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Cost sharing between co-registrants with different data requirements

Introduction

Under REACH, registrants only have to pay for data they actually need for registration:

- Registrants of the same substance may have different data requirements. This can be because of their tonnage band or the type of their registration, for example, substances registered as certain intermediates.
- In addition, registrants may not need to share certain parts of the jointly submitted data for other reasons. For example, registrants who have their own equivalent data and do not want to pay again, or registrants who consider that the jointly submitted data is not of sufficient quality, may consider opting-out from the specific endpoint and provide their own data.
- However, if a registrant relies on a study from a higher tonnage band for the classification and labelling of their substance, they may need to find an agreement on sharing costs for that study, too. Such a possibility is not reflected in this scenario for the sake of simplicity.

In practice, a registrant joining an existing joint submission might not need to pay for all of the jointly submitted data, but only for certain parts or even none of it. This example shows typical cases for registrants that need different access to data.

Cases

Some typical cases, as well as the costs such registrants need to share, are described below.

Case 1: Full registration, 1-10 tonnes per year (tpa), member: The standard information requirements as defined by Annex VII to REACH apply: In this example, the registrant does not have any own data and, therefore, needs to buy a letter of access to all required data in the tonnage band and share costs related to the joint submission.

Case 2: Full registration, 10-100 tpa, member: The standard information requirements as defined by Annexes VII and VIII to REACH apply: In this example, the registrant does not have any own data and, therefore, needs to buy a letter of access to all required data in the tonnage band and share costs related to the joint submission.

Case 3: Full registration, 1-10 tpa, member with partial opt-out: The standard information requirements as defined by Annex VII to REACH apply. However, in this example, the registrant has decided not to rely on the jointly submitted data for the physico-chemical properties of the substance, for example, because they have their own data or because they want to rely on read-across data from another substance. Such an opt-out from certain endpoints is possible according to the criteria of Article 11(3). The registrant only needs access to the other required (vertebrate) data and the joint submission.

Case 4: Full registration, 1-10 tpa, member with full opt-out: The standard information requirements as defined by Annex VII to REACH apply. However, the registrant has decided not to rely on any of the jointly submitted data, but on alternative information to fulfil all standard information requirements. Such an opt-out from all endpoints is possible under the criteria of Article 11(3). The registrant only needs access to the joint submission (and only has to pay their share of the costs related to the joint submission).

Case 5: Full registration, 1-10 tpa, member, relying on Annex III: In principle, the standard information requirements as defined by Annex VII to REACH apply. However, this registrant does not need to submit ecotoxicological or toxicological information unless they own them, as they can show that the substance is of low risk and does not meet the criteria set in Annex III to REACH. Consequently, the registrant only needs to submit the non-vertebrate data. In this example, the registrant does not have any non-vertebrate data and, therefore, has chosen to buy a letter of access to it. In addition, they need to share costs related to the joint submission.

Case 6: Transported isolated intermediate, <1 000 tpa, strictly controlled conditions: For this registration type, only data that is freely available to the registrant needs to be submitted. Therefore, they do not need to share any costs related to data, which is not freely accessible for them. However, the joint submission obligation applies regardless of the need to share data, and the registrant has to pay their share of the costs related to the joint submission.

Case 7: Transported isolated intermediate, <1 000 tpa, not strictly controlled conditions: For intermediates that are not handled under strictly controlled conditions, the standard information requirements in their tonnage band apply (1-10 tpa, 10-100 tpa, or 100-1 000 tpa).

In this example, the intermediate is manufactured or imported below 100 tpa. Therefore, the standard information requirements as defined by Annexes VII and VIII to REACH apply. In this example, the registrant does not have any own data and needs to buy a letter of access to all required data for the tonnage band and share costs related to the joint submission.

Case 8: Transported isolated intermediate, >1 000 tpa, strictly controlled conditions: According to Article 18(3) of REACH, the information requirements as defined by Annex VII to REACH apply. In this example, the registrant does not have any own data and needs to buy a letter of access to all required data and share costs related to the joint submission.

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Data and cost sharing	Full registration, 1-10 tpa, member Case 1	Full registration, 10-100 tpa, member Case 2	Full registration, 1-10 tpa, member with partial opt-out Case 3	Full registration, 1-10 tpa, member with full opt-out Case 4	Full registration, 1-10 tpa, member, relying on Annex III Case 5	Transported isolated intermediate, <1 000 tpa, strictly controlled conditions Case 6	Transported isolated intermediate, <1 000 tpa, not strictly controlled conditions Case 7	Transported isolated intermediate, >1 000 tpa, strictly controlled conditions Case 8
Annex VII, physico-chemical data	X	X			X		X	X
Annex VII, (eco)toxicological data	X	X	X				X	X
Annex VIII, (eco)toxicological data		X					X	
Annex VIII, fate and behavioural data		X					X	
Administration*	X	X	X	X	X	X	X	X
Token	X	X	X	X	X	X	X	X

* This includes costs related to the overall SIEF administration that cannot be allocated to any single information requirement, such as SIEF communication, surveys, SIEF website and financial management of the SIEF. The *Guidance on data sharing* (see: Annex III “Cost itemisation”) indicates whether the cost items can be seen as data-related or administrative.

Notes

It is possible to opt-out from individual studies and from the entire jointly submitted data. The registrant, who opts out cannot be forced to share costs of data that they do not need.

Due to the specific information requirements for intermediates, these are **in effect** not required to share data-related costs. Therefore, these registrants may agree to set up a separate joint submission for intermediates only. More information can be found in the *Guidance on data sharing*, Chapter 6.2.

Keep in mind that other (full) registrants of the substance may still request access to the data submitted by the intermediate registrants, namely for the vertebrate data.