[redacted]

Helsinki, 22 September 2017

The Claimant

[redacted]

Copy to:
The Other Party

[redacted]

Decision number:
Dispute reference number:
Name of the substance:
EC number of the substance:

[redacted]

DECISION ON A DISPUTE

a) Decision

Based on Article 30(3) of Regulation (EC) No 1907/2006 ('REACH Regulation')[1],

> ECHA grants you the permission to refer to the information you requested from the Existing Registrant, [redacted], of the above-mentioned substance.

According to Article 30(3) of REACH, the Existing Registrant shall have a claim on you for an equal share of the cost, which shall be enforceable in the national courts, provided that the full study report(s) is made available to you.

The reasons of this decision are set out in Annex I. The list of studies ECHA grants you permission to refer along with copies of (robust) study summaries can be found in Annex II and III, respectively. Instructions on how to submit your registration dossier are provided in Annex IV.

b) Procedural history

On 7 July 2017, you ('the Claimant') submitted a claim concerning the failure to reach an

[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC, *OJ* L 396, 30.12.2006, p.1, as last amended.

[redacted]

agreement on data sharing with [redacted] ('the Other Party') as well as the related documentary evidence to 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 by 28 July 2017. By e-mails dated 14 July and 19 July 2017, the Other Party requested an extension of the deadline to provide the requested evidence. You were consulted on such request on 19 July 2017. Taking into account your objection as well as the absence of justifications, ECHA rejected the Other Party's request. On 27 July 2017, the Other Party provided a letter by which they explain their position to ECHA accompanied by a set of documents. For the purpose of the Agency's assessment of whether every effort is made to reach an agreement, only those that have been exchanged between the two parties were taken into account[2].

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.

Advice and further observations

ECHA reminds both parties that despite of the present decision they are still free 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.

Yours sincerely,

Christel Schilliger-Musset[3]

Director of Registration

[2] Decision of the Board of Appeal of ECHA of 17 December 2014 in Case A-017-2013, *Vanadium*, paragraph 99.

[3] 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 OF THE DECISION

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 by another registrant, Article 30(3) of the REACH Regulation requires ECHA to determine whether to grant the claimant 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, 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. The assessment is based on the exchanges of information between the two parties.

Making every effort to share the data and their related costs in a fair, transparent and non-discriminatory way means that the parties negotiate the sharing of data and related costs as constructively as possible, to make sure that the negotiations move forward swiftly by expressing their arguments and concerns and replying to each other's questions and arguments. Where a party has concerns about the other party, it must justify these concerns and give the other party the opportunity to address them. Moreover, where a party promises to provide certain information within a certain timeline, keeping their promise and being reliable and consistent is part of making every effort.

Summary of factual background

On 4 July 2016, the Claimant initiated the negotiations requesting a price quotation for a Letter of Access (LoA) for the tonnage band [redacted] and [redacted]/y[4]. In their reply, the Other Party provided the price of the LoA for [redacted] t/y[5]. The price of the LoA for tonnage band [redacted] remained unanswered irrespective of the reminders sent by the Claimant[6].

As regards the price of the LoA for [redacted] t/y, the Claimant asked clarification on whether the [redacted][7] and service fee[8] were included in the provided price.

In September and October 2016, the Claimant requested a confirmation of the price or the latest calculation, expressing their client's willingness[9] to purchase the LoA urgently.[10] The Other Party did not reply to the request but provided the Substance Identity Profile (SIP) and asked for a confirmation from the Claimant that their substance meets the specification[11]. The Claimant affirmed, stating that the substance meets the SIP conditions[12].

[4] See the Claimant's message dated 04/07/2016

[5] See the Other Party's message dated 14/07/2016

[6] See the Claimant's messages dated 15/07/2016, 02/08/2016, 04/08/2016, 09/08/2016, 15/08/2016, 30/08/2016, 12/09/2016 and 19/09/2016

[7] See the Claimant's message dated 15/07/2016

[8] See the Claimant's message dated 12/09/2016

[9] See the Claimant's message dated 27/10/2016

[10] See the Claimant's messages dated 19/09/2016, 21/10/2016, 24/10/2016 and 27/10/2016

[11] See the Other Party's message dated 27/10/2016

[12] See the Claimant's messages dated 27/10/2016 and 21/11/2016

[redacted]

On 7 November 2016, the Other Party informed that *'the costs for the LoA covering different tonnages are available'*[13] and on 9 November 2016, the Claimant received confirmation of the LoA price for tonnage band [redacted] t/y[14]. The question as to whether [redacted] was included in the price remained unanswered[15]. In addition, the Claimant requested the Other Party by several e-mails to provide them with the respective invoice in order to receive the LoA[16].

In response to the requests for the invoice, the Other Party requested the Claimant to provide a data sharing agreement template and the pre-registration number of the substance[17]. The Claimant provided the requested information pointing out that a data sharing agreement should already be in place between the Other Party and two other members of the joint submission[18]. On 28 November 2016, the Other Party acknowledged receipt of the template and pre-registration number, and announced that *'[they] will start to process the contract'* and their service provider '*will accompany the process of handling over the token'*[19]. In addition, they informed that the Claimant could expect to receive the invoice by the first half of January 2017[20].

In December 2016, the Other Party asked for the name of the non-EU manufacturer to be included in the agreement[21]. The Claimant provided the name of a company and subsequently corrected it with another company name (hereinafter 'Claimant's client' or 'client')[22].

In January 2017, the Other Party requested a statement to be signed by the management of the Claimant's client confirming that (i) the Claimant's client is the only receiver of the LoA, (ii) the Claimant's client is the producer of the substance and (iii) the Claimant's client is the exporter into the EU of the substance[23]. The Claimant explained that their client is a non–EU manufacturer and has appointed them to act as Only Representative and therefore their client cannot be an importer in the EU. Moreover, they explained that their client will not export into the EU directly but via a trader (*'the actual exporter and importer'*). Consequently, the Claimant delivered the statement including the provisions (i) and (ii) [24].

Following the Claimant's explanations, the Other Party recommended that the importer contact them directly[25]. The Claimant clarified their appointment as the Only *Representative 'to carry out the required registration of the substance that is imported'* and, by referring to the ECHA Guidance on registration, they explained that *'this will relieve the EU importers within the same supply chain from their registration obligations, as they will be regarded as downstream users'*[26].

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[13] See the Other Party's message dated 07/11/2016

[14] See the Other Party's message dated 09/11/2016. Note that from this point onwards this is the tonnage band of the Claimant's request.

[15] See the Claimant's messages dated 09/11/2016 and 15/11/2016

[16] See the Claimant's messages dated 15/11/2016, 18/11/2016, 21/11/2016, 23/11/2016, 24/11/2016, 25/11/2016, 29/11/2016, 02/12/2016, 16/12/2016, 04/01/2017, 06/01/2017, 17/01/2017, 19/01/2017, 22/02/2017, 01/03/2017, 09/03/2017, 16/03/2017, 22/03/2017, 07/04/2017, 25/05/2017 and 08/06/2017

[17] See the Other Party's message dated 24/11/2016

[18] See the Claimant's messages dated 24/11/2016 and 25/11/2016

[19] See the Other Party's message dated 28/11/2016

[20] See the Other Party's message dated 30/11/2016

[21] See the Other Party's message dated 01/12/2016

[22] See the Claimant's message dated 02/12/2016

[23] See the Other Party's messages dated 05/01/2017 and 06/01/2017

[24] See the Claimant's message dated 10/01/2017

[25] See the Other Party's message dated 11/01/2017

[26] See the Claimant's message dated 12/01/2017

[redacted]

On 16 January 2017, the Other Party informed that the statement was not considered satisfactory and asked for *'an original valid letter from [the Claimant's client] factory which is signed and stamped by the [Claimant's client]'*[27]. The Claimant sent the document signed and stamped by their client on the following day. On 19 January 2017, the Other Party requested that the original letter should be on *'business paper of [the Claimant's client], signed and stamped'* and include (in addition to provisions (i) and (ii) mentioned above) that the client is the owner of licences for the manufacture and the sales of the substance[28].

On 6 February 2017, the Claimant provided the requested statement signed by the person in charge of REACH Regulation[29]. The Other Party acknowledged receipt and requested the original to be sent by post, which they received on 17 February 2017[30].

On 22 February 2017, the Claimant reiterated their request to receive the invoice. The Other Party informed that the latter would be sent after verification of the provided information[31].
During the verification, the Other Party questioned the identity and role of the person signing the statement[32].

