

4. 06. 2014

[REDACTED]

**Sent via encrypted email and registered mail**

Copy to:

[REDACTED]

**Sent via encrypted email and registered mail**

Reference number: DSH-63-3-[REDACTED]-2013

Decision number: **DSH-63-3-D-[REDACTED]-2013**

**DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 63(3) OF THE BIOCIDAL PRODUCTS REGULATION (EU) No 528/2012 (BPR) REGARDING THE [REDACTED] [REDACTED] [REDACTED] [REDACTED] STUDY FOR THE ACTIVE SUBSTANCE [REDACTED]**

Dear Mr [REDACTED],

In accordance with Article 63(3) of the Biocidal Products Regulation (EC) No 528/2012 (BPR), the European Chemicals Agency (ECHA) has examined the claim and information you as representative of the prospective applicants (hereinafter referred to as "the prospective applicants") submitted on 9 December 2013, regarding the failure to reach an agreement on data sharing with the data owners, represented by [REDACTED] (hereinafter referred to as "the data owners"), for the [REDACTED] study for the active substance [REDACTED].

Article 63(1) of the BPR requires the prospective applicant and the data owner to "make every effort to reach an agreement on the sharing of the results or studies requested". Further, according to Article 63(4), "[c]ompensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner". If no agreement can be reached, Article

- 
- 1 See Annex for the list of prospective applicants
  - 2 See Annex for the list of the data owners

63(3) mandates ECHA on request to *"give the prospective applicant permission to refer to the requested tests or studies, 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"*.

When a data sharing dispute claim is lodged with ECHA, the Agency requests both parties to submit documentary evidence regarding the negotiations, to ensure that both parties are heard and that ECHA can base the assessment of the efforts on the complete factual basis. On this basis, ECHA conducts an assessment serving to establish whether the parties have fulfilled their legal obligation to make every effort aimed at sharing the studies and their related costs in a fair, transparent and non-discriminatory manner.

While ECHA takes note that negotiations on the sharing of data between the prospective applicants and the data owners have been preceding the entry into application of the BPR, the assessment conducted by the Agency is based on documentary evidence as of 1 September 2013 only. This is due to the fact that the requirement to make every effort in the data sharing negotiations has only become mandatory with the entry into application of the BPR. Furthermore, the assessment only takes into account the negotiations up to the date of the submission of the dispute claim as the moment of the alleged failure of the data sharing negotiations.

After a formal check of completeness of your dispute submission, ECHA found that additional information and clarifications were required. On 20 December 2013, ECHA therefore invited you to clearly identify with whom you negotiated the sharing of data and to complete the submitted documentation regarding the data sharing negotiations. You submitted the list of contacts you received following your inquiry, and informed that one of the data submitters who you had contacted had *"transferred our letter to the lawyer company [REDACTED] [REDACTED]"* who is the assigned representative of all five data submitters" by your email dated 8 January 2014. In the same message, you also listed the dates of your email exchanges with the data owners. On 15 January 2014, ECHA informed you that a full *"access to all crucial documents in relation to the dispute"* is essential for performing the dispute assessment, and invited you to provide the missing documentation. With your email dated 16 January 2014, you provided missing emails and letters which were exchanged between you and the data owners.

After an assessment of this information, on 6 February 2014 ECHA requested you to clarify whether you negotiated on behalf of [REDACTED] [REDACTED] only or on behalf of several prospective registrants. ECHA further informed you that the scope of a data sharing dispute claim is always limited to those companies which were actually part of the data sharing negotiations or had clearly mandated a representative to negotiate on their behalf, and that upon request of the data owners it is part of making every effort to disclose the number and identity of all involved parties. With your email dated 7 February 2014, you submitted a list of the members of your consortium comprising manufacturers, distributors and formulators, and informed ECHA that your *"consortium is fast growing"*. On 18 February 2014, ECHA reiterated that *"the identity of all prospective applicants must be submitted with the dispute claim"*, and suggested two possibilities to proceed with your dispute claim: (i) to unambiguously identify the prospective applicants, in order for ECHA to limit the dispute claim to these parties; or (ii) to withdraw the dispute claim and possibly re-submit the claim, after ensuring *inter alia* that all prospective applicants negotiated jointly. On 19 February 2014 you provided ECHA with a list disclosing the identity of all involved prospective applicants, which lead to ECHA informing on 24 March 2014 that your claim had been accepted for further processing.

On the same date, ECHA requested documentary evidence regarding the negotiations up to the date of the submission of the dispute claim, i.e. 9 December 2013, also from the data owners. This information was submitted by the data owners to ECHA on 7 April 2014.

#### The result of the assessment

**As a result of the assessment, ECHA has decided not to grant you the permission to refer to the information you requested from the data owners.**

The detailed justification is set out in the **Annex** to this decision.

#### General observations

ECHA would like to make some general observations in order to facilitate a future agreement:

- Making every effort in reaching an agreement requires both the prospective applicant(s) and the data owner(s) to find alternative solutions to unblock the negotiations and to be open and proactive in their communications with the other party. In case a party receives an unsatisfactory reply, which it considers unclear, invalid or incomplete, it is the responsibility of the recipient to challenge that answer, by addressing constructive, clear and precise questions or arguments to the sender;
- Each party shall give reasonable time to the other for providing appropriate answers to its questions;
- Making every effort to find an agreement also means that the parties exhaust their means to find an agreement. When negotiations are substantively progressing and no regulatory deadline is imminent, it is preferable to continue the negotiations;
- If the future data sharing negotiations would fail again, the claimant is free to submit another claim, covering the efforts subsequent to the present decision. ECHA reminds both parties that the outcome of a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, ECHA strongly encourages the parties to continue their efforts to reach an agreement that will be satisfactory for both parties;
- ECHA is never a party in the negotiations. Therefore, all arguments have to be communicated between both parties directly.


#### Appeal

In accordance with Article 63(5) and Article 77 of the BPR, an appeal against this decision may be brought to the Board of Appeal of ECHA within three months of the notification of this decision. The procedure for lodging an appeal is described at <http://echa.europa.eu/web/guest/regulations/appeals>.

Contact

Should you need to follow up on this particular matter, please contact ECHA using the following email address: [datasharing-disputes@echa.europa.eu](mailto:datasharing-disputes@echa.europa.eu), and stating the above-mentioned reference number in any correspondence in relation to this decision.

Yours sincerely,

  
Geert Dancet  
Executive Director

Annex:

Detailed outcome of the assessment of the data sharing dispute  
List of prospective applicants  
List of the data owners

**Annex to decision DSH-63-3-D- [REDACTED]-2013****DETAILED OUTCOME OF THE ASSESSMENT OF THE DATA SHARING DISPUTE**

The following provides the detailed outcome of the assessment of the data sharing dispute between the prospective applicants and the data owners, under Article 63(3) of the Biocidal Products Regulation (EC) No 528/2012 (BPR).

This assessment takes into account the negotiations from the period between 1 September 2013 and 9 December 2013, i.e. from the entry into application of the BPR until the submission of the dispute claim to ECHA, and is based on the information provided by both the prospective applicants and the data owners.

**Based on this information, as a result of the assessment, ECHA has decided not to grant the prospective applicants the permission to refer to the information requested from the data owners.**

Article 63(1) of the BPR requires the prospective applicant and the data owner to "*make every effort to reach an agreement on the sharing of the results or studies requested*". Further, according to Article 63(4), "*[c]ompensation for data sharing shall be determined in a fair, transparent and non-discriminatory manner*". If no agreement can be reached, Article 63(3) mandates ECHA on request to "*give the prospective applicant permission to refer to the requested tests or studies, 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*".

While contacts between the parties have been on-going since February 2013 already, the prospective applicants formally started data sharing negotiations with their email of 6 September 2013, following the entry into application of the BPR. These negotiations concerned essentially the sharing of the [REDACTED] study.

In their initial reply to the prospective applicants' request to share data, on 18 September 2013 the data owners sent a "Best Efforts and Secrecy Agreement" to the prospective applicants, informing them that it would need to be signed "*in order to be able to proceed with the negotiations*". With their email dated 19 September 2013, the prospective applicant provided an amended "Best Efforts and Secrecy Agreement" as the initial version was "*not fitting exactly our case*". In their reply of 9 October 2013, the data owners reacted to the suggested changes and provided comments and suggestions for alternative wording of the disputed parts. On 11 October 2013, the prospective applicants announced their legal department was investigating these revisions and that the data owners would "*get our answer in due time*". When the data sharing dispute claim was lodged on 9 December 2013, the prospective applicants had not come back yet to the last proposals made by the data owners.

The prospective applicant did not challenge that the data owners requested the signing of "Best Efforts and Secrecy Agreement" as a prerequisite to start the negotiations. While the prospective applicants provided their amendments in a first round of comments, they did not further challenge the comments made by the data owners, nor did they come back with alternative proposals or precise arguments or questions and instead lodged the dispute claim to ECHA. This shows a failure to comply with the obligation to make every effort to reach an agreement.

Further, in their initial reply to the prospective applicants' request to share data, on 18

September 2013 the data owners stated they *"assume that you will be duly mandated by all the members of the [redacted] to represent them in these negotiations, but [...] reemphasize that individual agreements will need to be concluded with each of them"*. The data owners again underlined in their message dated 9 October 2013 that individual data sharing agreements would need to be signed by each company, and that they *"need to receive evidence that [redacted] is empowered to act on behalf of all the [redacted] members"*. With their email of 11 October 2013, the prospective applicants provided a *"verification for [redacted] as Lead Company of the [redacted]"*. In their reply of 18 October 2013, the data owners raised concern that *"this document is not sufficient, as we still do not have information about the companies you are representing"*. Additionally, they requested proof of the member companies having appointed [redacted] as lead company. In their email dated 27 November 2013, the data owners express their appreciation for the agreement of the potential registrants *"that you are willing to confirm the members of your consortium to us"*. Nevertheless, on 3 December 2013 the data owners remind again the prospective applicants that they *"are expecting confirmation before the meeting of who are the members of your consortium"*. The prospective applicants clearly accepted to provide this information, while they confirmed in their email dated 5 December 2013 that they *"agreed to disclose the members of our consortium before the actual negotiations start"*.

