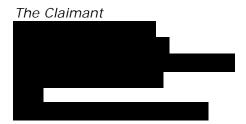
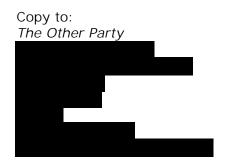


Helsinki, 21 September 2018





Decision number:
Dispute reference number:
Name of the substance (the 'Substance'):



DECISION ON A DISPUTE RELATED TO THE SHARING OF DATA

A. Decision

Based on Article 27(6) of Regulation (EC) No 1907/2006 ('REACH Regulation')1,

ECHA grants you permission to refer to the information you requested from the Existing Registrant of the Substance.

This decision is adopted under Articles 27(6) of Regulation (EC) No 1907/2006 ('REACH Regulation')² and Article 5 of the Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with REACH ('Commission Implementing Regulation')³.

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

¹ 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.

² 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.

³ 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.



provided in Annex IV.

This decision will be published in an anonymised version on ECHA's website⁴.

B. Observations

ECHA reminds both parties that despite 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.

According to Article 27(6) of REACH, the Existing Registrant shall have a claim on you for an equal share of the cost, which shall be enforceable in the national courts, provided that the full study report or reports (if applicable) are made available to you.

C. Appeal

Either party may appeal this decision to the Board of Appeal of ECHA within three months of its notification. The appeal must set out the grounds for appeal. If an appeal is submitted, this decision will be suspended. Further details, including the appeal fee, are set out at http://echa.europa.eu/web/guest/regulations/appeals.

Yours sincerely,

Christel Schilliger-Musset⁵

Director of Registration

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⁴ Available at https://echa.europa.eu/regulations/reach/registration/data-sharing/data-sharing-disputes/echa-decisions-on-data-sharing-disputes-under-reach.

⁵ 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 FOR THE DECISION

- A. Summary of facts
- I. Background

1.	This background is based on the information available to ECHA regarding the history and definitions of the technical identifiers and referred to by the parties during negotiations, and the relevant information from the registration dossiers that is available on the information on chemicals portal on ECHA's website.
2.	The Party upon their pre-registration that was linked to CAS number the CAS description an inquiry, which is a requirement for non phase-in substances under Article 26. After a subsidiary of the Other Party submitted an inquiry for the Substance, ECHA informed the Other Party's subsidiary that the was not suitable, because the mere reference to the CAS description was too imprecise. In order to help the Other Party's subsidiary to register the substance with a suitable identifier, and in order to provide the Other Party with a suitable identifier for their registration, ECHA engaged in a discussion with the Other Party on the correct identification of their substance. ECHA and the Other Party thus agreed that the substance should be described as Based on the agreement of the Other Party, ECHA created a more specific identifier for the substance: with and description
3.	It was not yet technically possible in of the Other Party to change of their registration dossier. Therefore, was left in use. Since 2014, ECHA enables registrants to request a change of identifier of their registration. ECHA has been in contact with the Other Party and the other registrants of to help them reach their expressed aim of joining all registrants of this substance in the joint submission using . The latest development in this respect was in the joint submission using the identifier of their registration to ECHA.
4.	Since 2011, inquiries for . Accordingly, ECHA assigned . as the inquiry identifier for the inquiry submitted by the Claimant prior to the current dispute. To enable registrants to fulfil their data sharing obligations, ECHA has provided potential registrants of with the contact details of registrants of particular the Other Party as the submitter of studies for . ECHA makes the contact details available using the associated substance functionality of REACH-IT that links the co-registrants pages of
5.	Based on the information on the chemicals portal on ECHA's website, which makes information from registration dossiers publicly available, dossiers for the chemicals portal on ECHA's website, which makes companies have registration (the Other Party), the companies the disseminated

information shows that the registrants use the name '



' in	the refere	nce substanc	e use	ed for	the	identification	of the	subs	stance.
Furthermore,	the disser	minated		info	rmatio	n included in	n the		
Summary and		Summary refer to					′. In	additio	on, the
disseminated	boundary	composition	and	legal	entity	compositions	have	the	name
				' .					