On 3 March 2017, the Other Party further requested the Claimant's client's licence of production of this substance[33]. The Claimant contested the ground for such request, pointing out that the Other Party has no *'authority to check the licence'*. On 9 March 2017, they reiterated their request to receive the invoice in order to complete their registration[34]. On 16 March 2017, the Other Party informed about the organisation of an internal meeting to discuss the matter and on 22 March 2017, they informed that they have decided to contact ECHA regarding the Claimant's case[35].

In April, after the Claimant asked about the progress of their request stressing the urgency to register the substance, the Other Party replied that they were awaiting a response from ECHA. On 28 April 2017, the Other Party informed the Claimant that ECHA had not yet replied to their question and they had *'strong believe that the company […] is not a real manufacturer for this substance'*[36].

In their reply, the Claimant pointed out the absence of grounds for such conclusion[37] and invited them to visit their client's production facilities[38]. After the Other Party's visit on [redacted][39], the Claimant provided a sample of the substance to the Other Party in order to check the sameness while reminding the Other Party that the result of such test is in principle the responsibility of the LoA purchaser and that they are willing to acquire the LoA

[27] See the Claimant's (internal) message dated 16/01/2017. Note that it refers to a phone conversation with the Other Party on the same date.
[28] See the Other Party's message dated 16/01/2017, 17/01/2017 and 19/01/2017
[29] See the Claimant's message dated 06/02/2017
[30] See the Other Party's message dated 07/02/2017 and 17/02/2017
[31] See the Claimant's and the Other Party's messages dated 22/02/2017
[32] See the Other Party's messages dated 28/02/2017, 01/03/2017 and 02/03/2017
[33] See the Other Party's message dated 03/03/2017
[34] See the Claimant's message dated 09/03/2017
[35] See the Other Party's messages dated 16/03/2017 and 22/03/2017
[36] See the Claimant's messages dated 07/04/2017, 26/04/2017 and the Other Party's messages dated 10/04/2017, 28/04/2017
[37] See the Claimant's message dated 02/05/2017
[38] See the Claimant's message dated 09/05/2017
[39] Note that the Other Party visited the Claimant's client factory on [redacted]. The Other Party provided minutes of this meeting but there is no evidence that those were provided to the Claimant.

[redacted]

at their own risk. They informed that they would submit a data sharing dispute to ECHA should they not receive the invoice for the LoA and testing results by 8 June 2017[40]. On 30 May 2017, the Other Party informed that the person in charge of interpreting the analytical results is out of office until 6 June 2017. On 8 June 2017, the Claimant reiterated the request to receive the invoice irrespective of the testing results[41].

On 12 June 2017, the Other Party informed the Claimant that they intend to prepare the contract. For that purpose, they asked for the draft sent previously as well as the address to be mentioned in the agreement. The Claimant replied on the same day with the address[42]. On 15 June 2016, the Other Party requested the Claimant to clarify their position and intention as the recipient of the LoA, i.e. if they intend to sell the LoA to other companies[43].

On 19 June 2017, the Other Party reminded the Claimant that they have not yet received their client's production license and requested to provide it *'quickly'*. The Other Party asked the Claimant whether *'they want to sell the LoA'*[44]. The Claimant explained that, as Only Representative, they purchase the LoA on their client's behalf and on 21 June, they provided the client's production licence[45].

On 23 June, the Other Party requested a licence from the environmental agency *'which details the production process, the production capacity of the relevant chemical and also regulates the emissions associated with the production'*[46]. On 28 June 2017, the Claimant provided the licence and questioned the grounds for such request from the Other Party.[47]

On 3 July 2017, the Other Party informed that they refuse to sell the LoA to the Claimant as the provided documents did not show that the client is a manufacturer of the substance and they stated that *'[the Claimant's] client needs to be regarded as a trading company'*[48]. On the following day, the Claimant replied that the Other Party is already in possession of certificates demonstrating that the client is the manufacturer of the substance, and in addition they informed that they would lodge a dispute[49].

On 7 July 2017, the Claimant filed the present dispute.

Assessment

At the outset, the Claimant requested a LoA for two tonnage bands, [redacted]. The Other Party ignored the request related to the second tonnage band despite the Claimant's reminders and the negotiations focussed on the LoA for the tonnage band [redacted] only.

First, ECHA observes that the Claimant accepted the price of the LoA as initially offered by the Other Party in July 2016. They reiterated their acceptance with the updated value of the

[40] See the Claimant's message dated 25/05/2017
[41] See the Other Party's message dated 30/05/2017 and the Claimant's message dated 08/06/2017
[42] See the Other Party's and the Claimant's message dated 12/06/2017
[43] See the Other Party's message dated 15/06/2017
[44] See the Other Party's message dated 19/06/2017
[45] See the Claimant's messages dated 19/06/2017 and 21/06/2017
[46] See the Claimant's message dated 23/06/2017
[47] See the Claimant's message dated 28/06/2017
[48] See the Other Party's message dated 03/07/2017
[49] See the Claimant's message dated 04/07/2017

price as provided in November 2016. The Other Party promised to send the invoice by the first half of January 2017.

Second, ECHA observes that, throughout the course of the negotiations, the Claimant sent repetitive reminders in order to receive the invoice with the agreed price, highlighting in several occasions their urgency to register. [redacted], the Other Party could not ignore that the Claimant was under an objective urgency to progress with their registration [redacted]. Making every effort in the negotiations entails that an existing registrant needs to take into account the urgency for the potential registrant to register, and not delay sending the invoice and the data sharing agreement.

Although parties are free to agree which party provides a data sharing agreement, it must be taken into account that the Other Party was not the only existing registrant of the substance. Two other companies, as identified by the Claimant, were also registrants of the substance, and therefore part of the same joint submission in line with the 'one substance one registration' principle. In this regard, ECHA notes that the Other Party ignored the requests as to why the existing data sharing agreement with the two other registrants could not be used in the present case.

Third, ECHA observes that the Other Party requested further information and documents from the Claimant. The Claimant complied with every request and provided the documentation in a timely manner but questioned the relevance and grounds of certain requests or the Other Party's competence in certain areas (e.g. status of manufacturer).

ECHA notes that the Other Party refused to sell the LoA mainly because of reservations on the identity and role of the non-EU manufacturer represented by the Claimant acting as the Only Representative. However, the Other Party remained vague in reasoning their requests. The objective sought by the Other Party was therefore unclear until they expressed in April 2017 their *'strong belief that the company […] is not a real manufacturer for this substance'*. Following this, the Claimant invited the Other Party to visit the factory, which took place in [redacted], thereby demonstrating their willingness to dismiss the doubts and prove the role of their client. However, the Other Party concluded in July 2017 that, *'till today we did not see a document which classified [the Claimant's] client as a manufacturer of chemical substance (at stake)'*.

In the context of negotiations, parties must give each other the opportunity to make known their views on the truth and relevance of the facts and circumstances on which they found their position. In this regard, when an existing registrant has serious doubts impeding the conclusion of the agreement, it must ensure that the potential registrant is clearly informed of the nature or origin of the doubts, so that it can make its views effectively known or it can provide counter-evidences before a conclusion is reached.

ECHA observes that the Other Party did not clearly express the reasons why the evidence provided by the Claimant as requested by the Other Party did not reach their expectations nor did they explain to the Claimant why the visit of the factory did not address their concerns. In seeking a specific type of document, the Other Party did not allow the Claimant to address the Other Party's actual concerns by other means.

In ECHA's view, the absence of reasoning and clear explanations as to the information sought by the Other Party demonstrate that the Other Party did not make every effort. Further, it shows that the Other Party did not have a real intention to enter into genuine negotiations and reach an agreement with the Claimant but rather to delay the negotiations.

[redacted]

Against this background, ECHA notes that by delaying the provision of the LoA invoice, by requesting information and documentation and reaching a conclusion without explaining the reasons and allowing the Claimant to counter the findings, the Other Party has effectively caused the failure of the data sharing negotiations and thereby failed to comply with their obligation to make every effort to come to an agreement.

Conclusion

Based on the above, ECHA concludes that the Claimant made every effort to reach an agreement on access to the joint submission in a fair, transparent and non-discriminatory way. On the other hand, by refusing to sell the LoA and not giving the opportunity to the Claimant to make their views effectively known as to the truth and relevance of the concerns or doubts of the Other Party, namely the status of the manufacturer, the Other Party did not make every effort to reach a fair, transparent and non-discriminatory agreement on the sharing of data and their costs as required by Article 30 of the REACH Regulation.

Therefore, ECHA grants the Claimant access to the joint submission and permission to refer to vertebrate data.

[redacted]

ANNEX III: COPIES OF (ROBUST) STUDY SUMMARIES