

**DECISION OF THE BOARD OF APPEAL
OF THE EUROPEAN CHEMICALS AGENCY**

21 May 2024

(Biocidal Products Regulation – Data-sharing – Every effort to reach an agreement on fair, transparent and non-discriminatory terms – Allegation of a breach of Article 95 – Error of assessment – Right to property)

Case number	A-011-2022
Language of the case	English
Appellant	Biofa GmbH, Germany Represented by Christian Stallberg and Julia Eickbusch NOVACOS Rechtsanwälte Partnerschaft mbH, Germany
Intervener	Armosa Tech SA, Belgium Represented by Koen van Maldegem, Maud Grunchard and Manon Ombredane Fieldfisher (Belgium) LLP, Belgium
Contested Decision	DSH-63-3-D-0028-2022 of 22 October 2022, adopted by the European Chemicals Agency pursuant to Article 63(3) of the Biocidal Products Regulation

THE BOARD OF APPEAL

composed of Antoine Buchet (Chairman and Rapporteur), Nikolaos Georgiadis (Technically Qualified Member), and Marijke Schurmans (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

Decision

1. Background to the dispute

1. This appeal concerns the sharing of data and costs relating to the substance silicium dioxide/kieselguhr (the **Substance**)¹ under the Biocidal Products Regulation (**BPR**)².
2. The Appellant supported the inclusion of the Substance in the work programme for the systematic examination of all existing active substances (the **Review Programme**) established under Article 16(2) of the Biocidal Products Directive (**BPD**)³.
3. Following the repeal of the BPD by the BPR, the Substance remains included in the Review Programme.⁴
4. Under the transitional regime established by Article 89 of the BPR, the Appellant was included in the list of authorised suppliers of active substances under Article 95 of the BPR (the **Article 95 list**). The Appellant is currently the only authorised supplier of the Substance included in that list.
5. On 10 May 2017, the European Commission approved the Substance as an existing active substance for use in biocidal products of product-type 18 (insecticides, acaricides and products to control other arthropods).⁵
6. On 1 March 2021, the Intervener contacted the Appellant in accordance with the fourth subparagraph of Article 62(2) of the BPR, with a view to sharing data and costs in order to seek inclusion in the Article 95 list.
7. Between 1 March 2021 and 16 August 2022, the Appellant and the Intervener had written exchanges in that regard. In addition, representatives of the Appellant and the Intervener met in person on 14 March 2022 to discuss matters pertaining to the Substance. Those exchanges concerned mainly two issues.
8. First, between March 2021 and May 2022, the Appellant and the Intervener negotiated on the data to which the Intervener should be granted permission to refer, the amount to be paid in exchange for the permission to refer, and the geographic scope of that permission. In particular, on 19 May 2022, the Intervener agreed to the Appellant's proposed conditions for sharing data and costs by signing a draft agreement which the Appellant had previously prepared.
9. Second, between March and August 2022, the Appellant and the Intervener discussed the existence of a potential infringement of Article 95 of the BPR on the part of a company which had been acquired by the Intervener, and the consequences of such a potential infringement.

¹ CAS No 61790-53-2.

² 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).

³ Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1).

⁴ 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).

⁵ Commission Implementing Regulation (EU) 2017/794 approving silicon dioxide Kieselguhr as an existing active substance for use in biocidal products of product-type 18 (OJ L 120, 11.5.2017, p. 7).

10. In the course of the discussions on this second issue, the Appellant made two consecutive requests to the Intervener. Firstly, the Appellant asked the Intervener to cease the potential infringement and remedy it by recalling certain products from the market. Subsequently, the Appellant asked the Intervener to compensate it for the damages allegedly caused by the potential infringement of Article 95 of the BPR.
11. On 16 August 2022, after having concluded that the discussions to reach an agreement with the Appellant under Article 63(1) of the BPR had failed, the Intervener submitted to the Agency an application for permission to refer under Article 63(3) of the BPR.
12. On 28 October 2022, the Agency adopted the Contested Decision. By the Contested Decision, the Agency granted the Intervener permission to refer to the data required for inclusion in the Article 95 list, subject to the payment to the Appellant of a share of the costs by 12 January 2023.