II. Summary of negotiations

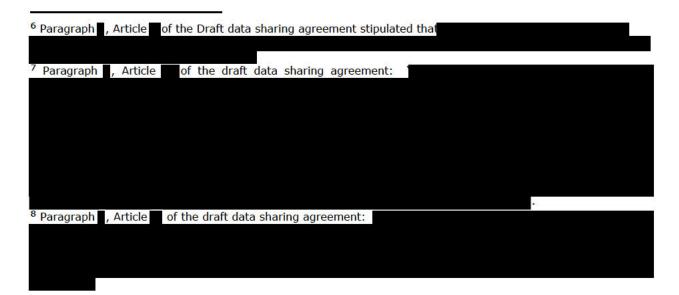
- 6. On 17 April 2018, the Claimant initiated the negotiations with the Other Party and wrote with reference to the communication they had with the lead registrant of the registration with the middle that they had first tried to obtain the necessary information from them, and were then referred to the Other Party. In their email they write that they understand that [they] should obtain from [the Other Party] the letter of access to the studies prepared by [the Other Party] and used by [the lead registrant] for the registration dossier for the transfer of the complete [their] registration and they requested to be provided with all documents and information for obtaining the Letter of Access (LoA). The Claimant asks the Other Party to reply as soon as possible to this request.
- 7. On the same day, the Other Party asked for additional information regarding the Claimant's request, i.e. the substance and the tonnage band of the Claimant's interest, and suggested time slots for holding a teleconference.
- 8. On 20 April 2018, the Other Party sent a reminder to the Claimant and inquired about the Claimant's official legal entity's name and whether the Claimant was an affiliate of the lead registrant of the joint submission for the
- 9. On 2 May 2018, the Claimant replied that they had already submitted an inquiry to ECHA and ECHA had referred them to the lead registrant of the joint submission for the prepared by [the lead registrant] makes reference to studies prepared by [the Other Party], in order to complete the registration the Claimant should contact the Other Party regarding the LoA. The Claimant wrote that they envisaged the substance production at a volume tonnes per annum and requested to be provided with 'a proposal of data sharing agreement [...] and [the Claimant's] quota of [study] costs to be shared' stressing their urgent need to complete the registration. With reference to the Other Party's email of 20 April 2018, the Claimant provided their legal entity's name and informed that '[the Claimant] is a company with a separate legal entity'.
- 10. By the email of 23 May 2018, the Claimant reminded the Other Party of their 'pending request', emphasising that the Claimant had provided the additional information requested by the Other Party in their last communication of 2 May 2018 and was in the urgent need to register. The Claimant requested again to be provided with a LoA to the Other Party's data within seven days 'otherwise [the Claimant] need[s] to formally start a claim before ECHA in order to speed up the process'.
- 11. On 28 May 2018, the Other Party provided the Claimant with the draft data sharing agreement 'for discussion purposes'. The Other Party underlined that '[a]s all other parties that have bought a Letter of Access need to be treated equally, only small changes can be made to this agreement'. In the text of the draft data sharing agreement drafted by the Other Party, they provide that '[the Other Party] as the lead registrant registered the substance

obtained from



(hereinafter referred to as "substance	1") (trade name	with
registration number	'. The draft agreement also set out that	
Other Party		
		!

