ECHA
EUROPEAN CHEMICALS AGENCY

CONFIDENTIAL

23 -07- 2013

[redacted]

Sent via REACH-IT to: [redacted]

Copy to:
[redacted]

Reference number: DSH-30-3-[redacted]-2013

Decision number: **DSH-30-3-D-[redacted]-2013**

DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 30(3) WITH THE [redacted] FOR THE SUBSTANCE WITH EC NUMBER [redacted]

Dear Mr [redacted],

In accordance with Article 30(3) of Regulation (EC) No 1907/2006 (REACH Regulation), the European Chemicals Agency (ECHA) has examined the claim and information your company, [redacted] submitted on 15 May 2013 regarding the failure to reach an agreement on data sharing under Article 30(3) of the REACH Regulation with the existing registrants of the substance [redacted] with EC number [redacted], represented by [redacted] and [redacted].

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 dispute on the sharing of studies involving vertebrate animal testing, Article 30(3) of the REACH regulation requires ECHA to determine whether to grant permission to refer to the information contained in the registration dossier, i.e. to the corresponding studies. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the information provided, so as to establish whether the parties have made every effort to ensure that the studies and their related costs are shared in a fair, transparent and non-discriminatory way.

Documentary evidence

The information you provided was considered complete and appropriately documented, as indicated in the communication ECHA sent to you on 21 May 2013. ECHA also received the information from [redacted] on 3 June 2013 and therefore conducted a contradictory assessment of the information provided by both parties. The assessment covered the exchange of communication up to the date of the claim.

The result of the assessment

As a result of the objective and contradictory assessment, ECHA has decided not to grant you the permission to refer to the information you requested from the existing registrants represented by [redacted] and [redacted].

Based on the information provided by both you and the other party, ECHA has concluded that you did not make every effort to reach an agreement on the sharing of information you requested under Article 30(1) of the REACH Regulation.

Factual background

The negotiations started on 13 February 2013 when [redacted] (hereinafter referred to as [redacted]) requested the letter of access (LoA) for 13 tests and asked for the price and the conditions. [redacted] were acting on behalf of [redacted] (hereinafter referred to as [redacted] or the Claimant), but did not disclose this fact at this point in time.

[redacted] and [redacted] (hereinafter referred to as [redacted]) represented the existing registrants in the negotiations. [redacted] replied on 14 February 2013. They tried to gain clarification on the pertinent tonnage band and deadline, explained that four companies shared the joint submission in 2010 and wrote that the letter of access was sold only as a full dossier, which also included annexes [redacted] and [redacted] as well as the chemical safety assessment and the chemical safety report. On the same day, [redacted] replied that they were "not interested in the LoA for the dossier", but only in the listed tests performed with vertebrate animals. They asked for the price of the studies that were listed in the previous email and referred to the mandatory nature of data sharing.[1]

A discussion regarding ownership of the studies and clarifications about the role of [redacted] and its relationship with [redacted] followed.[2] On 1 March 2013, [redacted] confirmed that [redacted] was acting on their behalf and that "[o]ne of the reasons why [redacted] has decided to go ahead with our own registration has been the information about your rejected dossier by ECHA and consequently the impossibility to get the LOA from [redacted]."[3] [redacted] responded on the same day by explaining that their dossier was not rejected by ECHA, but is non-compliant. They urge [redacted] to join their joint submission and explain that they are in discussions with the Belgian Competent Authority. A separate dossier by [redacted] would confuse these discussions. Later that day, [redacted] contacted [redacted] and asked about the prices and conditions for access to "the studies".[4] Shortly thereafter, [redacted] referred to their previous e-mail to [redacted] and wrote that they "were expecting a further response regarding the basis of cooperation from [redacted], of [redacted]], before progressing any further."[5]

Four days later, on 5 March 2013, [redacted] contacted [redacted] and stated that they would like to continue with their "own registration and strategy" because their consultants [redacted] had told them that the submission of an individual dossier would not affect the conflict between [redacted] and the authorities. They added that they also did not want to share the existing dossier covering three different grades with just one registration.

