Joint submission of the Chemical Safety Report (CSR)

Version 4 November 2010

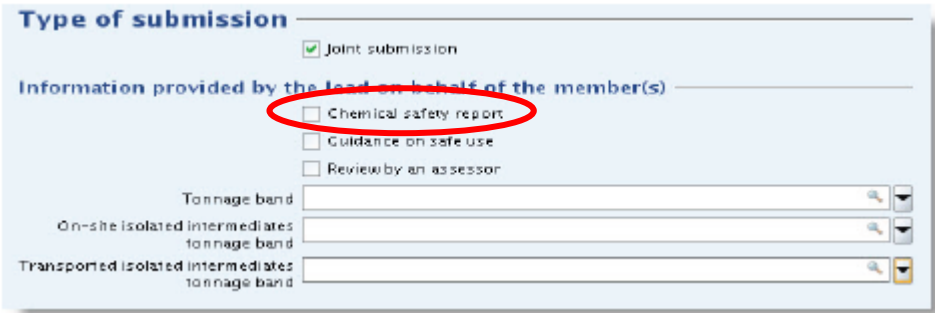
ECHA explains a number of technical options on joint submission of the CSR in the Data Submission Manual 19 (latest update: 28/09/2010). ECHA's statements in this manual on "preferred" or "recommended" options are, as stated by ECHA in the introduction, "not based on a pro and con analysis" and thus might not be the most appropriate from an industry perspective.

Cefic makes its members aware that they should very carefully choose one of the options now available considering all consequences and taking into account that the IT systems may be changing in this respect in 2011.

The REACH legal text (Article 11.1), as well as the ECHA IT systems, foresee the possibilities to submit the CSR individually or jointly. The decision is for every registrant to make, based on their own requirements. **Please note that submitting a CSR individually is not an opt-out.**

Registrants must also be aware that the selection of a joint or individual submission of the CSR entails a clear communication in the SIEF. An appropriate selection of the relevant options in the process of dossier creation in IUCLID5 is crucial.

The selection of the Lead Registrant must be consistent with the selection of the Member Registrants, otherwise there will be a failure of the business rules check during the submission process. These boxes are 'ticked' in the step 6 of the dossier creation wizard in IUCLID5:



When ticking the box 'Joint submission' the registrant must also tick the box whether the LR is submitting the CSR on his behalf (full or partly). If that is the case, this box must be ticked by both the LR and the Member Registrant.

In order to facilitate the decision as to whether CSR should be jointly submitted or not, the following paragraphs highlight the 'pros' and 'cons' of the various options:

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Analysis of 4 main options

1) No joint submission of CSR: CSR developed and submitted individually by each registrant

Pro	Con
Maximal protection of information on uses, quantities and company specific information	High workload at member registrants during individual development of CSR
CSR development and improvement on downstream user feedback possible without the involvement of other companies of the joint submission	Individually developed CSR would impact all Downstream Users (DU) as it may lead to non-harmonized use conditions (RMMs) communicated to DU.
The lead registrant has no obligations in the CSR development concerning specifics of member registrants. Thus specific opt-out issues can be addressed by the individual registrant (e.g. individual impurities). Lead Registrant has no update obligation.	Upon REACH evaluation (Article 41 and 44) the individual registrant will be directly contacted by ECHA in CSR related questions
No trustee has to be involved	

2) No joint submission of CSR: CSR developed jointly but submitted individually by each registrant

Pro	Con
Reduced workload at member registrants using jointly developed CSR	Higher workload at the lead registrant (or trustee) to collect CSR information and achieve agreement by member registrants
Jointly developed CSR will impact all downstream users and help to establish harmonized use conditions (RMMs)	The protection of information on uses, quantities and company specific information might require the involvement of a trustee
CSR improvement following downstream user feedback possible by each registrant without the involvement of other companies of the joint submission. Specific opt-out issues (e.g. individual impurities) can be addressed by additions to the jointly developed CSR	Upon REACH evaluation (Article 41 and 44) the individual registrant will be directly contacted by ECHA in CSR related questions
The lead registrant will not take over responsibilities for unlimited time in relation to the jointly developed CSR. Updates will be done individually, so no workload for LR.	

