ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY

17 November 2020

(Biocidal Products Regulation – Data and cost-sharing – Interest in pursuing a case – Right to be heard – Replacement of a contested decision by the decision of Board of Appeal – Conclusion of a data-sharing agreement)

Case number	A-006-2019
Language of the case	English
Appellant	Sharda Europe B.V.B.A., Belgium
Representatives	Claudio Mereu, Peter Sellar and Sandra Sáez Moreno Fieldfisher (Belgium) LLP, Belgium
Intervener	BASF Agro BV, the Netherlands – Freienbach Branch, Switzerland
Contested Decision	DSH-63-3-D-0019-2016/Re1 of 11 February 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), Sakari Vuorensola (Legally Qualified Member) and Katrin Schütte (Technically 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 alpha-cypermethrin (CAS No 67375-30-8).

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

3. On 1 December 2014, the Appellant requested the Intervener 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 1 December 2014 and 27 February 2016, data and cost-sharing negotiations took place between the Appellant and the Intervener. These negotiations did not lead to an agreement.

5. On 27 February 2016, the Appellant submitted to the Agency an application for permission to refer to the studies. Following the submission of the application for permission to refer, the Appellant and the Intervener each provided to the Agency a copy of the documentary evidence concerning their data and cost-sharing negotiations.

6. On 18 May 2016, the Agency adopted a decision rejecting the Appellant's application for permission to refer, pursuant to the second subparagraph of Article 63(3), on the grounds that the Appellant had not made every effort to reach an agreement with the Intervener.

7. On 11 August 2016, the Appellant filed an appeal against the Agency's decision of 18 May 2016. This appeal was registered as Case A-007-2016.

8. On 29 May 2018, the Board of Appeal issued its decision in Case A-007-2016, *Sharda Europe* ('the first decision of the Board of Appeal'). In its decision, the Board of Appeal held that the Agency had committed several errors in its assessment of the facts of the case. The Board of Appeal therefore annulled the Agency's decision of 18 May 2016, and remitted the case to the competent body of the Agency for re-examination.

9. Between 21 June and 16 November 2018, the Appellant and the Agency had several exchanges concerning the Agency's re-assessment of the Appellant's application for permission to refer. During the course of these exchanges, the Appellant stated that, following the first decision of the Board of Appeal, the Agency was required to grant it permission to refer to the studies, and provided a list of the studies to which it sought permission to refer. The Agency acknowledged receipt of these communications and stated that it would re-examine the facts and adopt a decision in due course.

10. On 11 February 2019, the Agency adopted the Contested Decision.

Contested Decision

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

12. In the Contested Decision, the Agency re-examined the data and cost-sharing negotiations between the Appellant and the Intervener in light of the first decision of the Board of Appeal. Based on this re-examination, the Agency found that the Intervener's efforts in the negotiations '*outweigh[ed] the efforts of the [Appellant]*', and that the Appellant had not '*exhausted the possibilities in the negotiations to find a fair, transparent and non-discriminatory agreement*'.

13. Consequently, the Agency held that the Appellant had not made every effort to reach an agreement pursuant to the second subparagraph of Article 63(3), and rejected the Appellant's application for permission to refer.

Procedure before the Board of Appeal

14. On 6 May 2019, the Appellant filed this appeal.
15. On 10 July 2019, the Agency filed its Defence.
16. On 30 September 2019, BASF Agro BV was granted leave to intervene in these proceedings in support of the Agency.
17. On 21 November 2019, the Appellant submitted observations on the Defence.
18. On 20 December 2019, the Intervener filed its statement in intervention.
19. On 17 January 2020, the Agency submitted observations on the Appellant's observations on the Defence.
20. On 10 February 2020, the Agency submitted observations on the statement in intervention. The Appellant did not submit observations on the statement in intervention.
21. On 30 March 2020, Katrin Schütte, alternate member of the Board of Appeal, was designated to replace Andrew Fasey in this case, in accordance with the first subparagraph of Article 3(2) 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 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.
23. On 3 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 Agency, the Appellant and the Intervener made oral submissions and answered questions from the Board of Appeal.

Events posterior to the filing of the appeal

24. On 30 April 2020, the Appellant and the Intervener concluded a '*data access agreement*' for alpha-cypermethrin. Pursuant to this agreement, the Intervener agreed to grant the Appellant permission to refer to the studies upon receipt of an agreed amount in '*compensation*'.
25. On 11 May 2020, following a measure of instruction adopted by the Board of Appeal pursuant to Article 15 of the Rules of Procedure, the Appellant submitted a copy of the '*data access agreement*' concluded with the Intervener.

