

Data Submission Manual 19: How to submit a CSR as part of a joint submission?



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Data Submission Manual 19: How to submit a CSR as part of the joint submission?

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1 Introduction

According to Article 11(1) of the REACH Regulation registrants of a substance may choose to submit their Chemical Safety Report (CSR) jointly or separately. The individual submission of a CSR is not regarded as an opt-out in the meaning of Article 11 (3), and thus does not need a particular justification. This applies to both, CSRs with exposure assessment and CSRs without exposure assessment.

This manual is about submission of a (fully or partly) joint CSR, with a particular focus on the CSR chapters relating to use, exposure assessment and risk characterisation.

The benefits of one CSR per substance are obvious: Users would receive harmonised and consistent exposure scenarios from all manufacturers and importers of the substance. The CSR could address environmental exposure and potential risks in a scientifically sound way based on the total manufacture and market volume. And finally, the authorities could limit their effort to evaluating one CSR per substance.

However, in practice it may be difficult to organise communication among the registrants in a way that all the necessary information on uses and conditions of use (including tonnage) needed to prepare the CSR (in particular the environmental part) are exchanged with the assessor of the lead registrant. Registrants may also find it difficult to maintain the mechanisms to update the joint CSR after first submission of the registration dossier. In addition, it may be difficult to determine who is to be held liable for the declarations on implementation and communication of risk management measures in part A of the joint CSR.

This guide aims to describe ways to practically carry out the joint or separate submission of the CSR or parts of it, taking into account the difficulties identified above. The overall objective is to ensure flexibility and transparency at the same time. The practical guide does not include a discussion on pros and cons of the different solutions.

2 Issues that may arise when preparing a joint CSR

The CSR contains eight different types of information to be considered when deciding whether and how to submit the CSR separately or jointly. The following table gives an overview.

CSR Part	CSR chapter	Information Content	Remark
A		Summary of risk management measures	
A		Declaration on implementation and communication of the risk management measures	Responsibility of each registrant, covering his own manufacturing and identified uses
B	1	Substance identity and chemical-physical properties	Same for all registrants fully or partly covered in a joint CSR
B	3-8	Intrinsic hazards of the substance and corresponding justifications	Same for all registrants fully or partly covered in a joint CSR
B	3-8	Justification for adaptation of information or testing proposals based on use and exposure considerations	Same for all registrants fully or partly covered in a joint CSR
B	2	Manufacture, identified uses, uses advised against; includes tonnage for manufacturing, own use and intermediates.	Consistency with corresponding IUCLID section of the single registrant to be ensured, as well as with the exposure scenarios described in section 9.
B	8	Emission characterisation (if substance considered as PBT or vPvB); includes tonnage break down to uses.	Differences in conditions of manufacturing, markets and conditions of use among the different registrants to be expected.
B	9,10	Exposure scenarios (conditions of use), related exposure estimates and risk characterisation for the identified uses; includes tonnage break down to uses.	Differences in conditions of manufacturing, markets and conditions of use among the different registrants to be expected.

The following situations may occur in practice:

- Joint submission of section 1 and section 3 to 8 of the CSR (part B), exclusively containing information related to the identity and intrinsic properties of the substance to be registered: It is assumed that the CSR information is normally consistent [identical] with the information in the joint submission of the Technical Dossier, regardless of whether the CSR is submitted jointly or separately.
- Nevertheless it may occur that the same substance has different hazard profiles (due to differences in impurity profile) to be documented in section 3-8 of the CSR (part B), potentially requiring different kinds of risk management measures. In such case separately submitted CSRs (part B) may differ in section 1 and section 3 to 8.
- Joint or separate submission of chapter 2, 9, 10 of the CSR (part B) on use, exposure and risk characterisation: These sections may include information that a registrant does not wish to share with co-registrants. Consequently, registrants may want to submit some or all information on use and exposure separately in an own CSR.
- Update of a dossier of a single registrant after registration regarding volumes (triggered by market developments) and/or identified uses and exposure scenarios (triggered by feedback from customers), also requires updates of the joint CSR.
- Submission of a CSR for the same substance at a later registration deadline may potentially require updating of the joint CSR (assumed the new registrant wishes to be covered in the joint CSR and the lead agrees).
- Submission of Part A (declaration on implementing and communicating risk management measures) and submission of Part B (content of the CSA) does not necessarily always go together. Thus registrants may submit a CSR only containing part A in which they make reference to specified parts of the joint CSR (part B) submitted by the lead registrant. However, it is also possible that a joint CSR contains a Part A on which all registrants jointly declare that they implement and communicate those exposure scenarios relevant for their manufacturing and use.
- In practice it may also occur that a jointly prepared CSR is submitted separately, including relevant modifications carried out by the single registrant before submission.

2.1 Issues related to Part A

The issues and the corresponding solutions regarding part A are summarised below. The technical implementation of the solutions is described in section 3 and 4 of this guide.

2.1.1 Part A1

In Part A1 of the CSR a summary of all risk management measures covered in the CSR is to be presented. The question arises how to summarise Risk Management Measures (RMM) described in the context of the exposure scenarios covered in the CSR (section 9 of the CSR) without losing relevant information or largely duplicating information.

- **Preferred solution:** Make reference to the RMMs described in the exposure scenarios in chapter 9 of the CSR.
- **Alternative solution:** Copy all risk management measures from all exposure scenarios (after having removed duplications) to part A.

2.1.2 Part A2

In Part A2 of the CSR a registrant has to declare that he implements the RMM related to manufacturing and own use described in the exposure scenarios contained in the CSR. This is relevant and specific to each registrant, and it is to be assumed that not all manufacturing sites are operated with the same RMM. So the question arises here, whether part A is part of a joint CSR (and thus collectively refers to the variety of manufacturing and own use conditions existing), or is to be submitted individually and refers to the single registrant's specific manufacturing and own use conditions.

- **Preferred solution:** Each registrant declares the implementation of the RMM separately in an own part A with reference to the applicable exposure scenarios in the joint CSR or specific exposure scenarios in his own CSR. This is to ensure transparency for the single registrant's own records and the authorities.
- **Alternative solution:** ECHA would accept a joint declaration by the lead registrant on behalf of the member registrants as well. Nevertheless each member registrant should be ready to demonstrate to the enforcement authorities which exposure scenarios from the joint CSR he implements.

2.1.3 Part A3

In part A3 of the CSR a registrant also declares that the RMM relevant for downstream users are communicated. This is applicable for each registrant and his market. For commodities, there may be substantial commonalities among the markets of different registrants. However, there may be also particular markets or niche markets for a substance with specific conditions of use for which the "mainstream" exposure scenarios are not applicable. So the question arises here again, whether part A is part of a joint CSR (and thus collectively refers to the variety of downstream use conditions existing), or whether it is to be submitted individually and refers to the single registrant's specific market only. It should be noted that a misfit between the scope of the declaration in part A3 of the CSR and the exposure scenarios actually communicated with the extended safety data sheets by the single registrants may lead to enforcement issues at member state level.

- **Preferred solution:** Each registrant declares communication separately with reference to the applicable exposure scenarios in the joint CSR or specific exposure scenarios in his own CSR. This is to ensure transparency for the single registrant's own records and the authorities.
- **Alternative solution:** ECHA would accept a joint declaration by the lead registrant on behalf of the member registrants as well. Nevertheless each member registrant should be ready to demonstrate to the enforcement authorities which exposure scenarios from the joint CSR he communicates to his customers.

