

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 11 of Regulation (EC) No 1907/2006 ('REACH Regulation')¹ and Article 3 of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH ('Commission Implementing Regulation')², and following the procedure laid down in Article 27 REACH Regulation by analogy,

ECHA grants you access to the joint submission requested from [REDACTED]

The reasons of this decision are set out in Annex I. The factual background of the dispute is described in Annex II. The instructions on how to submit your registration dossier are provided in Annex III.

a) Procedural history

On 8 November 2016, you ('the Claimant') submitted a claim concerning the failure to reach an agreement on the access to joint submission with [REDACTED] ('the Other Party') as well as the related documentary evidence to ECHA. To ensure that both

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.

² Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *OJ L* 3, 6.1.2016, p.41.

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 21 November 2016.

On 20 December 2016, ECHA requested you to provide a proof of payment. The proof of payment was provided on 7 February 2017 and amounted to [REDACTED] EUR.

b) 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>.

c) 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.

The present decision will be published on ECHA's website.³

Yours sincerely,

Christel Schilliger-Musset⁴

Director of Registration

³ Available at <https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach>.

⁴ 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.

Annex I: REASONS OF THE DECISION

According to Article 11 of the REACH Regulation⁵, all registrants of the same substance are part of the same registration under REACH ('joint submission').

The joint submission obligation was strengthened by the Commission Implementing Regulation⁶, and in particular Article 3, which confirms that, even in situation of opt-out within the meaning of Article 11(3) of REACH Regulation, all registrants shall still be part of one joint submission for the same substance. The objective is to encourage and foster discussions among the registrants of the same substance in view of ensuring the quality of the dossier.

In practice, the existing registrants provide access to the joint submission to potential registrants of the same substance. The terms and conditions on this access are agreed freely among the concerned parties.

A failure to reach an agreement prevents the potential registrant from registering, since a separate submission outside an existing joint submission for the same substance is no longer possible in accordance with the Commission Implementing Regulation. A remedy is therefore necessary.

In that regard, Article 3(1) of the Commission Implementing Regulation clarifies the duty of ECHA to ensure that all registrants of the same substance are part of the joint submission. Recitals 12 and 14 of the Commission Implementing Regulation reinforce this role of ECHA. This is underpinned in the operation of Titles II and III of the REACH Regulation, and in particular the mechanisms for data-sharing disputes.

It follows that, in case of a failure to reach an agreement on the access to the joint submission, the possibility is given to the potential registrant to submit a dispute to ECHA. A dispute brought to ECHA in that context requires the Agency to determine whether to grant access to the joint submission.

The substance at stake in the present dispute is a non-phase-in substance. The REACH Regulation, and in particular Article 27 thereof, foresees a mechanism to solve data-sharing disputes arising in relation with this type of substances. ECHA applies by analogy this mechanism to joint submission disputes.

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 made every effort to reach an agreement on the conditions for access to the joint submission.

Assessment

The Claimant first contacted the two existing registrants in order to identify the lead registrant of the joint submission. They requested the name of the joint submission and the token, free-of-charge. They explained that they are in possession of the relevant data and

⁵ Regulation (EC) N° 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.

⁶ Commission Implementing Regulation (EU) 2016/9 of 5 January 2016 on joint submission of data and data sharing in accordance with Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), *OJ L* 3, 6.1.2016, p.41.

do not have additional [REDACTED] data. The Claimant further explained that they have indeed received the full dataset from ECHA for the tonnage band [REDACTED] [REDACTED] during the inquiry process. The substance was notified in accordance with Directive 67/548/EEC ('non-phase-in substance') and the data submitted therein falls under the "12-year rule" of Article 25(3) of the REACH Regulation. They stated their commitment to use the requested information for the sole purpose of REACH registration of the aforementioned tonnage band, and to purchase a Letter of Access (LoA) in case of a potential later increase of their tonnage band and update of their registration for the data submitted less than 12 years previously.⁷

The Other Party identified themselves as the lead registrant and provided the LoA price of [REDACTED] EUR to enter the joint submission. They specified that the price only contains the administrative costs and does not include any rights to refer to studies.⁸

The Claimant asked the Other Party for details on the administrative costs covered by the LoA, as well as about the objectives and registration work covered by the requested price. They stressed that their registration is for [REDACTED] tonnage band and that they do not have additional data compared to the data received from ECHA during the inquiry process. They pointed out that the data contained in their dossier is the same as the data submitted by the lead registrant in the joint submission as visible from the dissemination page of ECHA's website.⁹

It appears therefore clearly from the Claimant's request that they do not intend to rely on any additional endpoint study records nor do they have data to contribute to the quality of the joint submission dossier. Their aim is solely to enter the joint submission in order to register and access the market.