- 12.On 8 June 2018, the Claimant provided their comments on the draft data sharing agreement and raised 'some points of concern': (i) regarding the compensation, referring to the Commission Implementing Regulation EU 2016/9, the Claimant requested to be provided with 'evidence of the costs borne for the Studies and with an explanation of the costs sharing model applied' as '[they] underst[ood] that other parties already entered into a Data Sharing Agreement with [the Other Party] for the same Studies for REACH purposes'; (ii) regarding paragraph Article 6, ; (iii) the Claimant pointed out that Article 25(3) applied to the data sharing agreement; (iv) concerning 'Liabilities and limitation of liability', the Claimant stated that 'the limitation [...][in liability was] not acceptable in the exclusive interest of [the Other Party]'; (v) regarding paragraph of Article of the data sharing agreement, the Claimant pointed out that relationships between the members of the joint were out of the scope of this data sharing agreement submission for and would be established 'by a specific REACH Agreement [between co-registrants] and the lead registrant of Substance 2]'; (vi) Further, regarding paragraph of Article 8, the Claimant did not accept the 'general limitations [...] in implementing business transactions' imposed by the Other Party; and (vii) the Claimant asked 'to change [the] jurisdiction and applicable law with or leave them under the international rules'. The Claimant asked to be provided with an amended draft of the data sharing agreement that would address the Claimant's concerns. Finally, the Claimant stated that `should [they] fail to find an agreement [by] 15 June 2018, [the Claimant] shall consider to formally open a claim with ECHA'.
- 13. On 28 June 2018, the Claimant wrote to the Other Party that they had not received an answer to their request of 8 June 2018 to amend the draft data sharing agreement and that was 'causing a serious delay' in their registration process; therefore, they were lodging the





dispute claim. They stated that the draft data sharing agreement proposed by the Other Party was 'not consistent with the market practice, with the REACH regulation and with the general guidelines provided by ECHA', and reiterated the issues raised in their email of 08 June 2018. Further, with reference to Recital 9 of the Implementing Regulation (EU) 2016/9, the Claimant wrote that the data sharing agreement 'fix[ed] the price for the access to the data in Euro without providing [...] any evidence of the costs borne for the Studies nor any explanation of the costs sharing model applied'. The Claimant cited Recitals 4 and 6 of the Implementing Regulation 2016/9, stressing that all agreements to share data for the REACH purposes 'should be structured in a way that all relevant costs are clearly described and identifiable'. The Claimant pointed out that 'access shall be granted to the studies also in order to avoid animal testing and could be limited only by the REACH regulation, i.e. 'limitation in relation to intellectual property rights and obligation to proportionally reimburse part of the costs borne for the studies', and that data sharing agreements 'cannot be an instrument for the lead registrant Company to obtain unjustified advantages and/or profits'. The Claimant considered that the Other Party was 'utilizing its Studies in order to obtain a favourable and unjustified contractual and commercial position'. Finally, the Claimant highlighted that they were lodging a dispute claim in view of their 'urgent need to complete the registration process and the evident lack of effort of [the Other Party] in reaching a Data Sharing agreement in line with the REACH regulation and the Implementing Regulation'.

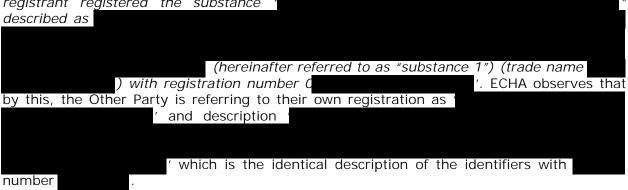
- 14. In their reply on the same day, the Other Party stated that there '[was] no obligation for [them] to share data with [the Claimant] as the substance [which the Claimant] intend[ed] to register, identified with the second (referred to as Substance 2) will be registered by a separate registration than the the[sic] different substance registered by [the (referred to as Substance 2) will be Other Party], identified by (referred to as Substance 1)'. 'Therefore, Substance 1 and Substance 2 do not fall within the mandatory data sharing imposed by the REACH Regulation and the Commission Implementing Regulation 2016/9, the Information and results of studies being applied by read-across from Substance 1 to Substance 2'. Thus, the Other Party 'enjoys contractual freedom without need to incorporate mandatory provisions' of the REACH regulation or the Implementing Regulation 2016/9. The Other Party stressed that 'in order to avoid any potential discriminatory treatment of companies in the same situation (all co-registrants of Substance 2), [the Other Party] proposes identical or very similar conditions to the co-registrants'. The Other Party further commented the Claimant's concerns regarding the draft data sharing agreement as follows:
 - i) Regarding compensation, the Other Party wrote that 'the data sharing [between the parties] does not fall within the mandatory data sharing imposed by the REACH Regulation'.
 - ii) Regarding paragraph Article of the draft data sharing agreement concerning the ownership of the data, the Other Party agreed to remove the clause from the draft agreement.
 - iii) The Other Party agreed with the comment by the Claimant regarding the applicability of Article 25(3) of the REACH regulation to the data sharing agreement.
 - iv) In relation to the Claimant's concerns on the liability limitations, the Other Party explained that the Other Party, as the data owner of all the data, had all the risks in relation with the potential breach of data access by the Claimant, whereas the Claimant had no such risks; thus, 'the positions of the two parties are therefore objectively different and the extent of liability must reflect this objective difference'.
 - v) The Other Party stated that in the situation where the Other Party became the lead registrant for the joint submission for the



- would be 'entitled to have such a position as owner of all the studies and information that the registration dossier of <u>Substance 2</u> is based upon'.
- vi) Further, regarding paragraph of Article the clause, the Other Party stated that 'the same clause ha[d] been accepted by all co-registrants of Substance 2 therefore it might seem discriminatory to other co-registrants [if the Other Party] were to accept another clause'.
- vii) In regards to provisions on dispute resolution and applicable law, the Other Party pointed out that 'with the exception of one agreement, previous data sharing agreements are governed by [law; therefore for consistency reasons [the Other Party's] position on [law remains unchanged'.]
- 15. On 6 July 2018, the Claimant submitted a claim under Article 27 of the REACH Regulation concerning the failure to reach an agreement on the sharing of information with the Other Party.
- 16. On 29 August 2018, ECHA requested the Claimant to provide a proof that they paid the Other Party a share of the costs incurred by the Other Party ('proof of payment'). The Claimant did not inform ECHA of any agreement voluntarily reached by the parties. The Claimant provided the proof of payment on 21 September 2018 amounting EUR
 - B. Admissibility of the dispute claim under Article 27(5)
- 17. A claimant can only submit a data-sharing dispute claim under Article 27 REACH and Article 2 of Implementing Regulation 2016/9, if it intends to register the same substance as the other party has registered. In this respect, the chemical identities of the substances are relevant, and not whether all registrants are in the same joint submission in REACH-IT.

18. ECHA	created with	name			
	' after the Other Party agreed that the	he registration for			
	would be best described as such, i.e. as				
	. Also the registration dossiers using		already	refer	to
7	or '	' in	various	parts	0
their r	registration dossier.				

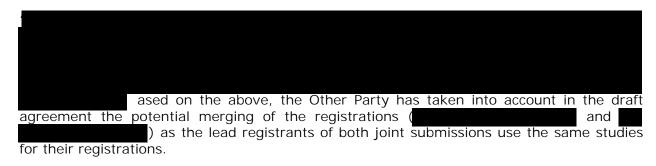
19. Furthermore, in the text of the draft data sharing agreement, submitted by the parties as part of the documentary evidence, the Other Party states that '[the Other Party] as the lead registrant registered the substance '



20. Also, paragraph of Article of the draft data sharing agreement foresees the possibility that

The same draft agreement also envisages the application of the Implementing Regulation 2016/9 in the future by setting out that:





- 21. On these grounds, and based on the facts described above in paragraphs 2-4, ECHA finds that the Claimant intends to register the same substance as the one registered by the Other Party. Therefore, the present dispute claim is admissible.
 - C. Assessment of the efforts made by the parties
- 22. When a dispute is submitted to ECHA pursuant to Article 27(5) of the REACH Regulation, ECHA performs an assessment of the parties' efforts to reach an agreement (Article 5 of the Implementing Regulation 2016/9). According to Article 27(6) of the REACH Regulation and Article 3(2) of the Implementing Regulation 2016/9, ECHA may grant permission to refer to the requested studies, if the claimant has made every effort to find an agreement on the sharing of the data and the access to the joint submission and the other party has failed to do so. The permission to refer is subject to the proof that the potential registrant has paid a share of the costs incurred by the previous registrant(s).
- 23. The obligation to make every effort to find an agreement that is fair, transparent and non-discriminatory is laid down in Articles 27(2) and 27(3) of the REACH Regulation. It is further defined in Articles 2 and 4 of the Implementing Regulation 2016/9.
- 24. Making every effort means that the registrants must negotiate as constructively as possible and in good faith. They must make sure that the negotiations move forward in a timely manner, express their arguments and concerns, ask questions and reply to each other's arguments, concerns and questions. They must try to understand the other party's position and consider it in the negotiations. Making every effort also means that the parties need to be consistent in their negotiating strategy. They should raise their concerns in a timely manner and behave in a consistent and predictable manner as reliable negotiators. When they face a dissent on an aspect, the parties have to explore alternative routes and make suitable attempts to unblock the negotiations. As the potential and existing registrants themselves bear the obligation to make every effort to find an agreement, they need to exhaust all possible efforts before submitting a dispute to ECHA with the claim that negotiations have failed.
- 25. Articles 27 of the REACH Regulation and 2(1) of the Implementing Regulation 2016/9 provide that registrants of the same substance must make every effort to reach an agreement on the sharing of the information requested by the potential registrant(s), and every effort also shall be made 'to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way'. The data-sharing agreement shall be clear and comprehensible to all parties and, shall include, inter alia, the itemisation for all relevant costs and a cost-sharing model with a reimbursement mechanism. According to Article 2(2) of the Implementing Regulation 2016/9, previous registrants must upon request provide potential registrants with the itemisation of all relevant costs and the proof of any study costs without undue delay. When the itemisation and justification of costs are provided, potential registrants are able to assess whether the requested compensation is fair, transparent and non-discriminatory. Any delays need to be justified, and a delay cannot in any case be justified if it results in obstructing potential registrants that have



contacted the other company in a timely manner from registering.

- 26. As explained above, ECHA assesses the efforts made by the parties in the negotiations that were outlined in section A(II), based on the documentary evidence provided by the parties.
- 27. At the beginning of the negotiations, the Claimant made a request for 'all documents and information for obtaining'9 the Letter of Access and later a request for 'a proposal of data sharing agreement [...] and [the Claimant's] quota of [study] costs to be shared'10. After they had received a draft data sharing agreement on 28 May 2018, the Claimant questioned the compensation for the data access set out in the proposed draft data sharing agreement, asked for proof of study costs and explanations of the cost sharing model employed by the Other Party, given that there were other co-registrants who had already bought the data from the Other Party. In absence of any reply from the Other Party, the Claimant made efforts to explain their concerns regarding the data sharing agreement, highlighting that the data sharing agreement was 'not consistent with the market practice, with the REACH regulation and with the general guidelines provided by ECHA'. The Claimant again pointed out that draft data sharing agreement set out the fixed price for an access to data 'without providing [...] any evidence of the costs borne for the Studies nor any explanation of the costs sharing model applied' and made efforts to explain to the Other Party that the data sharing agreement did not meet the requirements of the Commission Implementing Regulation in regards to the obligation to share data in a fair, transparent and nondiscriminatory manner, i.e. contained no cost breakdown and did not envisage the reimbursement mechanism.¹¹
- 28. The Other Party did not provide explanations regarding the cost sharing model, but reasoned that the Claimant will register 'by a separate registration than the the[sic] different substance registered by [the Other Party]. Therefore, mandatory data sharing imposed by the REACH Regulation and the Implementing Regulation 2016/9 would not apply, 'the Information and results of studies being applied by read-across from Substance 1 to Substance 2'. Regarding the Claimant's concerns about the fixed compensation for study access and request for proof of the study costs, the Other Party replied again that 'the data sharing [between the parties] does not fall within the mandatory data sharing imposed by the REACH Regulation' 12. However, without receiving the proof of the study costs and information on the cost-sharing mechanism, the Claimant had no possibility to assess whether the requested costs were reasonable and cost sharing was fair, transparent and non-discriminatory and to negotiate the sharing of the data and costs.
- 29. By not providing information on the cost sharing mechanism and evidence of the costs incurred, the Other Party prevented the Claimant from sensibly negotiating a fair, transparent and non-discriminatory agreement on the sharing of data and its cost. Thus, the Other Party did not make every effort to reach an agreement on data sharing.
- 30. The Claimant also made efforts to challenge some of the other contractual provisions of the data sharing agreement. Thus, the Claimant challenged the contractual obligation to agree in advance on the Other Party's future lead registrant role, in case the latter would join the existing joint submission for that such relationship between co-registrants should be determined by a separate agreement with the respective lead registrant for the joint submission for the Other Party reasoned that they would be 'entitled to have such a position as owner of all the studies and information that the registration dossier of Substance 2 is

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⁹ The Claimant; 17 April 2018
¹⁰ The Claimant; 2 May 2018
¹¹ The Claimant; 28 June 2018
¹² The Other Party; 28 June 2018



based upon'.13

- 31. The Claimant expressed their concerns regarding the clause on assignment of the agreement to third parties, the Other Party replied that 'the same clause ha[d] been accepted by all co-registrants of Substance 2 therefore it might seem discriminatory to other co-registrants [if the Other Party] were to accept another clause'14; hence, ruling out any possibility for further discussion on this issue with the Claimant. It thereby refused to make efforts to find a common understanding on this point.
- 32. The Claimant, company, also proposed to change the applicable law of the agreement under law or international rules to make things are more neutral for both parties instead of applying law as currently proposed by the Other Party, a company. The Other Party refused the proposal to change the applicable law for 'consistency reasons' since '[the] previous data sharing agreements are governed by law'. 15 Again, the Other Party ruled out further discussions and thereby refused to make efforts to find an agreement on a fair agreement with the Claimant.
- 33. ECHA notes that the Other Party made efforts to address some of the Claimant's other concerns by agreeing to delete the clause where the Other Party would undertake only 'reasonable efforts' for retention of the Claimant's rights to access the data in case the transfer of the data ownership took place in future. The Other Party also agreed with the Claimant's observation that Article 25(3) applies to the draft data sharing agreement. However, the abovementioned issues raised by the Claimant remained unsolved and prevented the parties from finding an agreement.
- 34. Further, ECHA notes that the Other Party proposed to hold a teleconference and that the Claimant did not comment on this proposal. However, subsequent communications between the parties and the Other Party's disregard for the applicable data sharing obligation established by the REACH regulation and the Commission Implementing Regulation indicates that holding a teleconference in the beginning would unlikely have overcome the fundamental disagreement between the parties on fair and transparent cost sharing that they encountered after the data sharing agreement had been provided and questioned by the Claimant. Given the urgent need to register and the Other Party's refusal to negotiate on the cost sharing in line with the REACH regulation and the Implementing Regulation 2016/9, the Claimant filed the present dispute claim as a measure of last resort.

Conclusion

- 35. ECHA concludes that the Claimant made every effort to progress the data sharing negotiations, in particular by requesting more information on evidence of the cost and the data sharing mechanism applied by the Other Party. They explained their concerns regarding fairness and transparency of the cost-sharing model and its compliance with the Implementing Regulation 2016/9. On the other hand, by refusing to provide the proof of costs and explanations of the cost sharing model, the Other Party effectively prevented the negotiations from progressing and did not fulfil their obligation to make every effort to find an agreement on data sharing in a fair, transparent and non-discriminatory way, as required by the Commission Implementing Regulation.
- 11. Therefore, ECHA grants the Claimant permission to refer to the studies specified in the Annex II.

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¹³ The Other Party; 28 June 2018

¹⁴ The Other Party; 28 June 2018

¹⁵ The Other Party; 28 June 2018

"ECHA reminds you that following Article 16 of Regulation (EC) No 1049/2001, the documents attached are subject to copyright protection."