[redacted]

Addressee (Claimant):

[redacted]

07 -09- 2015

Represented by:

[redacted]

Sent via REACH-IT

Copy to Other Party:

[redacted]

Sent via REACH-IT

Reference number of the dispute claim	DSH-30-3-[redacted]-2015
Decision number	DSH-30-3-D-[redacted]-2015
Name of the substance disputed	[redacted]
EC number of the substance disputed	[redacted]

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 30(3) OF THE REACH REGULATION (EC) No 1907/2006

Dear Mr [redacted],

On 22 June 2015, [redacted] represented during the data sharing negotiations by [redacted] (hereinafter referred to as 'the Claimant') submitted a claim concerning the failure to reach an agreement on data sharing with [redacted] (hereinafter referred to as 'the Other Party'), 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 Other Party to provide documentary evidence regarding the negotiations. The Other Party submitted the documentary evidence on 8 July 2015, as requested by ECHA.

Based on the documentation supplied by both parties, ECHA has decided to grant you, as the Claimant, permission to refer to certain studies from the Other Party for the above-mentioned substance.

The Other Party shall have a claim on you for an equal share of the cost, provided they make the full study report available to you, which shall be enforceable in the national courts according to Article 30(3).

The statement of reasons regarding the assessment of the data sharing dispute is set out in Annex I to this decision. The permission to refer concerns the studies indicated in Annex II.

As a remark, ECHA reminds both parties that despite of the present decision they are still at liberty to reach a voluntary agreement. Accordingly, ECHA strongly encourages the parties to negotiate further in order to reach an agreement that will be satisfactory for both parties.

In accordance with Article 30(5) of the REACH Regulation, both parties involved in the dispute may appeal against this decision 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,

[redacted]

Christel Musset
Director of Registration

Annexes:

Annex I: Statement of reasons regarding the assessment of the data sharing dispute
Annex II: List of studies subject to the dispute, to which ECHA grants the permission to refer
Annex III: Instructions on how to submit your registration dossier after resolution of the data sharing dispute procedure

Annex I to decision DSH-30-3-D-[redacted]-2015

STATEMENT OF REASONS REGARDING THE ASSESSMENT OF THE DATA SHARING DISPUTE

Article 30(1) of the REACH Regulation sets out as a pre-requisite that SIEF "*participant(s) and the owner [of the data] shall make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way*". In case of a dispute on the sharing of studies involving vertebrate animal testing which have already been submitted to ECHA, Article 30(3) of the REACH Regulation requires ECHA to determine whether to grant a permission to refer to the information contained in the registration dossier, *i.e.* to the relevant studies. 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, so as to establish whether the parties have made every effort to reach an agreement on the sharing of studies and their costs in a fair, transparent and non-discriminatory way.

ECHA's assessment regards exclusively the parties' efforts to reach an agreement on the sharing of information and its costs; it is not an assessment of whether the actual amounts under discussion are adequate or whether the height of the various cost factors is justified. This remains under the exclusive responsibility of the co-registrants.

Factual background[1]

The Claimant originally started the negotiations with the Other Party on 6 December 2012. They were later suspended and eventually resumed by the Claimant by email of 15 January 2015, informing that it wished to register [redacted] as soon as possible but at the latest in the second quarter of 2015.

On 4 February 2015, the Other Party provided the draft data sharing agreement, which mentioned a lump-sum of [redacted] EUR. The Other Party also stated that despite the fact that there was, by then, an additional co-registrant, the overall cost had increased from the originally proposed [redacted][2] EUR due to the fact that additional studies had been added to the dossier.

On 20 February 2015, the Claimant pointed out certain inconsistencies in the draft data sharing agreement, concerning *inter alia* the lump sum payment, which was seen as contradicting other provisions on refunds and potential future payments. Moreover, the Claimant pointed out that "the CEFIC model"[3] foresaw a 50% discount for in case of a restriction to the use of the data to REACH registration purposes only ('the REACH-only discount') as well as equal cost sharing between all members.

[1] The negotiations were conducted in German. Occasionally, English was used, especially with regard to the attachments to messages. The final exchange of messages between parties, before lodging the dispute, occurred also in English.
[2] See email dated 20 February 2013.
[3] Neither party referred to a precise document.

The Other Party answered on 2 March 2015, clarifying that the term "lump sum" was derived from previous draft data-sharing agreements and should have been deleted, as the provisions of the data-sharing agreement had meanwhile been aligned with the "CEFIC model". However, it pointed out that abandoning the lump sum approach had resulted in an increased price of the Letter of Access ('LoA'), as no lump sum rebate could be applied. They listed the dossier costs as follows: (i) physicochemical tests [redacted] EUR; (ii) toxicological and ecotoxicological tests [redacted] EUR (no risk premium applied); (iii) dossier preparation [redacted] EUR; (iv) administrative costs [redacted] EUR. However, in that communication the Other Party did not address the REACH-only discount.

By email of 20 March 2015, the Claimant again suggested to apply a 50% REACH-only discount, due to the fact that no co-ownership of the studies would be acquired and that the use would be strictly limited to REACH purposes. On this basis, it calculated the following costs: (i) physicochemical tests [redacted] EUR; (ii) toxicological and ecotoxicological tests [redacted] EUR. Consequently, considering the existence of a third co-registrant, this would result in total costs of [redacted] EUR for the Claimant instead of [redacted] EUR as previously quoted. In addition, the Claimant requested further clarification regarding the reimbursement mechanism under Article III, paragraph 5 of the draft data sharing agreement.

On 8 April 2015, the Other Party conceded that a REACH-only discount could be applied in certain cases. It argued, however, that it had performed the tests for its REACH registration, and that study ownership consequently did not as such confer any advantage. It therefore considered a 50% REACH-only discount to be unjustified and proposed a 44% reduction instead. Moreover, it stated that it is usual to apply a risk premium, which was not yet included in the draft data sharing agreement. The Other Party set that risk premium at 30%. On that basis, it re-calculated the cost and proposed a sum of [redacted] EUR.

On the same day, with regard to the REACH-only discount, the Claimant responded by arguing that as the EU market is less than 50% of the world market, and as it would have to acquire separate letters of access for other jurisdictions, a discount of at least 50% would be appropriate. Further, it argued that the risk premium as such is a very controversial concept and that it recommended its clients to refrain from applying a risk premium. While conceding that a risk premium is frequently used, it claimed that it is usually 10% and applied only for toxicological and ecotoxicological data, in line with the applicable ECHA Guidance on Data Sharing.[4] In this context, the Claimant also argued in detail that the actual risk involved in commissioning the studies does not justify a 30% risk premium.

In its reply of 9 April 2015, the Other Party stated that "the haggling is becoming grotesque". It stated that 70% of all [redacted] is marketed within the EU, and that to its knowledge the Claimant markets the substance almost exclusively in Europe. If this factor were to be included in the calculation, it would level out the 10% risk premium proposed by the Claimant, or lead to an even higher LoA price in case of a 30% risk premium. The Other Party however suggested "to stop haggling" and reiterated the previous terms of its offer.

[4] See ECHA Guidance on Data Sharing, Chapter "5.3.2.2 Specific Value Elements" (p. 102)

The Claimant replied on 11 May 2015, referring to a telephone conference of 13 April 2015[5], following which the Other Party had not come back to them as agreed. The Claimant suggested *inter alia* that, in the absence of an agreement on the 50% REACH-only discount, it should acquire co-ownership of the data. It also reiterated that it considered a 30% risk premium "fully out of proportion" and suggested a 10% risk premium instead, applicable only to toxicological and ecotoxicological data. Consequently, they proposed a price of [redacted] EUR.

On 13 May 2015, the Other Party re-stated it previous position, adding that "we see no reason for further debate".

The present dispute was lodged by the Claimant on 22 June 2015.

Assessment

ECHA would deem that parties have made every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way if they have negotiated the sharing of data and related costs as constructively as possible to make sure that the negotiations move forward by expressing their arguments and concerns and replying each other's questions and arguments with the aim of agreeing to a fair, transparent and non-discriminatory sharing of costs. In particular, this requires parties to be open and constructive when replying to valid arguments brought up during the negotiations, and to maintain a cooperative approach, respecting each other's legitimate questions and concerns.

The parties did not reach an agreement on two core issues during the negotiations: the application and magnitude (i) of the REACH-only discount and (ii) of the risk premium. ECHA's assessment will consequently focus on these two aspects.

(i) REACH-only discount

A REACH-only discount was suggested by the Claimant, with reference to "the CEFIC model"[6] and to the fact that no co-ownership was acquired and that the use of the data was limited to REACH purposes[7]. By providing such arguments, the Claimant made an effort to advance the negotiations.

In its reply, the Other Party addressed the Claimant's arguments and provided an explanation why in the case at hand it did not see a reason to apply a 50% REACH-only discount.[8] Instead, it proposed a decreased 44% REACH-only discount, combined with a 30% risk premium. It thus contributed to finding a mutual understanding on the applicable discounts and their justifications.

[5] Neither party provided the minutes of this phone call to ECHA. Any information on its content stems from the messages of 11 May 2015 and 13 May 2015 respectively.
[6] See emails dated 20 February and 20 March 2015.
[7] See email dated 8 April 2015.
[8] See email dated 8 April 2015.

The Claimant responded by providing yet further justification for their proposal of a 50% discount.[9] By doing so, the Claimant made further efforts with a view towards reaching a fair, transparent and non-discriminatory agreement on the sharing of costs.

In response, the Other Party challenged the justification of the Claimant's proposal with regard to the market share. At the same time, however, it expressed its unwillingness to engage in further discussions and reverted back to its previous position regarding the LoA price.[10] In doing so, it frustrated its previous efforts towards finding an agreement.

In a last attempt to unblock the discussions the Claimant proposed an alternative solution in the form of the acquisition of co-ownership in the data.[11] In doing so, it demonstrated its willingness to exert further efforts in order to address the Other Party's concerns.

However, the Other Party merely repeated that it was not available for further negotiations by stating "we see no reason for further debate"[12]. Thus, it effectively obstructed the negotiations and prevented the emergence of a common understanding on the REACH-only discount.

(ii) Risk premium

A risk premium of 30% of the overall cost was suggested by the Other Party[13] by reference to established practice, in reaction to the Claimant's proposal of a REACH-only discount.

The Claimant, while acknowledging the wide-spread use of risk premia, put forward detailed and reasonable arguments why the risk premium should be of 10% at most and should only apply to toxicological and ecotoxicological data. Thus, the Claimant made efforts aimed at finding a mutual understanding on a fair, transparent and non-discriminatory cost calculation.

The Other Party did not address any of the Claimant's arguments and merely suggested neutralising the Claimant's proposal of 10% risk premium with a decreased REACH-only discount.[14] Moreover, by bluntly proposing "to stop the haggling"[15] and to agree on the previously proposed terms, the Other Party not only failed to address the Claimant's arguments but also did not put forward any arguments justifying its proposal of a 30% risk premium. By failing to do so it effectively prevented reaching a common understanding on the costs.

In addition, as a general consideration, ECHA notes that although negotiating parties are free to consider applying risk premia, such premia must logically be limited to cost factors implying an actual risk borne by the existing registrant. In ECHA's view, such risk only exists in relation to studies commissioned by the existing registrant, where the success of the study and its outcome cannot be anticipated. A risk premium applied to cost components which carry no inherent risk, for instance the purchase of pre-existing studies,

[9] See email dated 8 April 2015.
[10] See email dated 9 April 2015.
[11] See email dated 11 May 2015.
[12] See email dated 13 May 2015.
[13] See email dated 8 April 2015.
[14] See email dated 9 April 2015.
[15] See email dated 9 April 2015.

would therefore not be justifiable in so far as the quality and the result of the study is already known.[16]

Conclusion

Based on the above, ECHA concludes that the Other Party did not make every effort to reach an agreement to share the data. In particular, the Other Party did not appropriately reply to the Claimant's arguments and merely insisted on the previous terms, thereby blocking the negotiations and preventing the parties from reaching a common understanding on cost calculation. Faced with the Claimant's explanations, the Other Party should have addressed those arguments and provided further justifications on the outstanding issues in order to allow the negotiations to continue until an agreement is finally reached. Not to do so, however, constituted a failure to comply with the obligation to make every effort to reach a fair, transparent and non-discriminatory agreement on the sharing of data and its costs as required by Article 30 REACH.

In contrast, by providing relevant arguments, by challenging the Other Party's arguments in a reasoned way, by providing alternative proposals to unblock disputed issues and by justifying their demands *inter alia* with references to ECHA Guidance and advice provided by industry associations, the Claimant acted in full respect of their legal obligation to make every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way.

Therefore, ECHA grants the Claimant permission to refer to certain data submitted by the Other Party, listed in Annex II to the present decision.

[16] See ECHA Guidance on Data Sharing, Chapter "5.3.2.2 Specific Value Elements" (p. 102)