2.2 Issues related to use and exposure information in Part B

A joint part B will contain **exposure scenarios** (and corresponding exposure estimates and risk characterisation) for manufacturing and the identified uses (including manufacturers' own uses). The exposure scenarios are meant to describe conditions under which control of risk is ensured. The means to ensure control of risk may be different from site to site depending on local conditions and investment cycles. The joint CSR is expected to include all the relevant types of risk management needed to ensure control of risk at the manufacturing sites and in the markets of the registrants jointly submitting the CSR.

For the environmental assessment the conditions at the different manufacturing sites and the conditions at downstream use (and subsequent life cycle stages) are to be connected with information on substance amounts (daily and annual) used under these conditions. The conditions relevant here include the technical conditions (including risk management) and the environmental conditions (e.g. locally available water volumes and treatment capacities for waste/water). A joint CSR is expected to include a breakdown of substance amount to the different conditions under which the substance is manufactured and used. This is to generate local and the regional release estimates.

A number of issues may **arise around Confidential Business Information (CBI) and competition law**. CBI issues may be related to sharing of information on manufacturing techniques, manufacturing volumes, particular own uses (and the corresponding volumes) or special downstream uses (and the corresponding volumes). It should be also kept in mind that sharing information related to volumes and customer groups can also create conflicts with EU competition law requirements. In general, if the number of registrants is low, CBI or competition law issues are more difficult to avoid.

- **Possible solutions: In many cases a third party (acting on behalf of the lead registrant) will be needed, that receives all the necessary information from the member registrants and aggregates volume and/or use-related information. This is to be done in a way that the single registrant cannot trace back sensitive information of other registrants. At the same time it needs to be ensured that the joint CSR is transparent enough to enable each single registrant to confirm that he is covered. Feedback from the third party to the single member registrant may be required. In addition, some member registrants may choose a hybrid solution: The joint CSR then only covers those uses that are common to most [all] of the registrants, and CSR information for more particular uses is submitted separately.**

2.3 Issues related to hazard information in Part B

For section 1 and 3 to 8 of Part B of the CSA (substance identity and substance properties) the joint submission may be straightforward, unless the composition of the substance for different registrants leads to a different classification of substance which may trigger different types of risk management measures.

- **Proposed solution: A separate CSR is submitted referring to the substance properties relevant for the specific substance composition.**

2.4 Issue related to updating mechanisms

Neither in a joint part B nor in a single registrant's CSR will it be possible to reflect all the possible combinations of conditions of use that drive the release and/or exposure at downstream use. While the lead registrant and member registrants can describe manufacture and own uses in all relevant aspects, a CSR will never be based on a "complete set of information" from all downstream uses. That is why REACH foresees a mechanism based on which downstream users:

- can go back to their suppliers if the communicated exposure scenarios are inappropriate or do not cover all the downstream user's uses,
- or can carry out an own chemical safety assessment for that use.

For the joint CSR, the issue arises how the lead registrant will ensure updating the joint CSR based on the feedback the different member registrants receive via their supply chains.

- **Preferred solution:** The lead registrant maintains the processes and infrastructure used for generating the joint CSR after first submission (as a service for all member registrants). Thus updating of the joint CSR is ensured based on request from single member registrants.
- **The alternative solution:** After registration, every registrant individually submits his own CSR (chapter 2, 9, 10) if updates regarding use, tonnages and exposure scenarios become necessary. This solution is however clearly less desirable, since the joint CSR will quickly lose its value as a source of information for registrants and authorities.

2.5 Issues regarding substance evaluation

In order to be able to carry out a correct substance evaluation, authorities require information on the tonnage for the different uses and conditions of uses (across all registrants). If the CSR(s) submitted for a substance are not transparent in this respect, the authorities may

- need to ask for more information and create a burdensome process for the involved parties or
- prioritise for substance evaluation, or launch restrictions based on very conservative assumptions.
- **Preferred solution:** Ensure transparency in all the CSRs submitted.

3 Practical guidance regarding the Joint CSR

In case a number of registrants decide to submit a joint CSR, it will cover part or all of the information required from registrants and will be submitted by the lead registrant.

3.1 Content

3.1.1 Part A

In order to ensure the transparency (which part of the CSR is relevant for which registrant) and to avoid any liability issues it is recommended that a joint CSR does not contain any part A.

Nevertheless ECHA will accept that the joint CSR contains a part A: joint declaration by the lead registrant on behalf of the member registrants. The distribution of liability between the lead registrant and the member registrants covered by the CSR would have to be settled through contractual arrangements between the registrants. Such Part A of the joint CSR could read as suggested below:

A1. Summary of Risk Management Measures
<i>The risk management measures are described for all Exposure Scenarios in Section 9 of part B of this document.</i>
A2. Declaration that risk management measures are implemented
<i>Each registrant, having decided to mandate the lead registrant to submit this CSR on his behalf, endorses the declaration that he implements those risk management measures described in section 9 of part B of this document, that are relevant to his manufacture and own uses.</i>
A3. Declaration that risk management measures are communicated
<i>Each registrant, having decided to mandate the lead registrant to submit this CSR on his behalf, endorses the declaration that he communicates those risk management measures described in section 9 of part B of this document to his customers, that are relevant for their uses.</i>
N.B. Please note: The distribution of liability between the lead registrant and the member registrants covered by the joint CSR would need to be settled through contractual arrangements

3.1.2 Part B

As long as the specific situation mentioned in section 2.3 is not applicable (no differences in hazard assessment due to different compositions of the substance) it is suggested that sections 1 and 3 to 8 are reported in a joint CSR.

The decision regarding the content of part 2 and 9-10 of the CSR depends on whether the uses are “spread and standard¹” or whether the uses are quite specific². It also depends on the number of registrants in the joint registration. The higher the number of registrants, the easier it is to not reveal specific information, once processed by a third party (“trustee”).

All the uses for which it is possible to avoid disclosure of sensitive information are to be described and assessed in sections 2 and 9-10 of the joint CSR. It is recommended that the total tonnage of all registrants covered by the joint CSR is taken into account for the assessment.

3.2 Development process

The joint CSR is to be prepared covering a number of manufacturing processes and uses, common among those registrants having decided to submit (part of) their CSR jointly. In order to develop such a joint CSR the members of the joint submission (including the lead registrant) need to do the following for each manufacture or use they want to be covered in the joint CSR:

- Inform the party working on behalf of the lead on their manufacturing process, the uses, the anticipated service life (if relevant), the related tonnage and the conditions of manufacture and use.
- Make sure that the information on manufacturing in section 3.1 of each registrant's IUCLID dossier is consistent with the information in section 2.1 of the joint CSR.
- Make sure that the information on identified uses (and subsequent service life) in section 3.5 of each registrant's IUCLID³ dossier is consistent with the overview table on identified uses in section 2.2 of the joint CSR and the exposure scenario titles in section 9 of the joint CSR.

In a joint CSR, the total tonnage for each use plays a significant role in the assessment for the environment. Consequently it is important that

- each registrant provides information to the lead or the third party preparing the joint CSR on the tonnage for each use that should be covered for his registration.
- the third party preparing the joint CSR informs back to each registrant which of his tonnage has been taken into account in the CSA.

