ECHA
EUROPEAN CHEMICALS AGENCY

CONFIDENTIAL

18. 12. 2014

Addressee (Prospective Applicant):

Sent via encrypted email and registered mail

Copy to Data Owner*:*

Sent via encrypted email and registered mail

Reference number of the dispute claim	DSH-63-3- -2014
Decision number	DSH-63-3-D- -2014
Name of active substance disputed	
EC number of the substance disputed	

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 63(3) OF THE BIOCIDAL PRODUCTS REGULATION (EU) No 528/2012 (BPR)

Dear Mr ,

On 3 October 2014, you submitted a claim concerning the failure to reach an agreement on data sharing with (the Data Owner) as well as the related documentary evidence to the European Chemicals Agency (ECHA). To ensure that both parties are heard and that ECHA can base its assessment on the complete factual basis, ECHA also requested the Data Owner to provide documentary evidence regarding the negotiations. The Data Owner did not submit the requested documentary evidence within the deadline, i.e. by 27 October 2014.

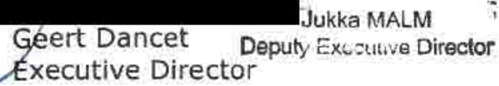
Based on the documentation supplied by you, ECHA has decided not to grant you permission to refer to the studies requested from the Data Owner for the above-mentioned active substance.

The statement of reasons regarding the assessment of the data sharing dispute of this decision is set out in the Annex I. General recommendations for further data sharing negotiations are provided in Annex II.

In accordance with Articles 63(5) and 77(1) 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.

Yours sincerely



Geert Dancet
Executive Director

Annexes:

Annex I: Statement of reasons regarding the assessment of the data sharing dispute
Annex II: General recommendations for further data sharing negotiations

Annex I to decision DSH-63-3-D-[redacted]-2014

STATEMENT OF REASONS REGARDING THE ASSESSMENT OF THE DATA SHARING DISPUTE

Article 63(1) of the BPR requires the prospective applicant(s) and the data owner(s) 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 the discussions between [redacted] the Prospective Applicant, and [redacted] the Data Owner, on the sharing of data for [redacted] predate the entry into operation of the BPR, this assessment only takes into account the period between 1 September 2013 and 3 October 2014, i.e. from the entry into application of the BPR until the submission of the dispute claim to ECHA[1], and is based on the information provided by the Prospective Applicant. The Data Owner did not submit the requested documentary evidence.

In their email dated 7 November 2013, the Data Owner suggested a compensation of [redacted]€ for the Letter of Access as "a fair compensation" representing about 10% of their financial efforts, while being "open to discuss payment terms". With a view to an earlier agreement between the Prospective Applicant and the Data Owner on another substance which amounted to [redacted]€, the Prospective Applicant in their reply of 14 November 2014 still found a "considerable gap" between the respective price ranges envisaged by the parties. They "believe [redacted] should be considered more favourably in terms of compromise in the present negotiation" claiming that "the '10%' statement you made is without fair context of the negotiations at hand".

With their email dated 13 December 2013, in order to come closer to a compromise figure the Prospective Applicant offered a price between [redacted] and [redacted]€ and in turn asked the Data Owner "to decrease its original figure to bring it somewhere between" [redacted] and [redacted]€.

The first draft data sharing contract was provided by the Data Owner on 22 January 2014. While this document was not made available to ECHA, it can be concluded from the email of the Prospective Applicant dated 5 February 2014 that this draft did not cover the cost and the Prospective Applicant asked the Data Owner to confirm their willingness to decrease their previous cost proposal. This is taken up by the Data Owner offering [redacted]€ in their email of 18 February 2014.

Other issues, i.e. the technical equivalence between the substances and a stewardship program regarding a closer cooperation between the parties were repeatedly discussed

[1] For further information, see also question "[911] What if negotiations have started before 1 September 2013?" in ECHA's Q&A section, available at http://echa.europa.eu/support/qas-support/qas

since the beginning of the negotiations, but with their email dated 5 February 2014 the Prospective Applicant indicated that they were willing to accept a compromise regarding technical equivalence. In the following, both the technical equivalence and stewardship program issues were not raised in the negotiations anymore, indicating that agreement was found on these two issues.

Following a meeting between the parties in Lyon, the Prospective Applicant sent the modified draft data sharing contract to the Data Owner on 15 April 2014. The draft at this stage included payment terms such as the amount of the base compensation; the number of instalments for settling the base compensation; the amount and ceiling of the supplemental compensations for additional uses; and the refund mechanism. According to the email of the Prospective Applicant the proposed changes concerned among others the timing of the payment scheme and the refund mechanism, however, the changes made in the contract by the Prospective Applicant at this stage are not made visible to ECHA.

In reaction to this, the Data Owner sent the contract back with their modifications on 25 June 2014. These modifications included *inter alia* proposing changes in the amount of the base compensation; in the number of instalments for settling the base compensation; in the amount and ceiling of the supplemental compensations for additional uses; and in the refund mechanism. The Prospective Applicant confirmed the receipt of the contract on 2 July 2014 and promised to start a consultation with colleagues and to "be back in touch shortly".

However, the Prospective Applicant only came back to the Data Owner with an email dated 2 October 2014, expressing his strong disappointment on the modifications made by the Data Owner to the draft contract received on 25 June 2014. The disagreement covers the above mentioned modifications made by the Data Owner to the draft contract. The Prospective Applicant also expressed the intention to submit a data-sharing dispute claim to ECHA. ECHA received the data-sharing dispute on 3 October 2014.

Based on the documentation provided, disagreement on the total compensation and the following cost items prevented the finalisation of the data sharing negotiations for [redacted] (1) the base compensation and the number of instalments for settling this base compensation, (2) the supplemental compensation as well as (3) the refund mechanism. Therefore, an assessment of the efforts made to reach an agreement is necessary.

Every effort to reach an agreement means that both parties shall negotiate the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward by taking up their arguments and concerns, as well as replying to and asking relevant questions.

ECHA notes that during the negotiations the Prospective Applicant did not negotiate constructively the cost of data for [redacted] The Prospective Applicant should have contributed more towards reaching an agreement regarding the actual cost and payment based on a common understanding of the cost of studies and under transparent circumstances. For instance, they could have requested a cost breakdown in order to

effectively challenge in detail the price and payment method proposed by the Data Owner, if the Prospective Applicant would have not considered it reasonable, in order to advance the negotiations and to reach a common understanding on the cost of the information. In the absence of this kind of efforts, the Prospective Applicant did not contribute effectively to reach an agreement on the sharing of data and cost for [redacted]

Although ECHA acknowledges that in their last email the Prospective Applicant clearly states the points of disagreement, when doing so they did not allow the Data Owner sufficient time to react to their comments. Submitting the data sharing dispute claim only one day after providing comments to the Data Owner cannot be considered reasonably long time for the Data Owner to clarify and substantiate their requests for amendments and therefore indicates that the Prospective Applicant did not make every effort in the data sharing negotiations.

Lodging a data sharing dispute with ECHA can only be a last resort in case the negotiations have failed and every effort to reach an agreement has been exhausted. ECHA, however, notes that the negotiations were in fact progressing. As the earlier negotiations have shown, after intense negotiations both parties were able to compromise and come to an agreement on other issues already, i.e. the technical equivalence between the substances and a stewardship program regarding a closer cooperation between the parties.

The above clearly demonstrates that the negotiations have not reached a standstill yet. The Prospective Applicant therefore did not comply with their obligation to make every effort to find an agreement, and failure to comply with this obligation leads to ECHA not granting the permission to refer.

ECHA stresses that, irrespective of the present decision, 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 their related costs.

As a closing remark, ECHA points out that it is in the parties' own interest to provide their complete negotiations. If they fail to find an agreement and the prospective applicant submits a data sharing dispute to ECHA, ECHA will assess the efforts they have undertaken on the basis of the records that they provide. In order to allow for a meaningful and exhaustive assessment of the efforts made during the negotiations, a company needs to be able to prove the efforts it has made. If the parties do not parts of the negotiations, ECHA cannot take these parts of the negotiations into account in its assessment. This is ultimately to their own disadvantage.

Annex II to decision DSH-63-3-D-[redacted]-2014

GENERAL RECOMMENDATIONS FOR FURTHER DATA SHARING NEGOTIATIONS

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

- ECHA would like to remind both parties that the data sharing dispute assessment relies on the information provided by both parties. Therefore, it is essential to provide a full set of documentation describing all efforts made in the negotiations;
- 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;
- Any compensation for data sharing, which can be considered not to be determined in a fair, transparent and non-discriminatory manner, should be challenged without delay requiring clarification and substantiation for the requested compensation;
- Each party shall give reasonable time to the other party 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 Prospective Applicant 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.

“ECHA reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection.”