2. Procedure before the Board of Appeal

13. On 16 December 2022, the Appellant filed its appeal.
14. On 10 March 2023, the Agency submitted its Defence.
15. On 13 March 2023, the Intervener was granted leave to intervene in these proceedings in support of the Agency.
16. On 13 April 2023, the Appellant submitted its observations on the Defence.
17. On 2 May 2023, the Intervener submitted its statement in intervention.
18. On 22 May 2023, the Agency submitted its observations on the Appellant's observations on the Defence.
19. On 5 June 2023, the Agency and the Appellant submitted their respective observations on the statement in intervention.
20. On 9 April 2024, a hearing was held on the Appellant's request. The hearing was held by videoconference in accordance with Article 13(7) of the Rules of Procedure⁶. At the hearing, the Appellant, the Agency and the Intervener made oral submissions and responded to questions from the Board of Appeal.

3. Form of order sought

21. The Appellant requests the Board of Appeal to:
 - annul the Contested Decision,
 - confirm that the effects of the Contested Decision are suspended,
 - and order the refund of the appeal fee, and
 - take such other or further measures as justice may require.
22. The Agency, supported by the Intervener, requests the Board of Appeal to dismiss the appeal as unfounded.

⁶ 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).

4. Assessment of the case

4.1. Arguments of the Parties and the Intervener

23. By its first plea, the Appellant argues that the Agency breached its fundamental right to the protection of property, as enshrined in Article 17 of the Charter of Fundamental Rights of the European Union (the **Charter**). According to the Appellant, granting permission to refer constitutes an interference with that right on the part of the Agency. The Appellant argues that in the present case this interference was not justified by Article 63(3) of the BPR because the Intervener was not acting in good faith during the negotiations and allegedly caused damage to the Appellant by failing to comply, or to cause a company which it acquired to comply, with Article 95 of the BPR.
24. By its second plea, the Appellant argues that the Agency neglected the principle of good faith in its assessment of the case. According to the Appellant, the Agency failed to take into account the potential infringement of Article 95 of the BPR.
25. By its third plea, the Appellant argues that the Agency committed the following two errors in its assessment of the facts of the case.
26. First, according to the Appellant, the Contested Decision is incorrect insofar as it states that the Appellant and the Intervener had agreed on the terms for sharing data and costs and that the Appellant unilaterally imposed an additional condition, namely the payment of alleged damages following the potential infringement of Article 95 of the BPR.
27. Second, according to the Appellant, the Appellant and the Intervener had orally agreed at a meeting on 14 March 2022 that the sharing of data and costs would be conditional to the compensation by the Intervener for the alleged damages arising from the potential infringement of Article 95 of the BPR.
28. At the hearing, the Appellant added that the Agency's error of assessment also constitutes a breach of the principle of good administration. The Appellant made clear, however, that this argument did not constitute a new plea in law but was merely a restatement of its other arguments under the third plea.
29. By its fourth plea, the Appellant argues that the Agency breached Article 63(3) of the BPR by failing to assess the efforts of the Appellant and the Intervener in a balanced manner. According to the Appellant, the Agency failed to take into account the fact that the Intervener had allegedly failed to comply, or to cause a company which it acquired to comply, with Article 95 of the BPR and failed to compensate the Appellant for the ensuing damages.
30. By the fifth plea, the Appellant argues that the Agency breached the principle of contractual freedom by granting the Intervener permission to refer. According to the Appellant, the Agency failed to take into account the oral agreement concluded on 14 March 2022 to the effect that the Appellant should be compensated for its loss of profit as a condition for the sharing of data and costs.
31. The Agency, supported by the Intervener, disputes the Appellant's arguments.

4.2. Findings of the Board of Appeal

4.2.1. Relevant legal framework and role of the Agency

32. Articles 59(1) and 60 of the BPR establish a protection period for data submitted for the purpose of the BPD and the BPR. Following those provisions, the competent authorities or the Agency which hold such data cannot use them for the benefit of a subsequent applicant unless the subsequent applicant obtains permission to refer to those data from the person benefiting from that protection period (**data owner**), or until the relevant time limit for data protection has expired.
33. Under Articles 62 and 63 of the BPR, a prospective applicant who requests data covered by the protection period may obtain the permission to refer to such data either by an agreement concluded with the data owner, or, where no agreement is reached, by a decision of the Agency.
34. Article 63(1) of the BPR provides that the prospective applicant and the data owner must make every effort to reach an agreement on the sharing of the results of the tests and studies requested by the prospective applicant.
35. Article 63(3) of the BPR further provides that where the prospective applicant seeks permission to refer to the data at issue from the Agency, the Agency must grant the prospective applicant permission to refer if (i) every effort has been made to reach an agreement, and (ii) the prospective applicant has paid the data owner a share of the cost of the data.
36. It follows from a combined reading of Articles 63(3) and (4) of the BPR that the first of the conditions referred to in the previous paragraph is fulfilled if every effort has been made to reach an agreement on the sharing of data and costs on transparent, fair and non-discriminatory terms.
37. The Agency's assessment of that condition must be balanced in the sense that it must be carried out on the basis of the negotiations as a whole, taking into account the actions of both parties to the negotiations and all other relevant circumstances.⁷
38. The Appellant's pleas will be examined in the light of those considerations.

