04 -10- 2013

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Reference number: DSH-30-3- 2013

Decision number: **DSH-30-3-D- 2013**

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

Dear Mr ,

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, submitted on 19 July 2013, regarding the failure to reach an agreement on data sharing under Article 30(3) of the REACH Regulation with the representing the existing registrants, for the substance with EC number

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 26 July 2013. ECHA also received the information from the on 9 August 2013 and therefore conducted a contradictory assessment of the information provided by both parties. The assessment covered exclusively 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 of [redacted] represented by the [redacted]

Based on the information provided by both you and the [redacted] ECHA has concluded that, at the date of the claim, 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.

The detailed justification is set out in an **Annex** to this decision.

General observations

Besides the result of the assessment, ECHA would like to make some general observations in order to facilitate a future agreement:

- Both potential and existing registrants still share a common data sharing obligation, and therefore are still required to make every effort to reach an agreement on the sharing of the information and of their related costs;
- ECHA encourages the parties to continue their efforts to reach an agreement that will be satisfactory for both parties. 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;
- Making every effort in reaching an agreement requires both parties to find alternative solutions to unblock the negotiations and to be open and proactive in their communications with the other party;
- Making every effort to reach an agreement also implies, for instance, that a potential registrant specifies and justifies their arguments or concerns unambiguously and comprehensively, as well as challenges the arguments of the existing registrant(s). In case a party receives and unsatisfactory reply, which it considers unclear, invalid or incomplete, it is their responsibility 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;
- If the further data sharing negotiations fail, the claimant is free to submit another claim, covering the subsequent efforts;
- ECHA is never a party in the negotiations. Therefore all arguments have to be communicated between SIEF participants regarding how the costs where defined using for example various percentage premiums;

Finally, Article 11 of the REACH Regulation imposes on multiple registrants of the same substance to submit one joint submission comprising the shared information.

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

Yours faithfully,

Geert Dancet
Executive Director

Jukka MALM
Director

Annex to communication DSH-30-3-[redacted]2013

DETAILED OUTCOME OF THE ASSESSMENT OF THE DATA SHARING DISPUTE

Article 30(1) of the REACH Regulation requires SIEF participants to "*make every effort to ensure that the costs of sharing information are determined in a fair, transparent and non-discriminatory way*". The following provides the detailed outcome of the objective and contradictory assessment of the data sharing dispute, under Article 30(3) of the REACH Regulation,

> between [redacted] (hereinafter referred to as '[redacted]' as only representative of [redacted]

and

> the existing registrants of [redacted] regrouped in the [redacted] (hereinafter referred to as '[redacted]' which is represented by [redacted] as manager of the [redacted] and by [redacted] (referred to as '[redacted]' as legal advisor.

Based on the communication between the parties, ECHA considers that [redacted] has not made every effort to reach an agreement with the existing registrants on the sharing of data under fair, transparent and non-discriminatory conditions.

I. Efforts relating to the timing of negotiations

Data sharing negotiations can be a complicated process, where the parties have to identify their data requirements and find an agreement on the costs of the data and on the modalities of sharing. ECHA expects diligent potential registrants to negotiate the sharing of data and related costs as constructively as possible. This implies, notably, that potential registrants make sure that the negotiations progress by initiating the negotiations sufficiently early before any registration deadline to make it possible to reach an agreement, by giving reasonable time to the other for providing appropriate answers to their questions or arguments and by replying to the messages of the other party in a timely manner.

In the present claim, [redacted] initiated[1] the negotiations with existing registrants on 14 March 2013, i.e. less than three months [redacted], and the last exchange of messages took place on 29 May 2013.[2]

The [redacted] has not only focused on finding an alternative wording to the disputed "certification" clause but also made efforts and replied to [redacted] emails in a very timely manner. By contrast, [redacted] has not reacted promptly on two occasions once at the end of April[3] and also at the end of May[4]. As the issues were left unattended by [redacted], the [redacted] sent a reminder and expressed their surprise[5], as to why "*after all the correspondence and efforts exchanged*", [redacted] had not reacted so far and reminded that if [redacted] is still interested "*to contract with the* [redacted] *for the data access*", they should do it as soon as possible.

