

1.5.3.4 Only representatives of “non-Community manufacturer”

Registration of substances imported into the EU on their own, in preparations or, in certain cases, in articles will have to be submitted by the EU importers. This implies that each individual importer needs to register the substance(s). **Natural or legal persons that manufacture substances, formulate preparations or produce articles outside the EU cannot by themselves register a substance(s).** However, although not responsible for any action under REACH, they can nominate an **only representative** established within the EU to carry out the required registration of the substance that is imported into the EU (*Article 8(1)*). This will relieve the EU importers within the same supply chain from their registration obligations, as they will be regarded as downstream users of the only representative.

Who can appoint an only representative?

According to *Article 8(1)* a “non-Community manufacturer” being a natural or legal person that is manufacturing a substance, formulating a preparation or producing an article that is imported into the Community, can appoint an only representative to fulfil the registration obligations of the importers. Distributors are not mentioned in *Article 8(1)* and can therefore not appoint an only representative. An only representative must be able to document who he is representing and is advised to attach a document from the “non-Community manufacturer” assigning him as only representative in IUCLID under section “1.7 Suppliers”.

Who can be an only representative?

An “only representative” is a legal entity established in the EU which has sufficient background in the practical handling of substances and the information related to them to be able to fulfil the obligations of importers.

It should be noted that an “only representative” is not the same as a “third party representative” referred to in *Article 4*. A third party representative can be appointed by a manufacturer, importer or where relevant downstream user to allow this potential registrant to remain anonymous vis-à-vis other stakeholders in the data sharing process. An only representative is not obliged to disclose to the other participants in the data sharing process the identity of the “*non-Community manufacturer*” he is representing (for more guidance see the [Guidance on data sharing](#)).

What shall a “non-Community manufacturer” do when appointing an only representative?

When appointing an only representative, it is necessary that the “*non-Community manufacturer*” provides his only representative with up-to-date information on the list of EU importers which should be covered by the registration of the only representative and the quantities imported into the EU.

The “*non-Community manufacturer*” has to inform all the EU importers in the same supply chain that he has appointed an only representative to conduct the registration thus eventually relieving the importers from their registration obligations. The list of the importers that are covered by the registration is to be reported in IUCLID in section “1.7 Suppliers”

A “*non-Community manufacturer*” can only appoint one only representative per substance. Both the only representative and the importer must be able to clearly document to enforcement authorities which imports are covered by the registration of the only representative. Otherwise, the importer remains responsible for all his imports.

What are the consequences for the EU importers ?

When an importer receives information from a “*non-Community manufacturer*” in his supply chain that an only representative has been appointed to cover the registration obligations, this importer will be regarded as a downstream user of the only representative for the tonnage covered by the registration of the only representative. This change of status from importer to downstream user only pertains to the same supply chain, i.e. to the tonnage imported from the “*non-Community manufacturer*” having appointed the only representative. If this importer also imports the substance from other non-EU suppliers, he still has to register the tonnage imported from this or these non-EU suppliers.

Although the importer will receive confirmation from his “*non-Community manufacturer*” on the appointment of the only representative, he should preferably also obtain confirmation in writing from the only representative that his imported tonnage and use is indeed covered by the registration submitted by the only representative. This would not only provide the importer with the contact point to whom he, as acting as a downstream user, can make his use known, but would also give the importer a clear documentation that the imports are indeed covered by the registration of the only representative, as otherwise he remains responsible for the imports.

In case the importer does not want to disclose all information on his use to the only representative, he can, as any downstream user, report to the Agency according to Article 38 and prepare a Chemical Safety Report in accordance with Annex XII (see the Guidance for Downstream Users).

What are the tasks of the only representative?

An only representative is fully liable for fulfilling all obligations of importers for the substances he is responsible for as a registrant. These do not only pertain to registration but also all other relevant obligations such as pre-registration, communication in the supply chain, notification of substances of very high concern (SVHC), classification and labelling and any obligations resulting from authorisations or restrictions etc. (see Art. 8(2)).

The only representative registers the imported quantities depending on the contractual arrangements between the “*non-Community manufacturer*” and the only representative.

REACH does not distinguish between direct and indirect imports into the EU and therefore such terms are not used in this guidance. As long as it is clear who in the supply chain of a substance is the manufacturer, formulator or producer of an article who has appointed the only representative and it is clear for which imports the OR is responsible, it does not matter what are the steps or supply chain outside the EU between the manufacturer, formulator or producer of an article and the importer in the EU.

It should, however, be pointed out that the use of the only representative facility creates the need for exact documentation on which quantities of the substance are covered by the only representative registration. This is because it will not be obvious which quantities of the substance will be covered by the only representative's registration (the manufacturer might not be aware of certain imports in formulations, the formulator might use his own only representative, etc.). The only representative will need this information to fulfil his obligation under Article 8(2) to keep available and up-to-date information on quantities imported and customers sold to. Moreover, the importer will also need to know whether a concrete quantity of the substance in a preparation is covered by the registration of the only representative of the substance manufacturer, as he would otherwise be subject to a registration requirement himself. This documentation will need to be presented to the enforcement authorities upon request.

The registration dossier of the only representative should comprise all uses of the importers (now downstream users) covered by the registration. The only representative shall keep an up-to-date list of EU customers (importers) within the same supply chain of the “*non-Community manufacturer*” and the tonnage covered for each of these customers, as well as information on the supply of the latest update of the safety data sheet.

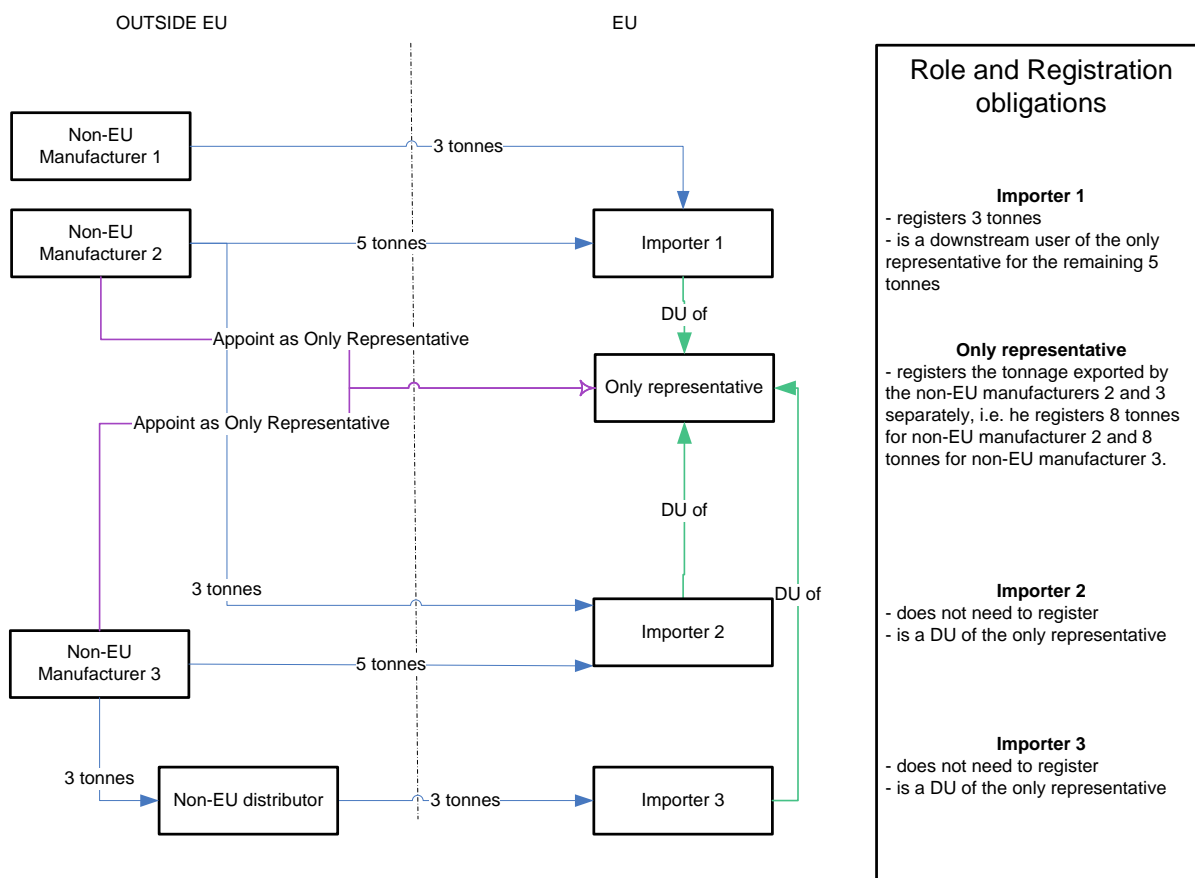
For phase-in substances the only representative will have to pre-register the substance in order to benefit from the extended registration deadlines and will subsequently become participant of the Substance Information Exchange Forum (SIEF) (see [section 3.4 of the Guidance on data sharing](#)).

Although the only representative is legally responsible for the registration, it can be anticipated that in most cases, it will be the “*non-Community manufacturer*” that will provide him with all necessary data for his registration dossier. If a “*non-Community manufacturer*” decides to change his only representative, the successor can submit an update of the earlier registration dossier provided that the earlier only representative agrees to this change. This agreement needs to be documented in the update. In order to prevent disputes, it is recommended to include clauses on the eventuality of a later change of the only representative in the contracts between the “*non-Community manufacturer*” and the only representative.

In the absence of an agreement by the earlier only representative, the successor will have to submit a new registration dossier. It is nevertheless possible for the new only representative to agree with the former only representative and to reuse the data and dossier of the former only representative to prepare his registration dossier.

The only representative can represent one or several “*non-Community manufacturers*”. If it acts on behalf of several “*non-Community manufacturers*” it must submit a separate registration for each of these substance manufacturers. The tonnage of the substance to be registered in each registration is the total of the tonnages of the substance covered by the contractual agreements with the only representative and the specific “*non-Community manufacturer*” represented by him. The information requirement for the registration dossier shall be determined according to this tonnage. By making separate submissions, the confidential business information of the “*non-Community manufacturer*” can be preserved and equal treatment with EU manufacturers can be ensured (EU manufacturers must submit separate registration dossiers for each legal entity).

Example: Role and registration obligations of different actors when an only representative is appointed



Guidance in case of import of a preparation

An importer of preparations is obliged to register the substances in the preparations he imports. For that he needs to know the identity and the concentration of the ingredients in the imported preparations, unless the exporting “*non-Community manufacturer*” appoints an only representative who carries out the registration instead of the importers. In that case, the “*non-Community manufacturer*” shall inform the importers that an only representative has been appointed. If the “*non-Community manufacturer*” appoints separate only representatives for the different substances in the preparation or only appoints only representatives for some of the substances in the preparation, this shall be communicated clearly to the importer, so he is aware of which obligations he is relieved of. In any case, the importer of the preparation and the corresponding only representative(s) must be able to document that the specific substance volume imported in the preparation(s) is covered by the registration dossier of the appointed only representative(s) of the “*non-Community manufacturer*” and if not, by the registration dossier of the importer himself.