4.2.2. Scope of the Agency's assessment under Article 63(3) of the BPR (fourth plea)

39. By its fourth plea, the Appellant argues that the Agency failed to take into account the fact that the Intervener had allegedly failed to comply, or to cause a company which it acquired to comply, with Article 95 of the BPR and failed to compensate the Appellant for the ensuing damages.⁸
40. It is not disputed by the Parties and the Intervener that, at the time of filing of the application for permission to refer, there was no substantive disagreement between the Appellant and the Intervener on the terms for sharing data and costs. The Appellant and the Intervener failed to reach an agreement because the Appellant and the Intervener have opposite views on making the conclusion of the agreement on sharing data and costs conditional on the prior compensation of the damages allegedly caused by the potential infringement of Article 95 of the BPR.

⁷ Decisions of the Board of Appeal of 23 August 2016, *Thor*, A-005-2015, paragraph 65, of 15 April 2019, *REACH & Colours and REACH & Colours Italia*, A-010-2017, paragraph 86, and of 23 July 2020, *Tecnofluid*, A-014-2018 to A-021-2018, paragraphs 91 to 93.

⁸ Paragraph 29 above.

41. Article 63 of the BPR does not require a prospective applicant to compensate such damages. It follows from the second sentence of Article 63(4) of the BPR, and from the repeated use of the term 'cost' in the legal text, that, to obtain permission to refer to protected data, a prospective applicant is not required by law to pay for anything other than a share of the actual cost of generating, gathering, and submitting the data to which it needs to refer.
42. Alleged damages are not a cost in that sense. Therefore, the compensation for alleged damages does not fall within the scope of the efforts to be made by the prospective applicant and the data owner within the meaning of Article 63(1) and (4) of the BPR. It is consequently also not part of the Agency's assessment of those efforts under Article 63(3) of the BPR. Awarding such compensation falls within the competence of the relevant national bodies, such as national courts.
43. The fourth plea must consequently be rejected.

4.2.3. Absence of an agreement on additional conditions (second part of the third plea, and fifth plea)

44. By the second part of the third plea, and by the fifth plea, the Appellant argues that the Agency failed to take into account the fact that the Appellant and the Intervener had agreed to make the sharing of data and costs conditional on the prior compensation of the damages allegedly caused by the potential infringement of Article 95 of the BPR.⁹
45. A data owner and a prospective applicant may conclude an agreement to make the sharing of data and costs subject to the fulfilment of additional conditions, beyond the scope of the efforts defined under Article 63(1) and (4) of the BPR.¹⁰ The compensation of alleged damages might be such a condition.
46. However, it is not established in the present case that the Appellant and the Intervener had agreed to make the sharing of data and costs conditional on the prior compensation of the damages allegedly caused by the potential infringement of Article 95 of the BPR.
47. It is not contested that representatives of the Appellant and the Intervener met in person on 14 March 2022 to discuss matters pertaining to the Substance. However, the written evidence presented in these proceedings and the statements of the parties in the hearing do not show that the Appellant and the Intervener concluded any contractual agreement. The email exchanges following the meeting of 14 March 2022 show, at best, that the Intervener was trying to be constructive on the issue of the potential infringement of Article 95 of the BPR in order to make progress on the sharing of data and costs. The two issues were seen by the Intervener as separate issues to be discussed in parallel.
48. In addition, and in any event, even assuming that an oral agreement had been concluded at the meeting of 14 March 2022, the Appellant confirmed in the hearing that the compensation of damages allegedly caused by the potential infringement of Article 95 of the BPR was not part of that alleged oral agreement. The oral agreement allegedly concluded at the meeting of 14 March 2022 only concerned the withdrawal of certain products from the market and their replacement. This is also borne out by the email exchanges following that meeting, which show that the compensation of alleged damages was raised by the Appellant at a later stage

⁹ Paragraphs 27 and 30 above.

¹⁰ Decisions of the Board of Appeal of 23 August 2016, *Thor*, paragraph 74, and of 7 March 2018, *Solvay Solutions UK*, A-014-2016, paragraphs 54 and 55.

and was never agreed by the Intervener.

49. In the absence of any agreement between the Appellant and the Intervener to make an agreement on the sharing of data and costs conditional on the prior compensation of the alleged damages caused by the potential infringement of Article 95 of the BPR, the Agency did not make an error of assessment in concluding that such compensation was a condition unilaterally imposed by the Appellant. The Intervener was not required to make every effort as regards this additional condition, which is not provided by law and was not agreed by the Intervener.
50. The second part of the third plea, and the fifth plea, must consequently be rejected.

4.2.4. Interim conclusion and remaining pleas (first and second pleas, and first part of the third plea)

51. It follows from the reasons set out in Sections 4.2.2. and 4.2.3. above that the Agency did not commit an error in concluding that the Intervener made every effort to reach an agreement on the sharing of data and costs on transparent, fair and non-discriminatory terms and that, consequently, the first condition in Article 63(3) of the BPR is fulfilled.
52. That conclusion is not called into question by the Appellant's remaining pleas.
53. First, contrary to the argument made by the Appellant under the first part of its third plea¹¹, the Contested Decision does not state that the Appellant and the Intervener concluded an agreement on the sharing of data and costs. The Contested Decision merely states that at the time of filing the application for permission to refer there was no substantive disagreement between the Appellant and the Intervener as regards the terms for sharing data and costs, and that the negotiations failed for a different reason. The first part of the third plea must consequently be rejected.
54. Second, contrary to the argument made by the Appellant under its second plea¹², the Agency did not neglect the principle of good faith in its assessment of this case.
55. In the first place, the Appellant itself did not argue that the Intervener acted in bad faith in the discussions concerning the sharing of data and costs, as there was no substantive disagreement in this respect.¹³
56. In the second place, the Agency was not required to determine whether the Intervener acted in good or bad faith in the discussions concerning the compensation for alleged damages arising from the potential infringement of Article 95 of the BPR, as this issue did not fall within the scope of the efforts the Agency was required to assess.¹⁴
57. The second plea must consequently be rejected.
58. Third, contrary to the argument made by the Appellant under its first plea¹⁵, the Agency did not infringe the fundamental right to property guaranteed by Article 17 of the Charter.

¹¹ Paragraph 26 above.

¹² Paragraph 24 above.

¹³ Paragraph 40 above.

¹⁴ Paragraph 41 above.

¹⁵ Paragraph 23 above.

59. It is true that the data protection period established under Articles 59(1) and 60 BPR falls within the scope of the fundamental right to property guaranteed by Article 17 of the Charter.¹⁶
60. However, Article 63(3) of the BPR provides a legal basis for the Agency to interfere in that right, and the conformity of that provision with the Charter is not challenged by the Appellant.
61. As stated above, the Agency did not commit an error in concluding that the Intervener made every effort to reach an agreement, so that the first condition for granting permission to refer under Article 63(3) of the BPR is fulfilled.
62. Furthermore, according to its operative part, the Contested Decision is conditional on the Intervener paying the Appellant a share of the cost of the data. It is not contested that that payment has been made, so that second condition is also respected.
63. The interference in the fundamental right to property guaranteed by Article 17 of the Charter is therefore justified.
64. The first plea must consequently also be rejected.

4.3. Result

65. It follows from the reasons set out above that all the pleas raised by the Appellant must be rejected. The appeal must consequently be dismissed.

5. Effects of the Contested Decision

66. As part of the order that the Appellant sought in lodging the present appeal, the Appellant requests the Board of Appeal to confirm the suspension of the Contested Decision.¹⁷
67. The suspensive effect of an appeal before the Board of Appeal is provided by law, under Article 77(2) of the BPR. The request of the Appellant to confirm the suspension of the Contested Decision must therefore be rejected as devoid of purpose.

6. Refund of the appeal fee

68. Under Article 4(4) of the Fee Regulation¹⁸ the appeal fee must be refunded if the appeal is decided in favour of an appellant. As the appeal is dismissed, the appeal fee is not refunded.

¹⁶ See judgment of 22 January 2013, *Sky Österreich*, C-283/11, EU:C:2013:28, paragraph 34.

¹⁷ Paragraph 21 above.

¹⁸ 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).

On those grounds,

THE BOARD OF APPEAL

hereby:

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

Antoine BUCHET
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal