Data sharing under REACH for phase-in substances within a SIEF[1]

Indicative steps for the individual route

1 Individual gathering of available information

– The potential registrant first assembles and documents all the information on the substance, that he has available **in house** (regardless of the envisaged registration tonnage): information on the intrinsic properties of the substance, on manufacture and uses, on exposure and on risk management measures.
– Available data from other sources, such as data in the public domain, should also be gathered.

2 Individual consideration of information needs

The potential registrant identifies precisely what are the information requirements for the substance he intends to register, considering in particular the tonnage band that is relevant to him. In considering his information needs, the potential registrant may consider the possible application of data waivers, for instance on the bases of uses/exposure patterns.

3 Identification of individual data gaps

The potential registrant assesses the relevance, reliability, adequacy and fitness for purpose of all gathered data for arriving at conclusions on the hazard assessment and for risk characterization. He determines for each property, which study shall be used in the assessment later on (key study). Normally this is the study of greatest relevance taking into account the quality, completeness and representativeness of the study.

He drafts robust summaries[2] (for key studies) or study summaries[3] (for other studies).
At this stage, the potential registrant is in position to compare the information requirements and information gathered and to identify whether there are information gaps that will need to be filled in before the registration dossier can be filed.

4 Request for missing data to other SIEF participants

If the potential registrant lacks data for purposes of his registration, he communicates with the other SIEF participants to determine if relevant studies are available.
Important: data sharing is obligatory for studies involving tests on vertebrate animals and voluntary for studies not involving vertebrate animal studies.
In other words, the potential registrant is obliged to request studies involving vertebrate animals, while he may request the study if it does not involve vertebrate animals.

The missing study is available within the SIEF (or in another SIEF based on read-across[4]).

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5 Sharing of available data

The potential registrant requests the missing studies from the relevant SIEF participant(s). Before the study is made available to the requesting participant, an agreement has to be reached on the cost of sharing the requested information. Following settlement on cost sharing, unless otherwise agreed, the owner must give permission to refer to the full study report within 2 weeks of receipt of payment.
The REACH regulation sets out a specific procedure in case the owner of a study refuses to provide proof of costs of the study or the study itself within a month from the request. The procedure differs for data on vertebrate or non-vertebrate animals.

6 Generation of new information/testing proposal

The potential registrant cannot proceed alone with the generation of missing data. He is obliged to obtain agreement that one member of the SIEF will perform, or arrange for a third party to make the study, on behalf of the others. The agreement has to be reached within deadline set by the European Chemicals Agency (ECHA); otherwise the decision will be taken by ECHA itself.
In case the participants do not agree otherwise, all participants who require the study are obliged to contribute to the costs for the elaboration of the study by a share corresponding to the number of participating potential registrants.
Within two weeks of payment, each SIEF participant has the right to receive a copy of the full study report.

7 Joint submission of data

REACH registrants are required to jointly submit information on the hazardous properties of the substance (studies and proposals for testing) and its classification and labelling and can, if they agree, also jointly submit the chemical safety report and/or the guidance on safe use. However, registrants are allowed to opt out from the joint submission under specific conditions.

The difficulty with the individual route is that it does not pave the way for the joint submission of data. It is therefore suggested to be used only in cases like sharing data with data holders[5] or when companies have justified reasons to opt-out from the joint submission of data.

1 SIEF: Substance Information Exchange Forum
2. Robust study summary: a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report.
3. Study summary: a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the relevance of the study.
4. Read-across approach: physico-chemical properties, human health effects and environmental effects or environmental fate are predicted for substances in a group by interpolation from data concerning reference substance(s) within the same group.
5. Data holders: any person holding information/data relevant to a phase-in substance and willing to share it can identify itself and lodge a request to the European Chemicals Agency with a view of being a participant in the SIEF for that substance, to the extent that they will provide information to other SIEF members. Data holders will receive a financial compensation for the data they share with potential registrants.

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