While the issue of disclosing the members of the prospective applicants' consortium was under discussion since the beginning of the negotiations, the above demonstrates that here, too, progress has been made. While the information initially provided by the prospective applicants did not meet the expectations of the data owners, on 5 December 2013, i.e. four days before lodging the dispute claim, the prospective applicants agreed to disclose their members as requested. Hence, both parties were expecting to be able to find an agreement on this issue. This is highlighted by the prospective applicants stating in their email dated 5 December 2013 that this step would mean that *"the actual negotiations start"*, i.e. that it could be reasonably expected that the negotiations had not come to a standstill yet. Therefore, ECHA considers that lodging the dispute claim was a premature step.

ECHA notes that the identification of the number of parties to benefit from the right to use or to refer to the study is objectively a critical aspect of the negotiations. Indeed, the representation of several entities by one negotiator should not affect the possibility to determine a proportionate or equal compensation between all the parties benefiting from the study. In addition, data owners may also be able to determine each individual share of the cost of the data in the light of the actual number of parties involved in that sharing.

ECHA notes that in spite of the recognition by the prospective applicant of the importance of this information for the negotiations and their guarantee to provide it to the data owners, the prospective applicants have rather decided to terminate the negotiations and to lodge a data sharing dispute to ECHA. By taking the initiative of terminating the negotiations without providing this important information, as agreed, the prospective applicants have failed to comply with the obligation to make every effort to reach an agreement.

Finally, in their first reply to the prospective applicants' request to share data, on 18 September 2013 the data owners suggested arranging a *"meeting in order to discuss the conditions for access to the study"*. In their message dated 15 November 2013, the data owners repeated their intention to *"meet with you in order to discuss the pending issues"*, which was accepted by the prospective applicants in their email dated 27 November. The data owners communicated the meeting date and location in the message of 3 December 2013, and the prospective applicants confirmed their attendance in their email dated 5 December 2013, with the meeting scheduled to take place on 18 December 2013 in Hannover, Germany.

The exchange referred to above shows that an agreement was found to hold a meeting on 18 December 2013 in Hannover, Germany. Both parties expected the negotiations to progress at this meeting. On 5 December 2013, i.e. four days before lodging the dispute claim, the prospective applicants confirmed again their participation in the meeting with the data owners. Such a commitment to further negotiate with the data owners demonstrates that the prospective applicants expected that attending a face-to-face meeting could advance the discussions and contribute to finding an agreement on the cost and data sharing, which demonstrates that negotiations had not failed at this moment. By lodging the dispute claim before the agreed meeting, the prospective applicant did not fulfil the obligation to make every effort.

Lodging a data sharing dispute claim with ECHA can only be a last resort in case the negotiations have failed and every effort to reach an agreement has been exhausted. The obligation to make every effort to reach an agreement equally applies to the prospective applicant and the data owner. In addition, with the legal deadline for inclusion of suppliers in the "Article 95"-list being 1 September 2015, the legal timeframe gives time for continued negotiations on the sharing of data and does not require these negotiations to be concluded in a faster time. The prospective applicants therefore did not comply with their obligation to make every effort to find an agreement. As highlighted above, this is part of the legal obligation to make every effort in the negotiations, and failure to comply with this obligation leads to ECHA not granting the permission to refer.

ECHA stresses that both parties still share the common data sharing obligation, and are therefore still required to make every effort to reach an agreement on the sharing of the information and of their related costs.

**LIST OF PROSPECTIVE APPLICANTS**

<b>Number</b>	<b>Company name</b>	<b>Country</b>
1	[REDACTED]	Germany
2	[REDACTED]	Germany
3	[REDACTED]	Germany
4	[REDACTED]	Germany
5	[REDACTED]	Germany
6	[REDACTED]	Germany
7	[REDACTED]	Germany
8	[REDACTED]	Germany
9	[REDACTED]	Germany
10	[REDACTED]	Germany
11	[REDACTED]	Germany
12	[REDACTED]	Germany
13	[REDACTED]	Germany
14	[REDACTED]	Belgium
15	[REDACTED]	Germany
16	[REDACTED]	France
17	[REDACTED]	Germany
18	[REDACTED]	United Kingdom
19	[REDACTED]	France
20	[REDACTED]	Germany
21	[REDACTED]	France
22	[REDACTED]	United Kingdom
23	[REDACTED]	The Netherlands
24	[REDACTED]	Germany
25	[REDACTED]	Sweden



**HIGHLY RESTRICTED**

26	[REDACTED]	Germany
27	[REDACTED]	United Kingdom

**LIST OF THE DATA OWNERS**

<b>Number</b>	<b>Company name</b>	<b>Country</b>
1	[REDACTED]	GERMANY
2	[REDACTED]	GERMANY
3	[REDACTED]	GERMANY
4	[REDACTED]	GERMANY
5	[REDACTED]	GERMANY