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[1] Cf. [redacted] email of 14 March 2013, 9:40.
[2] Cf. [redacted] email of 29 May 2013, 12:42 PM and [redacted] email of 29 May 2013, 4:15 PM.
[3] Cf. [redacted] email of 8 May 2013, 3:07 PM.
[4] Cf. [redacted] email of 28 May 2013.
[5] Cf. [redacted] emails of 16 May 2013, 2:07 PM and of 28 May 2013.

During the two and half months of negotiations, the exchanges have been intense and frequent. ECHA assessed their content and concluded that the [redacted] had provided more constructive, precise and timely alternative proposals on the issues raised by [redacted]. Finally, [redacted] kept silent as of 16 May 2013. It was the [redacted] that enquired[6] whether they are still intending to register [redacted] [redacted]. Finally, although the [redacted] replied to their last comment[7] and requested additional clarifications, [redacted] did not challenge or contact the [redacted] during more than one month and their last correspondence was only to inform the [redacted] [redacted] on 9 July 2013, that they are formally submitting *"a complaint to ECHA regarding [...] dispute and ultimate failure to reach agreement"*.

II. Efforts related to the claims

As a preliminary comment, ECHA notes that, in its email of 10 April 2013, [redacted] confirmed that they have no claim against the actual costs of the data to be shared and that their client are *"fully ready to conclude the* [terms and conditions for a letter of access] *along the lines indicated in* [the [redacted] email of 18 March 2013], *except for one remaining concern"*.[8] This remaining concern was the topic of all the data sharing negotiations until the submission of the data sharing claim to ECHA.

For the purpose of the present assessment and for the sake of clarity and exhaustivity, the efforts of the parties in the negotiations can be assessed in relation to various sequences: (1) concerns relating to a certification regarding boycott measures; (2) invitation for an individual assessment of the condition for certification and for an individual adaptation of the clause; (3) negotiations of the list of individual studies; (4) final initiatives to resolve the outstanding issues on certification.

1) Concerns relating to a certification regarding boycott measures

In its emails of 10 April 2013[8], [redacted] specified the reasons for its concerns regarding the boycott measures certification clause. More specifically, these explanations referred to the following:

- The confusing nature of the terminology used in the clause: [redacted] considered that the [redacted] should be *"referring to economic sanctions laws rather than boycott measures"*.
- The scope of the "boycott measures": [redacted] considered that *"under applicable international sanctions regulations, the mere fact of being domiciled in a sanctioned country is not a sufficient criterion for imposition of any penalty"*. Accordingly, such measures shall only apply to persons specifically designated by the legislation concerned.
- The absence of effect of "boycott measures" on REACH data sharing obligations: based on the above interpretation of the scope of the "boycott measures", [redacted] considered that because the [redacted] [redacted] *"will not transfer specifically prohibited goods or services to sanctioned persons or entities in a sanctioned country, it appears unlikely that the transfer of REACH registration data would violate any current rules"*.

ECHA notes that the explanation of the reasons of their concerns demonstrates an initial effort from [redacted] to reach an agreement.

However, ECHA also notes that the [redacted] has duly contested all these

[6] Cf. [redacted] email of 28 May 2013.
[7] Cf. [redacted] email of 29 May 2013, 16:15.
[8] Cf. [redacted] email of 10 April 2013, 3:55 PM.

explanations. In its email of 22 April 2013, while recognising the relevance of the terminology proposed by [redacted] the [redacted] substantiated its interpretation of the scope of "boycott measures" based on actual quotations of the relevant legislation. More specifically, these references demonstrated that both EU and US "boycott measures" do not apply to the activity of a list of persons domiciled in sanctioned countries, as argued by [redacted] but aim at prohibiting US and EU companies from providing, directly or indirectly, assistance or support to any person in a sanctioned country.[9]

Therefore, the explanations provided by the [redacted] called significantly into question the relevance of the arguments invoked by [redacted] which were based on the argument that the [redacted] would not be providing any benefit to designated persons in sanctioned countries.

