

## REACH Registration of Monomers in Polymers

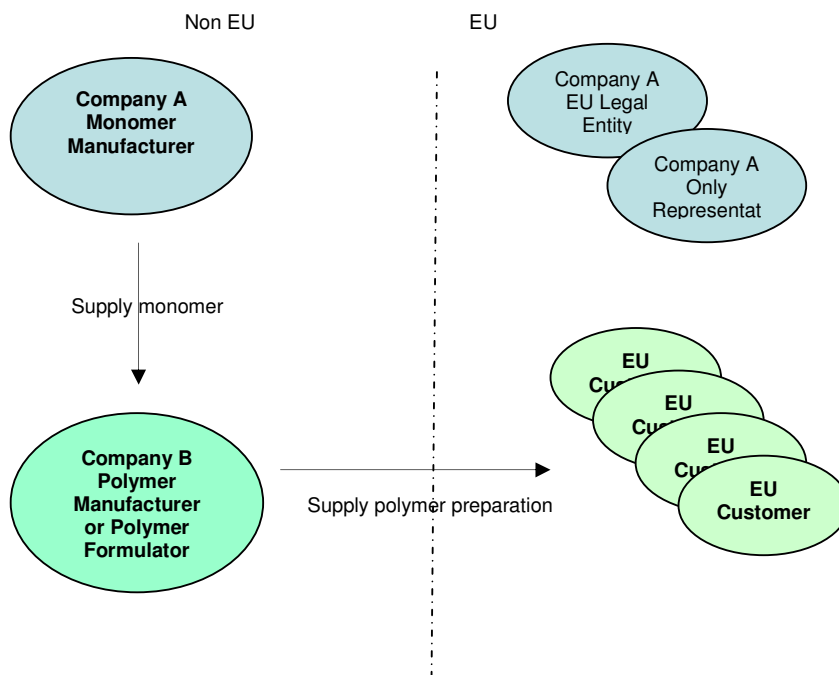
### Executive Summary

Article 6.3 of REACH states that any manufacturer or importer of a polymer shall submit a registration to the Agency for the monomer substance(s) or any other substance(s) that have not already been registered by an actor in the supply chain. The information collated must include tonnages greater than 1tpa and details of customers and uses.

This allows for a polymer importer to refer to the registration by their suppliers. In the case on non-EU manufactured monomers this may be via the appointment of an Only Representative (OR). Fischer<sup>(1)</sup>, commissioned by the VCI, provides the legal opinion on this process, concluding that the obligations can be met by appointment of an OR to complete the registration process and the nomination of Trustees to maintain records of Downstream Users and volumes imported into Europe.

This assessment reviews the practicality of this approach against the other options for registration, concluding that individual registrations should be made by the substance manufacturers but that the responsibility for compiling the information to confirm the polymer volume supplied to the EU is fully compliant with REACH should be taken by the polymer manufacturer.

### Registration of Monomers within the Supply Chain



There are 3 options as to who registers:  
 The EU customers importing the polymer  
 The non-EU manufacturer of the polymer (company B)  
 The non-EU manufacturer of the monomer (company A)

Any of these options is acceptable under the regulation. However, some have significant downsides and these are assessed within this document. This assessment requires an understanding of the obligations for registration of polymers imported to the EU.

## Registration obligations for polymers imported to the EU

The following information is extracted from the Guidance for Monomers and Polymers <sup>(2)</sup>:

*Polymers are exempted from the provisions on registration of Title II of REACH (Article 2(9)). The manufacturer or importer of a polymer is therefore generally not required to provide to the Agency any information related to the intrinsic properties of the polymer itself, with the exception of its classification and labelling when applicable (see Section 3.2.4).*

*According to Article 6(3), the manufacturer or importer of a polymer must however submit a registration to the Agency for the monomer substance(s) or any other substance(s), that have not already been registered by an actor up the supply chain, if both the following conditions are met:*

- (a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);*
- (b) the total quantity of such monomer substance(s) or other substance(s) makes up 1 tonne or more per year (the total quantity in this context is the total quantity of monomer or other substance ending up in the final polymer unbound or chemically bound to the polymer)*

*Therefore, the manufacturer or importer of a polymer will not need to register the monomer substance, or any other substance chemically bound to the polymer, if these have already been registered by the supplier or another actor up their supply chain. For most polymer manufacturers the situation will generally be that their monomers and other substances will be registered by the suppliers of these substances. However, for an importer of a polymer consisting of monomer(s) or other substance(s) fulfilling both the conditions (a) and (b) stated above, the monomer(s) or other substance(s) must be registered unless:*

- an only representative has been appointed by the non-Community polymer manufacturer to fulfil the obligations of the importer. In this specific case, it is the duty of the only representative to proceed with the registration of the monomer(s) (Article 8), or*
- the monomer substances or any other substances used for the manufacture of the polymer have already been registered up the supply chain, e.g. if they have been manufactured within the Community and exported to a non-Community polymer manufacturer.*

*Importers of polymers do not need to register the quantity of additives necessary to preserve the stability of the polymer as they are part of the polymer (see section 2.2).*

The guidance also states that 'In order to establish their obligations under REACH, and to avoid the need for carrying out any complex chemical analysis on the polymer composition, the importer of a polymer should preferably obtain from the non-Community polymer manufacturer at least the information on the identity of monomers and any other substance chemically bound to the polymer, as well as compositional details of the polymer substance'. This document reviews whether it is possible for the necessary information can be simplified to a polymer manufacture certificate of conformity to REACH registration.

## Appointment of an Only Representative – The Legal Opinion

The following information has been extracted from that analysis by Fischer <sup>(1)</sup>.

*Any non-EU person who manufactures a substance on its own, in preparations or in articles is eligible to appoint an OR. This is clarified as applicable to a non-Community monomer or polymer producer, a non-Community formulator or a non-Community producer of an article. It does not, however, apply to a non-Community distributor.*

*Additionally, once a manufacturer has appointed an OR then Articles 8(1) and (2) place the obligations of the importer on the OR. This includes that the OR "shall keep available and up-to-date information on quantities imported and customers sold to" (Article 8 (2)). However, this does not mean that the OR has to fulfill these obligations personally. Under specific circumstances, especially to protect confidential information of third parties (e.g. on the supply chain), the OR may involve a trustee. The trustee keeps the information available and can submit it to the ECHA (or the national authorities) on behalf of the OR. In such a case, the trustee would factually submit the information, but he would be obliged to do so, based on his contract with the OR. The bottom line is that the flow of information to the authorities would not be affected, and, at the same time, confidential business information could be protected effectively.*

## Options for Registration

Taking the guidance on monomers and polymers into account and using the assessment by Fischer it can be concluded that whilst the obligation is with the importer of the polymer to ensure that the qualifying components are registered, this may be by demonstration that the registration has been completed within the supply chain. If this is not the case then result will be that many customers importing polymers will be forced to register as separate legal entities. Each will need a registration and access to the composition of the polymer (monomer, reactants and additives) and letters of access to the dossiers. This will increase the complexity of the SIEF management and may force de-selection of suppliers that cannot demonstrate REACH registration. The table below summarises the issues associated with each option for registration within the supply chain.

Options for Registration	Pros	Cons
Company A EU Legal Entity registers import of monomer	EU established legal entity already registering includes imported volume and can place substance on the market on behalf of non-Community manufacturer	Only downstream users within the supply chain of the EU legal entity are supported. Non-EU polymer producers or formulators with customers within the EU will have to make other provisions (either register themselves or find alternative supplier or registered monomer)
Company B non-EU polymer manufacturer nominates OR to register polymer	Company B's supply chain will be supported through their registration.	Each polymer manufacturer in the role of Company B must appoint an OR (multiple registrations) and will require access to documentation complicating the SIEF with multiple downstream users. Company B will have to register all qualifying components within the polymer and submit multiple registrations. Companies in position of Company B may look to source raw materials from alternative registered supplier.
Company C non-EU formulator appoints OR to register preparations	Company C's downstream supply chain is supported through registration	Each manufacturer in the role of Company C requires composition details for the polymer supplied by Company B and must submit a registration for each qualifying substance. This results in multiple registrants of multiple substances and floods the SIEF with downstream users. Companies in position of Company C may look to source raw materials from alternative registered supplier.
EU Customers register	EU customer can demonstrate registration	Each EU customer requires detailed composition of the polymers or preparations and letters of access to multiple dossiers and data sets. Each SIEF becomes flooded with Downstream Users and customers may look to source material already compliant through alternative suppliers (potentially EU).
Company A non-EU monomer manufacturer appoints OR to register volume to support direct monomer export to EU plus downstream user polymer exports	One single registration supports the downstream supply chain for Company A non-EU monomer manufacturer	The appointed OR has the obligation to maintain information on volumes imported and customers sold to. A system for appointment of 'trustees' will be required.

### Conclusion: Registration at the top of the supply chain – The practical solution

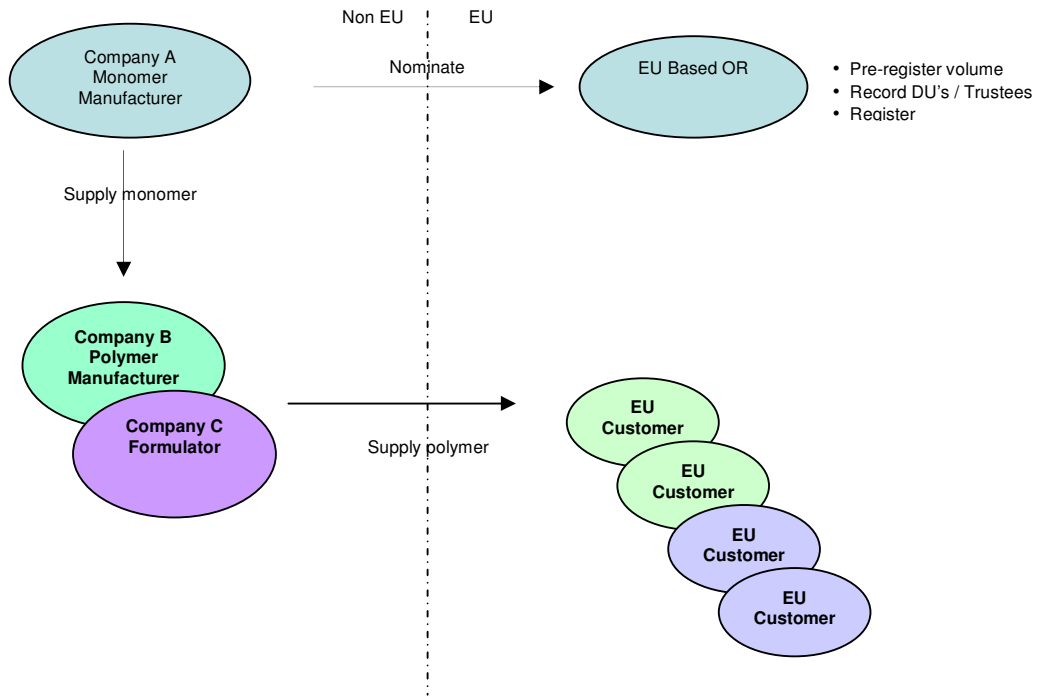
Registration by an Only Representative of the non-Community manufacturer is the only enabler to supporting the full supply chain. This reduces the risks to the manufacturer associated with loss of downstream users seeking alternative registered suppliers and over complication of the SIEFs. There are, however, some systems that require to be established to provide the necessary information to the Only Representative. The flowcharts in Appendix 1 & 2 demonstrates the overview of the practical implementation of this process

### References

1 The Only Representative under REACH – Legal Opinion – commissioned by the Verband der chemischen Industrie (VCI) – Rechtsanwalt Professor Dr Kristian Fischer