¹ assuming that the conditions of use are similar

² As the manufacture is also to be covered in the CSR, it also depends on whether the conditions for manufacture are “standard” or not

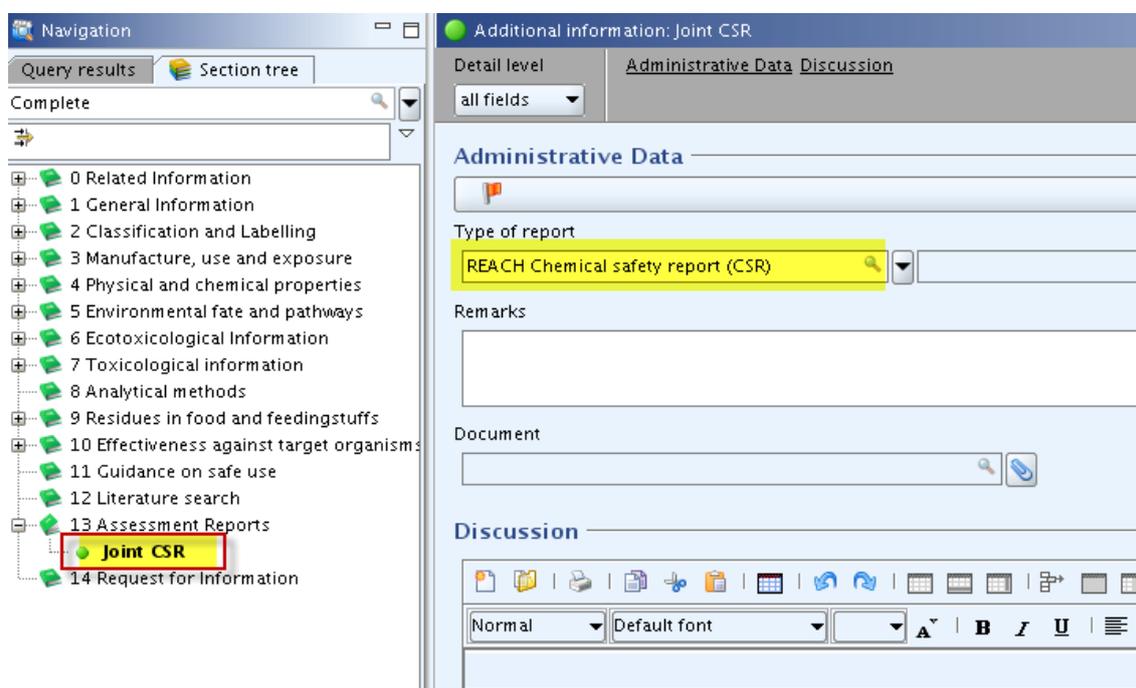
³ It is assumed that the list of uses (and related exposure scenarios) in a joint CSR is the result of a consolidation and assessment process taking into account the information from all the members. This (consolidated) list of identified uses is likely to include new or refined names for uses. Thus for the single member to recover the description of uses he provided to the third party, he needs to get feedback from this third party on the relationship between his input and what is described in the joint CSR.

3.3 Submission

The joint CSR is submitted by the lead registrant.

It must be attached in Section 13 of IUCLID (“Assessment reports”). In the field 'Type of report' the option “REACH Chemical safety report (CSR)” must be selected. Then the CSR must be attached in the field ‘Document’ of the endpoint study record⁴. For clarity, it is recommended to give the endpoint study record a name which reflects the content of the document, e.g. “Joint CSR” or “Joint CSR part B”. This is to easily identify the CSR among all the other documents that may be also attached to section 13 of IUCLID.

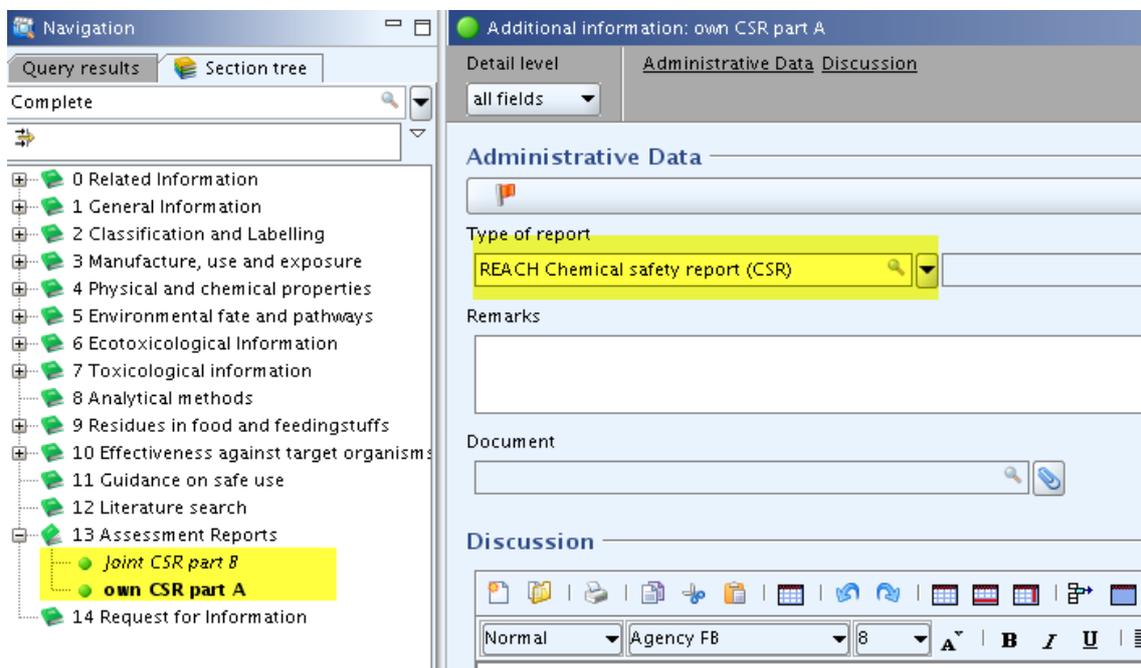
The following screenshot presents the dossier of the lead registrant, if he submits the full joint CSR on behalf of the member registrants.



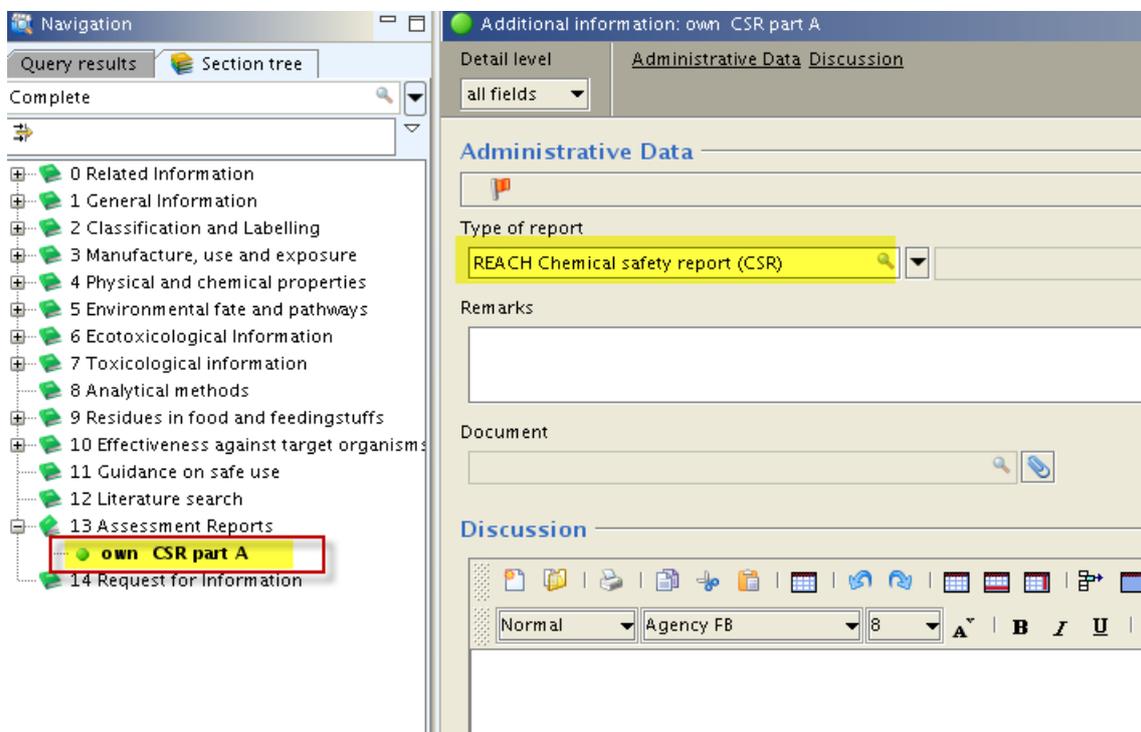
If the lead only submits part B of the joint CSR then he and each covered member registrant needs to submit an own part A (see next two screenshots).