In reply to these substantiated clarifications, [redacted] reiterated their position of principle[10] that the "boycott measures" cannot affect the sharing of data under the REACH Regulation for implementing international sanctions. In support to this, [redacted] invoked firstly that a "*decision to refuse to grant the letter of access will prevent* [their] *registration* [...] *entailing a delay of marketing and additional expenses*". However, ECHA considers this assertion as manifestly wrong, in so far as the submission of an incomplete dossier does not affect the right to manufacture or import a substance. Before the submission of a dossier, a potential registrant may lodge a data sharing claim to ECHA to challenge the outcome of the data sharing negotiations. If ECHA considers that the data sharing claim is justified, it will grant to that registrant a permission to refer to vertebrate animal data contained in the dossier, [redacted] the registrant will receive a registration number. [redacted]

Secondly, [redacted] claimed that "*neither the specific substance as such, nor the data* [of the Consortium] [...], *could provide any strategic value to countries targeted by the referenced boycott laws*". However, the extent to which the "boycott measures" can justify this generic view is not obvious, especially with regards to the provisions previously quoted by the [redacted] which include terms widening their scope (e.g. "*direct or indirect*" assistance, "*contribution*" to the expansion of Iranian production). Unfortunately, [redacted] did not substantiate its assertion with any legal analysis of the legislation concerned. In order to be fully constructive for the negotiation discussions, this assertion would have needed to be substantiated more precisely based on an analysis of the actual provisions of the "boycott measures", especially those quoted by the [redacted]

As a result, ECHA considers that, by providing clarifications on the scope of the "boycott measures", including on the basis of quotations, the [redacted] has made efforts to justify the concerns of its members that the activity of the consortium may engage their liability. In contrast, ECHA considers that [redacted] has not made sufficient efforts to demonstrate that the contested clause is not justified, by substantiating concretely why the "boycott laws" would not apply to the consortium members, or to the substance and the data concerned.

2) Invitation for an individual assessment of the condition for certification and for individual adaptation of the clause

ECHA notes that the [redacted] recognised the difficulty that the certification of compliance with "boycott laws" may pose in practice to potential registrants. More

[9] Cf. [redacted] email of 22 April 2013, 2:25 PM.
[10] Cf. [redacted] email of 08 May 2013, 03:07 PM.

specifically, the [redacted] pointed out that the certification clause also includes another section offering potential registrant the possibility to discuss individual cases: "*where a company cannot certify compliance with the* [boycott compliance certification clause], *but there is no violation of any boycott law* [redacted] *also allows for an* ad hoc *assessment of the situation of a particular company*".[9] The terms and conditions of the letter of access thus mitigate the risks that such complex laws would preclude some potential registrants from accessing the data, while not being actually in breach of them. With this approach, the [redacted] demonstrated overall efforts to address the difficulties that potential registrants may have to certify compliance with complex "boycott laws", while taking care of the alleged concerns that consortium members have for their own liability. With regards to [redacted] the [redacted] also applied this open attitude. The representative of the [redacted] invited [redacted] "*to get in touch with* [redacted], *to provide details of the issue raised by the required certification, and to propose a specific 'carve out'*", if [redacted] "*believes that* [redacted]*'s granting data access to it does not violate any boycott laws*".[9] This invitation confirms that even in the case where [redacted] would have had concerns with the possible non-compliance of its client with "boycott measures", the [redacted] was still willing to discuss the situation.[11]

In reply to this invitation, [redacted] simply specified[10] that their client "*has expressly stated its objections to the 'boycott' certification*" and that they "*frankly can only suggest a carve out of the whole certification statement as drafted*". [redacted] nevertheless clarified and offered "*as an alternative to the certification requested*" a short statement. In the absence of further supporting explanation from [redacted] ECHA understands that the aim of the proposed statement is mainly to remove the specific legal references to the "boycott measures" and only introduces a restriction to not "*knowingly*" use "*the rights granted [...] in violation of the boycott laws*". There may be legitimate legal arguments supporting the introduction of an intentional aspect in the clause. However, based on the previous correspondence, a diligent party should have reasonably expected that this interpretation of the scope of the "boycott" obligations could be a significant point of debate with the other party. ECHA believes that any explanation of the wording chosen by [redacted] for the proposed statement would have helped the [redacted] [redacted] and its members to understand and accept the concerns and the legal interpretation of [redacted] and would have promoted an adaptation acceptable by all. However, ECHA points out that [redacted] did not provide any legal justification of the proposed wording, other than the objection of principle to the certification already mentioned above.

In reply to this proposal, the [redacted] claimed their "*[willingness] to accept [the] proposed alternative wording of the certification, subject to [...] changes*".[11] However, in spite of this declared intention, ECHA notes that the alternative modifications proposed by the [redacted] does not take into account what seems to be the main aspects of the statement proposed by [redacted] (i.e. the intentional use of data) although the modified text includes some parts of the proposal of [redacted] Nevertheless, ECHA contends that if [redacted] had specified in detail their concerns and provided legal arguments supporting them, the [redacted] would have been compelled to take these points into account and to justify precisely its position on them in the course of the negotiations.