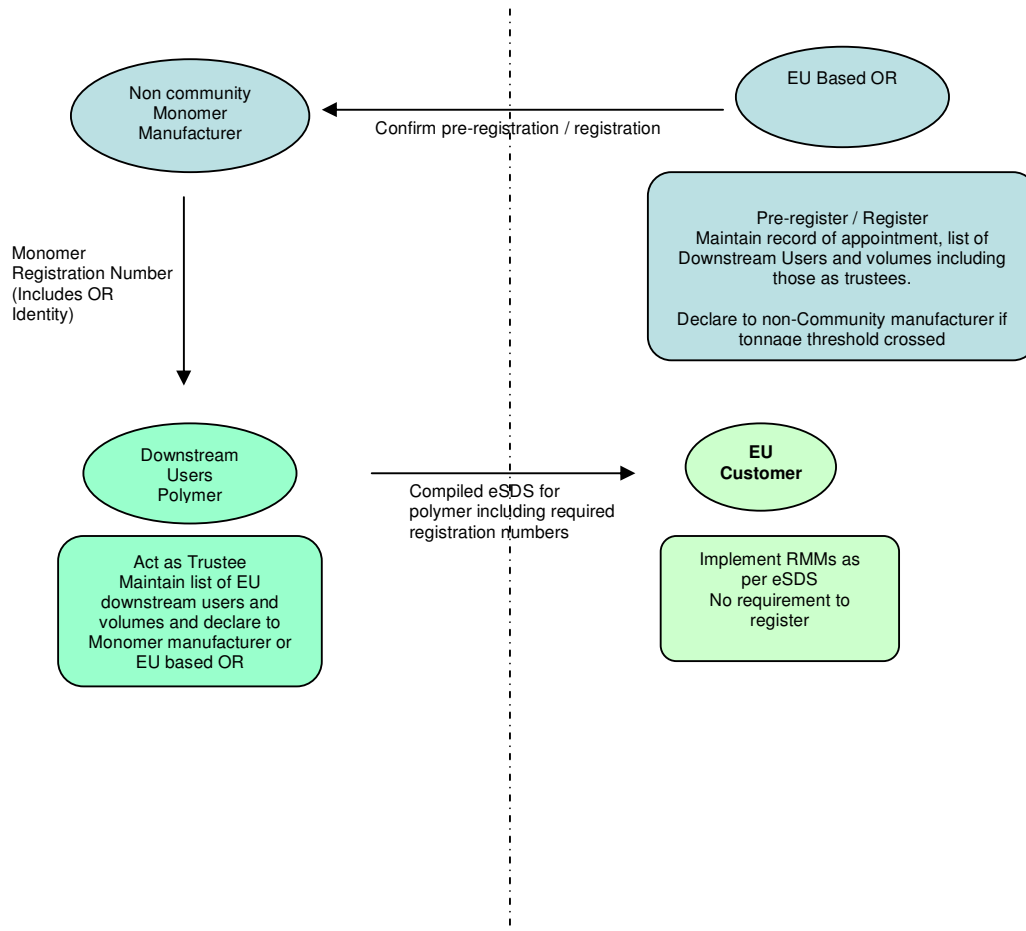
2 ECHA Guidance for monomers and polymers

**Appendix 1: Overview of Information Requirements for Use of Non-EU Monomer Manufacturer Registration**



Position in Supply Chain	REACH Obligations if Monomer Manufacturer Registers	Information Requirements
Company A: Monomer Manufacturer	Appointment of Only Representative	Declaration of substances, customers and volume bands to OR. This may be through nomination of one or more Trustees. Confirmation of identity of OR to Trustees
EU Based OR	Obligation to register correct volume band	Retention of identity of approved trustees and information from each trustee and Company A on volumes and uses
Company B / C: Non Community polymer manufacturer or formulator	Confirmation of volumes and uses to EU based OR if acting as trustee	Record of volumes exported to EU as 3 year average. Records to be retained for 10 years
EU Customer	No obligation to register Implement appropriate RMMs	REACH compliant eSDS from supplier

**Appendix 2: Information Flow for Registration Process of non EU Manufactured Monomers**



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