---

[1] Cf., message of [redacted] of 14 February 2013, at 15:42
[2] Cf., messages of [redacted] of 15 February 2013 at 13:31 and 16:15 and of 26 February 2013; and messages of [redacted] of 15 February 2013 and 27 February 2013
[3] Cf., message of [redacted] of 1 March 2013
[4] Cf., message of [redacted] of 1 March 2013
[5] Cf., message of [redacted] of 1 March 2013 at 15:48

On the same day, [redacted] asked about the grade(s) that [redacted] intended to register. They thought it critical that [redacted] and the [redacted] would align their registration strategies. They also addressed the necessity for the substance sameness check within the SIEF before [redacted] could conduct any vertebrate animal test in support of an individual registration dossier. On 8 March 2013, [redacted] sent the CAS and EC number of the substance that they were intending to register but added that the details of the composition of the substance were confidential and could not be shared. They again requested the conditions and the prices of the previously requested studies.

[redacted] replied that not all studies are equally relevant for all grades. They also reminded [redacted] that "normal processes of a SIEF would involve reaching a shared conclusion on sameness." Otherwise the data supplied might not be relevant to the substance of [redacted].[6] [redacted] replied on the same day that they would check the substance composition and the quality of the studies before purchasing the studies.

On 15 March 2013, [redacted] provided an approximate price for the requested studies. They also asked whether [redacted] would need the [redacted] as well as the [redacted], which are part of the Annex [redacted]. This question was repeated in a message of 18 March 2013, to which the offer for the previously requested studies was attached. This offer detailed the cost of every study individually and explained that the "costs have been derived taking into consideration the original study costs, a cost sharing arrangement whereby each confirmed registrant takes an equal share of the cost burden, the recommended practice of applying a risk premium (30%) and an administration premium (20%) to the basic total." The offer details that the studies would be made available to review their appropriateness upon payment of a deposit of 50 % of their costs.

On 20 March 2013, [redacted] requested a "detailed calculation of the prices of each study, including laboratory cost of each, risk premium, administration premium and number of registrants." They also asked for the removal of the risk premium from the physical-chemical tests. Moreover, they express their interest in verifying the quality of the studies. Finally, they changed the list of the studies they are interested in.[7]

[redacted] replied the same day that they had already provided an itemised estimate for each study and explained the methodology by which the costs were derived, including the risk and administration premiums. They refused to remove the risk premium, as the studies "still have the capacity to go wrong." Regarding the quality verification of the studies, they expressed the willingness to assemble the *Klimisch* scores as soon as the claimant would have finalised the requested list of studies. They pointed out that there was a waiver for the [redacted] and gave the price for the [redacted] They reminded [redacted] that the data sharing obligation is two-fold and that in case the claimant owns any studies it should be declared within the SIEF in order to prevent further testing done in the future.

[redacted], on 26 March 2013, replied that they have no studies for the two endpoints and provided a new and shorter list of requested studies.

An exchange of messages on the preparation of the letter of access ensued[8], in which [redacted] explained that they needed to review their standard LoA template "to deal with access to

[6] Cf., message by [redacted] of 13 March 2013
[7] They delete the [redacted] and add [redacted] and the [redacted] study done according to the [redacted] guideline.
[8] Cf., messages of [redacted] of 9 April 2013, 22 April 2013 and 23 April 2013; messages of [redacted] of 9 April 2013, 23 April 2013 and 26 April 2013

separate studies"[9]. On 30 April 2013, [redacted] contacted [redacted] and requested a final proposal as well as "the Token code". Otherwise they would inform ECHA about the dispute.

On the same day, [redacted] provided the LoA. They expressed their surprise that [redacted] referred to the token code, which would only be required for joint submissions. They added: "The whole point in this instance is that this is not a joint submission!"[10]

On 2 May 2013, further to some technical remarks, [redacted] [redacted] referred to the obligation to make a joint submission, explained that they would submit the dossier as an opt-out and that they needed the token code.