[redacted] commented the consortium's alternative wording by referring again to their objection of principle on the certification clause without further argument.[12] Further, [redacted] pointed out that "*the alternative wording* [proposed by the [redacted] *would impose conditions stricter than those imposed by the Consortium concerning all other SIEF members, which* [[redacted] *consider discriminatory treatment and cannot accept*". However, again [redacted] did not specify which conditions they considered to be stricter and did not

[11] Cf. [redacted] email of 08 May 2013, 11:27 PM. "*If there is any concern of non-compliance with economic or boycott laws, we should have further discussions*".
[12] Cf. [redacted] email of 14 May 2013, 11:41 AM.

demonstrate the discriminatory treatment with any legal argument. ███ left the ███ ███ without any element enabling them to accept or challenge their position, or even understand the nature of their concerns.

In the absence of supporting justifications from ███ throughout the discussions on the wording of the contested clause, the ███ could not have legitimately been expected to presume the arguments of the other party or to anticipate the basis of these arguments, in order to challenge them. This absence of sufficient argumentation constituted an obstruction in the negotiations. In the present case, the difficulties resulting from such obstruction are illustrated by the calls for detailed justifications from the ███ to ███

> *"If the ███ were to accept ███'s position and grant access to its data, all the Members of the ███ would be exposed to the risk of potential non-compliance with law. It is unclear to me why you feel this is reasonable; would you please explain?"* (emphasis added).[13]

> *"Would you therefore please indicate precisely which parts of the alternative wording you would like to see changed and propose specific amendments"* (emphasis added).[13]

The requests of the ███ for precise arguments and amendments that could have enabled the negotiations to progress remained vain. On the same day, ███ terminated the discussions on the wording by requesting "*one final time – does the Consortium grant or deny the requested data access in these circumstances?*".[14]

Based on the above, ECHA considers that the possibility offered by the ███ to address specific difficulties of potential registrants to certify compliance, as well as the specific invitations made to ███ to specify their concerns and arguments, demonstrate an effort of the Consortium to reach a data sharing agreement. In contrast, a repeated opposition to a constructive discussion, without other supporting argument than unsubstantiated objections of principle, does not show sufficient efforts from ███ to reach an agreement.

3) Discussions on a list of individual studies

In its email of 08 May 2013, ███ requested the ███ to identify all the studies contained in the dossier jointly submitted, while indicating those involving vertebrate animals.[15] ECHA understands from the correspondence available that the reasons for that request have been misunderstood. Indeed, in its initial request ███ specified the motivation by a "*possibility of a data sharing notification to ECHA*". In contrast, the ███ ███ understood from this request that ███ had the intention to negotiate access to data with individual data owners.[16] This misunderstanding explains the considerations of the ███ regarding the intended date of submission[17], the right to access to individual studies not owned by consortium members[18], or the cost of treating the request[19].

In any case, the ███ treated that request and diligently provided[20], eight

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[13] Cf. ███ email of 14 May 2013, 12:33 PM.
[14] Cf. ███ email of 14 May 2013, 02:13 PM.
[15] Cf. ███ email of 08 May 2013, 03:07 PM.
[16] Cf. ███ email of 14 May 2013, 3:38 PM.
[17] Cf. ███ emails of 14 May 2013, 12:33 PM and 3:38 PM.
[18] Cf. ███ emails of 14 May 2013, 3:38 PM and of 15 May 2013, 5:11 PM.
[19] Cf. ███ emails of 14 May 2013, 12:33 PM and and 15:38 PM, as well as the emails of 15 May 2013, 5:11 PM and of 16 May 2013, 4:19 PM.
[20] Cf. ███ email of 16 May 2013, 11:00 AM.

days after the request, the list of studies contained in the dossier [redacted] to [redacted] highlighting the ones involving vertebrate animals, while mistakenly believing that [redacted] were contemplating an alternative approach to submit a separate dossier.

In that respect, the correspondence available shows that in order to reach an agreement on the sharing of data, the [redacted] has demonstrated efforts to adapt to any alternative solution [redacted] would have contemplated, while the correspondence also shows that [redacted] did not have intention to negotiate access to the individual studies, although the REACH Regulation requires potential registrants to understand which data they need in their registration dossier in order to demonstrate the intrinsic properties of the substance they are manufacturing or importing. Reaching an agreement could have been possible if [redacted] had suggested to negotiate individually with the data owners within the SIEF, in order to fulfil their own registration requirements, without having to deal with the contested "certification".