⁴ In order to attach a document an “endpoint study record” needs to be created in IUCLID

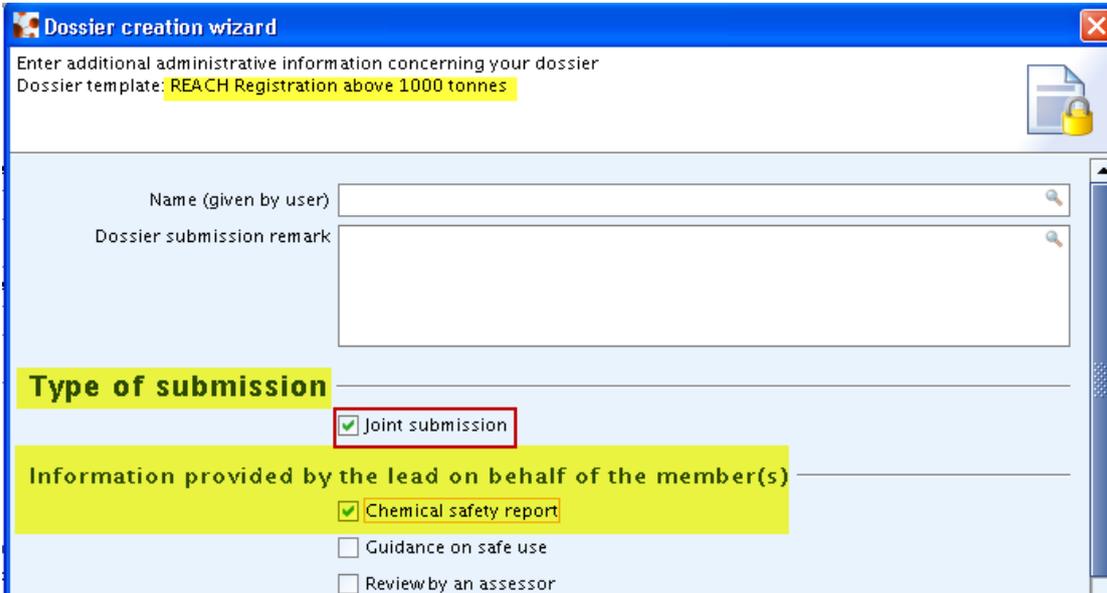
Lead registrant



Member registrant



At dossier creation time, the lead registrant needs to indicate, in the dossier header, which optional part(s) of the joint submission he submits on behalf of the members. For the CSR, he should tick the first box “*Chemical safety report*” in the appropriate section of the dossier header [i.e. “*Type of submission*” / *Information provided by the lead on behalf of the member(s)*”].



Dossier creation wizard

Enter additional administrative information concerning your dossier
Dossier template: REACH Registration above 1000 tonnes

Name (given by user)

Dossier submission remark

Type of submission

Joint submission

Information provided by the lead on behalf of the member(s)

Chemical safety report

Guidance on safe use

Review by an assessor

4 Practical guidance regarding the registrant's CSRs

The registrants being partly or fully covered by a joint CSR may decide to submit some parts of the CSR jointly via the lead registrant and other parts separately. Thus three general cases may occur:

- No individual submission and indication in the dossier header that a joint CSR has been submitted (see section 4.1.1)
- Individual submission of part A referring to a fully joint part B submitted by the lead (see section (see section 4.1.2)
- Individual CSRs via own submission complementing the joint CSR (see section 4.2)

The situation when each registrant submits an individual CSR (and not joint) is addressed in section 4.3.

The following sections provide practical advice on how to implement such solutions.

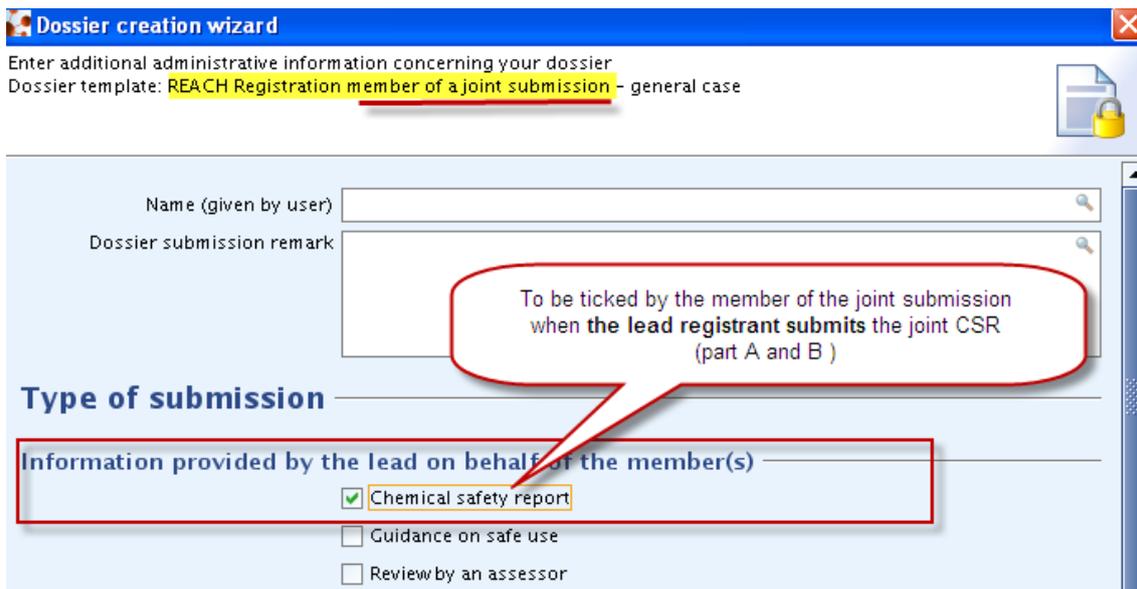
First of all, a registrant should decide whether all the information relevant to him (corresponding to the hazardous properties of his substance, to his manufacture and uses as well to the uses of his market) is covered in part B of the joint CSR or not.

This also applies to the lead registrant who consequently may have to submit (in addition to the joint CSR) his "own CSR" (including his own part A and his own complementary part B).

4.1 Registrant is totally covered in the joint CSR

4.1.1 Joint CSR contains part A

If the lead registrant has submitted the information for the joint CSR (part A and B) on behalf of a registrant, no separate CSR is required from that member registrant. In such a case, at dossier creation time, the **member registrants** need to indicate in the dossier header (section of the dossier header "*Type of submission*" / *Information provided by the lead on behalf of the member(s)*"), that the CSR is provided by the lead on behalf of the members.



