ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

3 November 2020

(Biocidal Products Regulation – Data and cost-sharing – Right to be heard – Every effort – Contractual agreement making the sharing of data conditional on the prior establishment of chemical similarity – Payment of a share of the cost – Manifestly unreasonable amount)

Case number	A-009-2019
Language of the case	English
Appellant	Solvay Solutions UK Limited, United Kingdom
Representatives	Koen Van Maldegem and Peter Sellar Fieldfisher (Belgium) LLP, Belgium
Contested Decision	DSH-63-3-D-0020-2016/Re1 of 6 May 2019, 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; the 'BPR')

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman and Rapporteur), Andrew Fasey (Technically Qualified Member) and Sakari Vuorensola (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

Background to the dispute

1. This appeal concerns the sharing of data and costs relating to the active substance tetrakis(hydroxymethyl)phosphonium sulphate (2:1) (EC No 259-709-0; 'THPS').

2. The Appellant is the data owner of several studies ('the studies') on THPS within the meaning of Article 59 of the BPR (all references to Articles concern the BPR unless stated otherwise).

3. On 10 October 2012, Dow Benelux B.V. requested the Appellant to provide it with a letter of access for the studies, in accordance with Article 59(1)(a), in order to seek inclusion in the list of active substance suppliers established under Article 95.

4. Between 10 October 2012 and 26 August 2016, data and cost-sharing negotiations took place between the Appellant and Dow Benelux B.V.

5. During the course of these negotiations, Dow Benelux B.V. and the Appellant concluded an '*Every effort and secrecy agreement*', setting out a framework for the negotiations. Clause 7.2 and 7.5 of this agreement provides:

   '*Chemical similarity of the Parties' respective THPS specifications shall be assessed by a technical consultant chosen by the Parties.*

   […]

   When, irrespective of the will of the Parties, no Chemical similarity can be established between the specifications, by the appointed consultant, the Parties will have to stop negotiating a Data Sharing Agreement'.

6. On 18 November 2015, a technical consultant appointed by the Appellant and Dow Benelux N.V. found that its assessment of the chemical similarity of the two sources of THPS was '*inconclusive*'.

7. Dow Benelux B.V. subsequently applied to the Agency for an assessment of the chemical similarity of the two sources of THPS in accordance with the decision of the Agency's Management Board No 31/2013 of 18 December 2013.

8. On 22 July 2016, the Agency concluded that the two sources of THPS were not chemically similar.

9. The Appellant subsequently refused to share data and costs with Dow Benelux B.V. until such a time as Dow Benelux B.V. could establish that the two sources of THPS were chemically similar.

10. On 26 August 2016, Dow Benelux B.V. applied to the Agency for permission to refer to the studies. Following the submission of the application for permission to refer, Dow Benelux B.V. and the Appellant each provided to the Agency a copy of the documentary evidence concerning their data and cost-sharing negotiations.

11. On 14 November 2016, the Agency adopted a decision granting Dow Benelux B.V. permission to refer to the studies pursuant to the second subparagraph of Article 63(3).

12. On 16 December 2016, the Appellant filed an appeal against the Agency's decision of 14 November 2016. This appeal was registered by the Registry of the Board of Appeal as Case A-014-2016.

13. On 7 March 2018, the Board of Appeal issued its decision in Case A-014-2016, *Solvay Solutions UK* ('the first decision of the Board of Appeal'). At paragraphs 52 to 69 of its first decision, the Board of Appeal held, in essence, that the Agency had failed to take into account the fact that Dow Benelux B.V. did not comply with Clause 7.5 of

the '*Every effort and secrecy agreement*'. The Board of Appeal annulled the Agency's decision of 14 November 2016 and remitted the case to the competent body of the Agency for re-examination.

14. On 6 May 2019, the Agency adopted the Contested Decision.

Contested Decision

15. The Contested Decision is based on the second subparagraph of Article 63(3).

16. The Contested Decision states:

'*The present decision re-examines the dispute. It bases itself on the findings by the Board of Appeal on the efforts of the parties to establish chemical similarity and the fact that the chemical similarity of the substances of the Parties could not be confirmed. As suggested by the Board of Appeal, this decision examines whether the data sharing obligation under the BPR also applies, where substances are not chemically similar, and whether Parties can waive their data sharing obligations in an agreement under private law. Finally, it will assess the Parties' efforts*.'