4) Final initiatives to resolve the outstanding issues on certification

ECHA notes several initiatives of the [redacted] to address [redacted] concerns while [redacted] [redacted] [redacted], in spite of indications in the preceding correspondence of [redacted] desire to terminate the negotiations.

- Granting of a provisional access to data pending the resolution of outstanding issues

  By a first initiative, the [redacted] offered to grant [redacted] a provisional access to the Consortium's data pending the resolution of outstanding issues regarding the wording of the certification clause.[21] More concretely, the [redacted] pointed out that "*unfortunately,* [[redacted] *raise all of these issues at a very late stage, although the* [redacted]*'s terms and conditions have been available for a long time. If* [redacted] [[redacted] client] *is required to register by* [redacted], [the [redacted] *recommend that* [redacted] *pay the access fees for the dossier concerned now.* [The [redacted] *will keep the money in escrow, subject to resolution of the outstanding issue over certification*".

  [redacted] required a clarification on some aspects of this offer.[22] The [redacted] provided on the same day the required clarifications[23], although these seemed to have been still not clear enough for [redacted][24] After, the [redacted] referred to the clarification it previously provided[25], [redacted] never discussed or referred again to that offer.

  ECHA notes that this initiative for practical arrangements from the [redacted] showed its good intention by attempting to accelerate the letter of access purchase process and may have enabled [redacted] to submit a complete dossier by the required deadline, while negotiations over outstanding issues would have continued.

- Provision of a singular certification scheme

  After the last correspondence from [redacted] questioning the above-mentioned offer, the [redacted] took again the initiative to propose another alternative solution to accommodate [redacted] concerns while taking account of the concerns of the [redacted] [redacted] More specifically, the new "*qualifier*" was based on a modification of the certification for [redacted] only aiming at meeting "*the objections* [[redacted] *raised previously by*

[21] Cf. [redacted] email of 14 May 2013, 3:38 PM.
[22] Cf. [redacted] email of 15 May 2013, 8:49 AM.
[23] Cf. [redacted] email of 15 May 2013, 5:11 PM.
[24] Cf. [redacted] email of 15 May 2013, 6:32 PM.
[25] Cf. [redacted] email of 15 May 2013, 7:42 PM.

limiting the certification explicitly to actual exposure for [redacted] entities".[26]

After a reminder pointing out the time necessary to implement the offer if accepted[27], [redacted] replied on the same day indicating that their client "*is carefully reviewing* [the] *latest offer*" and asking three questions for clarification.[28] The [redacted] replied on the same day that "*the answer to all of your questions is affirmative, subject to (1) [redacted] approval, which* [[redacted]'s legal advisor] *will seek upon [redacted]'s approval, and (2) an administrative fee for manual process to cover some of* [the [redacted]] *additional cost. This fee is charged to all registrants that require a manual process, and is EUR [redacted].*"[29]

ECHA notes that [redacted] never commented, or even referred again to that offer from the [redacted] of a practical resolution of the outstanding issue.

[redacted] the [redacted] made several attempts to either maintain sound negotiation conditions by relieving [redacted] from the pressure of the [redacted] [redacted], or provide another proposal to resolve the outstanding certification issue.

If there were misunderstandings on certain aspects of these proposals, there was still an opportunity for any diligent potential registrant to explore these offers. ECHA considers that, by taking these initiatives on its own motion, the [redacted] made further efforts. In contrast, ECHA notes that [redacted] although being the party that was directly affected by the time pressure, did not make the efforts necessary to continue the negotiations and resolve the outstanding issues.

III. Conclusion

Based on the above assessment, ECHA considers that the [redacted] made every effort to reach an agreement and to ensure that the costs of sharing data are determined in a fair, transparent and non-discriminatory way, as required by Article 30(1) of the REACH Regulation while [redacted] did not.

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[26] Cf. [redacted] email of 16 May 2013, 11:20 AM.
[27] Cf. [redacted] email of 16 May 2013, 2:07 PM.
[28] Cf. [redacted] email of 16 May 2013, 2:15 PM.
[29] Cf. [redacted] email of 16 May 2013, 4:19 PM.