In its reply, however, the Other Party justified the amount of the requested price by generically referring to their '*actual situation and a common practice in industry*' as well as to other ongoing negotiations between the parties.¹⁰

ECHA notes that the present dispute is indeed affected by the situation where the Claimant and the Other Party were negotiating in parallel for the access to [REDACTED] joint submissions with reversed roles, i.e. the Claimant is the lead registrant and the Other Party is the potential registrant. These negotiations and the arguments exchanged in that context are referred to repeatedly in the negotiations at hand.¹¹

If, as a general rule, practices among the industries, e.g. the average market price, can be regarded as a relevant indicator to determine the administrative work related to the creation and administration of a joint submission, ECHA observes that, in the present case, the Other Party set the price by solely mirroring the prices requested by the Claimant in relation with other joint submissions to which the Other Party sought access. In other words, the price does not appear to be based on an objective market comparison but rather on subjective criteria pertaining to the parties' relationship.

Therefore, for the present assessment ECHA cannot consider these arguments related to other substances. ECHA highlights that the parties are under the obligation to reach a fair, transparent and non-discriminatory agreement regardless of potential disagreements in their negotiations for other substances. Efforts made in these negotiations may be assessed by ECHA in another dispute case, should the potential registrant decide to refer the matter to ECHA.

Against this background, ECHA notes that the Claimant intended to focus the discussion on identifying the work for the creation of the joint submission at stake and the efforts for

⁷ See document reference no. 1

⁸ See document reference no. 2

⁹ See document reference no. 3

¹⁰ See document reference no. 4

¹¹ See documents reference no. 4, 5, 6, 9, 10 and 12

generating a token.¹² For that purpose, they gave a detailed cost overview and amount of work relevant to the tasks required to prepare the type of dossier in question. They made own calculations and brought arguments why, given the specificities of the non-phase-in substance registration and absence of data compensation due to the "12-year rule", the creation of the joint submission should not result in significant administrative workload and costs.¹³

The Other Party listed administrative work like conducting a survey to potential and individual registrants, a data gap analysis, management, and communication. However, they did not indicate the actual costs incurred for each item, nor did they provide objective justifications for these cost items as the Claimant had requested.¹⁴ Moreover, ECHA notes that the Other Party included the work related to their own inquiry as an administrative task, and subsequently related cost, to be shared among all (potential) registrants.¹⁵

Each registrant is individually responsible for the submission of their own (member) registration. The costs related to each parties' own inquiry are therefore not to be included in the share of joint submission costs between all (potential) registrants. It must also be recalled that cost-sharing according to the REACH Regulation and the Commission Implementing Regulation must ensure that only the cost incurred is being shared and profit-making is not taking place.

Moreover, as pointed out by the Claimant, determining the sharing of costs in a fair, transparent and non-discriminatory way implies that the overall costs are shared by the total number of co-registrants.

It was therefore legitimate for the Claimant to obtain clarification on the allocation of costs as well as the nature of these costs since the individual share is eventually dependent on the total costs.

However it does not appear clearly from the information provided by the Other Party how this cost itemisation, allocation and compensation mechanism were defined. By failing to provide the requested clarifications, the Other Party deprived the Claimant from assessing and understanding the requested price, and from asserting their right for fair, transparent and non-discriminatory cost sharing. Providing this information was a necessary effort to ensure progress of the negotiations about an agreement on access to the joint submission. As a result, the Other Party failed to make every effort and to fulfil the transparency requirements of Article 2 of the Commission Implementing Regulation.

Conclusion

In light of the above, the Claimant shall be granted the access to the joint submission of the non-phase-in substance in accordance with Article 27(6) of REACH Regulation.

¹² See document reference no. 5, 7

¹³ See document reference no. 7

¹⁴ See document reference no. 13

¹⁵ See document reference no. 13



Annex II: FACTUAL BACKGROUND OF THE DISPUTE

The table below summarises the negotiations between the parties:

CHRONOLOGY TABLE		
Reference number	Submission date	Article
	8/11/2016	27(6)

Ref. no.	Date	Content	Remark
1.	06/07/2016	<p>The Claimant approaches the Other Party to inform about their intention to <i>'notify the new substance'</i>. They mention the OSOR principle as a trigger to join a joint submission. The Claimant asks who of two existing registrants has created a joint submission (JS) and took the role of the Lead Registrant (LR) in order to request the JS name and security token.</p> <p>They further explain that ECHA provided them with data for free during the inquiry (12 years rule) and they don't require any additional data. Their request is limited to the access to the joint submission for their registration in the tonnage band  and they expect to receive the token <i>'free-of-charge'</i>. They declare that the requested JS name and security token will be solely used for registration purposes under REACH in the aforementioned tonnage band. The Claimant is aware that in case they need to pass  threshold they have to purchase a Letter of Access (LoA) for the data <12 years.</p>	
2.	11/07/2016	<p>The Other Party (OP) confirms that they are the LR on behalf of their client. They inform that the LoA to enter the joint submission for  is  € in 2016 and it <i>'only contains the admin costs and no rights to refer to any studies'</i>.</p>	
3.	11/07/2016	<p>The Claimant highlights that they don't require a Chemical Safety Report (CSR) and will <i>'only submit a member dossier prepared by [themselves] without further </i>' and therefore <i>'only need a security token and JS name (both easily generated in REACH-IT)'</i>. They ask for the detailed administrative costs covered by the LoA and ask to <i>'list in detail what objectives and registration work is covered by the costs'</i>. Further, they point out that the dossier of the OP disseminated on the ECHA website has the same data that they have received during an inquiry without any additional data.</p>	



Ref. no.	Date	Content	Remark
4.	12/07/2016	The OP explains that the fee calculated to enter the joint submission is based on their ' <i>actual situation and a common practice in industry</i> '. As an example they mention [REDACTED] substances where the Claimant is a LR and the cost for a token to join a joint submission to register as intermediate without access to any of the Claimant's data varies from ca. [REDACTED] to [REDACTED] €.	
5.	12/07/2016	The Claimant explains that the situation with the [REDACTED] substances given as example is different because those are intermediates and require searching for available information in literature, within the SIEF and in-house, evaluation of classification and labelling according to GHS, and compilation of the IUCLID file. While for the substance in question the data are already received from ECHA, therefore only the ' <i>(much lower) effort of generating a token</i> ' is required.	
6.	15/07/2016	The Other Party comes back to the mentioned [REDACTED] examples highlighting that for those substances they indicated a full opt-out and that therefore ' <i>the situation or workload [...] is the same</i> ' as for the present case.	
7.	22/07/2016	The Claimant underlines that they have a lot of experience in preparing various dossiers; and intermediate and NONS dossiers have different structure and workload. They further give an example of a cost-structure based on the hours needed to complete different tasks, concluding that the work needed to create the joint submission and to generate the token would cost around [REDACTED] €, which would then be divided by the number of registrants. In case of [REDACTED] registrants, this results only in [REDACTED] € per company. Finally, discussing the requested [REDACTED] € for the token for the present NONS dossier, the Claimant argues that if this amount is charged to each registrant, it would result in [REDACTED] € for preparing the dossier. As this is ' <i>more than 10 times higher compared to the effort [the Other Party] really had to spend</i> ', they request the OP to ' <i>check again [their] cost situation based on the effort [they] had</i> '.	
8.	25/07/2016	The Claimant clarified that the e-mail of 22/07/2016 related to NONS-substance in question for the submitted dispute.	
9.	29/07/2016	The OP informs that they will draft the details for the LoA cost for the substance in question. They also ask whether the Claimant could send them LoA calculations for the other two substance where the Claimant is a LR.	
10.	15/08/2016	The Claimant asks if the OP had time to ' <i>check the price for the joint submission of the NONS-substance</i> '. Additionally, they announce they will send the requested information in relation with the	



Ref. no.	Date	Content	Remark
		two intermediate JS emphasising that ' <i>NONS and the intermediate registration are two different things.</i> '	
11.	16/08/2016	OP informs they will ' <i>prepare the information</i> ' for the Claimant.	Only provided by OP
12.	19/08/20216	The Claimant informs the OP regarding the cost breakdown and work done to prepare the intermediate dossiers according to the request of the OP.	x
13.	22/08/2016	<p>The OP emphasises that they also requested only token to the joint submission and will perform the rest of work by themselves, i.e., '<i>data research</i>' and compilation of their '<i>individual dossier with available data by opt-out way</i>'.</p> <p>On the other hand they provide the justification for their work related to the NONS registration. It includes survey to potential and individual registrants, work related to inquiry, data gap analysis, management, communication, etc.; they conclude that the work related to the preparation of intermediate dossier is not that different from the preparation of the NONS dossier and '<i>that LR for NONS-registration is the same process as Phase in registration</i>'.</p>	

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