

Recommendations for splitting of SIEFs:

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Decision to split by the SIEF

Firstly, there should be a justified case for splitting a SIEF based on the discussions on substance sameness. Please bear in mind the guidance on substance identity: http://guidance.echa.europa.eu/docs/guidance_document/substance_id_en.pdf

It has to be emphasized that splitting of a SIEF is not justified because of differences in the properties a substance might have or because of e.g. different manufacturing processes, but only because of a differences in substance composition which are determinant for the substance identity.

SIEF members are advised to elaborate a document agreed at the level of the initial SIEF explaining the reasons why a split has taken place in order to be used in possible subsequent communication with ECHA/national authorities.

SIEF communication by the consortium/SIEF leadership

Following a decision to split the SIEF, this must be communicated to all SIEF members.

The two¹ “new SIEFs” formed after the split should choose two different identifiers to describe the two substances (EC number, CAS number, name).

Creation of Joint submission by the Lead Registrant

¹ There may be more than two SIEFs as a result of a split. In this description we have limited it to two ‘new SIEFs’ for the sake of simplification.

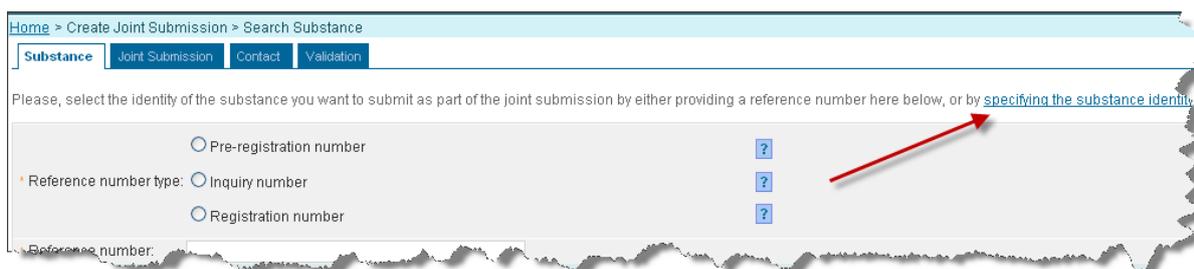


Each Lead Registrant (two SIEFs -> two Joint submissions -> two Lead Registrants) must create a Joint submission object (JSO) in REACH-IT.



Manual selection of the substance identity

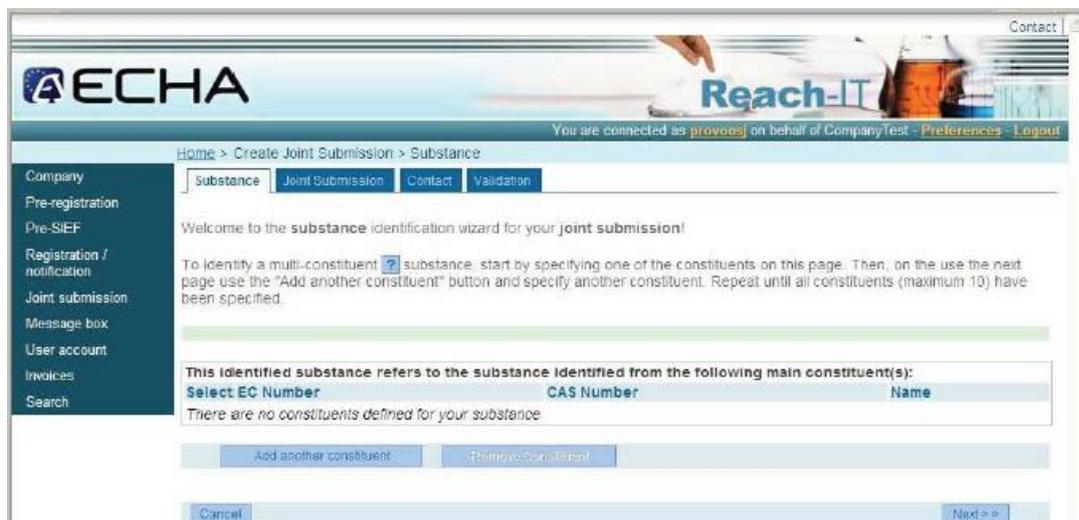
Upon creation of the JS, the LR should specify the identity of the substance manually.



Click on 'add another constituent' and specify the substance using the identifier(s) defined in the newly created SIEF. You should not use the 'old' EC number that was maybe used in the pre-registration that lead to the creation of the initial SIEF. The EC name or the CAS number linked to the EC entry for the substance that was initially pre-registered should not be used, either otherwise the JS module in REACH-IT will automatically linked the JS object to the EC number used in the initial SIEF (i.e. before the split).

Only an EC entry, CAS information or a IUPAC name which is specific to the substance should be used for identification of the substance in the joint submission created in REACH-IT.





Home > Create Joint Submission > Substance

Welcome to the **substance** identification wizard for your **joint submission**!

To identify a multi-constituent [?](#) substance, start by specifying one of the constituents on this page. Then, on the next page use the "Add another constituent" button and specify another constituent. Repeat until all constituents (maximum 10) have been specified.

This identified substance refers to the substance identified from the following main constituent(s):

Select EC Number	CAS Number	Name
There are no constituents defined for your substance.		

Buttons: Add another constituent, Remove Constituent, Cancel, Next >

When the LR submits his dossier using the identifier(s) agreed in the new SIEF (exactly the same as the one used in the JSO), during the Business rules check, the system will identify the lack of EC number and will automatically assign a new temporary EC number.

If a CAS number has been used for a mono constituent substance, this number will start with '600-...'. If the submission used a name as identifier, it will start with '900-...'.

It should be noted that these new numbers are generated automatically by the system without any further check at this stage.

The LR should then communicate to the JS members the exact identifier(s) used for the creation of the JS object in REACH-IT and the new temporary EC number².

Submission by the other SIEF members

Once the LR has successfully³ submitted the lead dossier, the other members of the JS can then submit their registration dossiers. They have two possibilities: either using the EXACT identifiers, or rather the temporary EC number assigned after the lead submission. This first possibility to use the same identifier(s) is more error prone and is therefore not the recommended route.

Note: Although it is accepted that one of the two SIEFs could use the 'old' EC number, it is recommended that both SIEFs follow the above process and therefore two new EC numbers will be created.

² Please note that the initial submission by a member can be made only based on the substance identifier(s) encoded by the lead in the JS object. The same temporary EC number will then be automatically assigned to the member registration. For any subsequent submissions by the members (i.e. updates), the temporary EC number should be reported in the dossier.

³ For the time being the lead dossier must be complete. In the next release of REACH-IT, the lead dossier will have to pass the business rules step before the members can submit.





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