REACH compliant imports!

Seeking Downstream User status for imported chemicals can be a difficult and risky task.

According to the Regulation (EC) No. 1907/2006 (REACH), it is the obligation for the recipient of a product, that consists out of chemical substances in the scope of REACH, especially when purchased from outside the EU, to clarify and document the individual REACH role (Importer / Downstream User) before a substance is placed on the market - even when an OR is involved.

Art. 8 / 3 identifies the obligation of the non-Community manufacturer (and not by the OR) to provide information to the importer along the actual supply chain, if an OR has been appointed.

It should be mentioned that in the case, where the supply chain starts outside the community, the non-community manufacturer – if he has appointed an OR - should also be regarded as the supplier (REACH Art.3 par.32) located outside the community, where the recipient acc. REACH Art. 3, par. 34, is the acctual importer who can claim Downstream User status, only in the case were the volume is covered by the OR.

But still, just knowing that an OR has been appointed by the non Community manufacturer does not automatically mean that the importer can claim Downstream User status for the imported substances or mixtures.

If no robust documentation can be provided by any legal entity that is responsible for placing a substance or mixture on the market, this legal entity remains in the REACH role of an importer, with all legal obligations, especially the registration obligation.

In order to become a downstream user and recipient for imports with no registration obligation the following points shall be addressed:

1. Has the manufacturer outside the EU appointed an OR?
2. Does the OR cover the substance(s) that are relevant for me?
3. Does the OR know my legal entity and the substance volumes that we import?
4. How do we document our downstream user status for imported substances or mixtures?

The above mentioned points are addressed in a simple scheme (page 2); as an option to implement a robust process in the company to assess who is responsible for placing a substances or mixtures on the EU market.

Excurse – The Only Representative and his principal

When an OR has been appointed by a manufacturer/supplier located outside the EU – according to Article 8 a mutual service relationship has been established by and between the two independent companies.

In the case that the Only Representative (OR) is <u>not</u> responsible for placing the substances or mixtures on the market[1], he is a regulatory affairs service provider and it is his obligation to act on behalf of the principal's interests, i.e. the non-Community manufacturer.

That means:

- The principal determines the substances he appoints the OR for.
- The principal provides information on the volume and EU Customers[2] to the OR.
- The principal decides on the registration effort for the substance the OR is appointed.
- The principal decides if the OR covered substance:
  a) shall be pre-registered to finally become registered, in a certain tonnage band or
  b) if a substance shall be pre-registered, but <u>not registered</u>.

The OR obligation as a service provider is to consult the principal and request regulatory relevant information and document it for his legal entity, being responsible for the substances he covers.

It is his obligation to pass on necessary regulatory information to his principal, so he (as the manufacturer/supplier outside the EU) is enabled to pass on information down the actual supply chain.

Since the OR is not part of the actual supply chain, according to REACH Art. 8 he relies solely on information, provided to him by his principal. If the principal fails to provide relevant information e.g. inform the OR on

[1] Example: Multinational companies may use their EU legal entities to act as Only Representative for non-Community manufacturing sites. In this specific case, the OR is the actual importer who places on the EU Market.
[2] This means also that the principal decides which of his EC based customers become covered by the OR and which not.

quantities supplied to EU Importers, the OR cannot cover those according to his REACH role – Only Representative.

Four step check for an EU Legal Entity to determine and document their REACH role (I/DU), when an Only Representative is involved!

1. OR Identification
Has the non-Community manufacturer appointed an Only Representative (OR)?

NO → EU Legal Entity (LE), who is placing on the market = **Importer**
-> Obligation to register!

Yes

2. Substance Identification
Does the OR cover the substance we import?

NO → EU Legal Entity (LE), who is placing on the market = **Importer**
-> **Obligation to register!**

Yes

3. Substance Volume Tracking (SVT)
Does the OR know my legal entity and does he (cover) the volume my LE places on the market?

NO → EU Legal Entity (LE), who is placing on the market = **Importer**
-> **Obligation to register!**

Yes

4. Import Compliance Documentation !
EU legal entity has a valid confirmation document, that must match OR documentation?