17. As regards Clause 7.5 of the '*Every effort and secrecy agreement*', the Contested Decision states that data owners and prospective applicants cannot '*waive*' the data-sharing rules set out in the BPR by means of a contract. Whilst the parties to a data and cost-sharing negotiation may agree to assess, as a preliminary point, the chemical similarity of their respective sources of an active substance, the BPR requires a data owner to share data and costs even if the sources of an active substance are not chemically similar. The Appellant was not, therefore, entitled to refuse to share data and costs on THPS on the grounds that it had not been established that its source of THPS was chemically similar to the one of Dow Benelux B.V.

18. The Contested Decision therefore finds that the Appellant failed to comply with the obligation to make every effort to reach a data and cost-sharing agreement, whilst Dow Benelux B.V. made every effort to continue the data and cost-sharing negotiations. The Contested Decision also finds that Dow Benelux B.V. paid the Appellant a share of the cost of the studies.

19. The Agency therefore granted Dow Benelux B.V. permission to refer to the studies.

Procedure before the Board of Appeal

20. On 19 July 2019, the Appellant filed this appeal.

21. On 25 July 2019, Dow Benelux B.V. was informed of the filing of the appeal in accordance with Article 6(5) 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; the 'Rules of Procedure').

22. On 4 September 2019, an announcement of the appeal was published in accordance with Article 6(6) of the Rules of Procedure.

23. On 23 September 2019, the Agency filed its Defence.

24. On 25 September 2019, the deadline for submitting applications for leave to intervene expired without any applications being received.

25. On 4 December 2019, the Appellant submitted observations on the Defence.

26. On 27 January 2020, the Agency submitted observations on the Appellant's observations on the Defence.

27. On 12 May 2020, Sakari Vuorensola, alternate member of the Board of Appeal, was designated to replace Sari Haukka in this case, in accordance with the first subparagraph of Article 3(2) of the Rules of Procedure.

28. On 4 June 2020, a hearing took place at the Appellant's request. The hearing was held by video-conference in accordance with Article 13(7) of the Rules of Procedure. At the hearing, the Appellant and the Agency made oral submissions and answered questions from the Board of Appeal.

Forms of order sought

29. The Appellant requests the Board of Appeal to annul the Contested Decision and order the refund of the appeal fee.

30. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

31. The Appellant raises seven pleas in support of its appeal, namely that the Agency:

- breached Articles 62 and 63, and the Appellant's property rights in the studies, by granting Dow Benelux B.V. permission to refer without verifying whether Dow Benelux B.V. still had an interest in obtaining permission to refer (first plea),
- misused its powers, and breached the principle according to which a matter that has been adjudicated by a final decision of a court of law may not be pursued further by the same parties (principle of *res judicata*), by failing to reject the application for permission to refer submitted by Dow Benelux B.V. on 26 August 2016 following the first decision of the Board of Appeal (second plea),
- breached the principle of the freedom of contract by holding that, under the second subparagraph of Article 63(3), permission to refer can be granted even in a situation in which the parties to a data-sharing dispute have contractually excluded to negotiate such a permission to refer (third plea),
- breached Article 18 of the Rules of Procedure by failing to comply with the reasoning of the first decision of the Board of Appeal (fourth plea),
- breached the Appellant's rights of defence by failing to hear the Appellant before the adoption of the Contested Decision (fifth plea),
- adopted the Contested Decision on an incorrect legal basis by basing it solely on the second subparagraph of Article 63(3), rather than on the second subparagraph of Article 63(3) in conjunction with the dispositive part of the first decision of the Board of Appeal, and Article 18 of the Rules of Procedure (sixth plea),
- breached the second subparagraph of Article 63(3) by adopting the Contested Decision after the expiry of a time-limit of 60 days from the date when the first decision of the Board of Appeal was issued (first part of the seventh plea),
- breached the second subparagraph of Article 63(3) by granting Dow Benelux B.V. permission to refer to the studies despite the fact that a share of the costs of the studies was paid by Dow International Finance Sàrl rather than by Dow Benelux B.V. (second part of the seventh plea), and
- breached the second subparagraph of Article 63(3) by granting Dow Benelux B.V. permission to refer to the studies despite the fact that Dow Benelux B.V. paid an inadequate share of the cost of the studies (third part of the seventh plea).

