Only Representative Organisation

Best Practice Guide

Version 2.0

June 2023

TABLE OF CONTENTS

ANNEXES

Annex 1 Documents required for SME verification.

Annex 2 ORO Position Paper 'Only Representatives and Safety Data Sheets'.

Annex 3 Commission letter to an ORO member regarding the OR obligations with regard to Safety Data Sheets.

Annex 4 Commission letter 24 April 2010, regarding the registration numbers on Safety Data Sheets.

CHANGES TO PREVIOUS VERSION

Version	Overview of Changes	Date
Version 1.0	First edition	2014
Version 2.0	Guide's revision covering the following: 1. Update of 'Legal text & official guidance' sections to align them with the applicable regulatory framework: a) Removal of the obsolete references to phase-in substances, pre-registrations, registration deadlines and clarification on tonnage calculation to align with Commission Implementing Regulation (EU) 2019/1692 on the application of certain registration and data-sharing provisions of REACH after the expiry of the final registration deadline for phase-in substances b) Updates regarding dossier update obligations, to align with Commission Implementing Regulation (EU) 2020/1435 on the duties placed on registrants to update their registrations under REACH c) Update regarding information requirements appliable to only representatives to align with Commission Regulation (EU) 2022/477 amending Annexes VI to X to REACH Regulation d) Update in line with Commission Regulation (EU) 2022/477 amending Annexes VI to X to REACH that requires Only representatives to identify the non-EU manufacturers they represent and related REACH-IT Manual and Q&As 2. Align with the updated ECHA *Guidance on registration*, version 4.0, August 2021, other relevant ECHA guidance documents, support material, and Questions & Answers. 3. Streamline the use of terminology throughout the document. 4. Update of visual and style elements in line with ORO's new branding elements. 5. Addition of dedicated chapter on complex non-EU supply chains ('Indirect Supply').	2023

1. INTRODUCTION TO THE GUIDE AND ONLY REPRESENTATIVE ROLE

Only Representative Organisation

The Only Representative Organisation (ORO) is the international trade association of REACH 'Only Representatives'. Only Representatives have a role that enables non-EU companies to place their product on the EU market in accordance with Article 8 of REACH (1907/2006). ORO has over thirty members, all of which take their role seriously. ORO is an accredited stakeholder of the European Chemicals Agency (ECHA) and as such contributes as observer to its various bodies and networks.

The Only Representative keeps in custody his client's right to access to the European market. Reliability, competence, and sense of responsibility are obvious requirements. ORO wishes to ensure that its members meet all of these requirements. For this reason, one of the fundamental qualifications and requirements for Only Representatives who are, or wish to become, members of ORO, as adopted by the ORO General Assembly, is the following:

"ORO members will actively strive to work in accordance with the ORO Best Practice Guide"

Purpose

Only a small portion of the REACH legal text is devoted to the Only Representatives' role and activities. This is unlike most other roles under REACH, which are in different ways addressed in ECHA Guidance. This lack of guidance affects not only the Only Representatives, their Principals (non-EU clients) and the importers covered by their services, but also REACH inspectors. During inspections the requirements for Only Representatives' are not always clear and there are considerable national differences in the requirements that are put forward.

This Best Practice Guide (BPG) is aimed at helping both the Only Representative and the REACH inspectors to know what can and should be expected from Only Representatives. It also clarifies the limits to the Only Representatives' obligations and responsibilities.

This Best Practice Guide informs the non-EU producers and their EU based customers. The Only Representatives' Principals are shown what is required from them to enable the Only Representative to deliver the required service. The importers/downstream users are shown what they can, and cannot, expect from an Only Representative.

The purpose of this Best Practice Guide is to provide a de facto standard for the work of all Only Representatives, including those who are not ORO members.

The BPG is available on the public access part of the ORO website. All those with an interest in the work of Only Representatives are encouraged to download, read and use the document. Updates and additions will be announced and published on the ORO web site.

For each identified issue this guide provides Best Practice; a recommended way in which to address the issue. In practice other methods may exist that obtain the same result. Where this is the case, there is no objection against employing these other methods.

Structure of this document

In this ORO Best Practice Guide each chapter addresses a specific topic. All chapters have a uniform format and contain at a minimum the following sections:

Topic	• A short description of the topic addressed in the chapter and the issues at play. • A list of subjects for which Best Practice is recommended.
Legal text & Official Guidance	• The most relevant parts of legal text. • Where applicable a reference to a relevant legal analysis or ORO position paper. • The most relevant parts of ECHA Guidance Documents. • Relevant correspondence from the European Commission, ECHA or other authorities.
Best Practice	• A short description of the issue or topic • Best Practice recommendations. • References to other chapters in the Best Practice Guide.

Occasionally, where necessary for a good understanding, more sections have been added.

Revisions and versions

ORO aims to keep the Best Practice Guide complete with topics of relevance to its readership and to have regular revisions to ensure the alignment with the latest regulatory framework and best practices.

We follow the regulatory developments on topics relevant to the ORO membership and aim to revise the Guide as seen necessary.

Users are advised to visit the ORO web site regularly to ensure that they have the latest version.

Users of this BPG in need of further clarification or wishing to suggest changes or additions are invited to contact ORO at secretary@onlyrepresentatives.org.

Terms used

Some terms used in this Best Practice Guide have a specific meaning; these are defined below. Unless indicated differently other REACH terms are used as defined in the legal text.

Principal, non-EU manufacturer	The non-EU based manufacturer of substances, formulator of mixtures or producer of articles who is a customer of the Only Representative and who has appointed the Only Representative in accordance with REACH Art.8. For the ease of reading, within some chapters the following terms are used: • Manufacturer: The non-EU manufacturer, non-EU producer • Formulator: The non-EU formulator of mixtures
Only representative (OR)	An EU/EEA based natural or legal person appointed as an Only Representative by a non-EU manufacturer of substances or non-EU formulator of mixtures or non-EU producer of articles in accordance with REACH Article 8.
Downstream User (DU)	Unless indicated differently this means an Importer who, because of the appointment of the Only Representative, is regarded as a 'Downstream User' in accordance with REACH Art.8.
European Union, EU, Non-EU & EU based	REACH Regulation applies in the European Union Member States as well as in Norway, Iceland, and Liechtenstein, which are members of the European Economic Area (EEA). Although this is the case, these terms are used for the sake of brevity. Thus, reference to the 'European Union', 'EU' and 'EU based' include the EEA countries and 'non-EU' excludes them. Following the withdrawal of the United Kingdom from the European Union, the UK became a non-EU country. However, the Protocol on Ireland/Northern Ireland ('IE/NI Protocol') provides that REACH applies to and in the United Kingdom in respect of Northern Ireland. REACH does not apply in other parts of the United Kingdom.[1]
Substance on its own	Substance not being part of a mixture.
Common mixtures	Mixtures such as denatured ethanol or blended motor fuels. Their composition often conforms to industry standards and is not confidential. They can be purchased from several different producers, in the same way as most 'substances on their own'.

[1] As per ECHA Q&A 1700, the implications of the IE/NI Protocol on a practical level, as relates to the OR services, include:

- substances manufactured in or imported to Northern Ireland need to be registered with ECHA, including substances imported from United Kingdom to Northern Ireland;
- substances shipped from Northern Ireland to the EU/EEA are not considered 'imported' from the registration perspective;
- an Only Representative based in Northern Ireland is considered equal to an Only Representative in the EU/EEA;
- a manufacturer, formulator or an article producer in Northern Ireland cannot appoint an only representative.

Proprietary mixtures	Mixtures that can only be purchased from one single producer and are easily recognisable as such, both in documentation and physically and often also in packaging.
Late OR appointment	Refers to the situation where, until the appointment of the Only Representative, importers have themselves fulfilled their REACH obligations. After the OR appointment these obligations are transferred to the OR.
To compile a Safety Data Sheet	Making / producing / authoring a Safety Data Sheet. Can be done by an authoring service. If the compiler of the Safety Data Sheet is different from the supplier, the company, department or person that has compiled the Safety Data Sheet may be identified under section 16 in the SDS. The responsibility for the supply of the Safety Data Sheet remains with the supplier of the substance or mixture to which the Safety Data Sheet relates.
To provide or supply a Safety Data Sheet	Fulfilling the legal requirement of REACH Art.31. To 'Provide a Safety Data Sheet' means the same as to 'Supply a Safety Data Sheet'.
The supplier of a Safety Data Sheet	The person or company who provides the SDS. This must be the same as the supplier of the product to which the SDS relates. The supplier of the Safety Data Sheet is identified as such under section 1.3 of the Safety Data Sheet.
Distribution of Safety Data Sheets	Making the Safety Data Sheets available to those needing them. Can be done on paper, as a computer file, via a web site or in another convenient way. On behalf of the supplier, distribution can be done by a service provider. The distributor of the SDS need not be the 'supplier of the SDS'.

Disclaimer

The Only Representative Organisation, the authors and editors have done everything reasonably possible to avoid mistakes and to ensure that the recommendations in this Best Practice Guide are correctly based upon the legal text, commonly accepted interpretation of the legal text and, unless indicated otherwise, the most recent versions of the applicable ECHA Guidance Documents. The reader is however reminded that the text of the REACH regulation is the only authentic legal reference. Neither the Only Representatives Organisation nor the authors or editors are in any way liable for any incorrectness or incompleteness in this Best Practice Guide.

2. QUALIFICATIONS & REQUIREMENTS FOR AN ONLY REPRESENTATIVE

Topics

The Only Representative is the representative of a non-Community producer and therefore, his reliability, competence and sense of responsibility reflect on the reputation of his non-EU client. It is an important decision for a non-Community producer to choose the right Only Representative, with whom a long-term contractual relationship will be established.

Mutual trust is a pre-requisite because the Only Representative keeps in custody his client's right to access to the European market. The other side of the coin is that the Only Representative is legally liable if the applicable REACH obligations are not met. His clients therefore must enable him to do his work and provide all the necessary information correctly and in a timely fashion.

Non-Community manufacturers and formulators should therefore, before committing themselves, ascertain that their prospective Only Representative is competent and reliable. They should also ensure that their administrative systems can provide timely information necessary to the Only Representative.

The REACH legal text and the ECHA Guidance Documents do not specify in detail the qualifications and requirements for an Only Representative. REACH Article 8(2) contains a generic statement, that the Only Representative. '*…shall have a sufficient background in the practical handling of substances and the information related to them'.* This is however not further defined.

Another requirement is that the Only Representative is a natural or legal person established in the European Union.

This BPG chapter addresses the following:

- The necessary qualifications and requirements for Only Representatives.
- Documentation of the Only Representative's qualifications
- Criteria for the selection of an Only Representative

Legal text & official guidance

REACH Art.8.2

> *'…. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, ….'*

ECHA *Guidance on registration*, version 4.0, August 2021:

> ***2.1.2.5 Only Representative of a non-EU manufacturer***
>
> ***'Who can be an only representative?***
>
> *An only representative must be a natural or legal entity officially established in the EU according to national legislation and must have an EU official address where they can be contacted by the*

enforcement authorities. Most EU Member States require that the official address of the only representative is in the EU Member State where they are established. An only representative should have sufficient background in the practical handling of substances and the information related to them to be able to fulfil the obligations of importers.'

ECHA Q&A:

15. Who can appoint an only representative?

According to Article 8(1) of REACH, a natural or legal person established outside of the EU who manufactures substances, formulates mixtures, or produces articles, can nominate an only representative located within the EU to carry out the required registration of their substances that are imported as such, in mixtures and/or in articles into the EU. Distributors are not mentioned in Article 8(1) of REACH and thus cannot appoint an only representative.

The reference to the EU covers both the EU countries and the EFTA countries that have adhered to the EEA (European Economic Area) Agreement, that is Iceland, Liechtenstein, and Norway.

The only representative will have to fulfil the registration obligations of importers (Title II of REACH) and comply with all other obligations of importers under the REACH Regulation. More information on the only representative role and the consequences for the EU importers is provided in the Guidance on registration, section 2.1.2.5- 'Only representative of a 'non-EU manufacturer''.

16. Who can be appointed as an only representative?

A non-EEA company may, by mutual agreement, appoint a natural or legal person established in the European Economic Area (EEA) to act as their only representative (see Q&A 15[2]). According to Article 8(2) of REACH this representative shall comply with all obligations of importers under REACH.

Therefore, the only representative must be established in the EU and is required to have sufficient background in the practical handling of substances and the information related to them. More information on the only representative is also provided in the Guidance on registration, section 2.1.2.5- 'Only representative of a 'non-EU manufacturer''.

17. What is meant by the "sufficient background" of an only representative?

The requirements related to the appointment of an OR are outlined in Q&A 17. There are no detailed requirements or criteria regarding what is regarded as "sufficient background in the practical handling of substances and the information related to them" other than what is laid down in Article 8(2) of REACH.

18. Is there a special procedure to appoint an only representative?

Becoming an only representative (OR) is a matter of mutual agreement between the non-EU manufacturer and the natural or legal person established in the EU who is being appointed as an only representative.

[2] https://echa.europa.eu/support/qas

Non-EU manufacturers need to send a letter confirming this appointment to their only representative who must keep it available in case of inspection by the relevant Member State's enforcement authority. No such letter must be sent to ECHA; however, it can be uploaded in REACH-IT and IUCLID by the OR. In addition, information on the non-EU manufacturer must be provided in REACH-IT.

Furthermore, the non-EU manufacturer shall inform the importers within the same supply chain of the appointment of the only representative according to Article 8(3) of the REACH Regulation. These importers shall be regarded as downstream users.

ECHA support pages:

Why and how to appoint an only representative?

The only representative must be established in one of the EU Member States or in Iceland, Liechtenstein or Norway. That Member State will then enforce the requirements related to your substance when imported into the EU.

It will be the task of the only representative to comply with all the obligations with which the importers of your products would have to comply. This includes submitting a [inquiry] and a registration dossier for the substance imported into the EU to the European Chemicals Agency (ECHA) before the relevant deadlines expire. It will also be the task of the only representative to keep the information available and update on i) the quantities imported and ii) the importers covered by the appointment, as well as to iii) supply the latest update of the safety data sheet. The only representative must therefore have a sufficient background in the practical handling of substances and the information related to them.

Only representatives need to be able to document for the enforcement authorities that they have been appointed by your company and for which substance and volume the appointment applies. They may also indicate in the registration dossier by whom they were appointed. They need to be able to document that your company has informed the importers who are covered and who may benefit from the only representative having fulfilled the importers' obligations.

Tasks and services

The legal text, ECHA's Guidance documents and the ECHA Helpdesk do not further define the necessary qualifications and requirements for Only Representatives.

These necessary qualifications and requirements can however be derived from the tasks and services of an Only Representative. They are partly based on the legal requirements and partly on the service agreement with his Principal. Due to his position the Only Representative is often the most important REACH adviser and service provider to his Principal.

Tasks and services of an Only Representative may, but do not necessarily always, include:

- Advising his Principal, the non-Community manufacturer or formulator, on REACH to enable correct implementation of REACH
- Secure handling of confidential information and data
- Establishing, managing, and maintaining REACH-IT accounts

- Submitting inquiries, registrations, C&L notifications, PPORDs and authorization dossiers
- Keeping correct and up-to-date records of substances, documentation, imported and re-imported quantities and importer contact details, including those in complex non-EU supply chains.

The Only Representative may also:

- Confirm the Downstream User status to EU Importers for the covered substances and issue REACH compliance certificates to Downstream Users and customs authorities
- Ensure the distribution and compliance of Safety Data Sheets (SDS)
- Verify appropriate Company Size selection by the Principal
- Communicate with ECHA, enforcement authorities, lead registrant and co-registrants (formerly SIEFs), consortia and actors in the Principal's supply chain.

Best Practice

1) The necessary qualifications and requirements for Only Representatives

Because no satisfactory requirements regarding the qualifications and requirements for an Only Representative exist, ORO has established quality standards for its members. These are minimum criteria which every ORO member company (except Associated Members) must meet.

Best Practice is therefore:

Only Representatives should adhere to the ORO Membership-criteria, which are the following:

> *'ORO Members, with the exception of Associated Members, must be active as Only Representatives under REACH Article 8 and shall:*
>
> - *Be in compliance with REACH Article 8 requirements*
> - *Have a clear understanding of REACH and the applicable regulatory and administrative processes*
> - *Be competent in handling large amounts of data, including confidential information*
> - *Employ competent people with relevant technical qualifications and experience*
> - *Have a permanent physical presence of at least one competent person in the EU. (There is no objection against the operation of a back-office in a non-EU country.)*
> - *Have a Sustainability Process in place, which adequately addresses the risks for the non-EU Producer in case of bankruptcy or long-lasting absence of key personnel*
> - *Have a professional liability/indemnity insurance specifically covering the Only Representative activities*
> - *Promote the good reputation of Only Representatives generally through proper behaviour, active communications with parties and professional execution of services*
> - *Actively strive to work in accordance with the ORO Best Practice Guide*

- *Cooperate fully where his Principal wishes to transfer to another Only Representative or to move the REACH obligations to an importer, unless there are compelling circumstances to do otherwise*
- *Not use contact details of registrants, (former) pre-registrants, co-registrants, notifiers or other submitters of information obtained from REACH IT for promotional or marketing purposes.'*

2) Documentation of the Only Representative's qualifications

The Only Representative must be able to demonstrate that they are established in the European Union and comply with the ORO Membership Criteria.

Best Practice is therefore for the Only Representative to have available for prospective Principals:

- Official Certificate of the Only Representative's establishment in the Community (e.g. from a Commercial Register)
- Proof of an insurance policy covering Only Representative business
- Proof of expertise and qualification of Only Representative's employees, e.g. through CVs and résumés of key staff
- Confirmation through self-declaration of the operation of a robust administrative system to fulfil the tracking obligations and for secure data storage
- Availability of a draft contract for review which covers all reasonably foreseeable business situations, such as organisational change and possible cessation of activity by either party, and is overall 'reasonable and fair'.

Please note: What the requirements are for a 'reasonable and fair' contract, will be addressed in a future chapter of the Best Practice Guide.

3) Criteria for the selection of an Only Representative

As mentioned above, non-EU manufacturers should, before committing themselves, ascertain that their prospective Only Representative is competent and reliable. Membership of ORO, though much appreciated, is not a pre-requisite, but meeting the qualifications and requirements for Only Representatives is.

Best Practice is therefore that the non-EU producer ascertains that the prospective Only Representative:

- Is a member of ORO or at least actively strives to work in accordance with this Best Practice Guide
- Provides appropriate documentation on his qualifications upon request
- Has available a draft for the Only Representative contract that is complete, reasonable, and fair.

3. IDENTIFYING IMPORTER WHERE AN ONLY REPRESENTATIVE IS APPOINTED

This chapter only addresses the identification of the importer under REACH for situations where an Only Representative has been appointed.

This chapter does not necessarily provide an answer to the question of who is to be regarded as the Importer in situations where no Only Representative has been appointed, and who in that situation, as a consequence, has the obligations to register the imported substances.

Topics

Importers of substances or mixtures have considerable obligations under REACH, including registration. Where a non-EU manufacturer or formulator has appointed an Only Representative, these obligations are transferred from the Importers to the Only Representative. The Importers no longer have these obligations as long as they feature correctly in the Only Representative's records.

The Only Representative must record which importers are covered by his activities. (For the quantities that need to be recorded see Chapter 5 on Volume tracking). This must be done to the satisfaction of enforcement authorities. This ensures that both his Principal's customers and the other actors in the supply chain are secure in relying on the registrations and relevant notifications submitted by the Only Representative.

The importer is not necessarily the same legal entity in whose name customs are cleared. Import is the 'introduction into the customs territory of the Community'; and the 'customs territory of the Community' includes the territory of all the EU Member States, their air space and their territorial waters.

The following is addressed in this chapter:

- Easily identifiable importers
- The Principal's agent
- Imported products owned by non-EU companies
- Imported products under customs supervision
- Other complicated supply chain situations

Legal text & official guidance

REACH Art.8 Only Representative of a Non-Community Manufacturer

> *1. A natural or legal person established outside the Community who manufactures a substance on its own, in preparations or in articles, formulates a preparation or produces an article that is imported into the Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title.*

2. The representative shall also comply with all other obligations of importers under this Regulation. To this end, he shall have a sufficient background in the practical handling of substances and the information related to them and, without prejudice to Article 36, shall keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet referred to in Article 31.

3. If a representative is appointed in accordance with paragraphs 1 and 2, the non-Community manufacturer shall inform the importer(s) within the same supply chain of the appointment. These importers shall be regarded as downstream users for the purposes of this Regulation.

ECHA *Guidance on registration*, version 4.0, August 2021

2.1.2.4 Who is responsible for the registration in case of import?

… The responsibility for import depends on many factors such as who orders, who pays, who is dealing with the customs formalities, but this might not be conclusive on its own.

For example, in the case of a 'sales agency' established in the EU and acting as an intermediary, i.e. transmitting an order from a buyer to a non-EU supplier (and being paid for that service) but taking no responsibility whatsoever on the goods or the payment for the goods and not having their ownership at any stage, then, the sales agency is not to be considered as the importer for the purposes of REACH. The sales agency is not responsible for the physical introduction of the goods.

When interpreting the term 'importer' according to the REACH Regulation, it is not possible to fall back upon the Regulation (EU) No 952/2013 laying down the Union Customs Code (UCC). In many instances it will be the ultimate receiver of the goods (the consignee) who is the legal entity that is responsible for the import. However this is not always the case. […]

The 'non-EU manufacturer' or supplier who is exporting a substance or mixture into the EU has no responsibilities under REACH. The shipping company that is transporting the substance or mixture normally has no registration obligation either. Exceptions may occur under specific contractual arrangements, for example if the shipping company is established in the EU and can be identified to act as the importer of the substance for the purposes of REACH.

2.1.2.5 Only representative of a 'non-EU manufacturer'

Obligations of the only representative regarding the registration of substances

The roles of only representative and importer are not interchangeable. Thus, it is not possible to update a dossier in order to change from one role to another.

The role of an only representative is substantially different from that of an importer'. While the registration of an only representative can cover multiple importers in the EU, it only covers imports from the one non-EU manufacturer that has appointed the only representative.

In contrast, an importer does not represent another legal entity but acts on their own behalf. An importer is physically introducing the substance into the EU customs territory and placing it on the market, and their registration covers all quantities of the substance imported in the EU, regardless of the non-EU source.

ECHA support pages:

> ***Why and how to appoint an only representative?***
>
> *The registration by an only representative can cover volumes of a substance imported into the EU both directly from non-EU manufacturers and via non-EU distributors or formulators. Thus, as long as your company can keep track and document the channels through which the substance or mixture is imported into the EU, the volumes can be covered by the only representative. Non-EU manufacturers can change their only representative. Registration requires the registrant to sign-up to the REACH-IT system. Only legal entities established in the customs territory of the EU, Norway, Iceland or Liechtenstein can sign-up to REACH-IT.*

Best Practice

1) Easily identifiable importers

The most common situation is that the importer is clearly identifiable. This is the case where one EU based company orders products from the Principal, pays for the goods, has ownership of and authority over the products and decides where they should be stored or delivered.

Best Practice is therefore the following:

- Where one EU based company orders products from the Principal, pays for these products, has ownership of and authority over the products and decides where they should be stored or delivered, this company is to be considered the importer under REACH.
    - Where the importer can thus easily be identified, there is no need for separate agreements or a specific mention of the importer's contact details in the documents accompanying the importation of the products.

2) The Principals' agent

The Only Representatives' Principal may employ a sales agent. For good reason ECHA Guidance warns explicitly that such agents cannot automatically be considered 'importers'. Sales agents often do not have ownership and authority over the imported products and are not actually responsible for the importation or placing the product on the market.

Where an agent may not be regarded as importer, someone else must be the importer. Upstream, the Principal, who is non-EU based and therefore by definition cannot be the importer. Lacking other likely candidates, the first EU based owner of the imported products is the most likely to be considered the importer in case of an inspection.

Best Practice is therefore:

- Where the Principal employs an agent, this agent shall only be considered the importer under REACH if, when the products arrive in the EU, he actually has ownership of, and full authority over, these products.
- Where the Principal's agent does not meet the requirement above, the first EU based owner of the products is to be considered the importer under REACH

3) Imported products owned by non-EU companies

Non-EU companies, by definition, cannot be the importer under REACH. Frequently, however, non-EU based companies still own the chemicals after they have entered the EU. The Only Representatives' Principal may himself still be the owner, or some other non-EU company to whom the product has been sold. Often, but not always, these products remain under customs supervision until some EU based company purchases them.

In this case, even though there has been 'import' (the product has entered the EU customs area), there is not yet an 'importer'. As a result, the 'importer' in this case must be found further down the supply chain.

Best Practice is therefore:

- Where the Principal's products remain temporarily under his ownership and responsibility after they have physically entered the EU, the first EU based company later owning the products should be identified as the importer.
    - In this case the documents accompanying the Principal's products should clearly state the contact details of the Only Representative, to ensure that actors further down the supply chain can be certain that the REACH obligations for the substances in the products have been met.
- Where the products are present in the EU but have been sold to another non-EU company the first EU based company in the supply chain owning the product should be identified as the importer under REACH.
    - In this case the second non-EU owner must disclose the contact details of this first EU based owner of the products to the Only Representative. If the second non-EU owner does not wish to disclose these contact details, the Only Representative cannot cover these imports. A separate confidentiality agreement between Only Representative and the second non-EU owner may solve the issue.

4) Imported products under customs supervision

Where chemicals are under customs supervision, REACH does not apply unless they are 'treated or processed'. Bulk chemicals, such as fuels, are however often blended with other substances while under customs supervision. In this situation REACH does apply, but no importer can yet be identified, and it could therefore be unclear who is responsible for REACH compliance. However, since an Only Representative has been appointed, the REACH obligations can be fulfilled.

Best Practice is therefore:

- When a Principals' products, introduced to the EU but still owned by the Principal, are being treated or processed under customs supervision, the Only Representative should encourage his Principal to ensure that REACH obligations are met even in advance of the identification of the first EU based customer.
    - For example: blending with registered substances only, availability of appropriate Safety Data Sheets etc.
- Where, as described above, it is ensured that REACH obligations are met in advance of the identification of the first EU based customer, the documents accompanying the Principal's products should clearly state the contact details of the Only Representative.

5) Other complicated supply chain situations affecting the identification of Importer

In practice there will be more complicated situations in the supply and transportation chain than addressed above. In such cases the Only Representative and his Principal should decide on a case-by-case basis who is the importer.

Best Practice is therefore:

- In complicated supply chain situations not addressed in this chapter, the Only Representative, with the help of his Principal, should decide which EU based company is to be considered the importer. In doing so they should stay as close as possible to the Best Practice recommendations given in the sections above.
- Where a case-by-case decision is needed, it should be formally agreed who in the supply chain will be on the Only Representative's records as the importer under REACH. This agreement should be between the Principal and this importer. The Only Representative must be informed of this agreement.
- Where it is necessary to identify the importer on a case-by-case basis, the documents accompanying the Principal's products should mention both the contact details of this importer and the Only Representative.

Remark: When no Only Representative has been appointed, an agreement on who should be considered the importer under REACH could be misused. For example, where one single EU company holds the registration of a substance, several non-EU producers could contractually designate this legal entity as their 'importer under REACH', without actually doing business with this 'importer'. They could thus avoid or drastically reduce the cost of registration. This misuse will however not occur where an Only Representative has been appointed, since the Only Representative is appointed by non-EU manufacturers or formulators and will hold separate registrations for all his Principals, even if they produce the same substance.

4. REACH COVERAGE IN A COMPLEX NON-EU SUPPLY CHAIN ('INDIRECT SUPPLY')

Please note that this chapter is solely about REACH coverage (tracking of substance volumes and corresponding EU importers) in complex non-EU supply chains. Communication regarding Safety Data Sheets (SDS), uses, etc. are not part of this chapter.

Topics

Complex Non-EU supply chains and Only Representatives

A non-EU manufacturer of a substance often appoints an Only Representative for the registration of a substance in a particular tonnage band. In addition to supplying this substance directly to an EU importer, the non-EU manufacturer may also supply the substance first to another non-EU actor (formulator, polymer manufacturer, distributor, trader) who then supplies this registered substance, on its own or in a mixture, again to another non-EU actor or exports it to the EU.

According to the REACH Regulation, the responsibility for REACH compliance of imported chemical products is initially in the hands of the EU importer, as he places the products on the EU market. This means that he must register all substances contained in the imported products accordingly under REACH or prove that substances are exempt from this obligation. However, the importer can only fulfil this obligation if he knows the exact compositions of all his imported products, in order to be able to determine the total imported quantities per substance and the registration obligation or the exemption from it. In the case of indirect EU imports and confidential product compositions, however, it may be impossible for the EU importer to comply with these obligations.

If a substance has already been registered by the OR of a non-EU manufacturer or formulator, the non-EU manufacturer/formulator may, by mutual agreement, provide REACH coverage to its downstream supply chain, subject to certain conditions, ultimately relieving the EU importer from its registration obligations and related costs. In this case, however, the Only Representative must keep available up-to-date information on the quantities of substances imported and the importers supplied, in accordance with REACH Article 8(2).

This arrangement can be economically beneficial, but also correspondingly complicated and extremely complex and time-consuming to implement. Due to the many possible variations arising from the complexities of the respective linked supply chains and material flows, where different manufacturers, formulators, distributors, traders and Only Representatives may contribute to an imported product and its REACH compliance, this document cannot provide a standardized approach to be followed by all actors in the supply chains. Therefore, the purpose of this document is rather to describe which activities should be carried out in relation to the REACH requirements in order to ultimately be able to ensure the REACH compliance of a product imported into the EU and to fully exempt the importer (for the imported product quantity) from his registration obligations and to effectively put this importer in the "watertight" status of a downstream user.

As the information to be exchanged may be sensitive business information, the parties involved may enter into non-disclosure agreements if necessary. The ways how the parties may conceal such sensitive details from each other is not further specified in this document.

It should be noted here as well that the Only Representative may need to obtain information on indirectly supplied customers and confidential product compositions, without which he cannot fulfil his obligations as OR. However, this may violate competition laws if the Only Representative discloses information about indirect supply chain actors to other parties without having in place clear agreements with the affected parties.

For this reason, it is important to consider another solution, namely an Only Representative trustee service via a consultancy company that is fully independent of the supply chain actors involved and based in the EU, to serve as a point of contact for the REACH enforcement authorities in case of controls.

The trustee acts on behalf of the Only Representative, provides coverage confirmations to supply chain actors, tracks and keeps available information on quantities of products and/or substances supplied and imported, and the corresponding EU importers. A trustee may also have a role in monitoring the reported substance tonnages and their distribution among the Downstream Users covered by the registration, with the view on preventing the use of the registration number by other companies not covered by it.

Unlawful practices in demonstrating REACH compliance

It is worth noting here that a substance must be registered before the manufacture or import can start at an annual quantity of one tonne or more. Once registered, only the company that completed the registration and any Downstream Users within its supply chain may rely on the registration reference number and include it in their relevant documentation and confirmations of REACH compliance.

It is illegal to rely on the REACH coverage confirmations from another supply chain to import identical substances into the EU. To address this challenge, it is important that the original confirmed product/substance quantities and a list of importers confirmed by the supplier are checked against the actual imports, as practicable, by due diligence processes and keeping the detailed records.

As an extension of the challenge described above, certain disreputable companies may also try to use registration numbers of other registrants to appear as being REACH compliant to the downstream actors in their supply chain. Such ‘free-riding’ is not only illegal, but also goes against the interests of the manufacturer, who has borne the costs for the registration, is responsible for it (via an OR) and naturally wants to limit the use of the registration to his own customers.

However, it should also be noted here that just the existence of a registration number does not confirm the REACH conformity of an import. For example, a substance that has been registered in a certain volume band but is then placed on the EU market in a quantity larger than the registered quantity, is not REACH-compliant despite the existence of a registration number. Possible issues detected in the original registrations may also lead to lack of compliance although a registration number may still be active.

<u>Non-EU supply chains involving Formulators</u>

As described previously, complex issues can inevitably arise in complex non-EU supply chains, especially when non-EU formulators are involved. Examples of this are:

- The non-EU manufacturer supplies the registered substance to many different non-EU formulators, of whom several use the substance to produce a mixture that is further exported to the EU.

- The non-EU formulator uses many different ingredients, supplied by many different non-EU manufacturers, who in turn have appointed different ORs. (For example, an average portfolio of cosmetic products will contain over a hundred different substances. Even if the individual substance quantities used may be less than 1 tpa, the total imported quantities of the individual substances may exceed the 1 tpa threshold for a single EU importer, which consequently imposes a registration obligation on the importer.)
- The non-EU formulators may purchase the registered substances through distributors that are part of the non-EU supply chain.
- The non-EU formulator may purchase the substance from an up-stream formulator, as part of a mixture consisting of a small number of different substances. These substances may be produced by different manufacturers and a certain substance in the mixture may not always be supplied by the same manufacturer.
- The non-EU manufacturer may employ a toll manufacturer for the substance in question, and the OR appointed by the toll manufacturer may not be the same as the OR appointed by the manufacturer.
- Over time, changes may occur in the non-EU supply chain that affect REACH compliance of the imported mixtures.

Formal roles of the Only Representatives

There is no legal obligation to provide REACH coverage to customers. The manufacturers / formulators have paid for the registrations and have determined the appropriate tonnage bands and uses to be covered. Therefore, the decision whether or not to grant REACH coverage to a customer or downstream supply chain is purely a business decision of the manufacturers or formulators. Similarly, whether or not to apply for such coverage is a business decision of downstream formulators or EU importers. There may be reasons to prefer a separate registration.

Manufacturers and formulators from non-EU countries do not fall directly under the scope of REACH and thus have no corresponding direct obligations, even if they have appointed an OR. Regardless of what information these companies exchange with their customers or what they agree upon, once the decision is made that REACH coverage is granted to the downstream supply chain and the OR has issued appropriate confirmations to them, it is the legal responsibility of the OR, in the case of an importer inspection, to demonstrate to the competent authority that the confirmed imported product quantities are indeed REACH compliant.

REACH does not provide a clear description of the tasks and obligations of Only Representatives in this case, but these can be logically derived accordingly:

- If the Only Representative has registered a substance for a manufacturer/formulator, he is officially the registrant and must therefore ensure that he grants REACH coverage to the downstream supply chain only for those substances that he has registered for his principal and that the total annual quantity of a substance imported into the EU does not exceed the registered tonnage band. Here, not the individually imported substance quantity of the respective importers is to be considered, but the total quantity of the substance over all importers, who make use of the REACH coverage of the OR by having received a corresponding written coverage confirmation from him.

- The OR takes over the REACH responsibility for certain substances according to the instructions of the principal. In the case of mixtures, this may be individual substances or all substances contained. In this context, if the mixtures are confidential compositions, the OR may also have to assume REACH responsibility for those substances that are exempted from registration, such as substances placed on the market with a total quantity <1tpa, reimported substances, substances falling under REACH Annex V, etc. This often requires deeper insight into the supply chains and may cause confidentiality issues, as he may need to gain knowledge about indirect supplies as well as other possibilities for REACH coverage.
- Once an Only Representative grants REACH coverage to its principal's downstream supply chain and confirms this accordingly, regardless of which scenario applies to the supply chain and the product compositions supplied, he must comply with the requirements of REACH Art. 8(2), which states that up-to-date information on quantities imported and customers sold to must be kept. As REACH does not provide for an explicit exemption, these requirements also apply to substances registered in a tonnage band >1000 tpa!

As a result, the Only Representative must keep the required documentation up-to-date at all times and, in the event of an inspection, be able to provide this information to the competent authorities in a timely manner.

Communication in a complex non-EU supply chain

This chapter describes the information and documentation that ORs and supply chain actors should have and what should be considered to ensure full REACH compliance in order to be able to withstand REACH controls by the responsible authorities. It does not describe how the required information can or should be obtained, as due to the many possible variables and complications in non-EU supply chains, there is no single recommended method that can be applied.

In situations where confidentiality is not an issue in the supply chain, where that supply chain is fairly simple and where there is a straightforward business relationship between the actors in the supply chain, the required information and documentation is relatively easy to obtain. However, as already explained under "Non-EU supply chains involving formulators", in other cases the supply chain, of chemicals used in mixtures, can be very complicated.

In such complicated cases, it is much more difficult for the Only Representative and the respective supply chain actors to obtain the necessary REACH coverage for all substances in the imported mixtures or rather to ensure their REACH compliance. The following best practices do not provide explicit solutions to the difficulties they may encounter.

Legal text & official guidance

ECHA Guidance on registration (Version 4.0, August 2021)

2.1.2.5 Only representative of a 'non-EU manufacturer', section 'Who can appoint an only representative?'

REACH does not distinguish between direct and indirect imports into the EU. REACH specifies which non-EU actors can appoint an OR, but it does not indicate that these non-EU actors must be the direct suppliers to the EU importer. Therefore, it does not matter if there are other supply chain actors outside of the EU between the non-EU actor appointing an only representative and the EU

importer, as long as these do not change the identity of the substance. However, it is essential that there is a clear identification of the:

- *substance, and of the*
- *'non-EU manufacturer' who has appointed the only representative, and*
- *which imports the only representative covers with their registration.*

Best practice

1) Checks by supply chain actors, for products to be delivered to the EU

Since the EU importer of a chemical product is responsible for the REACH compliance of the respective substances contained and placed on the EU market, the importer must ensure that this compliance is actually given before the import takes place, as otherwise he may be importing illegally! This is done either through own registrations or by providing evidence that individual substances are exempt from the registration requirements. If the importer is unable to do this, he must rely on the support of his supply chain, which means obtaining appropriate written confirmation via his non-EU supplier that the quantity of his imported product and all the substances it contains are covered by one or more of the supply chain's Only Representatives and that the imported product is therefore 100% REACH compliant. If the importer receives coverage for only part of the product to be imported, he remains responsible for the remaining part himself. However, this makes it impossible for him to import the entire product if he does not know the product composition and thus cannot ensure REACH compliance for the remaining part of the product himself.

Before a decision is made on whether to submit a request for REACH coverage, the supply chain actor concerned should carry out a series of checks. The purpose of these checks is to avoid the administrative burden of an unnecessary (and possibly useless) REACH coverage request and to inform the next supply chain actor of possible restrictions on the use of the substance/product.

Best Practice is therefore:

- Assess the following aspects of the regulatory landscape and needs:
    - Have the substance manufacturers or formulators appointed Only Representatives who can provide REACH coverage for all contained substances?
    - Are full registrations of the contained substances available? *(for example, registrations for intermediate use only are not of benefit for substances in imported mixtures)*
    - Are the necessary uses covered by the registrations?
    - Are there 'uses advised against' that may prevent its applicability?
    - Is a substance subject to authorisation or will it be in the foreseeable future? Check ECHA sources, such as the Public authorities coordination tool (PACT) as an initial indication, if substance identities are disclosed to you.
- If these checks show that there is no useful registration or that the existing registration(s) may not be sufficient to market a substance or mixture in the EU, the supply chain actor must look at other alternatives. These alternatives are not subject of this chapter.

Provided that the previously mentioned checks do not result in a restriction for import into the EU and EU importers are dependent on REACH coverage of the supply chain, the respective supply chain actors can now take care of the coverage procedure.

As already mentioned at the beginning, due to the many possible variations resulting from the complexity of the respective linked supply chains and material flows, no single best practice approach can be established at this point. Instead, it will be explained for the respective actors what is essential to pay attention to in order to ensure watertight, 100 percent REACH compliance for a product imported into the EU.

2) EU importers

Since in the case of a REACH control it is first of all the EU importer who is obliged to prove the REACH conformity of an imported product, he is also the one who needs a corresponding written statement from his supply chain which confirms that he is exempt from his registration obligations for the imported product and that he can therefore be considered as a downstream user for this import.

The confirmation should have the following essential contents or meet requirements:

- Name of the covered product (indicating the substances to which the confirmation applies). This should match the product name on the shipping documents.
- Maximum allowable import quantity of the product to which the confirmation applies.
- The percentage of substances included for which the confirmation applies. This should ideally always be 100%, as otherwise the importer remains responsible for the REACH compliance of the remaining product portion himself, but may not be able to fulfil this without knowing the product composition.
- The calendar year, or a restricted period within a calendar year, in which the confirmed product quantity may be imported. Determining the quantities on a calendar year basis is needed for monitoring the annual tonnage band of the registration.
- Name and contact details of a person/company established in the EU who has issued the confirmation and who, in case of a REACH inspection, is able to disclose to the authorities all necessary information about the supply chain and the products and Only Representatives involved.

When an EU importer receives a REACH coverage confirmation, the importer should ensure that the contact person/company named in the confirmation is based in the EU and ideally meets the qualifications of an Only Representative. This contact should also be able, at all times, to provide the authorities or the respective Only Representatives with up-to-date information on covered EU importers and their imported substance quantities, as this is the only way that the respective Only Representatives involved can comply with the requirements of Article 8(2) REACH. In this respect, it is by no means sufficient if this information is only compiled in a subsequent year, as an authority check can take place at any time. At the same time, it must be kept in mind that an issued confirmation can only be valid if it is ensured that all relevant information on covered EU importers as well as their imported substance quantities is actually available completely and correctly.

This means that the contact listed on the confirmation itself must ensure that all quantity calculations on which the validity of this confirmation is based are under its control and are not dependent on its own quantity calculations of third parties in the downstream supply chains, because it can very

quickly happen that higher import quantities are reported back than were ever delivered. In other words, the coverage procedure behind a confirmation must ensure that all confirmations issued are immediately (and permanently) valid, without the need to later obtain further information from the supply chain.

3) Only Representatives

As explained in the previous paragraph, Only Representatives confirming REACH coverage to a supply chain must always keep in mind that they must be able to fulfil the obligations under REACH Article 8(2). Thus, an EU importer can only be placed in downstream user status if the data on the importer and its imported substance quantities are available in up-to-date form. If this information is not directly available to the Only Representative - for example for reasons of confidentiality - he must ensure that it is held for him by an independent party so that it can then be made available to the authorities promptly on request.

Likewise, the Only Representative must be able to prove at any time that the substances he confirms are actually registered in the relevant tonnage bands or are exempt from registration (annual import <1 tpa, re-imported substances, etc.). The issuance of coverage confirmations automatically means the assumption of REACH responsibility for the Only Representative, regardless of whether the substance is subject to registration or not.

4) Manufacturer/Formulator

It is important for non-EU manufacturers or formulators to be familiar with the basic requirements of the REACH regulation as well as the obligations imposed on their appointed Only Representatives, in order to be able to offer functioning REACH coverage to downstream supply chains and ultimately to EU importers. To this end, they should obtain appropriate training from the Only Representatives they appoint.

In particular, it is very important to understand that it is first necessary to ensure that the REACH requirements can be met before any physical delivery of a product is made that is to be exported to the EU. If a product has already been placed on the EU market and then it subsequently turns out that, for example, a contained substance has not been registered, then an illegal import has taken place!

Likewise, the manufacturer or formulator should provide mechanisms to ensure that the tonnage bands in which substances have been registered cannot be exceeded. Even though a subsequent volume band update of an existing registration is usually possible here, this can mean a significant cost factor for the manufacturer/formulator.

Last but not least, the manufacturer/formulator should always check that the volume of a product for which REACH coverage has been requested by downstream customers is not higher than the volume actually supplied. This is necessary to prevent customers from bringing the same product, originating from a different supply chain, into the EU at the expense of the manufacturer/formulator's registration (‘free-riding’). This also applies to substances registered in the volume band >1000 tpa!

5. VOLUME TRACKING, FULL OR PARTIAL COVERAGE, INFORMATION EXCHANGE

Topics

REACH calls for Only Representatives to keep available and up-to-date information on quantities imported and customers sold to.

Complications can occur in cases of 'late OR appointments' – situations where, until the appointment, the importers have themselves fulfilled their REACH obligations. After the Only Representative's appointment these obligations are transferred to the Only Representative.

When an Only Representative is appointed late, several questions arise regarding the level of recordkeeping necessary to appropriately document import quantities, in particular since these quantities provide the basis for the tonnage band determination and respective registration requirements.

The following topics are addressed in this chapter:

- Distinction between full and partial coverage of the Principal's imports
- Distinction between substances on their own, common mixtures and proprietary mixtures
- The meaning of 'Up-to date'
- Full coverage: Substances on their own & Common mixtures
- Full coverage: Proprietary mixtures & confidentiality
- Partial coverage of imports
- Records of quantities marketed in the period preceding the late appointment of an Only Representative
- The Principal does not supply timely information on quantities
- How long should records be retained.

Full or partial coverage of the Principal's imports

The first distinction is made between the following two situations:

The Only Representative covers all the Principal's imports:

The Only Representative's registrations are in tonnage bands that are 'high enough' to cover the sum of all the imports of the Principal's products.

- In most cases, this will be the normal situation. The Principal appoints an Only Representative to discharge all his customers (the importers) from their REACH obligations.
    - Where substances are registered in the > 1000 t/a tonnage band, this is automatically high enough to cover all the Principal's imports.

The Only Representative covers a limited part of the imports:

The OR's registrations are in tonnage bands that do not fully cover the total of all the Principal's products imported into the EU.

- This situation may, for example, occur where a bulk chemical is mostly sold to large importers who have their own registrations. The Only Representative's registrations are in this case reserved for smaller importers who have not registered the substances themselves.

Remark: Complex non-EU supply chains with multiple Only Representatives involved in the import of mixtures are not addressed in this chapter. The topic is addressed to a significant extent in the new chapter on complex supply chains and indirect supply.

Substances on their own, Common mixtures and Proprietary mixtures

The second distinction needs to be made between 'Substances on their own', 'Common mixtures' and 'Proprietary mixtures'.

- Substances on their own: Substance not being a part of a mixture.
- Common mixtures: Mixtures such as denatured ethanol or blended motor fuels. Their composition often conforms to industry standards and is not confidential. They can be purchased from several different producers, in the same way as 'substances on their own'.
- Proprietary mixtures: Mixtures that can only be purchased from one single producer and are easily recognisable as such, both in documentation and physically and often also in packaging.

For the purpose of this chapter, 'Substances on their own' and 'Common mixtures' are treated in the same way.

Legal text & official guidance

REACH Article 3 (30) defines the method to calculate annual tonnages:

> *'per year: means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years.'*
>
> Note: Already existing on the EU market 'phase-in substances' were being subjected to the registration system in different phases over time, rather than immediately in one go. However, after the third registration deadline of May 2018, all substances must be registered before they are imported into the EU in quantities of 1 tonne or more per year, unless they are exempted from registration or regarded as registered. Once registered, averaging of production or import volumes for the three preceding calendar years cannot be done anymore. Today production or import volume per calendar year determines tonnage band assessment that triggers data

requirement and registration fees to be paid when updating the registration or assessing such update needs (see Article 1 of Commission Implementing Regulation (EU) 2019/1692[3]).

REACH Article 8: Only representative of a non-Community manufacturer

"2. The representative … shall keep available and up-to-date information on quantities imported and customers sold to ….

REACH Article 36: Obligation to keep information

1. Each manufacturer, importer, downstream user and distributor shall assemble and keep available all the information he requires to carry out his duties under this Regulation for a period of at least 10 years after he last manufactured, imported, supplied or used the substance or preparation….

There is no legal text requiring the Only Representative to keep records on imports not covered for his Principal (ref. to *Full or partial coverage of the Principal's imports*).

Commission Regulation (EU) 2022/477 of 24 March 2022 amending Annexes VI to X to REACH Regulation

Annex VI to Regulation (EC) No 1907/2006 (REACH) is amended as follows:

(b) the following point 1.1.4 is added:

'1.1.4. Where an only representative has been appointed in accordance with Article 8(1), the following information regarding the natural or legal person established outside the Union who appointed the only representative: name, address, telephone number, email address, contact person, location of the production site(s) or formulation site(s), as appropriate, company website, as appropriate and national company identification number(s), as appropriate.'

ECHA *Guidance on registration*, version 4.0, August 2021:

2.1.2.5 Only representative of a 'non-EU manufacturer'

What should a 'non-EU manufacturer' do when appointing an only representative?

A 'non-EU manufacturer' can only appoint one only representative per substance. The 'non-EU manufacturer' needs to provide the only representative with up to date information on the EU importers which should be covered by the registration and the quantities imported into the EU. This information may also be supplied by other means (e.g. it may be notified directly to the only representative by the EU importers) depending on the arrangements made between the 'non-EU manufacturer' and the only representative.

[3] *COMMISSION IMPLEMENTING REGULATION (EU) 2019/1692 of 9 October 2019 on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and of the Council after the expiry of the final registration deadline for phase-in substances, OJ L259/12, 10.10.2019.*

The only representative registers the imported quantities depending on the contractual arrangements between the 'non-EU manufacturer' and the only representative.

The 'non-EU manufacturer' needs to inform all the concerned EU importers in the same supply chain that they have appointed an only representative to conduct the registration thus relieving the importers from their registration obligations. The only representative's registration should indicate the quantity of the imported substance it covers.

Obligations of the only representative regarding the registration of substances

'The registration dossier of the only representative should contain all uses of the importers (now downstream users) covered by the registration. The only representative must keep an up-to-date list of EU customers (importers) within the same supply chain of the 'non-EU 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.

The only representative is legally responsible for the registration and should be contacted by importers for any information related to registration in the EU. The only representative should contact the 'non-EU manufacturer' to obtain as much information about the substance as possible to prepare the registration. An only representative must be able to document who they are representing, and it is advised to attach a document from the 'non-EU manufacturer' appointing them as only representative in their registration dossier. Although it is not mandatory to include this information in the registration dossier, it needs to be presented to the enforcement authorities if they request it.

…. Each registration should cover the total tonnage of the substance included in the contractual agreements between the only representative and the specific 'non-EU manufacturer'. The information requirements for the registration dossier must be determined according to this tonnage.

What are the consequences for the EU importers?

When an importer receives information from a 'non-EU manufacturer' in their supply chain that an only representative has been appointed to cover the registration obligations, this importer will be regarded as a downstream user for the tonnage covered by the registration of the only representative. If this importer also imports the substance from other non-EU suppliers, the importer still must register the tonnage imported from these non-EU suppliers unless these have appointed only representatives to cover the respective imports. The importer must be able to document to enforcement authorities upon request, which of their imports are covered by the registration of the only representative and which are covered by their own registration.

The appointment of an only representative by the 'non-EU manufacturer' creates the specific need for importers to keep documentation on how they comply with their duties under REACH. Upon request they will need to show to the enforcement authorities that all quantities of the substance they import have been registered. Therefore, for the purposes of enforcement the importers should keep records on which imported quantities of the substance are covered by the only representative registration and which imported quantities are not. In case of import of mixtures, the importers will also need to know what quantity of the substance in a mixture is covered by an only representative registration, as they would otherwise be subject to a registration requirement themselves. This documentation will need to be presented to the enforcement authorities upon request.

The importer will receive confirmation from the 'non-EU manufacturer' on the appointment of the only representative. The importer should preferably also obtain confirmation in writing from the only representative that their imported tonnage and use is indeed covered by the registration submitted by the only representative. This would provide the importer with the contact point to whom they, being regarded as a downstream user, can make their use known, and would also give the importer a clear documentation that the imports are indeed covered by the registration of the only representative. In addition, the importer needs to obtain sufficient information from the 'non-EU manufacturer' and/or from the only representative in order to be able to fulfil their obligation to compile their safety data sheet, where relevant.

The importer, regarded as a downstream user, may decide to perform their own chemical safety assessment. This requires considerable effort, so it is advisable that the importer carefully considers the option of making their use known to the only representative.

Import of mixtures when an only representative is appointed

An importer of mixtures is obliged to register the individual substances in the mixtures they import and needs to know the chemical identity and the concentration of the substances in the mixtures. If the 'non-EU manufacturer' of the mixture, or of the individual substances in the mixture, appoints an only representative, it will be the only representative who will carry out the registration of the individual substances instead of the importers.

The 'non-EU manufacturer' will inform the importers that an only representative has been appointed. If the 'non-EU manufacturer' appoints separate only representatives for the different substances in the mixture, or appoints only representatives for some of the substances in the mixture, this information needs to be communicated clearly to the importers, so that they are aware of which obligations they are relieved of and which obligations they still have to fulfil regarding the registration of the substances.

In any case, the importers of the mixtures must be able to document which quantities of the substances imported in the mixtures are covered by the registration dossier of the only representatives and, where relevant, which quantities are covered by the registration dossier of the importers themselves.

2.2.6 Calculation of the volume to be registered

According to REACH, before a substance is manufactured or imported in quantities of one tonne per year…it has to be registered, unless an exemption applies. …The volume of the substance will also determine the information to be submitted in the registration dossier. REACH defines four tonnage bands (1 to <10 tonnes, 10 to <100 tonnes, 100 to <1000 tonnes, 1000 tonnes or more per year) and the standard information requirements for each of them. If the volume of the substance reaches the lower limit of a tonnage band, the standard information requirements for that tonnage band apply.

2.2.6.1 Calculation of the total volume

In a registration, the registrant must report in tonnes the volume they manufacture or import per year. They need to calculate the total volume of the substance that is intended to be manufactured and imported and that is not exempted from registration or regarded as registered. This is the estimated quantity in tonnes that is expected to be manufactured or imported in the calendar year

of registration (1 January to 31 December). If the manufacturing starts only later in a particular calendar year, the registration dossiers can cover the expected tonnes for the next full calendar year rather than the remaining months of the first calendar year, to avoid the need for a very quick update of the registration dossier for the second year.

…If a registrant manufactures or imports the same substance at different sites which belong to the same legal entity, the volume of the substance to be registered is the total volume of the substance manufactured or imported at the different sites. This is because the sites are not separate legal entities. If a substance is imported in several mixtures, the volume of the substance in each mixture has to be aggregated.

Best Practice

1) The meaning of 'Up-to date'

The records of the Only Representative must be 'up-to-date'. This is understood as being sufficiently recent to be able to determine whether the Only Representative's and importers' REACH obligations are complied with, and which importers are covered by his services.

Best Practice is therefore:

- Importer contact details should be provided to the Only Representative before the first shipment to the importer arrives. For the importers, it is important that they can be certain of coverage from that moment on and can prevent potential supply chain delays.
- All substances together with their registration information should also be in the Only Representatives' records before the first imports arrive.
- The annual quantities of the substances imported should be provided to the Only Representative in the first six months after the reporting year.

If the quantities imported are indicated by the Principal as likely to surpass a tonnage band threshold necessitating a registration or a change to a registration, the Principal should timely provide the Only Representative with records of the imported volumes.

Furthermore, the timelines for providing various dossier updates by the registrants have been clarified in the COMMISSION IMPLEMENTING REGULATION (EU) 2020/1435 of 9 October 2020 on the duties placed on registrants to update their registrations under Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L331/24, 12.10.2020 and provide a useful insight in the interpretation of being 'up-to-date'. For example, if changes in the annual imported quantities result in an increase of tonnage band or cessation of import, the Only Representative would need to update their registration within 3 months or 6 months in case of testing proposals. Similarly, any change in the registrant's identity, such as their name or address need to be updated within 3 months.

2) Full coverage: Substances on their own & Common mixtures

In the case of Substances on their own & Common mixtures, the importer may buy the same product from other sources. The importer should therefore be able to demonstrate to the competent

authorities which part of his purchases are covered by an Only Representative's registrations. The importer himself is responsible for the registration of the other part of his purchases.

Best Practice is therefore the following:

- The Principal provides in the first six months each year to his Only Representative the quantity sold to each separate importer of each substance in the previous year.
- The Only Representative checks that the tonnage bands of his registrations still adequately cover the total amount imported for each substance as provided by the Principal.
    - Where substances are registered in the > 1000 t/a tonnage band, this is automatically the case. No separate check is necessary.
- The Only Representative annually records the quantities of each separate substance sold to each separate importer.
-
- The Only Representative or the Principal on request annually confirms to the importer of each separate substance the quantity sold to him according to the Only Representative's records. With this confirmation the importer can demonstrate which part of his imports are covered by the Only Representative. In case of confirmation by the Principal, the Only Representative should receive a copy of this confirmation.

3) Full coverage: Proprietary mixtures & confidentiality

In the case of proprietary mixtures, the formulation of these mixtures may generally not become known to the importer. As a result the actual amount of the substances contained in these mixtures cannot be revealed to the importer.

Since however these mixtures are easily recognisable as such, inspectors can still ensure that the REACH obligations for these products are adequately covered by an Only Representative.

Best Practice is therefore the following:

- The Principal provides to the Only Representative annually the total quantity sold in the Community for each of the substances in his mixtures which the Only Representative shall record.
- The Only Representative checks that the tonnage bands of his registrations still adequately cover the total amount imported for each substance.
    - Where substances are registered in the > 1000 t/a tonnage band, this is automatically the case. No separate check necessary.
- The Principal provides the Only Representative with a list of the product names of the mixtures sold in the EU.
- The Only Representative or the Principal annually confirms to the importer which of the Principals' products are covered by him. With this confirmation the importer can demonstrate that his imports of the proprietary mixtures are covered by the OR.
    - Often this confirmation will be for 'all the products produced by the Principal', in which case a separate listing of these products is not necessary.

- If the Principal fears parallel imports which are not covered by the Only Representative, he may provide the Only Representative with the quantities and product names of all the separate mixtures (not substances) sold to each separate importer. The Only Representative, on request, should then confirm these quantities for each separate product to the importer.

4) Partial coverage of imports

Where the Only Representative covers only a part of the imports originating from a Principal, care must be taken that those imports covered by the Only Representative can be clearly distinguished from those for which the REACH obligations remain with the importers.

Best Practice is therefore:

- Where the Principal sells to importers who have their own adequate registrations, these importers should not receive the Only Representative appointment letter from the Principal or the confirmation from the Only Representative. Their contact details should not be officially recorded by the Only Representative.
    - There is no harm in knowing who these importers are, but from the records it should be clear that they are not covered by the Only Representative.
- Where a change takes place and an importer who was previously covered by the Only Representative no longer is, this should be communicated by the Principal to the importer and confirmed to the importer by the Only Representative. The change must be clearly recorded by the Only Representative.
- Where a Principal sells to an importer and only a part of these sales is covered by the Only Representative, the Principal should clearly communicate this to the importer including the maximum quantities covered by the Only Representative. The arrangement should be confirmed to the importer by the Only Representative. The Only Representative must clearly record the accompanying documentation.

5) Records in case of a late OR appointment

Quantities preceding the late appointment of an Only Representative

Whether assigned late or not, the Only Representative should, if at all possible, maintain records of imported volumes for a sufficient number of years to legally determine the correct tonnage bands for the registrations, unless the OR starts his coverage with a registration in the > 1000 t/a tonnage band.

There may, however, be cases where this information cannot be obtained. The Principal may, for example, not know the previously imported quantities if previous exports to the EU were made by a non-EU distributor. Note that there is no specific legal text regarding the recording by the Only Representative of imported tonnages before his appointment.

Best Practice is therefore:

- Where the Principal knows that quantities of substances previously placed on the market in the EU have not surpassed 1 tonne per year, the Only Representative should obtain suitable written documentation of this from his Principal. This documentation should be recorded for the substances in question.

- Where the Principal knows the quantities of substances previously placed on the market in the EU and these have exceeded 1 tonne per year, the Only Representative could still obtain from his Principal the total annual import tonnages for the previous several years, so that the tonnage band can adequately reflect the volume intended to be imported annually.
    - Where the OR starts his coverage for the principal with a registration in the tonnage band > 1000 t/a, there is no added value in obtaining annual import tonnages for the period preceding his appointment.

Where the Principal does not know the quantities previously placed on the market in the EU, the Only Representative may assume that all previous imports, if any, were below one ton per importer or were registered by the previous importers.

6) <u>The Principal does not supply timely information on quantities</u>

For the Only Representative to fulfil his duties, it is required that information provided by the Principal is timely and adequately detailed.

The Only Representative delivers his services based on the information provided to him by the Principal which is assumed to be correct and complete.

Should such information fail to be provided, the Only Representative should actively engage with the Principal to explain the importance of this information. If the client persists in failing to provide data, the Only Representative may consider that there may not have been any imports of the substance(s) and record zero tons import or even consider this as grounds for termination of the mutual agreement.

Should additional information, which is material to the service, such as new studies, updated safety data sheets, etc., become available during the year the Principal has an obligation to provide this to the Only Representative.

Ensuring the supply of correct, comprehensive, timely and adequately detailed information by the Principal can only be addressed in the contract between the Only Representative and the principal.

If the necessary information is not available, the Only Representative may be found not in conformity of the legislation. The Only Representative should therefore actively request his Principal to provide necessary information. In doing so and keeping record of his requests, the Only Representative will be able to show the necessary due diligence.

<u>Best Practice</u> is therefore:

- The supply of correct, comprehensive, timely and adequately detailed information by the Principal shall be addressed in the contract between the Only Representative and the principal.
- The Only Representative should annually, or more frequently, if necessary, ask the Principal to provide the required information on quantities sold and EU importers covered. Where no timely answer is received, he should remind the Principal of his request. The Only Representative should keep records of his requests and reminders.

7) How long must records be kept

Article 36 tells manufacturers, importers, downstream users and distributors to keep all relevant information for a period of ten years. Article 8.2 obliges Only Representatives to keep information 'without prejudice to Article 36' (Obligation to keep information). As a result, even though Article 36 does not mention Only Representatives explicitly, these have the same obligations as importers.

Best Practice is therefore:

- The Only Representative will keep records and documents for a period of at least 10 years.
- Where a Principal changes Only Representative or appoints an exclusive importer, the 'old' Only Representative continues to keep those records for the remainder of the required period, unless they are fully transferred to the new Only Representative or the exclusive importer. The new Only Representative or exclusive importer must in that case agree in writing to keep those records for the remainder of the required period.
- Where a Principal ceases completely to export into the EU or leaves REACH compliance to multiple importers, the Only Representative shall keep the existing records for the remainder of the required period.

8) Avoiding Double registrations

Importers may have registered the same substance that has been registered by an Only Representative on behalf of a Principal. These importers may purchase the same substance from several different non-EU producers.

The ECHA Guidance on Registration (Version 4.0, August 2021) currently indicates a requirement for data exchange between Only Representative and Importer which may be open to interpretation. This chapter clarifies this requirement.

Where an importer, purchasing from the Only Representative's Principal has submitted a registration for the substance; two situations must be distinguished.

- The importer also purchases the substance from other non-EU producers
- The importer purchases the substance from the ORs Principal outside of the OR arrangement.

In both cases, the EU importer is responsible for REACH coverage of the substance himself and shall submit his own registration dossier if required. The Only Representative will not cover these imports and is not considering these imports in his own tonnage report records.

9) The importer also purchases the substance from other Non-EU producers

While the ECHA guidance could be read to indicate that the Only Representative and the Importer must be able to demonstrate to the authorities which tonnages are covered by each party, this is not the case. Instead, the OR and the Importer each have a separate obligation to demonstrate the quantity of the substance which is covered by their respective registration if requested by a national enforcement authority.

There is, after all, no contract between the Only Representative and the Importer and the information could be commercially sensitive if it were inadvertently shared between the parties.

Also, this information, even if it were possible to collect it, would serve no purpose in the enforcement of REACH. The Only Representative is in no way responsible for the REACH compliance of the importer other than for the products supplied by his Principal.

Best Practice is therefore:

- The Only Representative should for importers who also buy the same substance from other suppliers fully follow up the BPG recommendations in this section, especially those under 'Full coverage: Substances on their own & Common mixtures'.
- The Only Representative should maintain all correspondence with his Principal regarding requests for importer details and import quantities, as appropriate backup documentation.

10) Importer's purchases outside the OR arrangement

This subject is addressed in the Chapter on *'Volume tracking'* and especially in '*Partial coverage of the imports*' section.

11) Non-EU Company details to be available to the OR and provided in REACH-IT

An Only Representative needs to specify in the registration dossier the identity of the "non-EU manufacturer" they are representing. ECHA Q&As 1984 and 21 have been updated with the new requirements following the 2022 amendment to REACH[4].

Since the enforcement of this amendment (14.10.2022) Only Representatives are also required to indicate the identity of the non-EU manufacturers in REACH-IT. However, disclosure of the non-EU manufacturer's identity via ECHA dissemination tool is optional and not taking place by default.

In REACH-IT, Only Representatives must provide the following information to identify the non-EU manufacturer they represent:

- Name of the non-EU manufacturer.
- Address of the non-EU manufacturer, and website when available.
- Name and contact details of a person working at the non-EU manufacturer. The person must be employed by the non-EU manufacturer, however there are no specific requirements related to the role of the person in the company, or to where this person should live.
- Location of the production or formulation sites.
- National company identification number of the non-EU manufacturer. This national company ID number is assigned by the company registry of the country where the company is established. This information is optional and needs to be obtained from the non-EU manufacturer.

[4] COMMISSION REGULATION (EU) 2022/477 of 24 March 2022 amending Annexes VI to X to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 98/38, 25.3.2022.

Additionally, the following information can be included in IUCLID section 1.7: the name of the non-EU manufacturer represented by attaching a letter of appointment in the field "Assignment from non-EU manufacturer". A "list of importers" can also be submitted within the dossier but it is not advised, as this would require unnecessary updates, without added value. However, the Only Representative has to keep records on importer identity and make these available to enforcement authorities on request.

6. SME CLAIMS

Topics

REACH has been structured to enable lower registration cost for SMEs (Small and Medium Sized Enterprises). For the sake of fair competition and equal treatment, ECHA verifies the size of companies claiming to be SMEs.

When an Only Representative is appointed, the company size declared by the Only Representative, must be that of his Principal, the non-EU Company being represented. In case of errors or failure to pass the ECHA verification process, the Only Representative will be invoiced for the resulting additional registration fee and, where applicable, 'administrative charges' of up to EUR 19 900 (current value in 2023). It is in the Only Representative's interest to avoid SME claims that are incorrect, or for which the supporting documentation will not be robust enough to withstand ECHA's verification.

For Only Representatives, the assessment of whether the fee reduction for SMEs applies shall be determined by the relevant data of the enterprise that is represented by that OR, including relevant information from linked and partner companies of that enterprise, in accordance with the Commission Recommendation 2003/361/EC outlining the conditions regarding qualification as micro, small or medium-sized enterprise. Step-by-step instructions to help determine the company size category in accordance with Commission Recommendation 2003/361/EC are available on the ECHA website (https://echa.europa.eu/support/small-and-medium-sized-enterprises-smes).

It must be pointed out that it cannot be expected from the Only Representative that he should be able to expertly interpret or review the Principal's documentation supporting his SME claim. Only Representatives are not accountants; they cannot be expected to be able to analyse the company accounts and legal documentation provided by his Principal. The Only Representative should however ensure that Principal understands the process and the associated implications, and provides, and is willing to defend, the required documentation.

The SME topic is particularly relevant for Only Representatives as many of their Principals are SMEs.

The following is addressed in this chapter:

- Company size determination
- Initial client engagement
- Periodic confirmation of company size
- Confirmation prior to registration of the substance
- Verification process
- Contractual arrangements

Legal text & official guidance

REACH Recital (8):

> *'Special account should be taken of the potential impact of this Regulation on small- and medium-sized enterprises (SMEs) and the need to avoid any discrimination against them'*

REACH Article 3(36):

> '*SME: means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises'*

Fee Regulation - Commission Regulation (EC) 340/2008 on the fees and charges payable to ECHA pursuant to REACH Regulation

Article 13(3)

> *The Agency may request, at any time, evidence that the conditions for a reduction of fees or charges or for a fee waiver apply.*
>
> *Where the evidence to be submitted to the Agency is not in one of the official languages of the Union, it shall be accompanied with a certified translation into any of those official languages.*

Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises (2003/361/EC)

Annex, Title 1, Article 2:

> *Staff headcount and financial ceilings determining enterprise categories:*
>
> *1. The category of micro, small and medium-sized enterprises (SMEs) is made up of enterprises which employ fewer than 250 persons and which have an annual turnover not exceeding EUR 50 million, and/or an annual balance sheet total not exceeding EUR 43 million.*
>
> *2. Within the SME category, a small enterprise is defined as an enterprise which employs fewer than 50 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 10 million.*
>
> *3. Within the SME category, a microenterprise is defined as an enterprise which employs fewer than 10 persons and whose annual turnover and/or annual balance sheet total does not exceed EUR 2 million."*

ECHA Guidance on Registration (version 4.0 August 2021)

10.1 Calculation of applicable fees

> *"When calculating the fee, the following parameters are taken into consideration:*
>
> - *[..]the registered tonnage band;*
> - *claim for SME fee reduction, if applicable.*
>
> *When declaring SME (micro, small and medium enterprise) size and claiming for the SME fee reductions, a registrant must upload a **complete set** of supporting documentary evidence to their REACH-IT account, under the Menu section 'Company size'. Only representatives have to upload supporting documents of the non-EU enterprise which they represent.*
>
> *Where a registration is submitted by an Only representative, the company size of the 'non-EU manufacturer' is decisive for the fee and must be entered into the relevant field in REACH-IT, not the company size of the Only representative. That is, the assessment of whether the reduction for SMEs applies shall be determined on the applicable ownership structure, headcount, turnover and balance sheet data related to the 'non-EU manufacturer', in accordance with Recommendation 2003/361/EC.*

*ECHA may check at **any time** whether companies which claimed SME status, and thus paid reduced fees for their registrations, meet the requirements defined by Commission Recommendation 2003/361/EC. Where such a verification results in finding that the registrant did not meet the definition, and hence not entitled to the fee reduction, the registrant is liable to complete their registration by paying the difference between the reduced fee and the full registration fee, and to pay an administrative charge, if applicable.*

Company Size Determination

The SME system stems from a common methodology in the EU under the auspices of DG Enterprise (Commission Recommendation 2003/361/EC). ECHA references this methodology and provides further guidance. A considerable amount of Guidance, including an 'SME-test' can be accessed through the following links:

- http://echa.europa.eu/en/support/small-and-medium-sized-enterprises-smes/sme-fees-under-reach-and-clp
- SME self-assessment questionnaire: Electronic SME test

Determining whether a company is entitled to an SME claim can be a complex process. It not only depend on its headcount, turnover and balance sheet, but also on the ownership of the company and the level of inter-connectedness with other enterprises. The fact that Only Representatives deal with non-EU companies often adds to the complexity.

This BPG does not attempt to improve on existing guidance but rather points towards the principles and the procedures that Only Representatives are recommended to follow vis-à-vis their Principals. With regard to the content of this complex subject, the reader is encouraged to familiarise themselves with above mentioned supporting guidance documents.

For convenience, the proposed approach is broadly as follows:

Summary of 5 key steps to company size determination:

1. **Is the company Autonomous, Linked or Partnered**

   Linking and Partnering are defined based on the levels of ownership and other influences by/in other entities (upstream and downstream) ***at the time of each submission*** of the specific Substance Registration in REACH-IT. Keep in mind that indirect relationships are also to be considered. Provision is made for certain investors (Business Angels, Venture Capital Firms etc.) to hold a certain holding without affecting autonomy.

2. **Reference years for Financial and Headcount Data**

   ECHA uses the term 'concrete submission', interpreted as being the submission of a Registration, Update, Notification etc. The two full accounting periods immediately prior to this should be used as the basis of company size. An enterprise may lose/acquire an SME status only if the SME ceilings are exceeded/fallen below over two consecutive accounting periods and therefore two accounting periods are considered.

3. **Determine Headcount, Turnover and Balance Sheet**

   The determination of size is based on Headcount and ***a choice of*** either Turnover or Balance Sheet.

4. **Overall Enterprise Data**

   If the company is Linked or Partnered (upstream and/or downstream) at the time of the submission, the calculation of Overall Enterprise size for the non EU client must include the aggregated headcount, balance sheet total and turnover of all such linked and partnered enterprises.

5. **Determine Company Size**

   The following table defines the criteria for determination of company size. If a Principal, together with all its partner and linked enterprises, does not meet criteria below, it is considered to be 'large'. No SME claim can be made on its behalf.

Enterprise category	Headcount	Turnover or Balance sheet total	
medium-sized	< 250	≤ 50 million euro	≤ 43 million euro
small	< 50	≤ 10 million euro	≤ 10 million euro
micro	< 10	≤ 2 million euro	≤ 2 million euro

Best Practice

1) **Initial Client engagement**

Initial client engagement will generally be followed by one or more inquiries. At this stage REACH-IT already demands a declaration of company size. Although there are no consequences for the inquirer in the case of errors and ECHA does not perform company size verifications on these submissions, it is important that the Only Representative's Principal declares his company size correctly.

Best Practice is therefore:

- At the time of initial engagement and inquiry the Only Representative should determine if the Principal's company could possibly be entitled to an SME claim.
- The OR should explain to the client the cost savings which will occur if the SME claim is to be made, and the level of diligence needed to support this. The client should then decide if they wish to pursue this course of action.

Where the Principal may be entitled to an SME claim, the following applies:

- At the time of inquiry the Only Representative should explain to the Principal the importance of a correct SME claim and how company size is determined. The Only Representative should share the links to guidance with his Principal and encourage the Principal to do the 'SME-test'. (See links above).
- If the Principal claims to fall into an SME category, the Only Representative should request his Principal to provide documentary evidence of its company size based on the principles in the Guidance above.
- When creating a REACH-IT Account, the Only Representative should apply the company size which has been confirmed by his Principal.
- When the Only Representative becomes aware of a change in the company size of his Principal, he should make the appropriate change in the REACH IT account within 3 months.

- The company size **must** be re-confirmed prior to submission of any substance registration through this account

2) **Periodic Confirmation of Company Size**

Company sizes change. But even if the Principal's company does not grow or shrink, mergers, acquisitions, change in ownership etc. may lead to a change in SME status. Both the Principal and the Only Representative should be aware of such a change in SME status.

Best Practice is therefore:

- Where the Principal claims SME status, the Only Representative should check annually with the Principal if any changes have taken place that would lead to a change in SME status in the previous accounting period.
- Where a change in SME status has occurred, the Only Representative should amend the REACH IT account accordingly, within the deadline of 3 months.

3) **Confirmation prior to Registration of Substance**

In the case of a registration, an erroneous or non-defensible SME claim unavoidably leads to severe financial consequences. Hence it is critically important that the company size submitted is correct and defensible with documentary evidence at the time of submission.

Best Practice is therefore:

- Where the Principal claims SME status, the Only Representative should, well in advance of the submission of the registration, reaffirm the importance of a correct and defensible SME claim, the necessary documentary evidence and how to determine the correct company size by direction to the relevant guidance. The Only Representative should specifically point out that a change in the ownership structure may result in a change in SME status.
- The Principal is to submit to the Only Representative, a confirmation of company size and to provide supporting factual and official documentation to this effect before the registration is submitted. As the OR is not a professional in determining the adequacy of such documentation, best practice is for the Principal to provide a note from a third party (e.g. Financial Auditor) that they agree with the SME status of the client (For the documents required see Annex 1 to this BPG).
    - If the Principal is not claiming SME Status, no documentary evidence is required.
- Failure of the client to adequately confirm the company size or to provide the actual supporting documentation should prompt the OR to defer the submission or to submit the Registration under a 'Large' company designation.
- The OR should check that the company size is set correctly in REACH-IT and the associated Legal Entity prior to each submission.

Remark: As pointed out earlier, it cannot be expected from the OR that he should be able to expertly interpret or review the supporting documentation. The Only Representative may only be expected to ensure that Principal is in the position to take the correct decision and that he provides the required documentation.

4) **Verification Process**

Verification by ECHA is triggered pursuant to substance registration (or any other chargeable submission activity) when an SME status is claimed.

The Only Representative will be approached by ECHA as part of a verification process where SME status has been claimed. It is the Only Representative's task to be a professional liaison between ECHA and his Principal and ensure that the verification process is properly managed and that the timelines are realistic and achievable.

ECHA has over the past years refined the requirements in documentation for SME verification (see *Documentary evidence requested* section on ECHA's SME verification web page). Although the Principal should already have provided the Only Representative with SME documentation at the time of registration, this documentation may not be exactly what ECHA requires at the time of verification.

In the case of an SME check by ECHA, Best Practice is therefore:

- The Only Representative should engage with the Principal to explain the verification process and the additional evidence-based documentation which is required to ensure a successful outcome of the ECHA verification.
- The Only Representative should check the documentation received from the Principal at the time of the registration against the documentation required for verification, inform the Principal of any discrepancies and request the additionally required documents.
- Where timelines set by ECHA are too tight and not achievable, the Only Representative should ask for an appropriate extension.
- The Only Representative should, with full engagement with the Principal, follow through the process to its conclusion and ensure that any resulting financial transactions are executed correctly, thereby ensuring continued market access for the Principal.
- The Only Representative should check all other dossiers which may have been submitted for this Principal for their SME validity and, after having obtained his Principal's permission, inform ECHA if any discrepancies are identified.

5) **Contractual arrangements**

With regard to SME claims, the Only Representative is completely dependent on the information provided by his Principal. There must be no misunderstanding between Principal and Only Representative about the need for SME claims to be correct and the consequences when an SME claim is erroneous or for whatever other reason will not withstand ECHA's verification.

Best Practice is therefore:

- The contract between Only Representative and Principal should clearly reflect the Best Practice recommendations in this chapter, the Principal's ultimate responsibility and the fact that the consequence of an erroneous SME claim may be that the registration in question will be declared void.
- The OR should include a commitment from the client that, in the event of an SME Claim which is not supported by ECHA, that they will commit to pay the arising costs
- Additionally, a Bond could be considered to be in place to cover this financial overhang. While this may be possible with new clients, it may be difficult in practice to implement into existing contracts.

- In the absence of credible supporting information, the OR could consider defaulting to “Large” company size, where standard fees will apply, rather than the OR taking on the associated risk.

6) **Transfer of OR client with SME Status**

If a Principal decides to transfer their OR undertaking from one OR to another, and there is an SME Claim in place, particular attention should be paid to the determination and substantiation of the claim. The risk inherent here, is that the new PR inherits a financial risk due to inadequate process and/or paperwork being available to justify the claim.

7. SAFETY DATA SHEETS (SDS)

Topics

In the early days of REACH the responsibilities of Only Representatives regarding Safety Data Sheets have been much discussed. The ORO position paper and a Commission communication to one of the ORO members have however clarified the issues.

Since Only Representatives as Regulatory Service Providers for non-Community Manufacturers are not handling chemical products and are consequently not responsible for placing them on the market, they cannot be deemed as supplier of chemical products in the actual Supply Chain and therefore holds no obligation to provide SDS according to Article 31 of REACH.

Although the legal obligations of the Only Representative with regard to SDSs are small, Best Practice is that, where necessary, OR takes a role in the compilation and distribution of these documents.

Generally speaking, if the substance in question is hazardous, a Safety Data Sheet for the substance as such or the mixture containing this substance may have to be compiled by the importer or formulator along the supply chain. To enable this task, sufficient information for the accurate compilation of such an SDS must be communicated. Further information shall also be provided to the formulator when new hazard information or new harmonised classification becomes available.

For communications with Downstream users, see chapter 8 'Downstream user Communications'.

The following is addressed in this chapter:

- Availability of Safety Data Sheets in the supply chain
- Supply of Safety Data Sheets by an Only Representative
- Contractual arrangements between OR and Principal
- Sharing information
- Registration numbers on Safety Data Sheets for mixtures
- Dissemination records
- New hazard information or new harmonised classification

Legal text & guidance

The legal obligations of Only Representatives regarding Safety Data Sheets are addressed in the ORO Position Paper *'Only Representatives and Safety Data Sheets'* of June 2010, attached as Annex 2**: ORO Position Paper 'Only Representatives and Safety Data Sheets'** to this BPG.

Two Commission letters are relevant to this chapter. They are attached as annexes to this BPG:

- Annex 3: Commission letter to an ORO member regarding the OR obligations with regard to Safety Data Sheets
- Annex 4: Commission letter dd 24 April 2010, regarding the registration numbers on Safety Data Sheets

Best Practice

1) Availability of Safety Data Sheets in the supply chain

In the case of hazardous substances or mixtures being imported into the EU, the legal obligation to supply a REACH compliant Safety Data Sheet applies when the substance or mixture is placed on the EU market by the importer.

This however places the obligation to compile REACH Compliant Safety Data Sheet in the hands of an actor (the importer) in the supply chain who may not have the necessary information and knowledge.

Where this is the case, it is highly preferable that the non-EU Manufacturer of the hazardous substance or mixture provides the importers with REACH compliant Safety Data Sheets. The Only Representative should encourage the compilation of such REACH compliant Safety Data Sheets by their Principal for supply onto the EU market.

Best Practice is therefore:

- An Only Representative should encourage its Principal to compile REACH compliant Safety Data Sheets and to provide these to the importers, unless the importers can be expected to correctly compile the Safety Data Sheets themselves.
- Where the Principal cannot be expected to correctly do so himself, the Only Representatives should offer to facilitate the compilation and distribution of Safety Data Sheets. He may for example assist the Principal in finding an SDS authoring service, review the SDS and advise on areas of non-compliance, or advise on a REACH-compliant system for distributing SDSs to downstream users or offer such a system himself.

Where a non-EU supply chain is complex and involves a non-EU formulator and their OR, Best Practice is:

- If the substance is non-hazardous, the manufacturer's OR will inform the formulator's OR of this fact.
- If the substance is hazardous then information, which may include an eSDS, must be provided to the formulator to allow for preparation of a Safety Data Sheet for the mixtures produced by the Formulator.
- If new hazard information or new harmonised classification becomes available, the Manufacturer shall ensure this is communicated to the Formulator.

2) Supply of Safety Data Sheets by an Only Representative

The Only Representative has no legal obligation to supply Safety Data Sheets for the hazardous substances or mixtures exported to the EU by the Principal.

> *Note: Where Only Representatives themselves place hazardous substances or mixtures on the market in the EU, they do this in an additional role under REACH. For example, the role of Importer, Downstream User or Distributor. In that additional role they may very well have the obligation to provide a Safety Data Sheet. These additional roles are however not subject of this Best Practice Guide.*

If an Only Representative were the 'provider' of the Safety Data Sheet and identified as such under section 1.3, this would impose legal duties onto the Only Representative for the content, update, and distribution of the SDS to EU Downstream Users. Also, under national legislation, it would bring about considerable liabilities in the case of a mistakes in the Safety Data Sheet or if the Safety Data Sheet and the product that it refers to do not match.

Best Practice is therefore:

- An Only Representative shall not be named as the provider or supplier of Safety Data Sheet, unless explicitly agreed differently with his Principal.
- Where an Only Representatives compiles a Safety Data Sheet for his principal or for an importer, the principal or the importer shall be identified as the supplier of the document.
- The Only Representative shall be clearly identified as being the appointed Only Representative. This information may be provided in section 1.3. The OR's contact details may be provided in section 16.

3) Sharing information

Where an Only Representative has registered a hazardous substance, he holds the Chemical Safety Report (CSR) and therefore the information necessary to compile the extended Safety Data Sheet for that substance.

If the Principal or an importer wishes to compile an extended Safety Data Sheet for the substance, they should have access to content of the CSR.

There may however be cases where the Letter of Access contains stipulations that prevent the supply of the original CSR to a 3rd party. In such a case the Only Representative would be in breach of a contract if he were to distribute the original CSR to either his Principal or an importer.

Best Practice is therefore:

- Where an Only Representative has registered a hazardous substance of which the LoA does not restrict the distribution of the CSR and his Principal or an importer wishes to make an extended Safety Data Sheet for the substance, the Only Representative may provide them access to the content of the CSR.
- Where the LoA restricts the distribution of the CSR, the Only Representative may offer to extract from the CSR the information necessary to produce the eSDS, or alternatively produce the eSDS himself.
    - Depending on the contractual relationship between Only Representative and Principal, the Only Representative may require the Principal's permission before providing an importer with access to the CSR.

4) Registration numbers on Safety Data Sheets for mixtures

In accordance with REACH Annex II the last four digits of the registration numbers for the hazardous substances in mixtures may be omitted in the Safety Data Sheet for the mixture under certain conditions.

This possibility exists for the benefit of EU based formulators who do not wish to identify their suppliers or who wish to source the same substance from different suppliers. Where this possibility is

used, the formulator must, upon request, provide the full registration numbers to competent authorities within seven days.

The same possibility is open to Only Representatives and their Principals. Since the Principal has no obligations under REACH, the Only Representative will have to provide the full registration number to the Competent Authority if requested.

The Only Representative will, resulting from his obligation to keep records, know the registration numbers of the substances. He may however not know which registration number applies to the substance in a certain batch of an imported mixture.

Best Practice is therefore:

- Where the Principal is a producer of mixtures and uses the possibility to omit the last four digits of the registration numbers of the substances in the mixture, the Only Representative must ensure that the Principal can provide him without delay with the full registration numbers of the substances used to produce a certain batch of a mixture.
- In such a case the Only Representative should have copies of the Safety Data Sheets as distributed by the Principal to the importers.

Remark: This situation will only occur in complex supply chains where the substances have not been registered by the OR of the non-EU formulator. Where the OR of the non-EU formulator has registered the substance in question, the registration number does not identify the Manufacturer/Importer of the substance, but the Only Representative. The non-EU formulator may source the same substance from different suppliers under this registration number.

5) Dissemination records

Where the importer provides Safety Data Sheets, he is obliged to keep a record of their dissemination.

Where the Principal provides Safety Data Sheets, he is under no obligation to record their dissemination. It is however highly preferable if these records are kept adequately and are available in the EU.

Best Practice is therefore:

- Where the Principal provides Safety Data Sheets, the Only Representative should encourage him to keep adequate records as intended under Art.31 REACH.
- Where the Principal keeps records of the dissemination of Safety Data Sheets he should be encouraged to provide the Only Representative with access to these records.

6) New hazard information or new harmonised classification

The Only Representative may become aware of new hazard information or new harmonised classification concerning a hazardous substance featuring in a Safety Data Sheet that is provided to the importers by his Principal.

As a consequence, it may be necessary to adapt the Safety Data Sheet to the new information. The Only Representative should in such a case inform his Principal and encourage him to arrange for the necessary adaptation of the Safety Data Sheets.

Best Practice is therefore:

- Where an Only Representative becomes aware of new hazard information or new harmonised classification of a substance featuring on a safety Data Sheet provided by his Principal, the Only Representative should inform his Principal and encourage adaptation of the Safety Data Sheet if necessary.

Please note: for other possible consequences of becoming aware of new hazard data, such as informing the Lead registrant or an update of the registration dossier, see Chapter 9 on Downstream User Communications.

7) Contractual arrangements between OR and Principal

There must be no misunderstanding between Principal and Only Representative with regard to the compilation and supply of Safety Data Sheets.

Best Practice is therefore:

- The contract between Only Representative and Principal should clearly reflect the Best Practice recommendations above under 'Supply of Safety Data Sheets by an Only Representative'.

8. COMMUNICATIONS WITH DOWNSTREAM USERS

Topics

There are several situations in which Only Representatives must communicate with the customers of their Principal, the 'Downstream Users'.

> *Remark: For clarity, in this chapter 'Downstream Users' are the Importers which are regarded Downstream Users as a result of the appointment of the Only Representative.*

This chapter addresses the communication with Downstream Users, other than the communication on quantities of chemicals imported and Safety Data Sheets. For quantities see chapter 5 on Volume tracking, for Safety Data Sheets advice see chapter 8.

The following situations are addressed:

- Appointment and Downstream User contact details.
- Identified uses: Registration on the basis of a Letter of Access.
- Identified uses: Registration dossier prepared by the Only Representative.
- Substances posing a previously unknown risk to human health or the environment.
- Unsolicited downstream user communications:
    - SDS request
    - New hazard data

Legal text & official guidance

The topic of downstream users and the communication with them is mentioned numerous times in the legal text and the ECHA Guidance. The communications between Only Representatives and the importers now regarded as Downstream Users is however hardly mentioned. While all Downstream Users obligations apply, we will aim to highlight the key articles.

REACH Regulation

Article 3(26)

> *Identified use: means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain, including his own use, or* ***that is made known to him in writing by an immediate downstream user****;*

Article 31: *Requirements for Safety Data Sheets*

> *Article 31(4) The safety data sheet need not be supplied where dangerous substances or mixtures offered or sold to the general public are provided with sufficient information to enable users to take the necessary measures as regards the protection of human health, safety and the environment, unless requested by a downstream user or distributor.*

Article 32: Duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required

Article 33: Duty to communicate information on substances in articles

Article 34: Duty to communicate information on substances and mixtures up the supply chain

Article 36 Obligation to keep information – referenced in Chapter 5 on Volume Tracking

Article 37 ***Downstream user chemical safety assessments and duty to identify, apply and recommend risk reduction measures***

> *(1) A downstream user or distributor* ***may*** *provide information to assist in the preparation of a registration.*
>
> *(2) Any downstream user shall have the right to make a use, as a minimum the brief general description of use, known in writing (on paper or electronically) to the manufacturer, importer, downstream user or distributor who supplies him with a substance on its own or in a mixture with the aim of making this an identified use. In making a use known, he shall provide sufficient information to allow the manufacturer, importer or downstream user who has supplied the substance, to prepare an exposure scenario, or if appropriate a use and exposure category, for his use in the manufacturer, importer or downstream user's chemical safety assessment.*
>
> *(3) For registered substances, the manufacturer, importer or downstream user shall comply with the obligations laid down in Article 14 either before he next supplies the substance on its own or in a mixture to the downstream user making the request referred to in paragraph 2 of this Article, provided that the request was made at least one month before the supply, or within one month after the request, whichever is the later. […]*
>
> *Where the manufacturer, importer or downstream user, having assessed the use in accordance with Article 14, is unable to include it as an identified use for reasons of protection of human health or the environment, he shall provide the Agency and the downstream user with the reason(s) for that decision in writing without delay and shall not supply downstream user(s) with the substance without including these reason(s) in the information referred to under Articles 31 or 32. The manufacturer or importer shall include this use in section 3.7 of Annex VI in his update of the registration in accordance with Article 22(1)(d).*

Article 38 ***Obligation for downstream users to report information***

Article 39 ***Application of downstream user obligations***

Article 56

> *(1) Distributors shall pass on such information to the next actor or distributor up the supply chain. Downstream users in receipt of such information may prepare an exposure scenario for the identified use(s), or pass the information to the next actor up the supply chain.*
>
> *A manufacturer, importer or downstream user shall not place a substance on the market for a use or use it himself if that substance is included in Annex XIV, unless:*
>
> *… (e) in cases where the substance is placed on the market, authorisation for that use has been granted to his immediate downstream user.*
>
> *(2) A downstream user may use a substance meeting the criteria set out in paragraph 1 provided that the use is in accordance with the conditions of an authorisation granted to an actor up his supply chain for that use.*

Relevant Annexes on the chemical safety assessment and Chemical Safety Report: ANNEX I and ANNEX XII.

ECHA Guidance for downstream users Version 2.1, October 2014

1.1.1 Registration

One of the main requirements of REACH is the registration of chemical substances. This means that each manufacturer or importer of a substance, if he manufactures/imports the substance at 1 tonne or more per year, must provide a defined set of information, in the form of a registration dossier, to the European Chemicals Agency (ECHA). This information includes the hazards of the substance and the expected exposure from using the substance.

If the substance is manufactured or imported in quantity of 10 tonne or more per year a chemical safety assessment (CSA) is required. Firstly, the hazards resulting from intrinsic properties of the substance are assessed (hazard assessment). If the substance fulfils certain hazard criteria, an assessment of the nature and extent of the exposure it is also required (exposure assessment and risk characterisation). The aim is to demonstrate that the risks stemming from exposure can be controlled with a set of operational conditions (OC) and risk management measures (RMM) designed for that use.

The CSA and its results are documented in a chemical safety report (CSR) which forms a part of the registration dossier. This should be updated whenever new relevant information is available.

How does registration affect you as downstream user? The registration process yields information on the substance hazard and risk. Information on recommended risk management measures for specified uses is detailed in the chemical safety report. This is provided, where applicable, in the form of exposure scenarios that are annexed to the safety data sheet (SDS). For mixtures, the relevant information from exposure scenarios may be included in the SDS in different ways according to the case.

Best Practice

1) Appointment and Downstream User Contact Details

It is important that it is established beyond doubt from which importers the Only Representative takes over REACH obligations and who, consequently become de facto 'Downstream Users'. Clarity is needed for the importers in question, the Only Representative, and the enforcement authorities.

For cases where it is not obvious who is the Importer under REACH, see Chapter 3 on Identification of the importer.

According to REACH Art. 8.3, the non-Community manufacturer must inform the importers within the same supply chain, (i.e. his EU-based customers) of the appointment of the Only Representative.

Best Practice is therefore the following:

- Upon initiation of the service, the Only Representative should inform the Principal of his duty to provide letters of nomination to his EU importers. Ideally, the OR should receive copies of these letters or other evidence of this action. It is essential that the OR is provided with an initial list of Downstream Users and their contact details.
- Although the Downstream User receives a letter of nomination of an Only Representative coming from the non-EU manufacturer, the Downstream User should also receive a written confirmation of this appointment from the Only Representative.

- The confirmation by the Only Representative should name the Principal, the products covered and the fact that, where necessary, registrations have been submitted in the appropriate tonnage bands. It is essential to identify clearly the imports for which the Only Representative is responsible. Within complex indirect supply chains, consideration for maintaining confidentiality of the Principal may be required.
- The Only Representative will maintain a current list of all Downstream Users for each Principal and their contact details and substance volumes. Later correspondence with the Downstream Users should be used to keep this information up to date.

2) **Identified Uses: Registration in an existing joint submission with a Letter of Access**

Registrations on the basis of a Letter of Access take place when a consortium has already finished the dossier and it has been submitted by the Lead Registrant. This is in most cases the preferred solution. Not only because there is a legal obligation to submit joint registration whenever possible, but also for cost reasons. Making a registration dossier 'from scratch' is generally much more expensive and time consuming than buying access to an existing joint submission.

This Lead Registrant's dossier normally addresses all the foreseeable uses. The consortium will have communicated with users of the chemicals. As a result, it is for the Only Representative a matter of checking whether the uses of the importers are adequately covered by the Lead Registrant dossier.

In most cases, the Chemical Safety Report (CSR) in registration dossiers for which Letter of Access (LoA's) are sold cover all the known uses of the registered substance. Sometimes however, for the same substance, Letters of Access are available for different dossiers, drafted by different consortia and submitted by different Lead Registrants. These different dossiers may cover different sets of uses.

Occasionally, the use of a Downstream User is 'unusual' and not covered by a Lead Registrant dossier. A registration that does not fully cover the uses of the Principal's EU-based customers must be avoided.

The Only Representative will, in some cases, be in a position to determine that the Downstream Users' uses are adequately covered without communication with his Principal or the Downstream Users. This may, for example, be the case with fuels, monomers in a polymer, components in proprietary mixtures, etc.

Downstream Users' uses not self-evident.

Where the Downstream Users' uses are not self-evident Best Practice is the following:

- Where a LoA to an existing dossier is used for a registration and the Downstream Users' uses are not self-evident, the Only Representative should check with the Principal if the identified uses in the dossier cover the actual uses of the Principal's customers.
- Where the Principal cannot confirm that all his EU customers' uses are covered, he may ask the Only Representative to contact the Downstream Users directly and check if their use of the substance is covered by the dossier.
- Where, for a single substance, more than one joint submission exists, the Only Representative should carefully check the uses covered by these submissions against the uses of the downstream users before choosing which submission to join.

Downstream Users' uses not covered in the CSR

It is possible that the Downstream Users' uses are not covered by the CSR in the Lead Registrants dossier or. Such uses should be avoided.

Best Practice is therefore the following:

- Where it is known to the Only Representative that a Principal's customer uses a substances in a way not covered by the CSR or a supplement to the CSR, he should inform his Principal and encourage the Principal not to supply the substance to the customer in question.

3) **Identified uses: Registration dossier prepared by the Only Representative**

When a CSR is prepared by the Only Representative, he should ensure that the Downstream Users' uses for the substance will be adequately covered. The Principal should provide the necessary information, based on information on realistic uses and conditions of use gathered from his customers.

Especially where the substance to be registered is a 'substance on its own' or a 'common mixture', the Downstream Users' uses of the substance may however not all be known to the Principal.

Best Practice is therefore the following:

- Where the Principal may not know all the Downstream Users' uses of the substance to be registered, the Only Representative will inform the Downstream Users of all of the exposure scenarios that are intended to be covered by the CSR and ask for confirmation that all their uses are covered.

Experience shows that not all Downstream Users will react adequately to this information and request for confirmation. Three different situations may occur, in which case Best Practice is the following:

- No response: A follow up communication should be made. If the Downstream User still does not respond, the Only Representative can currently assume that he has covered all uses. Although not a preferable solution, Downstream Users can make unsupported uses known later.
- Full Confirmation: The downstream user confirms that all its uses are covered by the CSR. In this situation, no further action is required on the Only Representative's part.
- Partial Confirmation: The downstream user confirms that not all its uses are covered by the CSR. In this situation, on receipt of the details of the additional uses that the Downstream User wishes covered, these should be communicated to the Principal. The Principal has the choice whether he wishes the additional uses covered. If he does, these uses can be added to the CSR and a new CSR generated. If he does not, the OR should communicate this to the Downstream User. It then becomes the Downstream User's responsibility to either stop applying the product for the non-covered uses or create a supplement to the CSR to cover these additional uses and report to ECHA.

4) **Previously unknown risk to human health or the environment**

An Only Representatives may become aware, for example as result of information from a SIEF member or his Principal or as result of newly generated test data, that a substance covered by him poses a previously unknown risk to human health or the environment.

In such a case, the Downstream Users should be informed.

Best Practice is the following

- Where the Only Representative becomes aware of a previously unknown risk to human health or the environment for one of the substances covered, the Only Representative should communicate this clearly to all affected Downstream Users. This includes PBT and vPvB properties as per Annex I 6.5.

5) **Unsolicited downstream user communications**

Occasionally, a Downstream User may take the initiative to contact the Only Representative directly. Given that the Only Representative is representing the Principal, the OR should act in a professional manner and provide accurate information in a timely fashion.

Some specific scenarios to be anticipated include:

SDS Request: The Downstream User wishes to receive a Safety Data Sheet.

Although not 'Best practice', it is possible that the Principal does not provide any Safety Data Sheets to his EU customers or does not proactively distribute them. Where this is the case, Only Representatives are sometimes asked for a Safety Data Sheet.

Best Practice is the following:

- If the Only Representative is distributing the Safety Data Sheets for his Principal, the Only Representative should check if the Downstream User is indeed a customer of his Principal. Assuming that this is the case, the SDS should be sent to the Downstream User, or he should be directed to the website if this is the chosen distribution vehicle.
- If the Only Representative is not distributing the Safety Data Sheets for his Principal, the Downstream User should be directed to the Principal.

New hazard data or inappropriate risk management measures: A downstream user communicates hazard data that they believe the OR or his Principal should be aware of or inappropriate risk management measures.

Best Practice is the following:

- Where a Downstream user communicates hazard data or inappropriate risk management measures, the Only Representative should evaluate the importance of the data from a REACH perspective and advise his principal.
- If the information warrants a change in the dossier of an already registered substance, the CSR and any Exposure Scenarios may have to be changed. ECHA will need to be advised and the registration dossier must be updated.
- If the information relates to a dossier in preparation, the data will need to be added to the IUCLID file. If the lead registrant is another company, the Downstream User would need to be directed to the Lead Registrant.
- In all of the above situations, the OR may have to negotiate with the Downstream User regarding data compensation costs.

ANNEXES

Annex 1: Documents required for SME verification

ECHA Information request

> *Please note: Over time ECHA has occasionally changed the exact wording of their requests for information. The text below dates from mid-2013; it is not guaranteed to be identical to the text in future ECHA letters.*

ECHA starts the verification process by sending a letter asking for information. Below the relevant text from such an ECHA letter is quoted.

1. *Ownership structure at the date of the submission(s) in REACH-IT, including all partner and linked enterprises upstream and downstream, taking into account any shares, voting rights or other exercise of influence relevant to determining linkages and partnerships, as appropriate, within the meaning of Article 3 of the Annex to the Commission Recommendation. Please note that the ownership structure is to include enterprises which are linked through other partner or linked enterprises, if applicable.*
2. *Copies of the official audited financial accounts, together with the accompanying notes and annual reports, for the two latest approved accounting periods preceding the time of the submission(s). Similar documents should be provided also for any partner and linked enterprises, in accordance with Articles 3, 4 and 6 of the Annex to the Commission Recommendation. In addition, in case the company concerned and/or any of its partner and linked enterprises draw up consolidated accounts or are included by consolidation in the accounts of another enterprise, you are requested to submit these consolidated statements with the accompanying notes and the annual reports for the two latest approved accounting periods preceding the time of the submission(s) as well.*
3. *Official certificate/information from an Official Authority confirming the headcount of staff that corresponds to the number of annual work units CAWU1), in accordance with Article 5 of the Annex to Commission Recommendation, for the two latest approved accounting periods preceding the time of the submission(s). Similar documents should be provided for all partner and linked enterprises in accordance with Article 6 of the Annex to the Commission Recommendation. In case this information is included in the annual reports or the notes to the audited financial statements, you are not required to submit these documents.*

Lessons learnt

Below are given a number of lessons learnt by Only Representatives who have successfully passed an SME verification.

> *Please note: This list is certainly not comprehensive and there is no guarantee that ECHA will always accept the solutions offered below!*

Annual reports: Annual reports generally contain the figures for both the reporting year and the preceding year. Although the required figures for both years are contained in the most recent report, it will only contain the notes for the most recent year. Since notes may contain important information, the full report of the previous year must also be submitted.

Audited financial accounts: In some countries, the annual accounts of very small companies are not truly audited. The accountant produces the accounts based on information provided to him by the management of the company. Such accounts produced by an independent external accountant are however accepted by ECHA.

Headcount: Unless information on the headcount is included in the annual report, ECHA requires a certificate from an official authority confirming the headcount. In some countries this sort of certificate from official authorities does not exist. In such a case it is recommended to ask the accountant who made the annual report, to produce a letter certifying the headcount.

Translations: If the information is not available in an EU language an official translation must be provided. Translation into English is best for rapid progress. It must be a 'certified' translation. The translation should make clear who the translator was. A document proving that the translator was 'certified' should be added.

Ownership structure 1: Where a company is autonomous, it may be difficult to prove that there are no linked or partnered enterprises. In such a case it is recommended to ask the accountant who made the annual reports to certify that Mr. Xxx is the sole owner of the company, has full authority over it and that he does not own any other companies or businesses.

Ownership structure 2: If the SME that is being verified itself owns other companies or parts thereof, the annual accounts often adequately describe these holdings. In that case no additional documents are necessary to describe this part of the ownership structure. It is however still necessary to provide the annual accounts of these other companies when they are to be considered as partner or linked enterprises.

Annex 2: ORO Position Paper 'Only Representatives and Safety Data Sheets'

Summary

Where importers wish to be provided with Safety Data Sheets (SDS) by either their non-European Union (EU)-based supplier or its Only Representative, this will have to be agreed on a Business-to-Business basis. Neither the non-EU based supplier nor its Only Representative (OR) has a legal obligation under REACH to provide safety data sheets.

In practice, non-EU producers often provide SDS to their European customers. They may do this for reasons of efficiency, quality assurance, or to safeguard confidential business information. Only in this particular case the OR must keep the information on the dissemination of the SDS available and up-to-date.

Only Representatives also often provide a service with regard to SDSs. They may prepare the SDSs for their non-EU based customers and may even distribute these to the importers. This, however, does not imply an obligation under REACH to do so, let alone a responsibility for the content or liability in the case of non-compliant SDSs.

The Issue

Where non-EU based producers of substances or formulations have appointed an OR, both importers and authorities often assume that the OR has the obligation to provide SDSs for the imported products.

This assumption is thought to be substantiated by REACH Art. 8.2 and 8.3, which state that the Only Representative '*shall also comply with all other obligations of importers under this regulation*' and that the importers '*shall be regarded as Downstream Users*'. In addition, Art.

8.2 obliges the Only Representative to '*keep available and up to date ….. information on the supply of the latest update of the safety data sheet referred to in Art. 31*.'

Legal analysis

No Obligation for the Non-EU Producer

- Art.31 obliges '*suppliers*' to provide '*recipients*' with an SDS. According to definition Art. 3 No. 32, a '*supplier*' is either '*a manufacturer, an importer, a downstream user or a distributor*'.
- Each of these four categories of REACH actors are defined as natural or legal persons '*established in the community*' (definitions Art. 3 Nos. 9, 11, 13 and 14). The non-EU based producer of substances, formulations or articles therefore is not, and cannot be, a '*supplier*' according to REACH.
- As a result, the non-EU based producer of the substance or preparation does not have the obligation to supply the importer with an SDS.

It may be interesting to note that for similar reasons, an EU-based company that is exporting to non-EU countries also does not have an obligation to provide a SDS to its non-EU customer. In this case, the non-EU customer is not a '*recipient*', since a '*recipient*' must also be an EU-based legal entity.

No Obligations for the Only Representative

- The first time that an obligation to supply a SDS exists in the supply chain is when one EU based legal entity (the *'supplier'*) supplies the product to another EU- based legal entity; the '*recipient*'.
- A downstream user who places a substance or preparation on the market is a '*supplier*' and has all the obligations associated with this role.
- The fact that through the appointment of an OR the '*importer*' has become a '*downstream user*', does therefore not relieve him of this duty to provide an SDS to his customers.

Discussion

Transportation and Storage

The safety of product transportation and storage en route from the non-EU producer to the importer does not fall within the scope of REACH. It is regulated elsewhere and special safety documents must be provided; also by the non-EU based producer.

Import Means Placing on the Market

It could be argued that since according to definition Art. 3 No. 12, '*import shall be deemed to be placing on the market*', the importer automatically becomes a '*supplier*' according to definition 32. If at the same time he could also be called a '*recipient*', he might, according to Art.32, have the obligation to provide himself with an SDS; however, only downstream users or distributors can be '*recipients*' according to definition Art. 3 No. 34. An importer cannot be a '*recipient*'. As a result, an importer does not need to provide himself with an SDS, and there is consequently also no such obligation for the OR.

This is analogous to the situation of the manufacturer, who also does not have to provide an SDS to himself. The obligation to provide an SDS arises as soon as the product is supplied to a recipient.

Where the importer has no obligation to provide himself with an SDS, there is also no obligation for the OR to take over any obligation from the importer.

OR Obligation to Maintain Dissemination Records

It is logical that if, in spite of the lack of any legal obligation, a non-EU producer or his OR disseminate SDSs, the OR is to keep the records associated to this dissemination. These records should be carefully maintained. The OR is the only EU-based legal entity eligible for this work.

An obligation to keep records in the case that there is a dissemination of SDSs may very well co-exist with a lack of a legal obligation to provide an SDS. The obligation to keep the records does not imply any legal obligation to provide the SDS in the first place.

REACH Annex II

REACH Annex II, under 'Requirements for the Compilation of Safety Data Sheets', Part A, subsection 1.3, mentions the Only Representative as a possible 'supplier'. This could be read as to mean that, in contradiction to the above, an Only Representative can be a supplier. The word supplier here however is not intended to be understood as the supplier of a product, but as the supplier of the Safety Data Sheet itself.

The title of this section makes this clear: 'Details of the supplier of the Safety Data Sheet'. As argued above, it is indeed possible that an Only Representative supplies Safety Data Sheets, even if he has no legal obligation to do so.

ORO Support

ORO is always prepared to support, contribute with its expertise and cooperate with ECHA, the European Commission and Member States in order to help find appropriate solutions for the implementation of REACH.

ORO is the professional industry association of Only Representatives, which represents the interest of non-EU manufacturers and ORs and has set-up quality standards for Only Representatives.

Annex 3: Commission letter to an ORO member regarding the OR obligations with regard to Safety Data Sheets

ARES Reference: ARES (2012)473810 – 18/04/2012.

Dear Mr XXX,

Thank you for the question concerning the REACH requirements for the OR and the safety data sheet that you addressed to the REACH Unit of DG Enterprise and Industry.

ORs are subject to a specific legal status outlined in Article 8 of the REACH Regulation. In order to tackle your question, Articles 8(2) and 31 of the REACH Regulation, as well as the adaptations brought by the Commission Regulation (EU) No 453/2010 to the Annex II to the REACH Regulation are relevant.

To answer your question, please note that our reply distinguishes three different situations:

a) Situation when the OR does not act as actual supplier in the supply chain;

b) Supply of the SDS when the OR also acts as an actual supplier of a substance;

c) Substances in mixtures.

a) The OR does not act as actual supplier in the supply chain

An OR is responsible, as a registrant, to ensure the consistency of the SDS with the registration dossier and the Chemical Safety Assessment in particular. To this end, they have to place the relevant exposure scenarios in an annex to the SDS covering identified uses and including specific conditions resulting from the application of Section 3 of Annex XI. They would need to provide the importer (now downstream user) with all that information. Additionally, in line with Section 1.3 of Annex II, the OR should be identified in the SDS if such SDS is supplied by the non-EU manufacturer to the importer (details of the non-EU manufacturer or formulator may also be provided). The registration number should be also provided by OR to the importer (now downstream user). In sum, the OR should be responsible for providing the importer (now downstream user) with all the necessary elements so that he is able to compile his own SDS for further recipients down the supply chain. In any case the individual importer (now downstream user) who supplies the substance further on the market will have to supply the SDS with his identification as the supplier of the SDS vis-à-vis his recipients of the substance.

b) Supply of the SDS when the OR also acts as an actual supplier of a substance

ORs could themselves be responsible for the physical introduction of a substance into the EU customs territory and subsequently act as suppliers of this substance to recipients in their supply chain.

In such a case, apart from the obligations mentioned above under point a), they have to provide SDS and have to be also indicated in it for the substance they supply to their recipients as per Article 31(1).

c) Substances in mixtures

Where the ORs were appointed by the non-EU manufacturers of substances, as opposed to non-EU formulators of a mixture, ORs are not in a position to bear the responsibility to provide an SDS for a mixture. Nevertheless, ORs should provide the mixture importer at least with the necessary elements regarding their registered substance with a view to facilitating the compilation of the SDS for the mixture.

For further inquiries on REACH and CLP matters, please contact the national REACH and CLP Helpdesk at the following address http://echa.europa.eu/reach/helpdesk/nationalhelp_contact_en.asp.[5]

Hoping that this reply answers your question, we thank you for having contacted the REACH Unit of DG Enterprise and Industry.

Yours sincerely,

Chemicals - REACH Unit
European Commission
DG Enterprise and Industry

The above represents the position of the concerned service of the European Commission and is not an official position of the European Commission. The Commission does not assume any legal liability or responsibility for the accuracy or completeness of the content of this message. This e-mail, including any files transmitted with it, is confidential and intended solely for the use of the individual to whom it is addressed. If you have received this message in error, please notify me as soon as possible.

[5] At the time of revision of this Guide, the URL for the Helpdesks has changed to the following: https://echa.europa.eu/support/helpdesks/

Annex 4: Commission letter dd 24 April 2010, regarding the registration numbers on Safety Data Sheets

EUROPEAN COMMISSION

DIRECTORATE-GENERAL FOR ENTERPRISE AND INDUSTRY
Chemicals, Metals, Forest-based & Textile Industries, Raw materials
Chemicals - REACH

Brussels,
ENTR/G1/RL/al /

Dieter Drohmann
ORO President
ORO AISBL
Chaussée de Roodebeek 206
B-1200 Brussels

Subject: Registration numbers on safety data sheets

Dear Mr. Drohmann,

Thank you for your letter of 24 April 2010 to Mr Otto Linher regarding the registration numbers on safety data sheets in case of only representatives of non-EU based formulators of mixtures.

The only representative appointed in accordance with Article 8(1) REACH fulfils the registration obligations on importers and, pursuant to Article 8(2), shall comply with all other obligations of importers under REACH.

As you mention, the Commission Regulation (EU) No 453/2010 amending Annex II to REACH[1] brings about the possibility for the suppliers of safety data sheets to omit the part of the registration number referring to the individual registrant of a joint submission, under certain conditions, with effect from 1 December 2010.

In the case of a substance, this possibility will be granted to the supplier who is either a distributor or a downstream user (see subsection 1.1 of Annex II, as applicable from 1 December 2010). In the case of a mixture, for substances indicated in subsection 3.2 of the safety data sheet, this possibility will be granted to the supplier of the mixture (see subsection 3.2.4 of Annex II, as applicable from 1 December 2010).

Furthermore, subsection 1.3 of the new Annex II specifies who is considered as a supplier of the safety data sheet for the purpose of this Annex. Only representative is specifically referred to in this subsection as a supplier of the safety data sheet who needs to be thus identified therein. The last paragraph of this subsection further specifies that where an only representative has been appointed, details of the non-Community manufacturer or formulator may also be provided.

---

[1] Commission Regulation (EU) No 453/2010 of 20 May 2010 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), OJ L 133, 31.5.2010, p.1

Commission européenne, B-1049 Bruxelles / Europese Commissie, B-1049 Brussel - Belgium. Telephone: (32-2) 299 11 11.
Office: BREY 12/112. Telephone: direct line (32-2) 299.63.28. Fax: (32-2) 298.88.21.
e-mail: Robert.Lindenthal@ec.europa.eu

Taking all this into account, in our view, as from 1 December 2010, the only representative of a non-EU based formulator of a mixture would be able to rely on the possibility granted by subsection 3.2.4 of new Annex II to omit the part of the registration number for the substances indicated in subsection 3.2 and referring to the individual registrant of a joint submission, i.e. individual four last digits of his own registration numbers.

However, in case he provides a safety data sheet to an actual importer of the mixture from outside the EU, he will be in direct contact with this importer in any case in order to relieve this importer of his obligations as importer under REACH. Similarly, the actual importer must be informed by his non-EU based supplier of the appointment of an only representative pursuant to Article 8(3) REACH. Consequently, there does not seem to be any particular confidentiality concern and no particular interest for omitting the individual part of the registration number at this stage in the supply chain.

The actual importer of the mixture (covered by the OR registration of substances in this mixture) shall be regarded as downstream user for the purpose of REACH. He shall be also regarded as supplier of the mixture and will be also granted the possibility to omit the part of the registration number referring to the individual registrant of a joint submission.

In any case, if an only representative omits part of the registration number, he will have to assume the responsibility to provide the full registration number upon request for enforcement purposes to the enforcement authority within 7 days upon request received either directly from the enforcement authority or forwarded by his recipient.

In conclusion, I believe that the current text of Annex II already provides the possibility to address your concerns.

Yours sincerely,

Graham Willmott
Head of Unit