On 3 May 2013, [redacted] addressed the request for a token. Given the "new fact" that [redacted] would plan to be part of the joint submission, [redacted] express their puzzlement as to why all previous requests addressed only individual studies, "when it is clear that access to the dossier via the token will give you the ability to reference all the studies and other data that you will need." [redacted] quotes the email sent by [redacted] on 1 March 2013, according to which [redacted] decided to prepare their own registration due to the alleged rejection of [redacted] dossier and "the impossibility to get the LOA from [redacted]." [redacted] repeated that the dossier has not been rejected and pointed out that the proposal to join the joint submission, but to opt out, contradicts [redacted]'s e-mail of 1 March 2013. [redacted] offered [redacted] to join the joint submission under condition that they pay the regular price for the LoA for the whole dossier, at no extra cost for the requested separate studies, and to refund [redacted] for the studies, for which ECHA would accept the opt-out. They considered this to "allow [redacted] to continue along its preferred line of registration while protecting the [redacted]'s position with respect to the value of its "token"." [redacted] presumed that the cost of the LoA would not be an impediment, since it had not previously been mentioned and is open to hearing "any other proposals that can safeguard the value of the 'token' for the [redacted]."

On 6 May 2013, [redacted] stated that the reasons for the opt-out were the high price of the LoA, which would "not have an appropriate registration strategy", as well as the non-compliance of the joint registration dossier. They then refered to a list of studies, for which they would like to purchase the right of use and state their intention to "complete an opt-out registration, highlighting the endpoints that will be sent according to the consortium dossier".

On the same day [redacted] pointed out that [redacted] had never expressed concern about the price of the LoA, nor did they ask [redacted] to provide a justification of the cost. They would do so on request. They reiterated their intention to discount the price based on the understanding of the opt-out. The letter also pointed out that [redacted] had not provided any explanation of how the request for access to studies would fit into an opt-out strategy. It reminded [redacted] that they received an offer for the mentioned studies on 15 March 2013.

By e-mail of 8 May 2013, [redacted] claimed that the last message by [redacted] had been caught in the spam filter. Finally, on 8 May 2013, [redacted] repeated its offers of 15 March 2013 for the individual studies and of 3 May 2013 for the 'token'.

[9] Message of [redacted] of 9 April 2013, cf., also message of 26 April 2013
[10] Cf., message of [redacted] of 30 April 2013

Assessment of the parties' efforts

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 corresponding studies. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the information provided, so as to establish whether the parties have made every effort to ensure that the studies and their costs are shared in a fair, transparent and non-discriminatory way.

Claimant's efforts

Based on the communication between the parties, ECHA concludes that [redacted], the Claimant, has not made every effort to reach a *fair, transparent and non-discriminatory agreement* on the sharing of the data and their cost.

During the negotiations, [redacted] several times changed the subject matter of the negotiation and thereby made it more difficult to reach an agreement. More specifically, they started the negotiations by requesting a number of studies in order to submit an individual registration.[11] They clarified that they did not want to participate in the joint submission[12], even after [redacted] had urged [redacted] to join it.[13] However, after receiving an offer for the requested studies and after the consortium had prepared a different LoA to refer to certain studies only, of which [redacted] was aware,[14] and on a very short notice before the submission of the claim to ECHA, [redacted] requested also the token code to join the joint submission.[15] The participation in the joint submission grants the Claimant more extensive rights than the mere right to refer to a list of specific studies. Hence, the Claimant changed the subject of the negotiations by including the participation in the joint submission at this point of the negotiations.

Finally, after having received an offer for joining the joint submission, they explained their intention to opt out due to the "high cost of the LoA for the dossier, which furthermore, does not have an appropriate registration strategy" and because the registration is non-compliant.[16] Instead, they wanted to follow their own registration strategy and refer only to certain studies from the joint submission.[17] At this point it became unclear whether they intend to participate in the joint submission and justify opting out from all endpoints except those that they have listed, or whether they plan to submit an individual registration outside the joint submission, given that their arguments concern the whole joint submission but they have explained shortly before why they intend to participate in the joint submission. In addition, the list of studies requested by the claimant changed over time.[18]

An agreement on the sharing of the data and their related costs cannot be reached if the data are not specified. While there may be situations where a future registrant realises

