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How to prepare and develop a Substance Identity Profile (SIP)

April 2018

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1. Purpose of the document

This document provides practical advice to registrants on how to develop and maintain Substance Identity Profiles (SIPs) and report these as boundary composition(s) in the lead registrant dossier.

It assumes that (potential) registrants have already agreed that they will register the same substance.

Note: Companies manufacturing and importing the same substance have to register that substance jointly. However, they may submit part or all of the information required separately.

2. Introduction

The *SIP* is a commonly used industry term. It documents the criteria that the (potential) registrants have agreed is the basis for selecting the representative data prescribed under Annex VII-XI of the REACH Regulation to be jointly submitted for the registered substance. It usually describes the composition(s) (or proxies for compositions of certain UVCB substances) that are covered by the data jointly submitted.

The *boundary composition* refers to the technical reporting in the IUCLID technical dossier of all the compositions of the substance covered by the registration. It can specify composition(s) not covered by the jointly submitted Annex VII-XI data, which a registrant decided to submit separately.

3. Where to start

3.1 Discussion on the SIP

The discussions on the SIP can take place through consortia or other cooperation and communication arrangements.

3.2 Typical information to be contained within a SIP

In general, the SIP should contain all necessary information to help (potential) registrants to judge if the jointly submitted Annex VII-XI data is representative for their specific composition of the substance.

From an administrative point of view, the SIP should state the name of the substance together with its numerical identifiers (EC number, CAS number). In addition, information about the companies providing the proposed SIP together with a date and a version number might be helpful to communicate updated versions to the (potential) registrants.

For well-defined substances, at least the identities of the main constituents, and all impurities that are relevant for classification and/or PBT assessment, should be provided together with EC/CAS identifiers, IUPAC names, and respective concentration ranges.

In the case of UVCB substances, a description of the constituents together with their concentration ranges may not be sufficient. In such cases, besides the composition

information, any other relevant parameter(s), such as the manufacturing process description, may need to be included. The manufacturing process description can be provided at a general level that avoids sharing of confidential business information, while ensuring that the (potential) registrants should be able to judge that their substance composition is covered by the jointly submitted Annex VII-XI data.

3.3 Multiple SIPs

More than one SIP can be created depending on how the (potential) registrants want to structure the jointly submitted Annex VII-XI data. For example, certain compositions that have impurities/constituents that trigger different classification and labelling can be described with their own SIP.

Each SIP should be reported as a separate boundary composition in the IUCLID technical dossier of the lead registrant.

Individual registrants should ensure that their specific composition is covered by the appropriate boundary composition(s).

4. Development of the SIP over time

4.1 When it's necessary

The SIP may need to be updated following the request of any (potential) registrant, if part or all of the jointly submitted Annex VII-XI data is also relevant for the composition that (potential) registrant manufactures or imports.

4.2 Evaluating the impact of a change

A (potential) registrant may wish to refer to the jointly submitted Annex VII-XI data while the specific composition(s) would not fulfil the criteria set out in the SIP. For example, different impurities may be present in the composition(s). In that case, the relevance of the jointly submitted Annex VII-XI data must be assessed. If the jointly submitted Annex VII-XI data would still be representative for the specific composition(s) in spite of the presence of different impurities, the SIP would have to be adapted to cover also these impurities.

On the other hand, if the jointly submitted Annex VII-XI data would not be representative for the specific composition(s) because of the presence of different impurities, the (potential) registrant could modify the data set with data covering all the compositions, including the one(s) of the concerned (potential) registrant. If data covering all the compositions would not be available, the (potential) registrant will have to submit data specific for his composition(s). This different data can be submitted jointly by the lead registrant and be the subject of an additional SIP. Alternatively, this different data can also be submitted separately by the (potential) registrant concerned (opt out).

4.3 Informing the (potential) registrants of a change

If a SIP needs to be updated or an additional SIP needs to be created, the concerned (potential) registrant(s) must be informed.

4.4 Update of the registration

If the SIP is modified by the inclusion of further criteria, the lead registrant should update the corresponding boundary composition by submitting a spontaneous dossier update. Similarly, if a different data set is submitted either jointly or separately, the lead registrant should report the corresponding boundary composition by submitting a spontaneous dossier update.

Each registrant should demonstrate that the composition(s) of his substance as manufactured or imported is covered by a boundary composition(s) and in turn is/are covered by the jointly submitted Annex VII-XI data.

5. Further information

Practical advice for new SIEFs https://echa.europa.eu/support/registration/working-together/practical-advice-for-new-siefs

Joint submission https://echa.europa.eu/regulations/reach/registration/data-sharing/joint-submission-of-data

Q&As on substance identity profile https://www.echa.europa.eu/support/qas-support/browse

"Appendix III - Substance identification and joint submission of data" of Guidance for identification and naming of substances under REACH and CLP https://www.echa.europa.eu/web/guest/guidance-documents/guidance-on-reach

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