32. The fifth plea will be examined first.

1. Fifth plea: Breach of the rights of defence

Arguments of the Parties

33. The Appellant argues, in essence, that the Agency breached the Appellant's rights of defence by failing to hear its views on the meaning and implications of the first decision of the Board of Appeal.

34. The Agency argues that the factual basis of the Contested Decision consists exclusively of the evidence provided by the Appellant and Dow Benelux B.V. following the filing of the application for permission to refer. The Agency was not required to hear the Appellant's views on the meaning and implications of the first decision of the Board of Appeal.

Findings of the Board of Appeal

35. The rights of defence, which include the right to be heard, are among the fundamental rights forming an integral part of the European Union legal order are enshrined in Article 41(2)(a) of the Charter of Fundamental Rights of the European Union (see judgment of 10 September 2013, *G. and R.*, C-383/13 PPU, EU:C:2013:533, paragraph 32).

36. The right to be heard guarantees all persons the opportunity to make known their views effectively during an administrative procedure and before the adoption of any decision liable to affect their interests adversely (see judgment of 11 December 2014, C-249/13, *Khaled Boudjlida* v *Préfet des Pyrénées-Atlantiques*, EU:C:2014:2431, paragraph 36).

37. That right pursues a twofold objective. On the one hand, it allows the administration to acquire full knowledge of the facts of a case and to correct any errors in its initial assessment. On the other hand, it ensures the effective protection of the persons concerned, allowing them to submit such information as will argue in favour of the adoption or non-adoption of a decision, or of its having a specific content (see, to this effect, judgment of 4 June 2020, *EEAS* v *De Loecker*, C-187/19 P, EU:C:2020:444, paragraph 69, and *Khaled Boudjlida* v *Préfet des Pyrénées-Atlantiques*, cited in the previous paragraph, paragraphs 37 and 59 of the judgment).

38. In the present case, it is common ground between the Parties that the Contested Decision significantly affects the interests of the Appellant. The Contested Decision grants Dow Benelux B.V. the right to refer to studies for which the Appellant is the data owner and which the Appellant submitted to the Agency for the purposes of the BPR. Such studies benefit from the protection defined in Article 59 for the period established by Article 60. The Contested Decision affects that protection despite the disagreement of the Appellant and consequently affects the interests of the Appellant.

39. The Agency was therefore required to place the Appellant in a position in which it could make known its views effectively before the adoption of the Contested Decision.

40. The Contested Decision is based on the assessment of two elements: (i) the documentary evidence of the data and cost-sharing negotiations, and (ii) the first decision of the Board of Appeal. Those two elements must be examined in turn.

41. First, as regards the documentary evidence of the data and cost-sharing negotiations, the right to be heard is respected if each party to a data and cost-sharing dispute is given the possibility to submit its own documentary evidence and its own arguments to the Agency during the course of the administrative procedure (see, to this effect and by analogy, Case A-017-2013, *Vanadium REACH Forschungs- und*

Entwicklungsverein, Decision of the Board of Appeal of 17 December 2014, paragraphs 94 to 101).

42. As the Appellant was given the possibility to do so (see paragraph 10 above), its right to be heard was respected in this regard.

43. Second, as regards the first decision of the Board of Appeal, that decision found that the Agency had committed an error in its assessment and remitted the case to the competent body of the Agency for re-examination. It therefore constituted a new factor which was highly relevant to the assessment of the case. The Agency itself acknowledged that the Contested Decision is based *'on the findings by the Board of Appeal on the efforts of the parties to establish chemical similarity and the fact that the chemical similarity of the substances of the Parties could not be confirmed'*. The Appellant should consequently have been given the possibility to submit its views on the implications of the first decision of the Board of Appeal.