It should nevertheless be noted that the member registrant needs to be ready to demonstrate to the authorities (on request) which parts of the joint CSR cover i) his particular activities and ii) the activities of the DUs he supplies. This means that the member registrant should be able to provide to the authorities the information that is suggested in the reference table described in section 4.1.2.

4.1.2 Joint CSR does not contain part A (Preferred solution)

If the lead registrant has submitted all information on behalf of the registrant for part B of the CSR but not for part A (as recommended) a separate submission of part A is required from the member registrants and the lead.

Part A would contain a standard text referring to part B of the joint CSR as well as a “reference table” describing which uses in the joint CSR apply to the single registrant. Such table should indicate which of the registrants’ (member and lead) manufacture and uses are being assessed and as such covered by exposure scenarios in the joint CSR. This table should also contain information which tonnage relevant for the registrant is covered in the joint CSR. Such information would ensure transparency of the information submitted for the registrants’ own records and for the authorities.

An example of such table is provided below:

Overview of manufacture/uses/service life relevant for the registrant (member and lead)⁵

Main life cycle stage	Reference ⁶	Name of manufacture, use or service life	Tonnage (tonnes/year)	Reference to exposure scenario in joint CSR
Manufacture	M-#			ES #
Formulation	F-#			
Workers uses in Industrial setting	IW-#			
Professional workers uses	PW-#			
Consumer end use	C-#			
Service life (by workers in industrial settings)	SL-IW-#			
Service life (by professional workers)	SL-PW-#			
Service life (by consumers)	SL-C-#			

⁵ Add or remove lines as appropriate.

⁶ It is proposed to set the reference numbers with the following rules: an abbreviation of the main life cycle stage followed by consecutive numbers.

Manufacture: M-#, Formulation: F-#, Industrial end use: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial settings): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.

Part A of the registrant (member and lead) could read as suggested				
A1. Summary of Risk Management Measures				
<i>The risk management measures are described in those Exposure Scenarios in Section 9 of part B of the joint CSR that are listed in the table below.</i>				
Overview of manufacture/uses/service life and reference to exposure scenario in joint CSR				
Main life cycle stage	Reference ⁷	Name of manufacture, use or service life	Tonnage (tonnes/year)	Reference to exposure scenario in joint CSR
A2. Declaration that risk management measures are implemented				
<i>I declare that the risk management measures referred to in section 1 are implemented.</i>				
A3. Declaration that risk management measures are communicated				
<i>I declare that the risk management measures referred to in section 1 are communicated to my customers, when they are relevant for their uses.</i>				

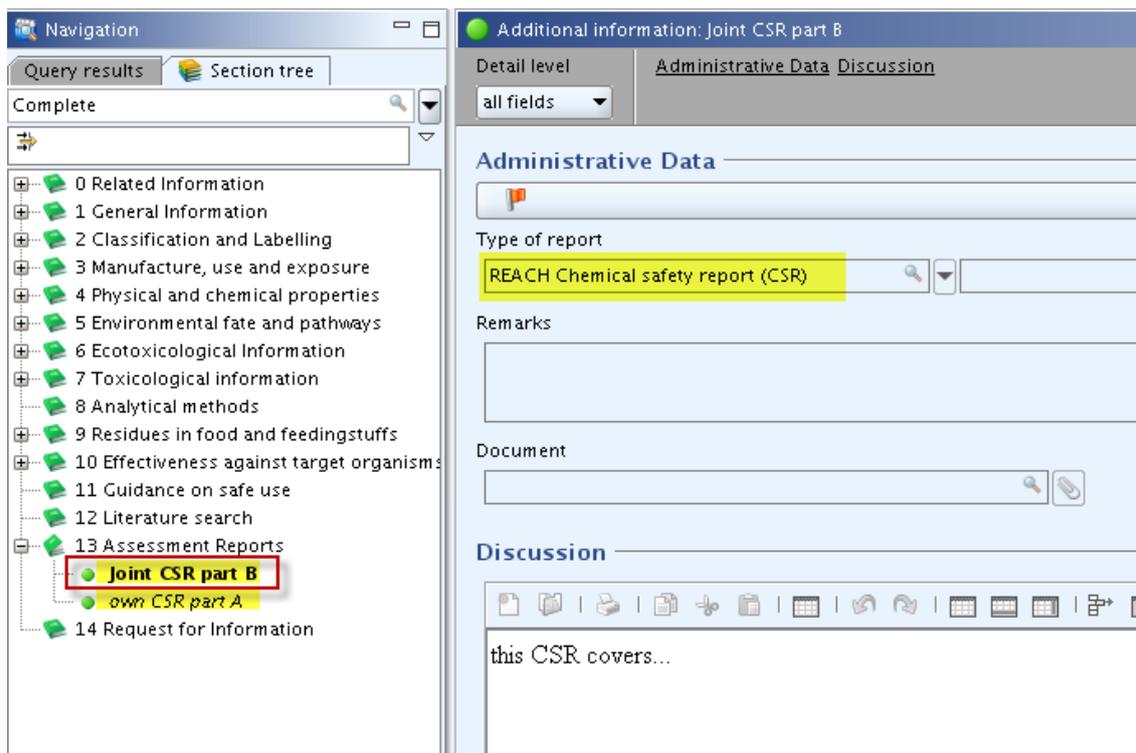
Such part A must be attached in Section 13 of IUCLID (“Assessment reports”). In the field 'Type of report' the option “REACH Chemical safety report (CSR)” must be selected. Then part A of the CSR must be attached in the field 'Document' of the endpoint study record. For clarity, it is recommended to give the endpoint study record⁸ a name which reflects the content of the document attached to the endpoint study record, e.g. “own CSR part A”. This is to easily identify the CSR among the various other documents that might be attached in section 13 of IUCLID.

The two following screenshots refer to the submission of the lead registrant and to the submission of a member registrant.

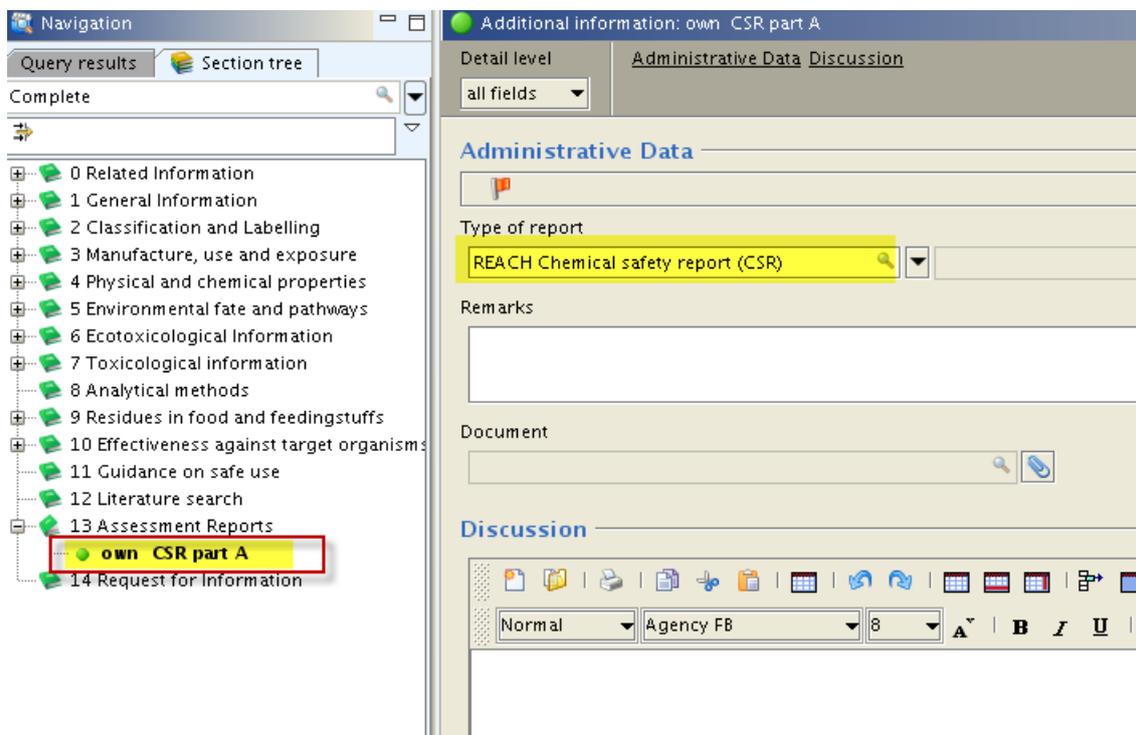
⁷ It is proposed to set the reference numbers with the following rules: an abbreviation of the main life cycle stage followed by consecutive numbers.

Manufacture: M-#, Formulation: F-#, Industrial end use: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial settings): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.

⁸ In order to attach a document an “endpoint study record” needs to be created in IUCLID

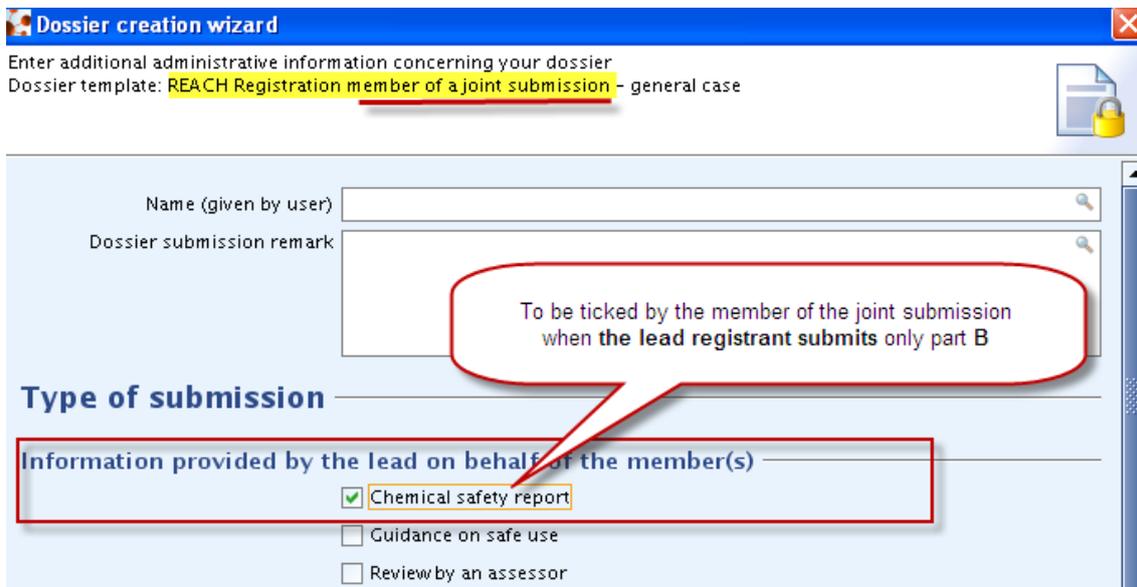


The screenshot shows the 'Additional information: Joint CSR part B' window. The left sidebar contains a 'Section tree' with 14 categories. 'Joint CSR part B' is highlighted in red. The main area is divided into 'Administrative Data' and 'Discussion'. Under 'Administrative Data', 'Type of report' is set to 'REACH Chemical safety report (CSR)'. The 'Discussion' section contains the text 'this CSR covers...'. The 'Detail level' is set to 'all fields'.



The screenshot shows the 'Additional information: own CSR part A' window. The left sidebar contains a 'Section tree' with 14 categories. 'own CSR part A' is highlighted in red. The main area is divided into 'Administrative Data' and 'Discussion'. Under 'Administrative Data', 'Type of report' is set to 'REACH Chemical safety report (CSR)'. The 'Discussion' section is empty. The 'Detail level' is set to 'all fields'. A rich text editor toolbar is visible at the bottom of the discussion area.

As it is not possible to re-develop IUCLID and REACH-IT in the light of these practical solutions, the following instructions must be observed⁹. If only part A of the CSR is submitted by the member registrant, at dossier creation time, he needs to indicate in the dossier header (section of the dossier header “Type of submission” / Information provided by the lead on behalf of the member(s)”), that the CSR is provided by the lead on behalf of the members.



4.2 Registrant is only partly covered in the joint CSR

If not all the manufacture/uses/service life relevant to the registrant are covered in the joint CSR, the registrant needs to carry out an own CSA for the uses, conditions of use and related volumes not covered in the joint CSR.¹⁰

The CSR submitted by the registrant contains part A and (part of) part B.

In order to ensure the appropriate transparency, Part A will contain a reference table as described in section 4.1.2 and could read as suggested below

A1. Summary of Risk Management Measures

The risk management measures are described

- *in the Exposure Scenarios in Section 9 of part B of this CSR and*
- *in those Exposure Scenarios in Section 9 of part B of the joint CSR that are listed in the table below.*

⁹ This process will be reviewed after the 1st registration deadline with the planned upgrade of IUCLID in 2011.

¹⁰ For the environmental assessment, the single member registrant needs to take into account the regional background concentration resulting from his uses and volumes covered in the joint CSR.

In order to ensure the appropriate transparency, Part A will contain a reference table as described in section 4.1.2 and could read as suggested below

Overview of manufacture/uses/service life and reference to exposure scenario in CSR

Main life cycle stage	Reference ¹¹	Name of manufacture, use or service life	Tonnage (tonnes/year)	Reference to exposure scenario in this CSR or in the joint CSR ¹²

A2. Declaration that risk management measures are implemented

I declare that the risk management measures referred to in section 1 are implemented

A3. Declaration that risk management measures are communicated

I declare that the risk management measures referred to in section 1 are communicated to my customers, when they are relevant for their uses.

The registrant must attach his own CSR in Section 13 of IUCLID (“Assessment reports”). In the field 'Type of report' the option “REACH Chemical safety report (CSR)” must be selected. Then the CSR must be attached in the field 'Document' of the endpoint study record¹³. For clarity, it is recommended to give the endpoint study record a name which reflects the content of the document attached to the endpoint study record, e.g. “own partial CSR part A-B” as several endpoint study records can be created. The following screen shots show section 13 for both, the lead registrant (joint CSR and own partial CSR) and the member registrant (own CSR).

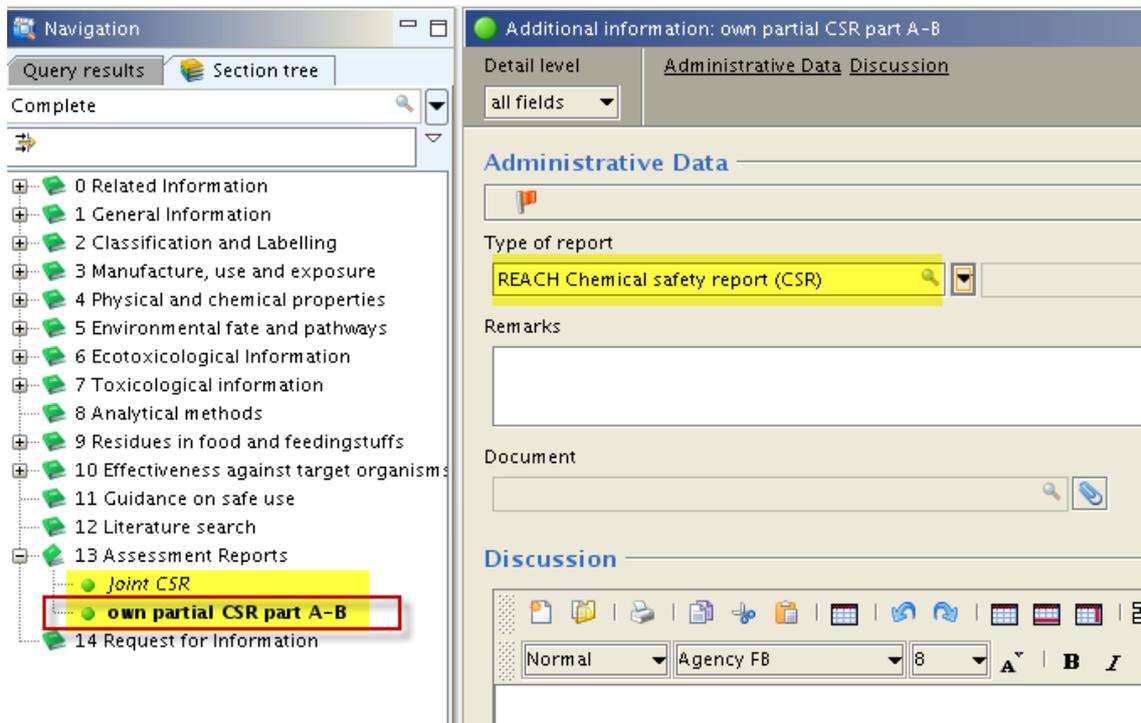
¹¹ It is proposed to set the reference numbers with the following rules: an abbreviation of the main life cycle stage followed by consecutive numbers.

Manufacture: M-#, Formulation: F-#, Industrial end use: IW-#, Professional end use: PW-#, Consumer end use: C-#, Service life (by workers in industrial settings): SL-IW-#, Service life (by professional workers): SL-PW-#, Service life (by consumers): SL-C-#.

¹² Add “(joint)” or “(own)” after each reference to a section 9.x.1

¹³ In order to attach a document an “endpoint study record” needs to be created in IUCLID

Lead



Navigation

Query results Section tree

Complete

- 0 Related Information
- 1 General Information
- 2 Classification and Labelling
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
- 7 Toxicological information
- 8 Analytical methods
- 9 Residues in food and feedingstuffs
- 10 Effectiveness against target organisms
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports
- own partial CSR part A-B**
- 14 Request for Information

Additional information: own partial CSR part A-B

Detail level Administrative Data Discussion

all fields

Administrative Data

Type of report
REACH Chemical safety report (CSR)

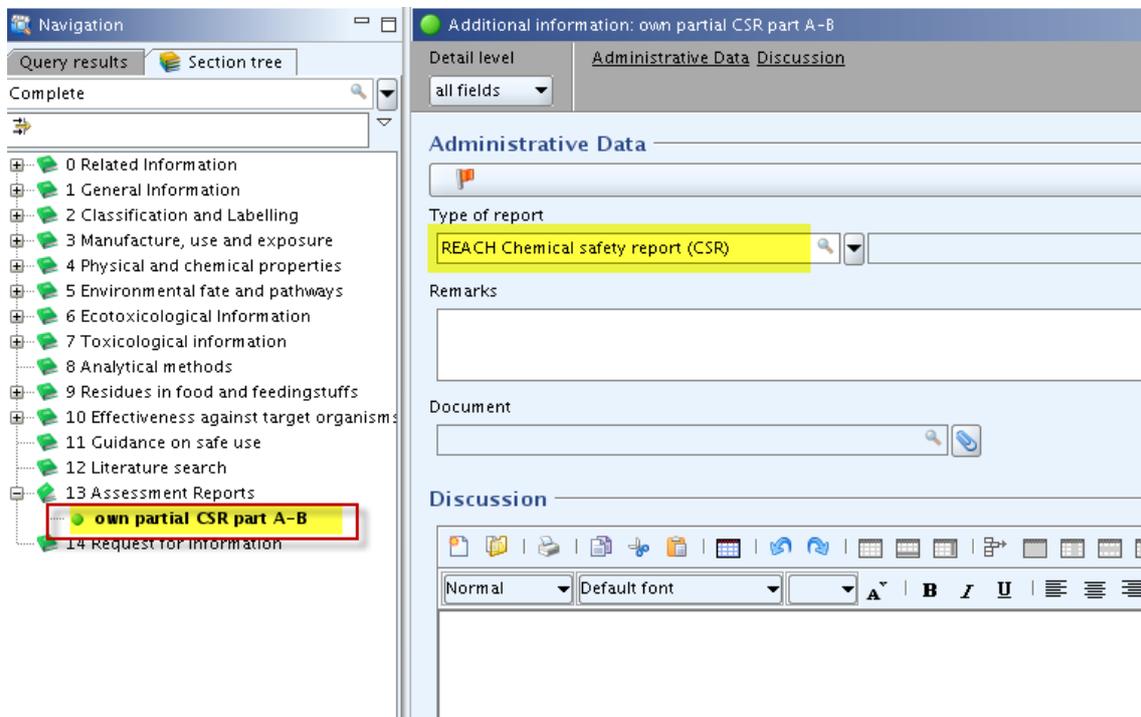
Remarks

Document

Discussion

Normal Agency FB 8 A B I

Member



Navigation

Query results Section tree

Complete

- 0 Related Information
- 1 General Information
- 2 Classification and Labelling
- 3 Manufacture, use and exposure
- 4 Physical and chemical properties
- 5 Environmental fate and pathways
- 6 Ecotoxicological Information
- 7 Toxicological information
- 8 Analytical methods
- 9 Residues in food and feedingstuffs
- 10 Effectiveness against target organisms
- 11 Guidance on safe use
- 12 Literature search
- 13 Assessment Reports
- own partial CSR part A-B**
- 14 Request for Information

Additional information: own partial CSR part A-B

Detail level Administrative Data Discussion

all fields

Administrative Data

Type of report
REACH Chemical safety report (CSR)

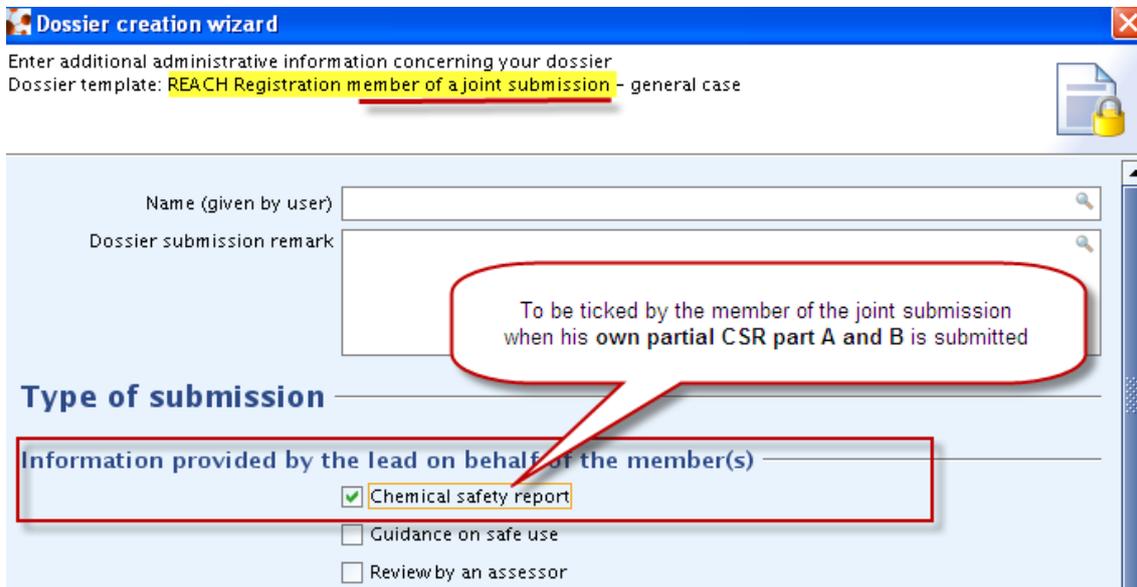
Remarks

Document

Discussion

Normal Default font A B I U

At dossier creation the **member registrant** needs to indicate in the dossier header (section of the dossier header “*Type of submission*” / *Information provided by the lead on behalf of the member(s)*”), that the information in the chemical safety report is provided by the Lead on behalf of him: he must select the “tick box” in the dossier creation wizard since a joint CSR is submitted as well¹⁴.



Dossier creation wizard

Enter additional administrative information concerning your dossier
Dossier template: REACH Registration member of a joint submission - general case

Name (given by user)

Dossier submission remark

Type of submission

Information provided by the lead on behalf of the member(s)

Chemical safety report

Guidance on safe use

Review by an assessor

To be ticked by the member of the joint submission when his own partial CSR part A and B is submitted

In addition the registrant has to ensure that the identified uses assessed in his own CSR are consistent with the uses reported in his IUCLID dossier, section 3.5.

4.3 Registrants submitting on their own

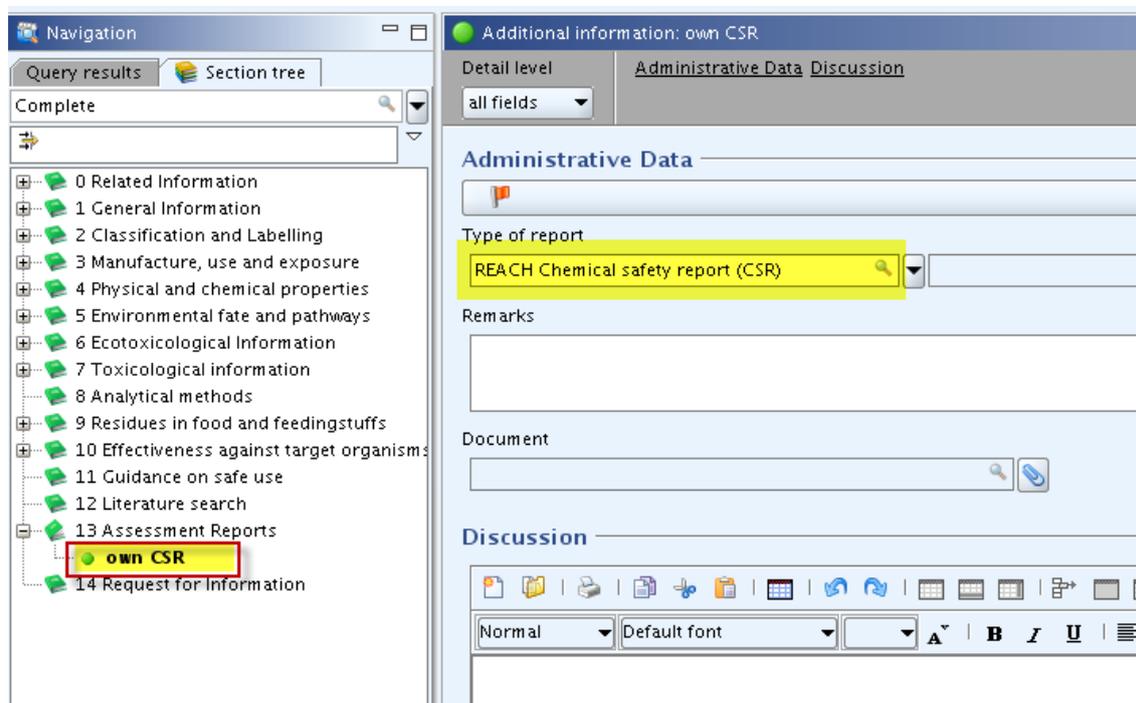
All registrants (lead or member) have the possibility to submit their CSR on their own. This may also include situations where the basis for the CSR has been partly worked out within the SIEF, but then each registrant submits on his own. Preparing a common basis in the SIEF would potentially increase the harmonisation of the information later on individually provided to the authorities and to downstream users.

Note: When submitting a CSR on his own (member registrant not covered at all by a joint CSR) several situations can occur for sections 3 to 7 of part B on the intrinsic properties of the substance:

- The registrant bases his assessment on the information reported in the lead registrant dossier (i.e he is not opting out for any study).
 - a. In principle, his assessment should lead to the same DNELs and PNECs derivation as those reported in the lead registrant dossier.

¹⁴ See FN 9. By combination of tick box information and name of attached file, the submission situation is transparent.

- b. Nevertheless in case the registrant would have a different interpretation of the data and derive different PNECs and DNELs he is strongly advised to report such information in the **endpoint summaries** of section 6 and 7 of his IUCLID registration dossier. In this case, make sure that the supporting information is provided only in the endpoint summaries and **not** in the endpoint study records, in order to prevent this information to be considered as an *opt-out* from the joint submission¹⁵.
- The registrant bases his assessment on a different source of information and has decided to *opt-out* from the joint submission¹⁶. In such a case he should provide the relevant information in **endpoint study records** and should also report the PNECs and DNELs in the **endpoint summaries** of section 6 and 7 of IUCLID.



At dossier creation the **member registrant** needs to indicate in the dossier header (section of the dossier header “*Type of submission*” / *Information provided by the lead on behalf of the member(s)*”), that the information in the chemical safety report is **NOT** provided by the Lead on behalf of him: this means that the tick box “Chemical safety report” should not be ticked.

¹⁵ For more information on how to indicated an opt-out from a joint submission, please refer to Data Submission Manual 4 ‘How to Pass Business Rule Verification (“Enforce Rules”)- Appendix 5.6 opt outs - available on ECHA website at http://echa.europa.eu/reachit/supp_docs_en.asp.

¹⁶ See footnote 15.

Dossier creation wizard ✕

Enter additional administrative information concerning your dossier
Dossier template: REACH Registration **member of a joint submission** - general case 

Name (given by user)

Dossier submission remark

Type of submission

Information provided by the lead on behalf of the member(s)

Chemical safety report

Guidance on safe use

NOT ticked

4.4 Summary of the submission by the lead and member registrants

Acting registrant submitting a CSR	Coverage of submitted CSR	Part A (preferred solution [1])	Part A (alternative solution [2])	Inclusion of Part B into dossier of the lead and member registrants	Tick box “CSR provide by lead” in IUCLID dossier header	Document name for the attached CSR in section 13 of IUCLID
Lead Registrant	Joint CSR, partly of fully covering lead and members	Not included	Included as joint declaration	Partial or complete (at least section 1 and 3 to 7)	Ticked	joint CSR part B [1] joint CSR [2]
Member registrant and lead registrant	Fully covered by joint CSR	Submits on his own	Not submitting on his own	Not included	Ticked	own CSR part A [1] ./ [2]
	Partly covered by joint CSR	Submits on his own		Partial or complete	Ticked	own partial CSR part AB
	Submit on his own	Submits on his own		Complete part B	Not ticked	own CSR