Forms of order sought

26. The Appellant requests the Board of Appeal to:
    - declare the appeal admissible and well-founded,
    - annul the Contested Decision,
    - grant the Appellant permission to refer to the studies,
    - order the refund of the appeal fee, and

- order the Agency to bear the costs of these proceedings.

27. The Agency, supported by the Intervener, requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

1. Need to adjudicate on this case

28. The Agency and the Intervener argue that, since the Appellant and the Intervener have concluded a '*data access agreement*' on 30 April 2020 (see paragraph 24 above), the Appellant retains no interest in pursuing this appeal.

29. An appellant's legal interest in bringing an appeal must exist on the day on which the appeal is brought, failing which the appeal will be inadmissible. Furthermore, the appellant's interest in obtaining satisfaction must continue until the final decision, failing which there will be no need to adjudicate (see, to this effect and by analogy, judgments of 16 December 1963, *Forges de Clabecq* v *High Authority*, C-14/63, EU:C:1963:60, at p. 371, and of 7 June 2007, *Wunenburger* v *Commission*, C-362/05 P, EU:C:2007:322, paragraph 42).

30. An appellant may retain an interest in pursuing a case in order to prevent an alleged unlawfulness affecting the contested decision from recurring in the future (see, to that effect and by analogy, *Wunenburger* v *Commission*, cited in the previous paragraph, paragraph 50 of the judgment, and judgments of 24 June 1986, *AKZO Chemie* v *Commission*, C-53/85, EU:C:1986:256, paragraph 21, and of 26 April 1988, *Apesco* v *Commission*, C-207/86, EU:C:1988:200, paragraph 16; see also judgment of 4 September 2018, *ClientEarth* v *Commission,* C-57/16 P, EU:C:2018:660, paragraph 48).

31. This interest in pursuing a case presupposes that the alleged unlawfulness is liable to recur in the future independently of the circumstances of the case which gave rise to the appeal (see, by analogy, *Wunenberger* v *Commission*, cited in paragraph 29 above, paragraph 52 of the judgment, and judgment of 27 September 2018, *Mellifera* v *Commission*, T-12/17, EU:T:2018:616, paragraph 28).

32. In the present case, some of the instances of unlawfulness alleged by the Appellant are liable to recur in the future independently of the circumstances of the present case. This is the case, in particular, as regards the Appellant's allegation of a breach of the right to be heard.

33. It follows that the Appellant retains an interest in pursuing this case. Accordingly, there is a need to adjudicate on the present appeal.

2. Substance

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

- exceeded its competence by re-assessing elements of the case which had already been ruled on in the first decision of the Board of Appeal (first plea),
- misused its powers by failing to grant the Appellant's application for permission to refer following the first decision of the Board of Appeal (second plea),
- breached Article 63(3) by re-examining the facts of the case rather than granting the Appellant's application for permission to refer following the first decision of the Board of Appeal (third plea),

- 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 comply with the reasoning in 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 (first part of the fifth plea),
- breached the Appellant's rights of defence by failing to wait for the expiry of the time-limit for an appeal under Article 77 before examining the Appellant's application for inclusion in the list established under Article 95 (second part of the fifth plea),
- committed an error in its assessment of the facts of the case as regards the scope of the Appellant's application for permission to refer (sixth plea),
- committed several errors in its assessment of the facts of the case as regards the Appellant's and the Intervener's efforts in the negotiations (seventh plea).

35. The first part of the fifth plea will be examined first.

Arguments of the parties

36. By the first part of the fifth plea, 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.

37. The Agency argues that the factual basis of the Contested Decision consists exclusively of the evidence provided by the Appellant and the Intervener 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.

38. Furthermore, the Agency argues that, if the Board of Appeal annuls a decision and remits a case to the Agency for re-examination, the Agency may take up the procedure at the point at which the illegality identified by the Board of Appeal occurred. In the present case, the Board of Appeal held that the Agency made an error in its assessment of the facts of the case, as they emerged from the documents submitted by the Appellant and the Intervener after the filing of the Appellant's application for permission to refer. The Agency was, therefore, entitled to repeat that examination without any further procedural steps and, in particular, without hearing the Appellant.