44. As the Appellant was not given the possibility to do so, its right to be heard was infringed in this regard.

45. An infringement of the rights of the defence, in particular the right to be heard, results in the annulment of a decision taken at the end of a procedure only if, had it not been for such an irregularity, the outcome of the procedure might have been different (see order of 14 April 2016, *Dalli* v *Commission*, C-394/15 P, EU:C:2016:262, paragraph 41, and the cited case-law).

46. The procedure under the second subparagraph of Article 63(3) has two possible outcomes: the Agency might grant or deny an application for permission to refer. It cannot be excluded that, had the Appellant been heard – before the adoption of the Contested Decision – on the implications of the first decision of the Board of Appeal, the Appellant might have persuaded the Agency to reject the application for permission to refer.

47. If the Appellant's right to be heard had been respected, the outcome of the procedure in this case might therefore have been different.

48. It follows that the fifth plea must be upheld, and the Contested Decision annulled.

49. There is no need to examine the remaining pleas.

2. Result

50. Pursuant to the second subparagraph of Article 77(1) of the BPR, which refers to 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), following its examination of a case the Board of Appeal may exercise any power that lies within the competence of the Agency or remit the case to the competent body of the Agency for further action.

51. As the Contested Decision must be annulled, it is necessary to examine whether the application for permission to refer submitted by Dow Benelux B.V. on 26 August 2016 should be granted or denied, or whether the case should be remitted to the competent body of the Agency for further action.

52. The case-file is sufficiently complete to allow the Board of Appeal to adopt its own decision on the application for permission to refer. Furthermore, Dow Benelux B.V. has been given the opportunity to be heard in these appeal proceedings (see paragraphs 21, 22 and 24 above).

53. Pursuant to the second subparagraph of Article 63(3), an application for permission to refer shall be granted provided that (i) the prospective applicant has made every effort to reach an agreement, and (ii) the prospective applicant has paid the data owner a share of the costs incurred.

2.1. Whether Dow Benelux B.V. made '*every effort*'

54. Dow Benelux B.V. and the Appellant concluded a contract, termed '*Every effort and secrecy agreement*', setting out the framework for their negotiations.

55. Pursuant to Clause 7.5 of the '*Every effort and secrecy agreement*', Dow Benelux B.V. and the Appellant would stop negotiating a permission to refer to the studies at issue if chemical similarity could not be established (see paragraph 5 above).

56. A technical consultant appointed by the parties found that chemical similarity between the two sources of THPS was '*inconclusive*'. Furthermore, the Agency found, on request by Dow Benelux B.V., that the two sources of THPS were not chemically similar.

57. Nevertheless, Dow Benelux B.V. sought to continue the negotiations, and eventually filed an application for permission to refer with the Agency. The Board of Appeal found, in paragraphs 60 and 61 of its first decision, that this action on the part of Dow Benelux B.V. constituted a violation of Clause 7.5 of the '*Every effort and secrecy agreement*'.

58. Clause 7.5 of the '*Every effort and secrecy agreement*' is part of a contractual agreement between Dow Benelux B.V. and the Appellant. None of the parties to this contractual agreement has challenged that clause before a competent body, such as the relevant national court.

59. Neither the Agency nor the Board of Appeal have the power to declare null and void a contractual agreement between private parties to a data and cost-sharing dispute. Similarly, neither the Agency nor the Board of Appeal can disregard – as if it had been declared null and void by a competent body – a clause in a contractual agreement between private parties to a data and cost-sharing dispute.

60. Dow Benelux B.V. therefore failed to make every effort by circumventing Clause 7.5 of *the 'Every effort and secrecy agreement'*, which has not been declared null and void by a competent body, in order to pursue the negotiations without having established chemical similarity between the two sources of THPS.

61. In these circumstances, the first of the two conditions for obtaining permission to refer, set out in the second subparagraph of Article 63(3), is not fulfilled.

62. In the interests of completeness as regards the implementation of Article 63(3) in the future, it is appropriate to examine also whether the second of the two conditions for obtaining permission to refer, set out in the second subparagraph of Article 63(3), is fulfilled.

2.2. Whether Dow Benelux B.V. paid a share of the cost

63. Dow Benelux B.V. paid the Appellant EUR [CONFIDENTIAL] as a share of the cost of the studies to which it sought permission to refer.