[11] Cf., messages of 13 February 2013, 14 February 2013, 15 February 2013, 1 March 2013, 5 March 2013, 8 March 2013, 20 March 2013, 26 March 2013 and 9 April 2013
[12] Cf., messages of 14 February 2013, 1 March 2013 and 5 March 2013
[13] Cf., message of [redacted] of 1 March 2013
[14] Cf., message of [redacted] of 9 April 2013
[15] Cf., messages of 30 April 2013 and 2 May 2013
[16] Cf., message of 6 May 2013
[17] Cf., message of 6 May 2013
[18] Cf., messages of 13 February 2013, 20 March 2013, 26 March 2013 and 6 May 2013, which again refers to the studies listed on 13 February.

during the negotiations that he needs other data than he originally thought, that is not the case here. [redacted] rejected a discussion of which studies are relevant for the substance grade they intend to register[19] and initially refused to join the joint submission[20] without a discussion. [redacted] could not have foreseen the changes of mind of [redacted], because [redacted] refused to discuss their motivation and needs and merely insisted on receiving price offers and the letter of access for whatever they requested.

By unilaterally changing the data requested through the negotiations, [redacted] did not contribute to finding an agreement on the sharing of the data.

Moreover, if [redacted] did not agree to the prices proposed by [redacted], they did not attempt to find an agreement and a common understanding on how the cost of the data should be shared. They could have done so by asking how [redacted] and the [redacted] reached the amounts they request for data sharing. If they would then have had concerns with regard to the price calculation, they could explain it to [redacted] and [redacted] to find an agreement on how the costs should be shared.

Although they asked detailed questions on the calculation of the costs for the individual studies in one message,[21] they appear to realise that some of their questions had already been answered[22] or to accept the price offered, because they asked for the LoA shortly thereafter[23].

[redacted] did not once ask how the price for the LoA for the complete submission had been calculated. To the contrary, they said from the outset that they are not interested in participating in the joint submission.[24] By not discussing with [redacted] how the price of the LoA for the joint submission was calculated, [redacted] did not make every effort to find an agreement on the sharing of the cost for the joint submission.

The claimant declared that he does not possess any of the two vertebrate animal studies that have been asked by the other party, although he also did not indicate whether he plans to conduct the tests or to waive them.[25] It is the responsibility of all SIEF members to assess every available study and try to reach an agreement on the sharing of the relevant studies for the registration dossier, *inter alia*, to avoid the duplication of tests. By not giving the other registrants an indication of how he intends to fulfil endpoints involving testing on vertebrate animals, [redacted] also displayed a lack of effort in data sharing negotiations and SIEF discussions.

Existing registrants' efforts

ECHA concludes on the basis of the communication between the parties that the existing registrants, represented by the [redacted] and [redacted], made every effort to reach an agreement with [redacted].

[redacted] provided answers to all questions received in a timely manner.

---

[19] Cf., message of 13 March 2013 at 9:41
[20] Cf., messages of 14 February 2013, 1 March 2013 and 5 March 2013
[21] Cf., message of 20 March 2013
[22] In particular, [redacted]s e-mail of 18 March 2013 already explained the cost, risk premium and administration premium for each study. The number of registrants (4) had already been provided by [redacted] on 14 February 2013
[23] Cf., message of 26 March 2013
[24] Cf., messages of [redacted] of 1 and 5 March 2013
[25] Cf., message of 26 March 2013

[redacted] also sent offers for both of [redacted]'s requests, both for individual studies[26] and for participation in the joint submission[27]. If their LoA for the sharing of the individual studies was delayed[28], this was due to the fact that they had to prepare a new kind of contract, as they explained in a separate message[29]. By reacting to all of the Claimant's requests, [redacted] tried to reach an agreement.

They also provided a breakdown of the costs of the studies before asked to do so by the claimant, and thus displayed commendable transparency.[30]

[redacted]'s offer for participation in the joint submission was a step in the discussions on the sharing of the data. The offer is based on the price for access to the full joint submission and foresees a subsequent discount when ECHA would have accepted the opt-outs by [redacted]. [redacted] expresses its openness, however, to discuss different pricing models, provided that they "can safeguard the value of the 'token'".[31]

This pricing model is based on a misunderstanding, because ECHA does not confirm that an opt-out is permissible. Instead, ECHA carries out compliance checks on a part of the dossiers received. If the opt-outs are permissible, this will not be explicitly confirmed by ECHA. ECHA will only issue a decision on compliance check if the opt-outs are not compliant. Existing registrants also have no prerogative to confirm whether an opt-out is permissible and can normally not charge potential registrants for studies, from which they intend to opt out. In the case at hand, however, suggesting [redacted] to pay for the full joint submission while remaining open to other suggestions was permissible, because [redacted]'s opt-out from the studies contained in joint submission was obviously not permissible.

[redacted] justified the opt-out with the high cost for the LoA for the dossier, the inappropriate registration strategy and the non-compliant registration.

In case [redacted] meant to "opt out" from the joint submission, it was sufficient to state that it is not possible to opt out from a joint submission. Registrants can only opt out from individual endpoints, if one of the conditions of Article 11(3) of the REACH Regulation is fulfilled for the endpoint.

The cost of the LoA for a whole dossier cannot justify opting out from individual studies. To justify opting out from an endpoint, the data and cost for the endpoint has to be assessed. However, [redacted] never asked for the price of the studies that were not in any of the lists it had sent to [redacted]. [redacted] did not opt out after they had heard how much it would cost to submit certain information jointly. An existing registrant can expect that the reasons for opting out have at least been subject to a brief discussion, before a potential registrant decides to opt out. It is not permissible to opt out from the joint submission of certain studies without first inquiring about their cost.

The inappropriate registration strategy and non-compliant registration are two ways of describing the same problem: the joint submission is incompliant, because it does not describe the identity of the registered substance in a compliant manner. Such incompliance cannot justify breaching Article 11 by not participating in a joint submission. A registrant could justify opting out from certain studies, where they are not suitable to describe the grade of the substance that he manufactures or imports under Article 11(3)(3) of the REACH Regulation. However, [redacted] has not assessed the usefulness of the studies for its

[26] Cf., [redacted]'s message of 18 March 2013
[27] Cf., [redacted]'s message of 3 May 2013
[28] It was sent on 30 April 2013 2013, and had been requested on 26 March 2013
[29] Cf., [redacted]'s message of 9 April 2013
[30] Cf., [redacted]'s offer dated 15 March 2013, sent on 18 March 2013
[31] Cf., [redacted]'s message of 3 May 2013

grade, but, to the contrary, has refused the discussion on the grades and the appropriateness of the studies for the various grades, which [redacted] suggested.[32]

Considering the fact that the opt-out was obviously not permissible, the existing registrants could propose to [redacted] to pay for the right to refer to the full joint submission and later to be refunded. Importantly, they expressed their willingness to discuss other pricing mechanisms that would safeguard their interests. Subsequent discussions on other mechanisms could also have clarified ECHA's assessment of opt-outs. [redacted], however, made no other proposal of how their intentions and the interests of the existing registrants could be achieved.

Conclusion

[redacted] made every effort to demonstrate that the conditions or costs of sharing the data have been determined in a fair, transparent and non-discriminatory way, as required by Article 30(1) of the REACH Regulation. The claimant did not make every effort in this respect. Therefore, ECHA does not grant [redacted] the permission to refer to the information requested from [redacted].

Legal consequences and obligations

[redacted]

[redacted]

In the letter dated 21 May 2013, ECHA explained to you the consequences in case the decision is not in your favour. Since ECHA decides not to grant you a permission to refer to the data disputed, [redacted]

Appeal

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 notification of this decision. The procedure for lodging an appeal is described at http://echa.europa.eu/web/guest/regulations/appeals.

[32] Cf., messages of 5 March 2013 and 8 March 2013

General observations

ECHA encourages [redacted] to:

- communicate clearly to the other party what its exact needs are;
- increase the trust by informing the other party of their own studies and discussing the sameness of the substance within the SIEF together with the rest of the SIEF members;
- ask which studies are contained in the offer and how they have been valued to understand the data and cost sharing approach proposed by the existing registrants;
- eventually challenge the proposed offers with concrete alternative solutions if it disagrees with them to unlock the negotiations and find a common understanding.

Both parties 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 of their related costs. If subsequent negotiations fail, a further data sharing dispute can be submitted.

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 EC number and the reference number in any correspondence in relation to this decision.

Yours faithfully,

[redacted]

Geert Dancet
Executive Director