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

Indicative steps for the collective route

1 Individual gathering of available information

– Each 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 but, in order to reduce costs, potential registrants may conduct the literature search collectively (for all SIEF participants).

2 Agreement on the form of co-operation/cost sharing mechanism

REACH does not prescribe the way in which participants in a SIEF should cooperate, such as by entering into a formal consortium agreement or otherwise.

Parties are therefore free to select the form of cooperation that suits them best and the main rules applicable to that cooperation, in terms of data and cost sharing.

3 Collection and inventory of information available to potential registrants

Potential registrants collect and put together in an inventory all information on the substance they have available between them. If literature searches have not been done individually, they should be done jointly at this step in order to gather all available information.

As an option, potential registrants may also consider at this early stage data available to data holders[2], in other SIEFs (read-across[3]) and outside of the SIEFs, in particular in situations where potential registrants know they do not have a full data set for registration purposes.

4 Evaluation of available information

– Potential registrants assess the relevance, reliability, adequacy and fitness for purpose, of all gathered data, for arriving at conclusions on the hazard assessment and for risk characterization.
– They determine 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.
– They draft robust study summaries[4] (for key studies) or study summaries[5] (for other studies).

5 Consideration of information needs

This step requires potential registrants to identify precisely what are the information requirements for the substance that they intend to register, considering in particular the tonnage band that is relevant to them and to all potential registrants, the parameters of the substance (relevant for technical waiving of tests) and uses/exposure patterns (relevant for exposure based waiving).

6 Identification of data gaps and collection of other available information

At this stage, potential registrants are in position to compare the information requirements and information gathered and to identify whether there are information gaps and consider how missing information can be generated. Before testing is conducted on vertebrates or a testing proposal made, potential registrants MUST verify whether the missing data is not available to data holders within the SIEF. They can also request data from data holders in other SIEFs (based on read-across).

7 Generation of new information/testing proposal

When there is an information gap which cannot be filled by non-testing methods, potential registrants have to generate new information (when annexes VII and VIII apply) or to prepare a testing proposal (when annexes IX and X apply). Potential registrants cannot proceed alone with the generation of missing data. They have the obligation to agree on one of them performing the study on behalf of the others. The agreement has to be reached within a deadline set by the European Chemicals Agency (ECHA); otherwise the decision will be taken by ECHA itself. 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.

8 Sharing of data cost

The sharing of data cost can be done in stages, for example, starting with the available data within the SIEF and then with the newly developed data, or as a single exercise, when all data is available. It is for the potential registrants and data holders involved to agree on the terms and conditions of this data and cost sharing and many options exist to structure and organize this. Potential registrants are only required to pay for studies they need in accordance with their tonnage bands.

9 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 collective route leads naturally to the joint submission of data.

1 SIEF: Substance Information Exchange Forum.
2. 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.
3. 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.
4. 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.
5. 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.