3) Joint CSR submission of part B + Individual submission of (part A+ partially part B)

Pro	Con
Reduced workload at member registrants referring to the jointly submitted CSR	Higher workload at the lead registrant (trustee) to collect CSR information and achieve agreement by member registrants
Jointly developed CSR will impact all downstream users and help to establish harmonized use conditions (RMMs)	CSR improvement following downstream user feedback only possible with the involvement of other companies of the joint submission (no fast response possible)
Upon REACH evaluation (Article 41 and 44) the lead registrant will be contacted by ECHA in jointly submitted CSR related questions, instead of individual members.	The protection of information on uses, quantities and company specific information might require the involvement of a trustee to assure competition law compliance.
	The lead registrant takes over responsibilities for unlimited time in relation to the update of jointly developed CSR. He will have to communicate any change to all member registrants.
	Splitting of the CSR document in up to three parts requiring discipline in documentation and reassembling the information for the extended SDS compilation. Specific company issues (e.g. due to individual impurities) must be addressed in the individually submitted Part B of the CSR.
	Only the lead registrant knows exactly what has been submitted to ECHA. The member registrants have no means to directly access the information in REACH-IT. This can be circumvented by an exchange of information outside REACH-IT.

4) Joint CSR submission (with no individual submission of part A or B)

Pro	Con
Reduced workload at member registrants referring to the jointly submitted CSR	Higher workload at the lead registrant (trustee) to collect CSR information and achieve agreement by member registrants
Jointly developed CSR will impact all downstream users and help to establish harmonized use conditions (RMMs)	CSR improvement following downstream user feedback only possible with the involvement of other companies of the joint submission (no fast response possible)
For members: The lead registrant will assume responsibilities for unlimited time in relation to the jointly developed CSR. He will have to communicate any change to all member	For the lead - the lead will take over responsibilities for unlimited time in relation to the jointly developed CSR. He will have to communicate any change to all member

registrants.	registrants.
	Only the lead registrant knows exactly what has been submitted to ECHA. The member registrants have no means to directly access the information in REACH-IT. This can be circumvented by an exchange of information outside REACH-IT.

Further considerations

Depending on the nature of the substance and the number of members of the joint submission the decision to choose one out of the options above can be influenced also by other criteria (e.g.):

- Type of chemical: common to downstream user industries well defined uses (no CBI) for “bulk chemicals” versus downstream user specific uses (CBI) for “specialty chemicals”
- Number of companies involved: the additional workload at the lead company has to be balanced with the reduced workload at the member registrants in case of jointly developed (and submitted) CSR. Thus in substances with a large number of member registrants the advantage might be considered larger than in substances with lower numbers of member registrants.
- Level knowledge in the SIEF

The considerations in the ECHA guidance on “data sharing” should be observed.

Conclusions:

The decision whether to go for a Joint development and/or Joint submission of the CSR in a SIEF depends on the situation of the companies and the substance in question.

In any case, when making this decision, all the registrants need to be aware of the implications on their own preparation of their dossier.

As the implications are significant, it is important that the lead registrant/consortium clearly communicates which of the options has been decided upon. Companies also need to be aware that there are two decisions in the process: (1) the lead has to allow the member registrants to refer to the CSR parts jointly submitted (2) only then each member registrant can decide if he wants to refer to the CSR parts jointly submitted by the lead registrant.

More information on how to practically include the CSR in the registration dossier for the different cases can be found in the ECHA Data Submission Manual 19: How to submit a CSR as part of a Joint submission? (*recently updated*):

http://echa.europa.eu/doc/reachit/dsm_19_how_joint_csr_en.pdf