64. In order to determine whether this sum constitutes '*a share of the costs incurred*' within the meaning of the first sentence of the second subparagraph of Article 63(3), it is necessary to examine the interpretation of that provision.

65. In interpreting a provision of European Union law, it is necessary to consider not only its wording but also the context in which it occurs and the objectives pursued by the rules of which it is part (judgment of 19 September 2019, *Gesamtverband Autoteile-Handel*, C-527/18, EU:C:2019:762, paragraph 30).

66. First, as regards the wording of the provision, the first sentence of the second subparagraph of Article 63(3) requires prospective applicants to pay '*a share of the costs incurred*'. This may mean any sum. The wording of the provision is therefore inconclusive.

67. Second, as regards the context of the provision, the second sentence of the second subparagraph, and the third subparagraph, of Article 63(3), provide that it falls to national courts to determine the '*proportionate share*' of the costs which a prospective applicant must ultimately pay.

68. It is clear from this provision that the Agency is not competent to determine, when examining an application for permission to refer, whether the share of the cost paid by a prospective applicant is proportionate in view of – for example – the actual cost of the studies at issue and the number of persons relying on them (see, to this effect, Case A-007-2018, *Sumitomo Chemical (UK) and Sumitomo Chemical Company*, Decision of the Board of Appeal of 10 March 2020, paragraphs 97 and 98).

69. This implies that, in order for a prospective applicant to obtain permission to refer from the Agency, the share of the costs which it pays need not necessarily be '*proportionate*'. It does not imply, however, that the Agency is not competent to examine the amount paid in any way.

70. Therefore, the context of the first sentence of the second subparagraph of Article 63(3) does not clarify whether any sum paid by a prospective applicant, however trivial, is sufficient to constitute '*a share of the costs incurred*' within the meaning of the first sentence of the second subparagraph of Article 63(3).

71. Third, as regards the objectives of the provision, the requirement to pay '*a share of the costs incurred*' pursues two purposes. The first purpose is ensuring that a prospective applicant seeking a permission to refer is willing to contribute to data costs. The second purpose is reducing the number of claims for compensation filed before national courts.

72. Those objectives would not be achieved if a prospective applicant could obtain permission to refer by paying an amount that is manifestly unreasonable and therefore amounts to an abuse of procedure.

73. The objectives of the first sentence of the second subparagraph of Article 63(3) therefore indicate that, in order to constitute '*a share of the costs incurred*', the amount paid by a prospective applicant must not be manifestly unreasonable having regard to the circumstances of the case.

74. It follows that the second of the two conditions for obtaining permission to refer, set out in Article 63(3), is fulfilled only if the amount paid is not manifestly unreasonable having regard to the circumstances of the case.

75. In the present case, during the course of the negotiations, the parties discussed compensation between one and two million EUR for the studies. Dow Benelux B.V. offered to pay EUR [CONFIDENTIAL]. In the event, Dow Benelux B.V. paid EUR [CONFIDENTIAL], which is an insignificant fraction of the sum at issue in the negotiations. Moreover, no justification has been put forward in these proceedings for the amount of the payment. The payment made by Dow Benelux B.V. is therefore manifestly unreasonable in the circumstances of this case.

76. The second of the two conditions for obtaining permission to refer, set out in the second subparagraph of Article 63(3), is therefore not fulfilled.

2.3. Conclusion on the application for permission to refer

77. It follows from the reasons set out in paragraphs to 54 to 76 above that Dow Benelux B.V. has not fulfilled either of the two cumulative conditions for obtaining permission to refer, set out in Article 63(3). Its application for permission to refer, submitted to the Agency on 26 August 2016, must therefore be denied.

78. A copy of this decision should be notified to Dow Benelux B.V.

Refund of the appeal fee

79. In accordance with Article 10(4) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation (OJ L 107, 17.4.2008, p. 6), the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal has been decided in favour of the Appellant, the appeal fee must be refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Annuls the Contested Decision.**
2. **Rejects the application for permission to refer submitted by Dow Benelux B.V. on 26 August 2016.**
3. **Instructs the Registrar to notify a copy of this decision to Dow Benelux B.V.**
4. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal