[redacted]

20 November 2019

The Claimant

[redacted]

Represented by

[redacted]

Sent via encrypted email and registered mail

Copy to:
The Other Party

[redacted]

Represented by

[redacted]

Sent via encrypted email and registered mail

Decision number: [redacted]
Dispute reference number: [redacted]
Name of the substance: [redacted]

[redacted]

DECISION ON A DATA SHARING DISPUTE

a) Decision

Based on Article 63(3) of the Biocidal Products Regulation (EU) No 528/2012 ('BPR'),

ECHA does not grant the Claimant permission to refer to the data requested from the Other Party.

The reasons of this decision are set out in Annex I. Advice and further observations are provided in Annex II.

b) Procedural history

On 25 September 2019, the Claimant submitted to ECHA a claim concerning the failure to reach an agreement on data sharing with the Other Party. It indicated that the dispute referred to a listing pursuant to Article 95 of the BPR for the substance [redacted] and that it had not submitted evidence of all the negotiations. On 2 October 2019, ECHA requested a clarification with regard to the substance at issue and the intention of Article 95 inclusion, as well as to the evidence. On the same day, the Claimant produced additional documentary evidence of the negotiations and clarified that the dispute was not related to an Article 95 listing. It further noted it was seeking access to data on [redacted] to submit a dossier for application for approval of the substance [redacted].

To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, on 8 October 2019 ECHA requested the Other Party to provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 22 October 2019.

c) Appeal

This decision can be appealed to the Board of Appeal of ECHA within three months of its notification. An appeal, together with the grounds thereof, shall be submitted to the Board of Appeal of ECHA in writing. An appeal has suspensive effect and is subject to a fee. Further details are described under http://echa.europa.eu/web/guest/regulations/appeals.

Yours sincerely,

Minna Heikkilä[1]

Head of Legal Affairs

[1] As this is an electronic document, it is not physically signed. This decision has been approved according to the ECHA's internal decision-approval process.

[redacted]

Annex I: REASONS FOR THE DECISION

Legal background

Data sharing under the BPR

1. Article 63(1) of the BPR requires prospective applicant(s) and data owner(s) to '*make every effort to reach an agreement on the sharing of the results of the tests or studies requested by the prospective applicant*'. If no agreement can be reached, Article 63(3) of the BPR mandates ECHA, on request, to '*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*'.

2. Accordingly, if ECHA finds that the prospective applicant complied with its obligation to make every effort to reach a fair, transparent and non-discriminatory agreement and paid the data owner a share of the costs incurred, the Agency shall grant the prospective applicant the permission to refer to the requested data.

3. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the documentary evidence on the negotiations as provided by the parties, to establish whether the parties made every effort to reach an agreement on sharing the studies and their related costs in fair, transparent and non-discriminatory way.

Active substance approval and Article 95 listing

4. Article 95 of the BPR establishes transitional measures concerning access to active substance dossiers, namely by laying down a list of all relevant substances and corresponding data owners. The underlying objective of Article 95 of the BPR is best described as cost sharing: to ensure a level playing field, on which all actors that benefit from an application contribute to its costs, affected parties are required to have access to a complete substance dossier, which is demonstrated with a letter of access.

5. Conversely, active substance approval is a qualitative assessment, the objective of which is the protection of human health and the environment. It is the first in a two-step process involving biocidal products – all biocidal products to be placed on the market or used require a product authorisation, and an authorisation can only be obtained after the active substance(s) contained in that biocidal product has been approved. Applicants for approval of an active substance must provide a complete dossier, and not merely a letter of access.

6. In a data sharing dispute for an Article 95 submission, the right to refer granted by ECHA can potentially cover all the data listed in Article 95(3) of the BPR, assuming this relates to an existing active substance in the Review Programme. By contrast, the right to refer granted by ECHA pursuant to Article 63 of the BPR can only cover vertebrate animal studies in the case of dispute for an application for active substance approval.

