# Cefic paper on Joint submission of intermediates[1]

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## INTRODUCTION

The aim of this paper is to clarify a number of points regarding the Joint submission of intermediates and to explain the various possible options in the form of Q&A.

*The term 'intermediate' is used throughout the document according to the REACH definition of intermediate (article 3.15) which has reduced registration requirements according to articles 17 and 18 i.e. under Strictly Controlled Conditions.*

This paper includes the following sections:

- **General**
- **'Multi-use' registration** (i.e. intermediate + non-intermediate)
- **Updates** (from intermediate to a regular dossier)
- **Authorisation**
- **Classification and labelling**

## General

### 1. Can there be two Joint Submissions (JS) for the same substance: one for Legal Entities with intermediate uses and another one for regular uses?

According to article 2.8, amongst others, the following articles do *not* apply for intermediates:

- articles 5, 6 & 7 (relating to general obligation to register)
- article 11 (relating to the obligation to submit jointly a registration dossier).

[1] For on-site isolated and transported intermediates under Strictly Controlled Conditions (SCC)



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In addition, Chapter 3 of Title II provides the general obligation to register for certain types of isolated intermediates, and article 19 establishes the joint submission obligation for intermediates.

The principle 'One substance One Registration' was explicitly included by the legislator in REACH. The joint submission of the same substance corresponds to an important aim pursued by REACH. Therefore, **ECHA strongly recommends submitting only one Joint Submission covering both intermediate and non-intermediate use**. The reason for this is that manufacturers/importers of the same substances form part of the same SIEF. Data sharing obligations apply to all participants belonging to a SIEF irrespective of whether the substance is used as an intermediate or not. Submission of only one Joint Submission will facilitate compliance with these obligations.

In principle it is possible that one joint submission dossier for the non-intermediate use of a substance is submitted according to Article 11 of the REACH Regulation and another for the use of the same substance as an intermediate according to Article 19. Technically, the REACH- IT system leaves open the option to have two Joint submissions for the same substance: intermediate and regular uses.

Should the SIEF decide to have two different JS, legal entities should carefully consider which one to join as they cannot be part of both. From an IT perspective:

- It is indeed technically possible to create two JS: one for the intermediate use and a different one for the regular use.
- The Lead Registrants can be different
- Each Lead Registrant will create its JS Object (JSO) and communicate the JSO name and the token to the members of his respective JS.
- The different names of the JSO must be self-explanatory for SIEF members
- Currently, it is technically NOT possible for a Legal Entity to register the same substance (i.e. with the same identifier) multiple times. As a consequence, it is NOT possible to register a substance multiple times by a Legal Entity through more than one joint submission (i.e. it is at present technically not possible for the same Legal Entity to make a 'standard' registration and a separate 'intermediate' registration). This IT implementation applies not only to joint submissions but also to individual submissions.

**'Multi use' registration**

**2. If there is a single JS, can a Legal Entity submit one single dossier for both intermediate and standard use?**

ECHA Guidance on registration (p.28) states that:
*"When a substance is manufactured or imported for several of these uses (for PPORD, as intermediate and for other uses) the registrant has the possibility to submit […] one registration dossier covering both the use as isolated intermediate and the other uses. If the manufacture or use(s) as intermediate are not under strictly*

*controlled conditions, then the manufacturer or importer needs to submit a "standard" registration dossier according to Article 10 .*
*If part of the tonnage manufactured or imported is for uses as intermediate under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirement of the registration dossier. Nevertheless the use as intermediate should be documented in the dossier, including the tonnage manufactured or imported for this purpose."*

**The conclusion is that handling in a single dossier both intermediates and other uses can be done.**

### 3. What if the same JS covers intermediate and regular uses what should the LR submit?

In order to cover uses as a regular + intermediate, the LR would provide a full dossier at the highest tonnage band necessary to cover co-registrants, indicating his own tonnage in the dossier header.

In this case the lead registrant must use a full registration template, for the appropriate tonnage band. The Lead Registrant can then declare an intermediate tonnage band while a full registration template is used. In order to allow this possibility a new patch has been included in the latest version of IUCLID5.2 released on the 21st of July 2010.

The general approach is that the **lead selects the template on what he submits on behalf of the Joint Submission. In the dossier header he indicates his own tonnage band(s).**

Each co-registrant would provide a member dossier either for a regular substance or SCC intermediate as the case may be, in which they specify their own tonnage in their dossier header.
The dossier itself is the same. The identified uses in section 3.5 (and in the CSR) would show intermediate use and so it would be obvious that the substance is an intermediate should the dossier be looked at in depth in the compliance check.

### 4. In case there are two Joint Submissions: intermediate and regular uses, and one member of the "intermediate JS" decides later to join the "regular JS". What are the practical implications?

If a Legal Entity has registered a substance through a joint submission, it cannot just switch to a different JS for the same substance. The initial registration would need to be 'closed' via the forthcoming 'cease manufacture' functionality of the legal entity change module in REACH-IT and a new registration would then need to be initiated.

In this case, legal entities need to be aware that there is a period until the new registration number is received. They are therefore advised to inform the national authorities prior to start this procedure.

The new member of the regular JS will have to pay the access to the data he needs according to his tonnage band in this JS.

Therefore, with the current technical IT implementation a Legal Entity is forced to stay with the same JS for the same substance, unless it wants to stop one registration and start a new submission process.

## 5. If one Legal Entity has only an intermediate use, SIEF discussions can be too burdensome, what are the options? If opt-out, is a justification needed?

In case of registration of an intermediate, articles 17 and 18 define the *limited* information to be submitted in the registration dossier. This Legal Entity has two options:

Open a separate JS for intermediates. Even if there is only one Legal Entity. Other Legal Entities may join later. Legal Entities should carefully decide which one to join (for intermediates or for regular use) as it is currently not technically possible to switch it afterwards without a cancellation and initiation procedure (see previous point). This option is not recommended by ECHA.

Opt-out, most likely invoking article 19.2(a) (it is disproportionately costly for this Legal Entity to participate in the Joint submission). When opting-out, the following points must be considered:

- A justification must be included in the registration dossier
- A Legal Entity opting out from all endpoints in a joint submission should still formally be a part of the SIEF and the joint submission (ie. submitting within the joint submission and entering a justification for all of the information where the opt-out is being applied). Separate registrations are seen as individual submissions, which might be in breach of Article 11.

The Legal Entity with only intermediate use should be allowed to get the token for a reasonable fee e.g. only the administrative costs as it is not obliged to purchase any data.

There are implications of opting-out namely a higher registration fee and a priority for dossier evaluation.

The Legal Entity who opts-out must still be aware of the need to have a harmonised Classification and Labelling (C&L) with other SIEF members.

## 6. Is a Legal Entity who only has intermediate use obliged to purchase data from the SIEF? What does 'available' mean in the case of an intermediate registration?

The articles 17 and 18 of the REACH Regulation state that any 'available existing' information must be submitted for the registration of intermediates.

'Available' means what is available to the Legal Entity at hand. For example, a Legal Entity intends to register an intermediate in the 100-1000 volume band. It will conduct an internal survey of all existing information in house. Other information already known to the Legal Entity e.g. by regularly monitoring publications, should also be included.

There is no need to purchase information from the SIEF, or generate new tests.

If the transported intermediate is above 1000 tonnes/year, the registrant needs to submit the information from Annex VII (article 18.3). In this case, he may need to buy data from the SIEF.

## 7. If the JS is only for intermediate uses, and there is one company with non-intermediate use, is the LR obliged to include this use in the JS and therefore submit a regular registration dossier? Can they transfer the LR role?

There is no obligation for the Lead Registrant of the intermediate dossier to expand the scope of the JS also to other uses. In this situation there are various possibilities:

1. The Legal Entity with the regular registration dossier may become the Lead Registrant. The previous LR can transfer the LR role to this company taking into consideration potential implications in already existing data and cost sharing arrangements. Note that, in this situation, the Lead Registrant would incur the extra costs associated with completing the full registration dossier (data acquisition and registration).

2. The Legal Entity with the regular registration dossier may decide to submit a separate registration. The JS for intermediates is not obliged to include the normal use and could decide to remain separate. In that case, the registrant has to submit its dossier alone (opening a separate JS for regular uses).

3. The other option is that one or more registrants with regular uses start to do a JS according to Art. 11. At the end there will be two JS for the substance: intermediate uses and regular uses. Legal Entities should carefully decide which one to join (for intermediates or for regular use) as it is not technically possible to switch it afterwards without a cancellation and initiation procedure (see previous point).

## Updates

### 8. How to 'update' an 'intermediate' dossier by other use(s)?

If a registrant has registered an intermediate dossier and intends to update it to include non-intermediate use:

- In IUCLID5 you have to include all the required information for the non-intermediate use.
- Then create the dossier selecting 'spontaneous update' with reason 'update of tonnage band'
- Finally, in REACH-IT you have to select dossier type 'registration' and submit the dossier

If this is related to a Joint submission there are two cases:

- The LR must cover in his dossier non-intermediate uses and the information relevant to the tonnage band. If this is not the case, the LR has to update his dossier first
- If the LR only covers intermediates and he does not want to include non-intermediate use then the registrant will need to submit the new information as an opt- out

## Authorisation

### 9. Are intermediate dossiers exempted from authorisation?

According to article 2.8, **intermediates are not subject to authorisation**. This article does not refer to strictly controlled conditions so substances with an intermediate use in the registration dossier (indicated in section 3.5) are not subject to authorization for this use.

## Classification and labelling

### 10. Classification and Labelling: obligation to participate in SIEF C&L discussions

The obligation to agree on a Classification and Labelling in the SIEF remains, even if different Joint submissions are done. **The SIEF must find ways to share the information on the agreed C&L between Legal Entities with intermediates and with regular uses.**

In some cases, the Legal Entities submitting an intermediate dossier will not have the data to support the classification. It should be possible to agree with the joint classification from the SIEF with no obligation to purchase data.