Findings of the Board of Appeal

39. 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).

40. 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).

41. 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).

42. In the present case, the Contested Decision significantly affected the interests of the Appellant by rejecting its application for permission to refer to the studies.

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

44. 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.

45. 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).

46. As the Appellant was given the possibility to do so (see paragraph 5 above), its right to be heard was respected in this regard.

47. 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.

48. In the Contested Decision, the Agency stated that *'[t]he present decision contains the re-examination [of the case], which takes the decision of the Board of Appeal into account'*. In its submissions in the present proceedings, the Agency stated that *'[c]alled upon to re-examine the dispute, and to again review all the efforts made by both parties in the negotiations, [the Agency] corrected the assessment of the negotiations of the parties in line with the BoA decision, and carefully balanced these efforts in the overall negotiations*'. 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.

49. The Agency had certain exchanges with the Appellant before the adoption of the Contested Decision (see paragraph 9 above). During the course of these exchanges, the Appellant stated that it read the first decision of the Board of Appeal as requiring the Agency to grant the Appellant permission to refer to the studies, subject to the Appellant providing a list of the studies. The Agency acknowledged receipt of the Appellant's communications, and stated that it was re-examining the facts of the case and would adopt a decision in due course.

50. However, observance of the right to be heard presupposes not only that the concerned person has the opportunity to put forward its arguments, but also that the administration takes those arguments into account, carefully and impartially, in coming to its decision (see, to this effect, judgment of 18 July 2013, *Commission and Others* v *Kadi*, C-584/10 P, EU:C:2013:518, paragraph 114).

51. In the present case, there is no indication that the Appellant's arguments, sent to the Agency following the first decision of the Board of Appeal, were taken into account in the Agency's assessment. Indeed, the Agency confirmed, in its submissions in the present proceedings, that it did not take those arguments into account because they post-dated the moment of filing of the application for permission to refer.

52. It follows that the Agency breached the Appellant's right to be heard as regards the first decision of the Board of Appeal.

53. 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).

54. 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 grant its application for permission to refer.

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

56. It follows that the first part of the fifth plea must be upheld, and the Contested Decision annulled.

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

3. Result

58. 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.

59. The case-file is sufficiently complete to allow the Board of Appeal to adopt its own decision on the application for permission to refer filed by the Appellant on 27 February 2016. Furthermore, the Appellant was heard in these appeal proceedings.

60. The Board of Appeal consequently considers it appropriate to replace the Contested Decision with its own decision.

61. When replacing a contested decision with its own decision, the Board of Appeal must take into account all the relevant facts and circumstances of the case as they stand at the moment of the adoption of the decision of the Board of Appeal.

62. Article 63(1) to (3) provide (emphasis added):

> `*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.*

2. *Where such agreement is reached, the data owner shall make all the scientific and technical data related to the tests and studies concerned available to the prospective applicant or shall give the prospective applicant permission to refer to the data owner's tests or studies when submitting applications under this Regulation.*

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. […]'

63. It is clear from these provisions that the Agency and the Board of Appeal may grant a prospective applicant permission to refer only where the prospective applicant has not reached an agreement with the data owner on the sharing of data and costs.

64. In the present case, the Appellant has reached an agreement with the Intervener on the sharing of data and costs on 30 April 2020 (see paragraph 24 above). Pursuant to the provisions of that agreement, the Appellant has a right to refer to the Intervener's studies provided that it pays an agreed amount in '*compensation*'.

65. As a consequence, in the present case the Board of Appeal can no longer grant the Appellant permission to refer to the studies under Article 63(3). By concluding the '*data access agreement*' with the Intervener in accordance with Article 63(2), the Appellant has precluded itself from obtaining permission to refer in accordance with Article 63(3).

66. The Appellant's application for permission to refer, submitted to the Agency on 27 February 2016, must therefore be rejected.

Application for the reimbursement of costs

67. The Appellant requests the reimbursement of the costs incurred for these proceedings. In accordance with Article 17a of the Rules of Procedure, the parties shall bear their own costs. The application for the reimbursement of costs must therefore be rejected.

Refund of the appeal fee

68. 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 the BPR (OJ L 167, 19.6.2013, p. 17), 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 the Appellant on 27 February 2016.**
3. **Rejects the application for the reimbursement of the costs of these proceedings.**
4. **Decides that the appeal fee is refunded.**

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal