Finding the right Only Representative

Introduction

REACH places no obligations on suppliers established outside the EEA, with the responsibility falling to their importing customers. In many cases such importers need support from their suppliers to fulfil their duties, and often the supplier wants to be actively involved to protect their EEA trade under REACH. As such, non-EEA companies that manufacture substances, formulate mixtures or produce articles may appoint an “Only Representative” to carry out the duties of those importers.

For many non-EEA producers choosing the right consultant can be difficult. This document aims to highlight some of the important points you may wish to consider when selecting your OR. Don’t forget, if you are looking for an Only Representative, or legal advice about an OR appointment, REACHReady’s Matchmaker scheme can put you in touch with reliable, suitable Approved Service Providers.

Finding the right Only Representative – the choice

Some key facts should be considered to put the advice in context:

1. The OR must be in the EEA and appointment is by the non-EEA substance manufacturer, mixture formulator or producer of articles.
2. The non-EEA principal may choose to do most of the technical work themselves and can take part in SIEF discussions.
3. The importers covered by the OR’s appointment need to be in contact with the OR so that tonnages can be tracked and exposure information can be exchanged.
4. The OR can be dismissed from their position by the non-EEA company, and may resign their role; commercial contract arrangements are important for all parties involved to ensure minimal interruption in supply. REACH-IT allows a change of OR to be reported to ECHA.

Legal details

The manufacturer, formulator or article producer located outside of the EEA must appoint the OR and the importers must agree the role of that OR. Non-EEA distributors cannot appoint an OR. Drawing a parallel with the Sole Representative under the former Notification of New Substances scheme, three stages are involved:

1. Letter from supplier appointing their OR and agreeing contractual arrangement
2. Letter from importers covered by the OR arrangement recognising the OR
3. Letter from OR to supplier and importers agreeing to their role.

The concept of writing 'letters' is not explicit in the regulation, but a defined recognition of the roles between the relationships is the first stage of establishing the OR. This written evidence should be kept on file in case of inspection by the authorities; it is not mandatory to include the documentation in the IUCLID dossier when the OR makes the full registration however it may be useful to do so. An example contract and text for these letters are attached as Annexes to this guide.

The choice of OR will depend largely on the level of work to be undertaken by the non-EEA appointer themselves. To make this easier, you may find it helpful to consider the types of OR in terms of the services offered:

1 Full service
2 Technical consultant
3 Legal advisory
4 Nominated own legal entity

Examples of types of organisations are summarised below; note that this division of roles is a simplistic and as a generalisation may not apply to all situations.

1. Full Service

Service offered by testing laboratory with active regulatory department that can offer a full service 'one-stop-shop' that includes the testing and generation of data.

Advantages: little input by the non-EEA company required. Useful if the non-EEA supplier has little technical capability or has limited resource to get involved.

Disadvantages: can be expensive and a large degree of control may be lost.

2. Technical Consultant

Technical consultants can often take on all activities except the actual testing. However, most good technical groups can arrange testing and monitor such work.

Advantages: if no testing is planned (e.g. if the OR is not the Lead Registrant and is taking on a minor role in the SIEF) these consultants can do everything that the full service can offer except the integrated testing.

Disadvantages: may result in reduced control; consultant may be doing 'easy' activities that you could do in-house at lower cost.

3. Legal

Legal firms with expertise in chemical legislation offering OR services will ensure the legal requirements are met and will be able to support companies involved with difficult or complex situations or substances.

Advantages: can ensure compliance to regulations and provide a solid base for SIEF negotiations. Ideal if the non-EEA supplier has good technical base and can handle a lot of the scientific work

themselves. They will also be a good choice if there are any confidential or intellectual property issues you need to protect.

Disadvantages: when the SIEF discussions become technical and test data needs assessing, support may be weak, although many legal firms have links to technical support.

4. Nominated own legal entity

Often the preferred solution for multi-national organisations with EEA subsidiaries. The appointed company may act in name only, the non-EEA appointer carrying out the technical and administrative work, or may take on all the registration work (akin to an in-house equivalent of #2).

Advantages: least expensive and will let the supplier keep in control of the registration process.

Disadvantages: may place additional strain on an organisation's REACH team. If the nominated legal entity has little expertise they may require significant support from the non-EEA company or perhaps from external advisers.

Summary

The roles taken on by the OR can include a number of activities and the following table attempts to represent the common responsibility areas.

The symbol '✓' indicates a role expected of the relevant type of OR,'O' is optional and '×' suggests a role not expected for such an OR category.

Role	Full service	Technical consultant	Legal	Nominated own legal entity acting in name only
Accept position of OR	✓	✓	✓	✓
Prepare commercial contract	✓	✓	✓	O
Identify precise REACH requirements	✓	✓	✓	×
Submit pre-registration details	✓	O	O	O
Accept official role on SIEF	✓	✓	✓	✓
Agree to work with importers (thereafter known as DUs)	✓	✓	✓	✓
Agree hazard assessment for single registration	✓	✓	×	×
Agree on data gaps and new testing strategies	✓	✓	×	×
Agree on legal arrangement of SIEF	✓	O	✓	×
Agree on costs of sharing data	✓	✓	✓	×
Propose testing strategies	✓	✓	×	×
Perform testing	✓	×	×	×

Consider exposure scenarios of DUs (and in turn, their customers etc)	✓	✓	×	×
Prepare CSR (where relevant)	✓	✓	×	×
Prepare SDSs to be consistent with registration details	✓	✓	×	×
Work with SIEF on IUCLID dossier (lead registration?)	✓	✓	O	O
Submit registration dossier	✓	O	O	O
Monitor supply patterns (volumes of import by each importer, use patterns, SDS checks etc)	✓	✓	✓	✓
Ensure Risk Management Measures are being communicated	✓	✓	✓	✓

What the non-EEA producer can do

It is important to realise that the non-EEA producer can do almost all the work themselves, from outside the EEA. What they cannot do is be the named registrant or take on the legal responsibilities themselves under REACH. Some of the items marked as '✓' in the table above under the 'acting in name only' role may not be possible to be carried out from outside the EEA.

The non-EEA supplier can therefore complete all the registration process including the CSR, SDS etc. Testing can be done outside the EEA as long as it meets the correct guidelines and the IUCLID documents completed. Any person representing the substance manufacture or import can hold the SIEF discussions and if meetings are held, specialists from outside the EEA can attend. Therefore, for organisations outside the EEA with good technical facilities, almost all the work can be done in-house.

Contracts

Getting the right contract is important as the OR will 'own' the registration and if the non-EEA appointer wants to replace the OR, there needs to be safeguards in place. The importers cannot fire the OR, but they can opt out of the arrangement by finding a new supplier or making their own registration. Although OR relationships need to be long term, they can be terminated and all parties need to be careful in setting out working arrangements.

A basic contract should cover the following:

- ✓ Confidentiality
- ✓ Data ownership
- ✓ Intellectual property
- ✓ Financial liability for fees and cost sharing
- ✓ Termination arrangements
- ✓ Mandated data

The fact that the relationship will need to go on far beyond the registration phase needs to be taken into account. A link to a model contract is given in Annex I to this guide.

Changing OR

The Only Representative can be fired, or an OR can terminate its agreement with the non-EEA appointer. In terms of the practicalities, the practical guide 8: how to report changes in identity of legal entity explains how to report OR changes in REACH-IT. The facility to change OR enhances competition between potential ORs and allows great flexibility for suppliers and importers.

On-going duties

REACH does not end when the registration is submitted or a registration number is granted. The exposure scenarios, CSR and CSA are on-going 'live' documents that need updating with new test data or new exposure details as necessary and the SDS is a live document that will need to be updated and revised as required. The OR will continue to have an essential role long after the registration is complete.

Annex I Model contract for appointing an Only Representative

Non-EEA manufacturers, formulators or article producers will need to draw up an agreement for the appointment of an OR. The German Association of Chemical Industry, VCI, https://www.vci.de/Seiten/Startseite.aspx, has published a model contract for 'Only Representatives' (ORs). This model contract has been drawn up by the law firm Redeker, Sellner, Dahs & Widmaier; a copy may be found on the REACHReady website, under *REACH, Resources*.

Annex II Example texts for use in letters between importers and the OR

1. Letter from importer X to OR Y

As importer of [the substance, S], we [the company, X], recognises the role of Y as Only Representative for the registration of this substance imported from the non-EEA supplier Z.

We are aware of our responsibility to keep Y informed of the tonnage imported under the scope of this registration. We also agree to keep Y informed of any adverse effects noted during use of the substance by us or our customers.

2. Letter from OR Y to importer X

The company Y has been appointed by the non-EEA producer Z of [substance, S] to act as their Only Representative for Registration under REACH. It has been agreed that you may import the substance directly from Z without making your own Registration, but you have the duty to inform us of the annual tonnage so that we can maintain records to ensure that the Registration is valid.

You must also inform us of any adverse effects noted in the use of the substance by you or your downstream customers. It is also noted that it is our obligation to keep you informed of any changes in the status of the Registration with respect to recognised uses and also to make available any hazard data that may impact on recommended risk management measures.

Further help

If you are looking for an Only Representative or legal advice on contracts of appointment why not contact us about our Matchmaker service at enquiries@reachready.co.uk or on +44 (0) 207 901 1444

Simply give us some details about your situation, your products and what service or support you need and we will put you in touch with suitable, reputable REACHReady Approved Service Providers. As a Gold subscriber you get priority access to this service.