of filing the data-sharing dispute (09:04 CET on 23 November 2017). The Contested Decision expressly states that such correspondence was not taken into account. This also constitutes a breach of the right to be heard.

73. Second, the Agency failed to take into account a number of shortcomings on the part of the Intervener over the course of the whole negotiations. For example, the Intervener negotiated inconsistently, failed to rely on certain contractual provisions in good time, filed two unsuccessful data-sharing disputes with the Agency concerning prallethrin, and failed to disclose possible differences between the hazard profile of prallethrin from its own source and that of Sumitomo Chemical (UK).

74. Third, the Agency distorted or misconstrued certain of the facts on which its assessment of the data-sharing dispute is based. For example, who proposed to include certain clauses in a draft data-sharing agreement in 2016, and the meaning of certain contractual clauses.

75. Fourth, the Agency incorrectly concluded that the Appellants did not make every effort by refusing to conclude a '*straightforward*' data-sharing agreement with the Intervener after 31 October 2017. The Appellants were entitled to refuse to conclude such an agreement at that point in time because it had come to their attention that the hazard profile of prallethrin from the two different sources might be different. The Intervener had submitted to the competent authority of the Hellenic Republic an *in vitro* test with different results to those from a similar *in vitro* test submitted by Sumitomo Chemical (UK).

Arguments of the Agency and the Intervener

76. The Agency, supported by the Intervener, argues that the second plea alleges a procedural irregularity, the Contested Decision being taken after the 60 days' time-limit, which had no impact on the outcome of the data-sharing dispute. Moreover, the Appellants have no interest in raising this irregularity because the time-limit of 60 days set out in Article 63(3) is to the sole benefit of prospective applicants.

77. In any event, according to the Agency, Article 63(3) must be interpreted as meaning that the Agency must inform a prospective applicant of the outcome of the assessment of the efforts of the parties within 60 days of receiving from the data owner documentary evidence of the dispute. In the present case, the Agency informed the Intervener on 9 February 2018 that it had concluded that the Intervener made every effort to reach an agreement with the Appellants, and the 60 day time-limit expired on 16 February 2018.

78. The Agency argues that Article 63(3) does not require a prospective applicant to pay a share of the costs to the data owner within 60 days of the Agency being informed of the data-sharing dispute. Article 63(3) only requires the payment to be made before the Agency formally adopts its decision to grant a prospective applicant permission to refer.

79. The Agency adds that it is not competent to assess whether the amount paid is adequate. According to the second and third subparagraphs of Article 63(3), this assessment is reserved to the national courts.

80. The Agency and the Intervener submit that on 31 October 2017 the Intervener accepted the terms and conditions proposed by the Appellants in their entirety. In those circumstances, there were no other efforts the Intervener could make.

Findings of the Board of Appeal

81. The Board of Appeal will first examine the second plea by which the Appellants claim in essence that the Contested Decision is vitiated by an error as that decision was not adopted within the time-limit of 60 days.

82. First of all, the Board of Appeal needs to define from when the time-limit set out in the second subparagraph of Article 63(3) begins to run. It is clear from a combined reading of the first and second subparagraphs of Article 63(3) that the time-limit of 60 days starts running with the filing of a data-sharing dispute by a prospective applicant. Indeed, the prospective applicant '*informs*' the Agency by filing its request for permission to refer.

83. Next, it is also clear from the wording of the second subparagraph of Article 63(3) that the Agency should adopt a decision on an application for permission to refer within 60 days of the filing of the data-sharing dispute by a prospective applicant.

84. In the present case, the Intervener filed the data-sharing dispute with the Agency on 23 November 2017. The time-limit set out in the second subparagraph of Article 63(3) expired on 22 January 2018. The Contested Decision, however, was adopted only on 1 March 2018.

85. The Agency therefore exceeded the time-limit set out in the second subparagraph of Article 63(3).

86. However, the second subparagraph of Article 63(3) is not drafted so as to be self-executing. Neither Article 63(3), nor any other provision in the BPR, foresees any consequences of a failure on the part of the Agency to respect the time-limit set out in the second subparagraph of Article 63(3); the application for permission to refer is neither tacitly rejected, nor tacitly accepted, nor does the Agency lose its competence to decide on the data-sharing dispute.

87. A breach of the time-limit set out in the second subparagraph of Article 63(3) can potentially give rise to a declaration by the EU courts that the Agency failed to act (Article 265 TFEU) or an award of damages (Article 340 TFEU).

88. When deciding on an appeal, the Board of Appeal examines whether the arguments put forward before it are capable of demonstrating the existence of an error vitiating the contested decision (see, by analogy, judgment of 20 September 2019, *Germany* v *ECHA*, T-755/17, EU:T:2019:647, paragraph 60).

89. Indeed, in accordance with Article 63(3), '*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*'. This means that the Agency must decide in favour of the prospective applicant if those two conditions are met.

90. Article 93(3) of Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007, p. 3), applicable to the present case pursuant to Article 77(1) of the BPR, provides that the Board of Appeal may exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

91. A breach of the time-limit referred to in Article 63(3) cannot lead to the annulment of the Agency's decision granting a prospective applicant permission to refer, if the Board of Appeal, at the time it takes its decision considers that the conditions for a decision granting a prospective applicant permission to refer were met when the contested

decision was adopted by the Agency.

92. The Board of Appeal will therefore now examine whether the two conditions in Article 63(3) are met in the present case. As set out in the previous paragraph, only in the event that these conditions were not met on the day the Contested Decision was adopted may the Board of Appeal exercise any power which lies within the competence of the Agency and decide on the dispute itself or annul the Contested Decision and remit the case back to the competent body of the Agency.

- *'Every effort'*

93. A prospective applicant can be found to have made every effort to reach an agreement even if it does not accept the terms and conditions proposed by a data owner. An interpretation to the contrary would deprive Article 63(4) of any effect as it would oblige a prospective applicant to agree to terms and conditions that may not be fair, transparent and non-discriminatory.

94. In the present case, however, the Appellants proposed certain terms and conditions to share data and costs (most recently and finally on 9 October 2017) and the Intervener agreed to all of those terms and conditions unconditionally (on 31 October 2017).

95. In these circumstances, there was nothing more the Intervener could do. The Agency could therefore reach no other conclusion than the one set out in the Contested Decision, namely that the Intervener had made every effort to reach an agreement with the data owner (Sumitomo Chemical Company).

96. The Appellants' arguments neither alter this conclusion, nor call into question the fact that the Intervener accepted all the terms and conditions proposed by the Appellants.

- *Payment of a share of the cost*

97. It is not disputed that the Intervener paid Sumitomo Chemical Company EUR [CONFIDENTIAL] before the adoption of the Contested Decision. This sum constitutes '*a share of the costs incurred*' within the meaning of the second subparagraph of Article 63(3). It is not necessary to rule on the question of whether this is a proportionate share of the costs since this does not fall within the competence of the Agency.

98. The Appellants can bring the matter to a national court in accordance with the third subparagraph of Article 63(3) in order for the proportionate share of the costs of the eight studies at issue to be determined, unless the parties are able to agree on that share after the decision granting the prospective applicant permission to refer has been adopted.

- *Conclusion*

99. Since both conditions of Article 63(3) set out in paragraph 89 above were fulfilled on the day the Contested Decision was adopted, the Agency was required to grant the Intervener permission to refer.

100. The second, third and fourth pleas must consequently be rejected. It is not necessary to examine whether, as the Agency submits, the Appellants' claim that the Agency exceeded the time-limit set out in the second subparagraph of Article 63(3) is inadmissible.

