REACH provisions for isolated intermediates

Intermediates

Substances meant to be consumed or transformed into another substance and therefore not intended to be present in the final manufactured substance.

Non-isolated intermediates

Substances which are not intentionally removed from the equipment in which the chemical processing takes place, except for sampling.

They are excluded from REACH.

Isolated intermediates

Residues of the isolated intermediates

Residues which are not transformed into another substance in a manufacturing process, will be typically discarded or disposed of as waste or recycled as intermediates. Where residues of the intermediate are found in the synthesised substance, they are covered – as an impurity – by the registration and evaluation of that other substance.

On-site isolated intermediates

(intermediates that remain on the site on which they are manufactured)

Manufactured in quantities of 1 tonne or more per year per legal entity, they have to be registered. However, reduced information requirements apply if they are **manufactured and used under strictly controlled conditions**. The registrant must only submit:

- the hazard classification;
- any information on the properties of the substance that is already available to him without any additional testing;
- information on the risk management measures applied and recommended to the user.

A chemical safety assessment is not required.
If it is not possible to conclude that the substance is manufactured and used under strictly controlled conditions, a full registration has to be submitted.

On-site isolated intermediates are not subject to authorisation but may be subject to limited substance evaluation by the Member State Competent Authority where the manufacturing site is located. They may be subject to restrictions.

If the substance is put on the market (i.e. made available to another legal entity on the same site), the provisions concerning the information in the supply chain and classification/labelling apply.

Transported isolated intermediates

(intermediates transported between sites)

Manufactured or imported in quantities of 1 tonne or more per year per legal entity, they have to be registered. However, reduced information requirements apply if the registrant confirms or states that he has received confirmation from the user (being in the EU or outside the EU) that the substance is **manufactured and used under strictly controlled conditions**.
The registrant must only submit (as for on-site isolated intermediates):

- the hazard classification;
- any information on the properties of the substance that is already available to him without any additional testing;
- information on the risk management measures applied and recommended to the user.

A chemical safety assessment is not required.
For transported isolated intermediates **in quantities of 1 000 tonnes or more per year** per manufacturer or importer, a limited set of additional information – corresponding to the annexe VII of REACH – needs to be generated, if not already available.
If it is not possible to conclude that the substance is manufactured and used under strictly controlled conditions, a full registration has to be submitted.

Transported isolated intermediates are not subject to authorisation but may be subject to evaluation and restrictions.

If the substance is put on the market (i.e. made available to another legal entity on the same site or on another site), the provisions concerning the information in the supply chain and classification/labelling apply.