ECHA
EUROPEAN CHEMICALS AGENCY

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23. 07. 2014

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Reference number: Joined cases DSH-63-3-[redacted]-2014 and DSH-63-3-[redacted]-2014

Decision number: **DSH-63-3-D-[redacted]-2014**

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 63(3) OF THE BIOCIDAL PRODUCTS REGULATION (EU) No 528/2012 (BPR) REGARDING THE STUDIES LISTED IN THE ANNEX FOR THE ACTIVE SUBSTANCE [redacted] WITH EC-NUMBER [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 submitted in the name of [redacted] (hereinafter referred to as "the Prospective Applicant") on 12 May 2014, regarding the failure to reach an agreement on data sharing with [redacted] and [redacted] (hereinafter referred to as "the Data Owners"), for the studies listed in Annex II for the active substance [redacted] with EC-number [redacted].

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*".

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. This assessment 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 informed you on 21 May 2014 that your claim had been accepted for further processing and asked you to confirm that you had mandated [redacted] to conduct the data sharing negotiations on your behalf. On 22 May 2014, you provided this confirmation. Also on 21 May 2014, ECHA requested documentary evidence regarding the negotiations up to the date of the submission of the dispute claim, i.e. 12 May 2014, from the Data Owners. In addition, ECHA requested the Data Owners to clarify whether [redacted] was mandated to conduct the negotiations also on behalf of [redacted]. On 4 June 2014, ECHA received the confirmation that [redacted] was mandated to conduct the negotiations on behalf of [redacted]. The Data Owners submitted the documentary evidence on 5 June 2014.

Following the receipt of this information, ECHA joined the data sharing dispute claims DSH-63-3-[redacted]-2014 and DSH-63-3-[redacted]-2014, because the negotiations were conducted together for both Data Owners who own the data jointly and concern the same data requested by the Prospective Applicant.

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 I** 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;
- Both parties still share the obligation to make every effort to find an agreement on data sharing after this decision, and are encouraged to take the present decision into account in their further 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, and stating the above-mentioned reference number in any correspondence in relation to this decision.

Yours sincerely,

[redacted]

Geert Dancet
Executive Director

Annexes:

Annex I: Detailed outcome of the assessment of the data sharing dispute
Annex II: List of studies requested

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

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 Applicant 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 up to 12 May 2014, i.e. the date of the submission of the dispute claim to ECHA, and is based on the information provided by the Prospective Applicant and the Data Owners.

Based on this information, as a result of the assessment, ECHA has decided not to grant the prospective applicant the permission to refer to the information requested from the Data Owners.

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*".

Factual background

The Prospective Applicant sent an e-mail to the Data Owners on 16 December 2013, requesting a cost proposal for data sharing of a number of studies. With their email of 19 December, the Data Owners confirmed receipt of the request and announced that due to the upcoming Christmas break they would only be able to come back to the prospective applicant "*by end of January*". The Data Owners provided a list of the costs of studies on 30 January 2014.

With their email of 24 February 2014, the Prospective Applicant proposed sharing of less studies, which they quoted, and asked that a contract be prepared. Further, they expressed their interest in reviewing the [redacted] study. The Prospective Applicant sent a reminder on 4 March 2014 asking "*when you will be able to provide*" the requested information.

Pending an answer from the Data Owners, they sent their own "*revised cost proposal*" on 12 March 2014 and stated that they "*would like to receive the contract for sharing of these studies within 15 days, this is due to the time delays already incurred*". On 17 March 2014, the Data Owners confirmed receipt of the request and provided an outline of the necessary steps they would have to undertake before agreeing on a contract and implementing it, explaining that there were "*more parties to coordinate and to agree on the contract and procedures, so that we cannot commit to your suggested dead line*". The following day, the Prospective Applicant asked the Data Owners to "*provide a realistic time-frame when data sharing will be finalised taking into consideration the procedure*" and repeated their interest

in evaluating the [redacted] study. The same day, the Data Owners replied that they "*cannot draw a concrete time line due to the fact that these steps are not depending only on us*" and that they "*have already initiated the preparation of the draft contract*".

Further, regarding the [redacted] study, they wrote that a secrecy agreement would need to be signed and asked the Prospective Applicant whether they should start drafting such an agreement. On 19 March, the prospective applicant announced they "*would be happy to sign a confidentiality agreement*" and asked if it was possible to review the study by post or email. The following day, the Data Owners informed that they needed to "*ask our consortium*" regarding "*the secrecy agreement and the process of viewing into the study*".

On 9 April 2014, the Prospective Applicant replied that they "*appreciate that there is a process to be followed for both the secrecy agreement for viewing of the study and also for the development of a data sharing contract*". They also wrote that they had "*received communication from ECHA [...] that ECHA assessments for data sharing disputes take into consideration the negotiation and communication process, such that all correspondence must be conducted in a timely manner*".

On 25 April, the Prospective Applicant enquired about the progress and asked for the "*expected date*" for both contracts. With their email dated 29 April 2014, the Data Owners sent the draft secrecy agreement "*for commenting*" and informed they were "*still working on the draft data sharing agreement*". On 7 May 2014, the Prospective Applicant provided their comments on the draft secrecy agreement. Two days later, they informed the Data Owners of their intention to lodge a "*data sharing dispute with ECHA due to the delay in the negotiation and communication process*". The Prospective Applicant lodged the data sharing dispute on 12 May 2014.

Assessment of the efforts made by the parties

Pursuant to Article 63(1) and (3) BPR, the obligation to make every effort to reach an agreement on data sharing rests on the prospective applicant and the data owner. Lodging a data sharing dispute claim with ECHA can only be a measure of last resort in case the negotiations have failed and every effort to reach an agreement has been exhausted.

It is an important element of making every effort to find an agreement that a party leaves the other party reasonable time to react to its statements, comments and proposals. Where a party does not leave the other party enough time, it hinders the progress of constructive negotiations, because a reasoned and substantial exchange of views, information and arguments cannot take place.

Where data sharing negotiations are progressing excessively slowly, a finding that a prospective applicant has made every effort to find an agreement and the other party has not made every such effort might be appropriate under certain circumstances. This would require, amongst others, that the prospective applicant has not started the negotiations too late, that he has justified to the data owners why the negotiations must be conducted particularly swiftly, and where the data owner cannot or does not explain any delays that he would be responsible for in reaction to the prospective applicant's explanation.

For instance, where a prospective applicant is concerned that the other party answers too slowly, making every effort would involve pointing out to the data owner that the replies are too slow and explaining why a faster reply is needed. Based on Article 95(2) BPR, a data owner can expect that a prospective applicant must be on the list established by ECHA under Article 95 BPR by 1 September 2015, and that negotiations should therefore be

concluded soon enough for the prospective applicant to be included in the list by that date. If the negotiations are more urgent for the prospective applicant, he would have to explain this to the data owner as a part of making every effort to find a swift agreement. If the data owner provides an explanation for the time it takes to reply and the prospective applicant disagrees with the explanation, it would be part of every effort on the side of the prospective applicant to challenge this explanation concretely.

In the present case, the parties had agreed to conclude a secrecy agreement before the disclosure of the [redacted] study. The Data Owners provided a draft secrecy agreement on 29 April 2014. The Prospective Applicant provided their comments to this draft with their email of 7 May 2014, showing that the negotiations were progressing and had not reached a standstill. However, the Prospective Applicant submitted the data sharing dispute a mere three working days later, on 12 May 2014. This did not leave the Data Owners reasonable time to react to the Prospective Applicant's comments. The Prospective Applicant has therefore not made every effort to find an agreement with the Data Owners.

As regards the speed of the negotiations, the Prospective Applicant repeatedly asked the Data Owners to provide a timeline for the cost proposal for data sharing and a summary of the [redacted] study for evaluation.[1] When the Data Owners provided the list of necessary steps for the preparation of the data sharing agreement[2] and explained that they "*cannot draw a concrete time line*", because several parties had to be involved[3], the Prospective Applicant expressed a general wish that the contracts should be concluded quickly. However, they did not challenge the Data Owners' explanation, but signalled their understanding that "*there is a process that needs to be followed*"[4]. Similarly, the Prospective Applicant did not object to receiving the cost information on the studies that he had requested on 16 December 2013 in the end of January, as he did not reply to the Data Owners' e-mail of 19 December 2014. Moreover, there is no apparent reason why these negotiations should be particularly urgent. The Prospective Applicant has stated no such reasons in the negotiations. Under the BPR, the Prospective Applicant would only need to be on the "Article 95-list" as of 1 September 2015[5]; they did not explain why they would want or need to be on the list earlier.

ECHA therefore concludes that the negotiations were progressing between the parties. The negotiations had taken approximately five months, but in light of the deadline of 1 September 2015, the remaining time was sufficient to reach a conclusion of the negotiations, especially considering that the parties had generally agreed that they would share data. Given that the Prospective Applicant accepted the Data Owners' explanation of the time it took them to react, there was no reason to attempt to shortcut the negotiations by submitting a data sharing dispute to ECHA a mere five days after providing comments on the draft confidentiality agreement to the Data Owners. Therefore, the Prospective Applicant did not make every effort to reach an agreement.

[1] Cf., the Prospective Applicant's e-mails of 4 March and 18 March 2014
[2] Cf., the Data Owners' e-mail of 17 March 2014
[3] Cf., the Data Owners' e-mail of 18 March 2014
[4] Cf. the Prospective Applicant's email dated 9 April 2014.
[5] Article 95(2) BPR