This document should identify
- (a) Non-Community manufacturer, (b) the OR and (c) the importer
- Substance (Product) covered by OR
- Quantity assigned for importer
- (Uses covered)
- (SDS received by Supplier?)

NO → **Missing Documentation!**
Regulatory compliance gap for the importer!

Downstream User status pending until this gap is closed!
Consequence = LE must assume importer status.
= **Importer** -> **Obligation to register!**

Yes

REACH Compliant Import
- EU Legal Entity, who is responsible for placing on the EU market = Downstream User
-> **No registration obligation!**

CONCLUSION:
EU legal entities purchasing substances or mixtures from outside the EU have the REACH obligation to determine and document their REACH role (I/DU) for every Import, especially when an Only Representative is involved!
If not all four check points above have a clear YES, the LE who is placing chemicals on the market is or must assume to be the IMPORTER, with all consequences.
It is highly recommended to have a valid documentation established (4) – before any substances or mixtures is placed on the market!

Comments and explanation to the scheme:

1. **Only Representative Identification!**
   Has the non-Community manufacturer **truly an OR appointed and is this relationship still established?**

RISKS:
- It has happened that non-Community manufacturers appointed an OR only for the pre-registration, but then failed to pay the OR for further services, or simply cancelled the contract with the OR.
- Sometimes non-Community manufacturers use old and/or outdated submission reports, or Certificates. In some cases, OR certificates were even illegally copied and used.

ToDo:
- Therefore, importers should carefully check if OR documents are valid and that they state clearly that the manufacturer outside the EU has appointed an OR as legal entity inside the EU and that this relationship is still established.
- It´s recommended to check on OR appointment this once a year with the non-Community manufacturer or confirming before any purchase.

2. **Substance Identification**
   Is the substance covered by the OR?

RISKS:
- A general statement from the non-Community manufacturer that an OR has been appointed may not be considered sufficient to prove that the imported substance is covered by the OR.
- A confirmation document should identify the substances or products (substances in product e.g. mixture, article, etc.) that the OR covers.

ToDo:
- Seek confirmation that imported substance, or substances in products requiring registration are covered by the OR.
- Importers shall seek clarification, or take on the responsibility as importer.

Remember:
The decision which substances are covered is made by the non-Community manufacturer, not by the OR.

3. **Substance Volume Tracking (SVT)**
   Is the volume that the EU Legal Entity wants to purchase covered?

RISKS:
- Where the OR is not part of the supply chain, he acts in the interest of his principal, the non-Community manufacturer. He has no obligations towards the importers who place the substances or mixtures on the market, because he has a mutual agreement with his principal, not with the principals EU customers.
- BUT - only if the EU importer knows, that every volume that he purchases form the non-Community manufacturer is covered by the OR - he can claim truly a downstream user status.
- The information on EU customers and volumes supplied have to be provided to the OR by his principal the non-Community manufacturer (acc. Art. 8 / 2) and both the OR and the importer rely on that this information is provided.
- The manufacturer is located outside the EU, so the regulation cannot be enforced on his side.
- In case where the non-Community manufacturer does not provide the OR the relevant information, the OR has no knowledge on importers and their volumes and consequently the OR cannot cover the volumes.
- If the non-Community manufacturer fails to provide information on OR, substance, and volume, the importer remains in its REACH role as importer with a registration obligation.

ToDo:

- Importers should request to receive information from their non-Community manufacturers / suppliers on the appointed OR, substance and volume for each import; if the non-Community manufacturer refers to the OR to seek such confirmation, it can be assumed that the OR is entitled to conduct the necessary steps to provide a REACH compliance document for the imports.

Remember:

- It is the principal of the OR who decides, if a substance will be registered or not.
- The principal also decides on the volume the OR should cover for the importers!
- Therefore, even if a substance has been pre-registered / registered, the volume remains important for importers.
- It must be confirmed that the quantity imported is covered as part of the tonnage band that the OR has claimed at ECHA.

4. Import Compliance Documentation

RISKS

- Authorities are checking documentation in writing. E-mails or oral confirmation are not sufficient as proof for OR coverage.
- Substance Volume Tracking (SVT) is an important issue for importers and OR´s, due to the fact that REACH offers different tonnage bands, and OR will register according to the decision of the principal. So even when a substance is registered, the OR may have limits to the volume and the importer should be aware on this.
- There is no legal obligation in the REACH regulation for an OR to confirm volumes towards the EU importers, but in case such documents are provided, they should identify the following:
    I. Identification of the parties involved:
        a) Non-Community manufacturer as the supplier
        b) OR assigned by the non-Community manufacturer/supplier
        c) EU Importer (DU) / recipient
    II. Identification of the **substance** and **volumes** covered by the OR
        a) Substance identified by EC-No. / CAS No. / Reg.No. / Pre-Reg No.; or, by identification of supplied products that the OR covers.
        b) Confirmation statement assigned to the importer that the OR covers the substance with his pre-registration / registration volume.
        c) Uses – if substance is registered (see safety data sheet).

ToDo:

- Where an OR is not part of the supply chain, the regulatory compliance obligation remains in the hands of every legal entity, being responsible for placing chemicals on the EU market.
- The initiative to become an "importing downstream user" should be driven by the Legal Entity that is placing chemicals on the market.
- In order to become an "**importing downstream user**" the importer shall have a written confirmation in his files from his non-Community manufacturer as his supplier that confirms that an OR for the substance is appointed and the tonnages imported are covered. The OR should have knowledge on the supplied document or even better, the OR even signs this document.
- For the legal entity that is importing and placing the substances or mixtures on the EU market, the best practice would be to integrate a REACH import compliance process in the purchase procedure
- IMPORTANT - before import!
    - ✓ Request written OR confirmation from non-Community manufacturer / supplier as described.
    - ✓ Request SDS (where Art. 31. is applicable).

Remember: There is no legal obligation for OR´s to provide importers with Import Volume Certificates in the REACH regulation text.

Still Only Representatives have the obligation to document for themselves the imported volumes they cover for internal regulatory obligation. In some cases, they do this by using Import Volume Certificates or other documents they issue.

Importers have the same documentation obligation in order to become downstream user for the imported substances or mixtures, but sometimes such documents are also needed to prove to EU custom authorities the regulatory compliance of imports, because they are responsible for placing the substances or mixtures on the EU market.

Importers that use registration numbers of Only Representatives to cover imported substances and volumes without valid documentation are acting non-compliant. In some cases, such behavior by importers may be seen as illegal, because if the importer and Only Representatives documents do not match - fraud can be suspected.

It should be noted that 2013 / 2014 the authorities in the ENFORCE 3 initiative were focusing on OR certificates and it is known to ORO that ECHA collects information provided by the OR certificates.

By doing so, ECHA gathers information on the OR activities and is in the position to inform member state enforcement authorities, if inconsistencies are identified.

ORO is supporting this enforcement action to check on Only Representatives under ENFORCE 3.

Important end notes:

If a non-Community manufacturer appoints an Only Representative this is an additional service to his EU customers.

There is no legal obligation to have an Only Representative appointed, nor is there any possibility to force the non-Community manufacturer supporting a substance or product.

There is no standard procedure, how OR cover documentations (Point 4) are provided.

It depends on the individual service agreements between the OR and their principals.
Therefore EU Importers should be aware on the specific procedure!

In some cases, the OR is integrated in the documentation process. In other cases a specific letter from a non-Community manufacturer states that a product is covered by an Only Representative and no tonnage limitation is given, the importer may assume that all products delivered to him are registered / pre-registered in the tonnage band required. As products may consist of more than one substance (i.e. mixtures) the importer may further assume in such case, that all (pre)-registration obligations are fulfilled.

However, it should be noted that the OR as such is not necessarily responsible for performing CLP notifications. The importer, even if he is considered a downstream user under REACH due to appointment of an OR, is still formally an importer and thus remains to have the CLP notification obligation.

Some non-Community manufacturers do even provide the service of performing group-CLP notifications through their OR but in this case still the consent of the EU importer for inclusion is required and he remains responsible – only the workload is taken away from him – not the responsibility.

This document is an official ORO Document.

In case you like comment or have questions, please feel free to contact ORO.

Only Representative Organisation (ORO) AISBL
Chaussée de Roodebeek 206
B-1200 Brussels
Belgium

info@onlyrepresentatives.org