[redacted]

Factual background

7. On 1 February 2016, the Parties signed a so-called [redacted] Task Force Deed of Adherence' ('DoA'). The DoA states that, subject to payment for access to data, the Claimant would be given a Letter of Access to enable it '*to obtain an Article 95 listing*' (section 2.2 of the DoA). Under section 3, 'Payments for data', Clause 3.2 of the DoA inter alia addresses different products of the Claimant [redacted].[2]

8. The remaining evidence submitted by the parties attests to their exchanges since January 2018. At that point in time, the Claimant informed the Other Party of its intention, subsequent to ECHA's redefinition of [redacted][3], to '*take over the orphan* [redacted] *title*', renamed [redacted]. It asked the Other Party for a '*full list of the studies and their endpoints*'. Moreover, it noted that some of its customers '*have asked about the process to gain LoA for the new second title of* [redacted]'.[4] The Other Party replied by sending the '*full list of data supporting the* [redacted] *dossier'.* With regard to the '*letter of access [the Claimant] can provide to customers seeking to register* [redacted] *products*', the Other Party stated it had '*updated the LoA currently in place*'.[5] It explicitly mentioned that '*under the DoA agreement*', the Claimant '*can rely on this data only for the purposes of continued ECHA listing or third party registrations in Europe, there is no direct access permitted*'.[6] When the Claimant asked for details on the [redacted] dossier update,[7] the Other Party noted the request referred to '*an updated LoA to support [the Claimant's] Art 95 listing*'.[8]

9. On 14 February 2019, the Claimant stated it needed to obtain access to data from the Other Party for [redacted], when it was preparing a table of endpoints needed for an active substance application for [redacted] and asked the Other Party to complete the list. It specified that the data was required to prepare '*the active dossier submission*'.[9] The Other Party reacted by stating that ECHA had '*carved out* [redacted] *as a separate* [redacted] *active substance*' and, in its understanding, the DoA allowed the Claimant one Letter of Access '*to support one* [redacted] *active substance*'.[10]

10. The Claimant sustained that the DoA did not restrict its '*right to use the shared data for further submissions (under* [redacted]*)*', since, at the time the agreement had been written, there was '*just one* [redacted] *dossier title*', for which its access to the data was envisaged. However, that [redacted] title '*has now been "split" to create* [redacted] *separate titles for* [redacted]', hence its rights '*to use the data for any of these* [redacted] *is not restricted in any way*'.[11] The Claimant added that, as '*subsequent title changes and redefinitions that followed are all derivatives*' of the initial [redacted] title, any other '*titles that are created from*' [redacted]

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[2] Clause 3.2 of the DoA reads as follows: '*Should [Technical Equivalence] not be confirmed (…) [the Claimant] shall pay any remaining fees due (…). Subject to a) such payments being made and b) to [the Claimant] undertaking to cancel with ECHA the ECHA Listing which was based on the Letter of Access #1 and/or #2 when [the Claimant] obtains an alternative listing with ECHA (or allowing the Task Force to take such action as it may deem reasonable to cancel the original ECHA listing), the Originating Members shall issue a letter of access to Sections A and C of the Dossier to support [the Claimant]'s own* [redacted] *dossier submission* [redacted]*.*'

[3] The redefinition occurred on 17 August 2016.

[4] Claimant; 25 January 2018.

[5] Other Party; 21/02/2018.

[6] Other Party; 17/04/2018.

[7] Claimant; 06/11/2018.

[8] Other Party; 09/11/2018.

[9] Claimant; 14/02/2019.

[10] Other Party; 21/02/2019.

[11] Claimant; 22/02/2019.

[redacted]

should be covered by the DoA.[12] In the Claimant's view, no clauses of the DoA stated any exclusion or restriction in granting it the '*simple set of test endpoints*' required.[13]

11. The Other Party, however, argued that the DoA gave the Claimant '*the right to support one active substance under the BPR*'.[14] According to the Other Party, [redacted] had been redefined to [redacted] and the Claimant had received both Letters of Access the DoA provided for in order to support the ECHA listing of [redacted]. The Other Party further noted that the DoA refers to a letter of access rather than providing endpoint studies.[15]

12. In April 2019, the Claimant noted that '*data sharing within the BPR is covered under Article 63(1)*' of that Regulation, and that, if necessary, it would launch a data sharing dispute before ECHA.[16] The Other Party reacted by stating that, if the Claimant's intention was to submit a request '*for the purpose of acquiring the right to rely on vertebrate and invertebrate data*' to support [redacted] as an active substance, it would comply with its obligations.[17] The Other Party added that such access would be '*under Art.62 of the BPR*' rather than under the DoA, and that whatever the Claimant '*may be eventually entitled to under the Art 62 requirements will clearly not, on any analysis, be sufficient to prepare [its]* [redacted] *dossier*', since it '*will still need access to study details*'. The Other Party suggested that the parties '*engage in structured negotiations (…) to seek to agree a price for [the Claimant]'s access to all of the data and details thereof that [it] will need for [its]* [redacted] *dossier – whether or not it falls within the scope of what [the Claimant] may be entitled to under Ar.62 BPR*'.[18]

13. On 24 May 2019, the Claimant submitted an inquiry to share data available for [redacted] to support their active substance dossier for [redacted] under Article 62(2) of the BPR to ECHA. This was notified by ECHA to the Other Party on 3 June 2019. The latter informed the Claimant it would start putting together a '*list of eligible data and the relevant costs of access*'[19] and advised the Claimant to proceed with the formal request, specifying the purpose.[20] The Claimant did so, asking the Other Party '*to complete a table with the endpoint data for the relevant studies*'.[21] The Other Party sent a '*valuation of the vertebrate data*'[22] with a cost breakdown featuring study cost, a list of the studies on vertebrate animals and their cost as well as other administrative cost entries and correcting factors[23]. The Claimant dismissed these as containing '*additional charges added to inflate*' the costs, rendering them unrealistic and unreasonable. The Claimant asked, '*given that [it had] already paid a full equal share of the costs of generating this data*', which charge would be appropriate for the completion of the list of endpoints sent.[24]

14. The Other Party replied that the Claimant had '*purchased the right to rely on the* [redacted] *data set for purposes of Art 95 listing for* [redacted]', a right it would continue to benefit from by remaining on the market as an active substance supplier. However, in its

[12] Claimant; 28/02/2019.
[13] Claimant; 14/03/2019.
[14] Other Party; e-mails of 26/02/2019, 12/03/2019.
[15] Other Party; 22/03/2019.
[16] Claimant; 05/04/2019.
[17] Other Party; 16/04/2019.
[18] Other Party; e-mails of 18/04/2019.
[19] Other Party; 03/06/2019.
[20] Other Party; e-mails of 03/06/2019, 07/06/2019.
[21] Claimant; 06/06/2019.
[22] Other Party; 13/06/2019.
[23] I.e. study monitoring, risk premium, inflation, reduction for [redacted] use only and reduction for reliability index.
[24] Claimant; 14/06/2019.

view, this right did not extend '*to a separate* [redacted] *substance*'. With regard to the costs presented, the Other Party noted that '*the detailed cost listings were derived from the Fleischer lists or actual study prices*', and asked the Claimant to explain why it considered the costs unjustified so that the parties could '*move towards an agreement*'.[25] The Claimant replied on 2 July 2019. It referred to the last two entries of the Other Party's cost breakdown, i.e. the 'Article 62 Handling Costs' and the 'Administrative Costs'. It suggested to reduce the former by a third, because it had already paid a third of the costs. It suggested to reduce the latter to a third. The Claimant also asked the Other Party to include non-vertebrate data.[26] The Other Party replied that it did not wish to share non-vertebrate data and asked the Claimant to confirm that it accepted the other cost items. It clarified that payments made for access to data for [redacted] were unrelated.[27] The parties continued to disagree on which costs should be paid.[28]

15. On 13 August 2019, the Claimant sent a '*letter before action*', where it offered to make a '*one off payment of* [redacted]' for access to the full dossier requested, including non-vertebrate data. In this regard, the Claimant re-stated its view that it had already paid '*for a full share of dossier access costs*' and accused the Other Party of '*double charging*' and trying to create barriers for the Claimant's access to the market, in view of the deadline ECHA established for its dossier submission (1 December 2019). The Claimant referred namely to section 3.2 of the DoA, stating that

> '*Article 3.2 on payments for data provides,* "…when [the Claimant] obtains an alternative listing with ECHA…, the Originating Member shall issue a letter of access to Sections A and C of the Dossier to support [the Claimant]'s own [redacted] and/or [redacted] dossier submission under [redacted] of the BPR." *This is explicit recognition that both* [redacted] *and* [redacted] *may be supported under the terms of the data access rights granted to [the Claimant].*'[29]

16. The Other Party again sent a cost breakdown for access to the [redacted] data, offering to negotiate '*access to a supplemental LoA not envisaged by the Deed*'. Alternatively, it suggested the Claimant could '*withdraw its reliance on the Article 95 LoA*' and receive the requested data without further cost compensation. It stated that '*beyond the Article 95 LoA already granted, only one LoA can be foreseen, this being to support* [redacted] *and only on the negotiated precondition that the article 95 LoA is withdrawn in accordance with Article 3.2.*' The Other Party quoted section 3.2 of the DoA in full, noting that Claimant could use its '*rights for an alternative LoA to support* [redacted] *if the preconditions are adhered to. This is the position negotiated between the parties and which has been consistently restated by [the Other Party] since [the Claimant] first requested access to the data to support* [redacted].' Moreover, the Other Party stated that the '*approx.* [redacted]' payment offer made by the Claimant corresponded to '*a final payment*' to be made under the DoA and hence could not be seen as a settlement offer.[30]

17. The Claimant again disagreed and counter-argued the narrative presented in the Other Party's letter, asserting that the Other Party's '*position provided no reasonable prospect for the parties reaching an agreement*' and did not address '*how manifest double charging for the same data breaches*' its data sharing obligations.[31] The Other Party noted that the

[25] Other Party; 25/06/2019.
[26] Claimant; 02/07/2019.
[27] Other Party; 04/07/2019.
[28] Claimant; e-mails of 04/07/2019, 23/07/2019. Other Party; e-mails of 09/07/2019, 31/07/2019.
[29] Claimant; 13/08/2019, particularly at p.6.
[30] Other Party; 27/08/2019, particularly at p.3.
[31] Claimant; 10/09/2019.

Claimant's offer '*simply constitutes the final payment for the original LoA. It is not an offer of further compensation which an Article 62/63 BPR negotiation requires. That offer thus bears no relation to compensation for access for the separate substance*'. The Other Party thus suggested a meeting between the parties' lawyers.[32] In response, the Claimant stated that the [redacted] sum '*was offered as a compromise sum*', and the '*fact that it also corresponds to the sum listed*' in the 'demerger agreement' does not cease to make it an offer. The Claimant did not reply to the Other Party's meeting proposal, rather informing the Other Party it had submitted a data sharing dispute to ECHA.[33]

Assessment

Introduction and scope

18. The Claimant submitted the present data sharing dispute with reference to the substance [redacted], for which it already has a listing as supplier under Article 95 of the BPR. Upon ECHA's request, the Claimant clarified that it sought access to the data for [redacted] for the purpose of making its own active substance dossier for [redacted].

19. Similarly, the purpose of the data sharing negotiations between the Parties was initially unclear. In the beginning of 2018, the Claimant informed the Other Party that ECHA had (in the aftermath of the redefinition of [redacted] into [redacted]) accepted its application to take over one of the orphan mixtures, [redacted]. However, the Claimant proceeded to ask the Other Party for the full list of studies on [redacted], as well as some clarifications with regard to its customers' position. The Other Party provided the list and clarifications, and the discussion between the parties progressed on the data and studies supporting [redacted] for a Letter of Access to the Article 95 inclusion of [redacted] throughout 2018, as is apparent from paragraph 8, above. In February 2019, approximately one year later, the Claimant requested access to [redacted] data for the submission of an application for approval of [redacted] and stated that it did not seek the listing of [redacted] under Article 95 of the BPR.

20. Consequently, the present dispute assesses the efforts of the parties to find an agreement to share data on [redacted] for the purpose of an active substance application for [redacted].

21. ECHA cannot interpret the DoA and whether it allows the Claimant to use the data for an Article 95 application and an active substance application in parallel. However, ECHA can assess the efforts of the parties to find and execute an agreement to share data on [redacted] for the active substance application for [redacted].

22. The Claimant has pursued a dual approach in its negotiations. The larger part of the Claimant's efforts was directed at finding one agreement that allows the Claimant to use the data on [redacted] both for its inclusion in the Article 95-list for [redacted] and for an active substance application for [redacted], simultaneously.

23. The Claimant also pursued a second line of negotiations, where it made efforts to reach a separate agreement to allow it to refer to the data for [redacted] for the purpose of an active substance application for [redacted].

24. The fact that the Claimant tried different approaches to find an agreement on data sharing

[32] Other Party; 20/09/2019.
[33] Claimant; 25/09/2019.

[redacted]

is in itself an effort to find an agreement. ECHA will assess the amount of efforts made in each of these lines of negotiations in turn.

Efforts to find one agreement that allows the Claimant to use the [redacted] data for more than one application under the BPR

25. The evidence of the negotiations provided by the Parties starts with the DoA, which is dated February 2016. It continues on January 2018 with e-mail exchanges. In the absence of evidence of the negotiations between the parties leading to the signature of the DoA in February 2016, the DoA must be seen as a summary of previous negotiations, recording the content of the negotiations of the parties up to that point in time.

26. Indeed, when the Claimant negotiated one agreement that would allow the Claimant to refer to the data on [redacted] both for an application under Article 95 for [redacted] and for [redacted] under Article 62, the discussions turned around clause 3.2 of the DoA (in section 3, 'Payments for Data'), and the possibility of issuing another Letter of Access '*to support [the Claimant]'s own* [redacted] *and/or* [redacted] *dossier submission under* [redacted] *of the BPR*'.

27. The Claimant read clause 3.2 as entailing that the payments made under the DoA cover not only the active substance listing for [redacted], but at the same time also a dossier submission for application for approval of [redacted]. As noted in paragraph 15, above, the Claimant interpreted the clause as an '*explicit recognition that both* [redacted] *and* [redacted] *may be supported under the terms of the data access rights granted to [the Claimant]'*. The Claimant insisted that it saw no restriction of its access rights in any manner under the DoA.

28. The Other Party, however, argued that '*beyond the Article 95 LoA already granted, only one LoA can be foreseen, this being to support* [redacted] *and only on the negotiated precondition that the article 95 LoA is withdrawn in accordance with Article 3.2*'.[34] It added that the Claimant could only use the data for the submission of an application for approval of [redacted] as an active substance if it would first cancel its current Article 95 listing for [redacted], quoting clause 3.2 in full. In particular, it pointed to the condition set out on clause 3.2, that is, subject '*b) to [the Claimant] undertaking to cancel with ECHA the ECHA Listing which was based on the Letter of Access #1 and/or #2*'. It added that, in such a case, the Claimant would receive the data without further cost compensation. In spite of asserting that the scope of the DoA was limited to one letter of access, the Other Party added that it was open to negotiating access for a supplemental LoA not envisaged by the DoA.[35]

29. In reply to the Other Party's suggestion that the Claimant could use the data without any further payment, but subject to cancelling its ECHA listing for [redacted], the Claimant merely restated that clause 3.2 of the DoA refers to '[redacted] *and/or* [redacted]'. With regard to the '*second LoA offer*', the Claimant accused the Other Party of trying to prevent its market access and double charging for the same data,[36] but never addressed the second condition in clause 3.2, or why it should not apply to the negotiations at issue.

30. To make every effort in data sharing negotiations, parties must address the arguments of the other side and reply to them, explaining and substantiating their position. In this case, the Claimant did not make the effort of replying to the Other Party's arguments in the negotiations, by challenging its interpretation of the DoA or showing why its reading would be incorrect. The Claimant therefore failed to make every effort to find an agreement.

[34] See paragraph 16, above.
[35] See footnote 2.
[36] See paragraph 17, above.

[redacted]

Efforts to find a separate agreement to share data for [redacted]

31. When the negotiation of one agreement to cover two applications under the BPR became difficult, the Claimant tried to unblock the negotiations by initiating negotiations on a separate agreement on sharing data for the active substance approval of [redacted]. This was a constructive attempt to unblock the negotiations and in itself an effort to find an agreement.

32. The Claimant made an inquiry to ECHA pursuant to Article 62 of the BPR, and the Other Party sent a cost breakdown. The Claimant reacted by stating that the costs were inflated and unrealistic. The Other Party replied that the presented costs were based on actual study costs and Fleischer list values, and asked the Claimant to explain its assertion.

33. The Claimant suggested that the data on non-vertebrate animals should also be included in the presented values, and proposed to reduce the 'Article 62 Handling Costs' by a third and the administrative costs to a third, without however justifying the latter. When the Other Party asked whether the Claimant agreed to the other cost items, including the data cost, the Claimant argued that payment for the data had already been agreed in a 'demerger agreement'.[37]

34. As is apparent from paragraphs 15 to 17, ultimately, the Claimant suggested that it would be permitted to use the data in return for a one-off payment of [redacted], which should give it full data access to data on both vertebrate and invertebrate animals. The Other Party replied that the Claimant's proposal was not an offer to pay for data, but '*the final payment for the original LoA. It is not an offer of further compensation*.' The Other Party suggested that the Claimant should either pay the costs presented in the new letter of access, or cancel its listing under Article 95 of the BPR to be able to access the data for the stated purposes without additional payment. The Claimant replied by saying that the fact that the suggested sum was also a sum listed for payment did not cease to make it an offer.

35. The Claimant thus made some efforts to negotiate a separate data sharing agreement for [redacted]. It made a reasoned suggestion to reduce one cost item. However, it altogether dropped its efforts to find a separate agreement on [redacted], when the Other Party asked whether it agreed with the other cost items, including the study costs. It reverted to claiming that it should only pay once and use the data for two applications, as explained in paragraphs 25 to 30 above.

36. In order to make every effort to reach a separate data sharing agreement for [redacted], the Claimant should have pursued the discussion of the items in the Other Party's cost breakdown that it disagreed with. It could have explained its concerns in a manner comprehensible to the Other Party. That would have allowed the Other Party to revise its standpoint, or to explain why the Claimant's concerns do not apply. As it did not do so, the Claimant did not make every effort to find a separate agreement on data sharing for [redacted].

Conclusion

37. ECHA recalls that the data sharing dispute mechanism under Article 63(3) of the BPR is a last resort measure, intended to give prospective applicants the possibility of obtaining a permission to refer to data when it has made every effort to find an agreement.

[37] The 'demerger agreement' is not part of the evidence.

[redacted]

38. On the one hand, the Claimant tried to find an agreement with the Other Party that it could use the data for its applications for [redacted] and [redacted] simultaneously. However, it did not make the effort of replying to the Other Party's argument that the Parties had foreseen that sharing for an active substance application would require a previous withdrawal of the Article 95 application, which it took from clause 3.2 of the DoA.

39. On the other hand, the Claimant tried to find a separate agreement on sharing data for an active substance application for [redacted], when it made an inquiry and commented on the cost breakdown it received from the Other Party. However, it did not make the effort of substantiating its concerns with the breakdown provided by the Other Party.

40. In light of the above, the Claimant did not make every effort in the negotiations.

41. Therefore, ECHA cannot grant the Claimant a permission to refer to the data requested.

[redacted]

Annex II: ADVICE AND FURTHER OBSERVATIONS

ECHA stresses that both parties still share the data sharing obligation, and are therefore required to make every effort to reach an agreement on the sharing of the information and of the related costs. Therefore, ECHA would like to make some general observations in order to facilitate a future agreement:

- The Parties should be clear in their requests and replies, the scope of their needs and their urgency.
- The Parties should pay attention to the arguments of their counterpart and respond to them in order to find a mutual understanding.
- Each party should be clear in its position.
- If the Claimant considers that the DoA covers data sharing for applications for [redacted] and [redacted] simultaneously, it should make more efforts to explain its understanding to the Other Party.
- If the Claimant intends to pursue a separate agreement to share data for [redacted], it should pursue those negotiations. In the framework of such negotiations, the Other Party can consider cost adjustments to account for the fact that the Claimant already uses the same studies for the [redacted] dossier. If the Claimant has particular concerns, it should explain them to the Other Party, rather than making blanket statements.
- Albeit there is no obligation to share data on non-vertebrate animals, ECHA encourages the Parties to try to find an agreement, which would also encompass such data.
- If subsequent negotiations fail, the Claimant is free to re-submit a dispute claim with additional evidence of every effort.