2.3. Fifth plea: breach of the precautionary principle

Arguments of the Appellants

101. The Appellants argue that the Contested Decision breaches the precautionary principle. The Contested Decision fails to address the Appellants' '*serious concern*' that the hazard profile of prallethrin from the Intervener's source might be different to the prallethrin from the source of Sumitomo Chemical (UK). In support of this argument, the Appellants rely on the decision of the Board of Appeal of 23 August 2016 in Case A-005-2015, *Thor*. According to the Appellants, in that decision the Board of Appeal held that technical equivalence or chemical similarity can be a pre-condition for the sharing of data.

Arguments of the Agency and the Intervener

102. The Agency, supported by the Intervener, argues that possible differences in the hazard profiles of prallethrin from various sources are not relevant in the context of a request to share data.

103. The Intervener argues that a recent *in vivo* study showed that the results of its previous *in vitro* test (see paragraph 16 above) were not conclusive.

Findings of the Board of Appeal

104. The present case must be distinguished from the case which gave rise to the decision of the Board of Appeal in *Thor*, cited in paragraph 101 above. In that case, the parties to the data-sharing dispute had agreed contractually that they would only share data if the two sources of the active substance were shown to be technically equivalent or chemically similar. In the present case, the Appellants and the Intervener have no such agreement.

105. Indeed, any possible differences in the hazard profile of prallethrin from the two sources – if such differences exist – will be taken into account during the course of the procedure for the approval of prallethrin as an active substance under Chapter II.

106. The fifth plea must consequently be rejected.

2.4. Sixth and seventh pleas: breaches of the principles of good administration and '*non-discrimination*'

Arguments of the Appellants

107. The Appellants argue that the Agency breached the principle of good administration in two ways:

- the Agency failed to correct the error made by the competent authority of the Hellenic Republic when it accepted the Intervener's dossier instead of rejecting it as incomplete, and
- the Agency included the Intervener in the list of active substance suppliers of prallethrin established under Article 95 despite the fact that, due to its incomplete dossier, it should not have been allowed to participate in the Review Programme.

108. The Appellants further argue that the Agency breached the principle of '*non-discrimination*' because it treated the Appellants and the Intervener in the same way (including both in the list of active substance suppliers established under Article 95) despite the fact that they are in different situations. The Appellants argue that the Intervener's dossier is incomplete and the Appellants' is complete.

Arguments of the Agency and the Intervener

109. The Agency, supported by the Intervener, argues that the sixth and seventh pleas are inadmissible because they challenge acts which the Board of Appeal is not competent to review.

Findings of the Board of Appeal

110. The sixth and seventh pleas challenge the legality of two decisions other than the Contested Decision. Namely, (i) the decision, by the competent authority of the Hellenic Republic, to accept the Intervener's dossier as sufficiently complete under Article 9 of Commission Regulation 2032/2003 (see paragraph 8 above), and (ii) the decision, by the Agency, to include the Intervener in the list of active substance suppliers established under Article 95 (see paragraph 11 above).

111. Neither of those decisions fall within the competence of the Board of Appeal, as set out in Article 77(1) of the BPR or Articles 4 and 7 of Delegated Regulation 1062/2014. Moreover, the Board of Appeal is not competent to issue instructions to the competent authority of the Hellenic Republic.

112. The sixth and seventh pleas must consequently be rejected as inadmissible.

113. As all the Appellants' pleas have been rejected, the appeal must be dismissed.

Application as to costs

114. The Appellants request the reimbursement of the costs they have incurred for these proceedings.

115. In accordance with Article 17a 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 to an appeal bear their own costs.

116. The request for the reimbursement of the costs incurred for these proceedings must therefore be rejected.

Refund of the appeal fee

117. Pursuant to Article 4(4) of Commission Implementing Regulation (EU) No 564/2013 on the fees and charges payable to the European Chemicals Agency pursuant to the BPR (OJ L 167, 19.6.2013, p. 17), if the appeal is dismissed, the appeal fee is not refunded. The appeal fee will therefore not be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

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

Sari HAUKKA
On behalf of the Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal