ECHA
European Chemicals Agency

Helsinki, 19 -11- 2010

[redacted]

EC NUMBER: [redacted]
REFERENCE NUMBER: DSH-30-3-[redacted]-2010

Decision No: DSH-30-3-D-[redacted]-2010

**DECISION RELATING TO YOUR DATA SHARING DISPUTE UNDER ARTICLE 30(3) OF REGULATION (EC) NO 1907/2006 WITH [redacted] FOR SUBSTANCE WITH EC NUMBER**

In accordance with Article 30(3) of Regulation (EC) No 1907/2006 ("the REACH Regulation"), the European Chemicals Agency (ECHA) has examined the information you (for the company [redacted]) provided on 15 October 2010, regarding failure in reaching an agreement on data sharing under Article 30(3) of the REACH Regulation with [redacted] as the lead registrant.

The information you provided was considered complete and appropriately documented, as indicated in our letter to you dated 20 October 2010. In addition, ECHA requested and received information from [redacted] regarding this dispute within the set deadline.

Article 30(1) of the REACH Regulation sets out as a pre-requisite that SIEF participants shall make every effort to demonstrate that the costs of sharing the data have been determined in a fair, transparent and non-discriminatory way. In case of dispute on the sharing of studies involving vertebrate animal testing which have already been submitted, Article 30(3) of the REACH regulation requires ECHA to determine whether to provide permission to refer to these studies. In order to guarantee the protection of the interests of each party, ECHA conducts an assessment of all the information provided, in order to establish whether a party has made every effort to ensure that costs the studies are shared in fair, transparent and non discriminatory way.

**As a result of this contradictory assessment, ECHA has decided to grant you permission to refer to the information requested from [redacted].**

More specifically, this permission concerns the studies involving vertebrate animal tests contained in the dossier, which belong to [redacted], or for which [redacted] is entitled to carry out the rights of the actual owner. However, this permission does not apply to studies involving vertebrate animals for which [redacted] has explicitly stated that it was not entitled to agree on sharing.

Accordingly, the permission to refer concerns the following studies:

1) [redacted]
2) [redacted]
3) [redacted]

4) [redacted]
5) [redacted]
6) [redacted]
7) [redacted]
8) [redacted]
9) [redacted]
10) [redacted]
11) [redacted]

On the basis of the information provided by both you and the other party, ECHA concluded that [redacted] had not made every effort to demonstrate that the 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. More specifically, as explained in detail in the assessment in Annex I, ECHA considers that [redacted] has not made sufficient efforts to justify the selection of the data submitted and the various changes of cost sharing methodology.

**Legal consequences and obligations**

As a result of this decision, you will find in Annex III the endpoint study records assessed in vertebrate animals and related to the properties of the substance at stake.

According to the REACH Regulation, [redacted] may only use the information attached for the purpose of registration (as per Articles 10 of the REACH Regulation) and must respect any property rights.

[redacted] must also follow the instructions on how to use the information provided in Annex II to submit their registration dossier. In addition, it is the registrants' responsibility to fulfil their legal requirements relating to the chemical safety report and recommended risk reduction measures under Article 14(3) of the REACH Regulation.

According to Article 30(3) of the REACH Regulation, [redacted] shall have a claim on [redacted] for an equal share of the cost, which shall be enforceable in the national courts, provided it makes the full study report available to [redacted].

Please be reminded that Article 30(3) only refers to requests regarding vertebrate animal data. If you need to complete your dossier with studies not involving vertebrate animals and have not been successful in reaching an agreement with the previous registrant on the sharing of this data, Article 30(4) of the REACH Regulation applies. It provides that the potential registrant "*shall proceed with registration as if no relevant study was available in the SIEF*". This requires that, in order to fulfil your registration requirements relating to your registration tonnage band, you perform these studies on your own, or together with other potential registrants facing similar difficulties. Nevertheless, Article 30(6) of the REACH Regulation also requires the national competent authorities to penalise the owner of the studies who has refused to provide them.

In accordance with Article 30(5) of the REACH Regulation, the potential registrant or the data owner may appeal against this decision to the Board of Appeal of ECHA within three months of receiving notification of this decision. The procedure for lodging an appeal is described at http://echa.europa.eu/appeals/app_procedure_en.asp.

Finally, we remind you that the outcome of a data sharing dispute procedure can never satisfy any party in the way a voluntary agreement would. Accordingly, should you wish to avoid the inconveniences resulting from this procedure, we encourage you to continue your efforts to reach an agreement that will be satisfactory for both parties.

Please send any further correspondence in relation to this decision to the following email address: datasharing-disputes@echa.europa.eu. Please state the above-mentioned EC number, the Reference number and the Decision number in any correspondence with ECHA in relation to this communication.

Yours faithfully,

[redacted]

Geert Dancet

Executive Director

Copy: [redacted]

Annexes:

Annex I: Detailed outcome of the assessment of the data sharing dispute [redacted] / [redacted]

Annex II: Instructions on how to submit your registration dossier under the "contingency" data sharing dispute procedure

Annex III: Endpoint study records related to the properties, assessed in vertebrate animals, of the substance with EC number: [redacted]

European Chemicals Agency

Annex I

## DETAILED OUTCOME OF THE ASSESSMENT OF THE DATA SHARING DISPUTE [redacted] / [redacted]

Article 30 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 note provides the outcome of the objective and contradictory assessment of the data sharing dispute between [redacted] (hereafter, [redacted]) and [redacted] (hereafter, [redacted]) under Article 30(3) of the REACH Regulation.

## I. UNILATERAL APPROACH TO DATA GATHERING AND DOSSIER DEVELOPMENT

Based on the available information, although [redacted] has volunteered to act as SIEF Formation Facilitator, [redacted] took first the initiative to contact [redacted] to propose its active collaboration in the preparation of the registration dossier.

> "*Although there are many others in the SIEF, we are aware that the work will fall between* [redacted] *and* [redacted] *to undertake the main activities on* [redacted] *. We are ready and willing to enter into discussions with you at any time you are ready to start the preparations*"[1].

[redacted] responded by a waiting reply six weeks after [redacted]'s offer and following a reminder[2]. No concrete collaboration was set up and [redacted] only offered to [redacted] to wait for the standard communication to be sent to all the SIEF participants[3].

The correspondence provided by both parties clearly shows that [redacted] has continuously demonstrated an interest in the development of the dossier, not only in terms of timing, but also with regard to the selection and assessment of the data to be included[4]. Various messages demonstrate explicitly the efforts of [redacted] to be actively involved in the assessment of the data used for the preparation of the dossier:

> « *You will be aware that we have really struggled with this matter* [i.e. [redacted] ] *because of the tiny amount of information that* [redacted] *have been prepared to share with us so far* »[5].

Or, later :

> « *We are still very keen to understand the details of the study, and to provide full support to* [redacted] *conclusions. However, this is almost impossible, given the fact that you are choosing to withhold safety information* »[6].

1 Email from [redacted] of 12 February 2009.
2 Respectively, emails from [redacted] of 30 March 2009 and 23 March 2009.
3 Email from [redacted] to all the SIEF participants of 10 August 2009.
4 Email from [redacted] of 06 November 2009.
5 Email from [redacted] of 01 April 2010.
6 Email from [redacted] of 07 April 2010.

We also note that [redacted] offered to provide studies to [redacted] (emails from [redacted] of 26 June 2009 and 17 November 2009). ECHA acknowledges that [redacted] 's concerns on specific aspects of the dossier were only addressed by [redacted] during the last year. However, we note that [redacted] acted only when requested, through telephone conferences (including 17 November 2009, 18 June 2010 and 24 August 2010) and meetings (on 27 April 2010 and 02 July 2010). The elements provided by the parties show that, although [redacted] has proactively sought to be involved in the development of the dossier, [redacted] has been reactive in updating [redacted] only when required, without involving it as actively as requested.

These elements demonstrate a unilateral approach of [redacted] with regards to [redacted] in the selection and assessment of the data to be included in the dossier.

This unilateral approach is unambiguously confirmed by other facts. Firstly, the SIEF agreement proposed by [redacted] is not a multiparty agreement between all the SIEF participants, but only a bilateral agreement between [redacted] and any other individual registrant. More importantly, the dossier has eventually been submitted by [redacted] without offering SIEF participants that were willing to be involved, such as [redacted] , any opportunity to give their assent on its content. Based on the available information, we also note that [redacted] has not informed [redacted] of successful registration of the substance.

By contrast, Article 11 of the REACH Regulation requires the lead registrant to act with the agreement of the other assenting registrants.

The unilateral submission by [redacted] of the joint registration dossier places any registrant that has not been directly involved in the development of the dossier in a situation of *fait accompli.*

Contrary to what was claimed by [redacted], Article 11 of the REACH Regulation requires multiple registrants of [redacted] to rely only on one joint submission, i.e. the registration submitted by [redacted]. It is therefore not correct for [redacted] to state:

> *"if* [[redacted]] *do not agree with* [[redacted]'s] *offer,* [it] *is free to refer to Art. 11(3) of REACH and opt out from the joint submission"*[7].

ECHA notes, however, that both parties may have considered the possibility to opt out in relation only to the most contentious endpoints, while remaining part of the joint submission.

Based on the above, the situation of *fait accompli*, which in itself is not compatible with the spirit of joint submission and data sharing, requires [redacted] to be even more diligent in ensuring that the sharing of the costs is determined in a fair, transparent and non-discriminatory way. Indeed, the unilateral selection of data and of the cost sharing methodology is likely to create legitimate suspicions from other registrants as to the fairness of the compensation requested.

As a result of its behaviour, [redacted] must therefore bear a specific responsibility in providing sufficient and relevant information justifying its choices in the selection of data and of the methodology for sharing the cost.

## II. LACK OF SUFFICIENT JUSTIFICATION ON SELECTED DATA AND ON CHANGES OF DATA SHARING CONDITIONS

It is not challenged by [redacted] that the methodology of the cost sharing calculation and the resulting compensation requested have been changed on several occasions during the year.

---

7 Email from [redacted] of 27 September 2010.

- During a telephone conference in November 2009, [redacted] indicated that the estimated share of the joint registration for [redacted] would be [redacted] Euro. This sum was agreed in writing by [redacted] in December 2009[8]. We understand that this estimate was based on [redacted] and [redacted] being the only two registrants for 2010 and on potential refunds for [redacted] when later registrants join.

- In June 2010, following another request for update from [redacted][9], [redacted] informed [redacted] of new cost sharing conditions, with an estimate of [redacted] Euro for the dossier, [redacted] Euro for the CSR, with an assumption of a total of [redacted] registrants by 2018 and no refund foreseen[10]. The CSR would not be shared entirely, as [redacted] considered certain parts as containing confidential information. [redacted] expressed its surprise and requested [redacted] to "*provide justification for both the agreed original proposal and* [the] *new proposal*"[11].

- [redacted] never provided any justification on these proposals. Instead, it informed [redacted] that an external consultant ([redacted]) had re-assessed the cost of the dossier, resulting in a significantly higher share to be paid by [redacted] ([redacted] Euro)[12]. [redacted] was also informed that five of the studies used in the dossier could not be covered by the deal and would have to be negotiated separately with their owner ([redacted])[13].

- In September 2010, [redacted] sent to [redacted] a detailed price list of the studies indicating that after the assessment by the external consultant the share of [redacted] would finally be [redacted] Euro, excluding the five studies. This sum was subject to potential refunds for [redacted] when later registrants join[14].

- Eventually, [redacted] provided [redacted] with a SIEF agreement taking partially[15] into account [redacted]'s request for a reduction resulting from the limited use of the data to REACH purpose only[16]. This resulted in a share for [redacted] of [redacted] Euro.

We note from the available information that [redacted] never provided any justification as to the cost calculation methodologies regarding the two first proposals ([redacted] and [redacted] Euro) as requested by [redacted][17]. In addition, the latest proposals ([redacted] Euro and [redacted] Euro) resulted in a very significant increase from the previous ones. This important difference has not been completely justified by [redacted], except by reference to "*a* [redacted]*% administration fee (filling in Robust Study Summaries in IUCLID) plus* [redacted]*% risk premium*"[18].

For these reasons, [redacted] has legitimately and without delay questioned the proposed agreement and particularly the following aspects[19].

Firstly, [redacted] requested clarification on the calculation of the cost of certain data in the spreadsheet provided. Later correspondence from [redacted] does not provide any clarification on that point.

---

8 Email from [redacted] of 17 December 2009.
9 Email from [redacted] of 03 June 2010.
10 See the letter of [redacted] to ECHA on 03 November 2010
11 Email from [redacted] of 25 June 2010.
12 Telephone conference between [redacted] and [redacted] on 24 August 2010 (see the letter of [redacted] to ECHA on 03 November 2010).
13 Email from [redacted] of 25 August 2010.
14 Email from [redacted] of 01 September 2010.
15 [redacted]% instead of [redacted]% as requested by [redacted].
16 Email from [redacted] of 20 September 2010.
17 Email from [redacted] of 25 June 2010.
18 Email from [redacted] of 01 September 2010.
19 Email from [redacted] of 02 September 2010.

Secondly, [redacted] requested justifications as to why the cost calculation methodology has changed from [redacted] methodology to [redacted] methodology. The correspondence from [redacted] does not show any clarification on this point, but [redacted] invited [redacted] to provide "*constructive suggestions for improvement*" [20]. Promptly after receiving the final proposal, [redacted] responded to [redacted] invitation and proposed an alternative cost sharing methodology[21]. [redacted] did not reply to the offer, considering that they "*have shown a great amount of cooperation and flexibility without, however, being able to solve the issue*"[22]. Instead, [redacted] requested that the negotiations be referred to the lawyers of the two companies. ECHA acknowledges that, in its correspondence, [redacted] consistently emphasized its intention "*to agree on fair, transparent and non-discriminatory terms and conditions with all SIEF members for* [redacted]"[23]. These are positive encouragements in a negotiation, but ECHA notes that [redacted] did not support its declared intention with more concrete efforts.

Thirdly, [redacted] questioned the selection of multiple studies for the same endpoint, pointing out particularly the requirement "*to pay, where the key study costs €* [redacted]*, a share of no less than 10 studies (for the same endpoint-* [redacted]*),with a total value of €* [redacted][24].
With regards to another endpoint ([redacted]), [redacted] offered to pay (at replacement value) a share of no less than 15 studies, none of them being identified as a key study, with a total value for 13 of them, of € [redacted]. ECHA acknowledges that [redacted] eventually agreed to charge for only one key study for all the endpoints, except for this last, particularly costly endpoint. [redacted] justified the unusually long list of studies by the mere fact that "*those are necessary for registration especially against the background of defending* [redacted] *self-classification of* [redacted] *and thus, strengthen the dossier*"[25]. ECHA considers that [redacted]'s concern resulted legitimately and directly from the fact that it had not been involved by [redacted] in the selection of the data, as repeatedly requested. Accordingly, [redacted] bears a direct responsibility in this concern and could have clarified it only by providing a detailed scientific justification of its approach, taking into account the relevance, adequacy and reliability of each data endpoint.

Fourthly, [redacted] questioned the relevance of two studies valued at [redacted] Euro, which are not assigned to any endpoint. Later correspondence from [redacted] does not provide any clarification on that point. However, consequently one of these studies was included in the final SIEF agreement proposed to [redacted] under endpoint [redacted] ([redacted]) as key study.

Finally, [redacted] disputes the timelines put forward by [redacted] to finalise an agreement on the sharing of data. According to [redacted], "*the time constraints are with the lead registrant to get the dossier submitted and not with the non-lead registrant. The non-lead registrant has time to register until November 30th once he has received the token from the lead registrant*"[26]. In the same line, [redacted] informed [redacted] that it "*will not respect any short deadline for reaction that lack any regulatory or other reasonable basis*"[27]. However, when a registrant has not been actively involved in the development and submission of a dossier, in spite of repeated requests, he may have legitimate concerns as to the timing for coming to a data sharing agreement. This is particularly true closer to the registration deadline, when the access of that operator to their market is at stake, while the other negotiating party does not have time constraint in that respect following successful registration.

---

20 Email from [redacted] of 06 September 2010.
21 Email from [redacted] of 22 September 2010.
22 Email from [redacted] of 27 September 2010.
23 Email from [redacted] of 06 September 2010. See also for instance, the emails of 13 and 27 September 2010.
24 Email from [redacted] of 06 September 2010.
25 Email from [redacted] of 02 September 2010.
26 Email from [redacted] of 22 September 2010.
27 Email from [redacted] of 27 September 2010.

[redacted] claims that [redacted] does "*not accept the fact that the data package of the joint registration dossier for* [redacted] *is quite high value*"[28]. ECHA understand registrants' legitimate concern to obtain an appropriate compensation for the data submitted. Nevertheless, a lead registrant not involving another active registrant in the development of the dossier must also understand its concerns and must therefore make particular efforts to make compensation claims transparent.

As a result of the above, ECHA considers that [redacted] has not made such efforts to justify the selection of the data and the various changes of cost sharing methodology. [redacted] has therefore not made every effort to demonstrate that the 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.

[28] Note from [redacted] to ECHA of 03 November 2010.