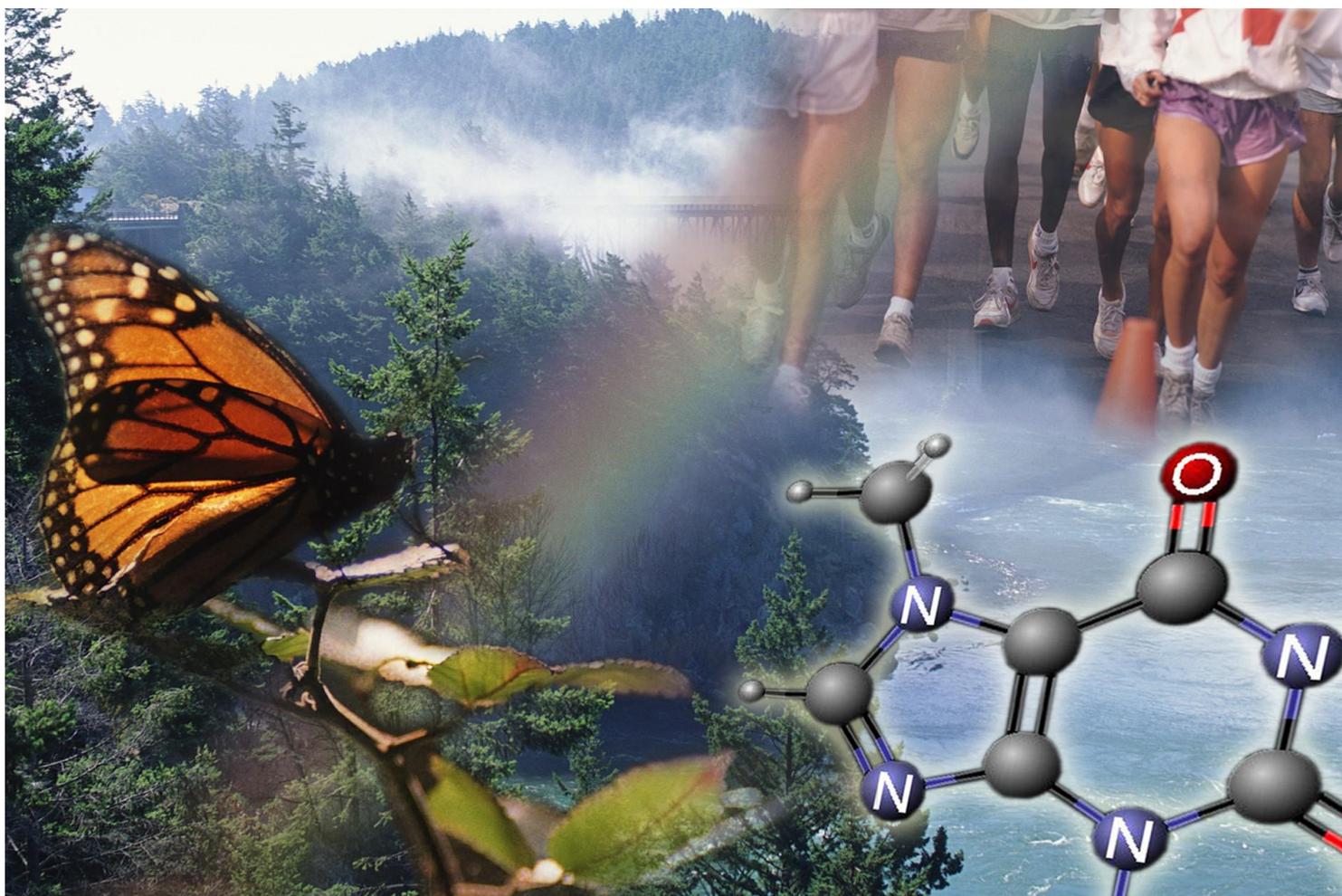


Guidance for monomers and polymers



June 2007

LEGAL NOTICE

This document contains guidance on REACH explaining the REACH obligations and how to fulfil them. However, users are reminded that the text of the REACH regulation is the only authentic legal reference and that the information in this document does not constitute legal advice. The European Chemicals Agency does not accept any liability with regard to the contents of this document.

PREFACE

This document describes the specific provisions for polymers and monomers under REACH. It is part of a series of guidance documents that are aimed to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents cover detailed guidance for a range of essential REACH processes as well as for some specific scientific and/or technical methods that industry or authorities need to make use of under REACH.

The guidance documents were drafted and discussed within the REACH Implementation Projects (RIPs) lead by the European Commission services, involving all stakeholders: Member States, industry and non-governmental organisations. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/reach_en.html). Further guidance documents will be published on this website when they are finalised or updated.

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1 INTRODUCTION

Polymers constitute the material of choice in a vast range of applications such as packaging, building and construction, transportation, electrical and electronic equipments, agriculture, as well as the medical and the sport sectors. The versatility of polymeric materials is based on the fact that the physico-chemical properties of polymers can be tailored by a careful adjustment of the composition and molecular weight distribution of the molecules constituting the polymer.

Owing to the potentially extensive number of different polymer substances on the market, and since polymer molecules are generally regarded as representing a low concern in relation to their high molecular weight, this group of substances is exempted under REACH from registration and evaluation. Polymers may however still be subject to authorisation and restriction.

Manufacturers and importers of polymers may also be required to register the monomers or other substances ending up as building blocks of the polymer, as these molecules are generally recognised as of higher concern than the polymer molecule itself.

2 DEFINITIONS

2.1 Monomer

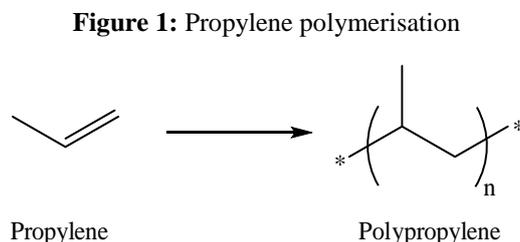
REACH defines a monomer as *a substance which is capable of forming covalent bonds with a sequence of additional like or unlike molecules under the conditions of the relevant polymer-forming reaction used for the particular process* (Article 3(6)). In other words, it is a substance which, under the polymerisation reaction, is converted into a repeating unit of the polymer sequence. Substances exclusively involved in the catalysis, initiation or termination of the polymer reaction are not monomers. Any monomer is therefore by definition an intermediate. Nonetheless, the specific provisions for the registration of intermediates under REACH do not apply to monomers.

For applications outside the scope of polymerisation, the same substance is not regarded as a monomer. If it is used as an intermediate, it might fulfil the conditions to benefit from the specific provisions for the registration of intermediates under REACH (see the [Guidance for intermediates](#)). Otherwise, it will have to follow all REACH requirements for a “normal substance” with registration requirements in accordance with Title II (see the [Guidance on registration](#)).

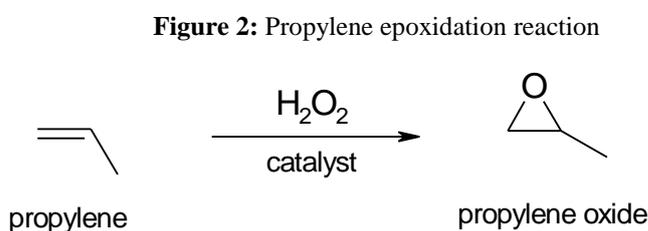
An illustration of the definition of monomer is provided in Example 1.

Example 1 Monomer definition: the propylene case

Propylene is to be considered as a monomer under REACH when it is used for the purpose of polymerisation process such as polypropylene manufacture, as illustrated in **Figure 1**:



Propylene may also be used for the manufacture of propylene oxide, for instance according to a catalytic epoxidation reaction with hydrogen peroxide. The reaction is illustrated in **Figure 2**. For this application, propylene is in fact an intermediate but is not regarded as a monomer.



Another example of application for propylene is its utilisation as fuel gas in certain industrial processes. In this specific case, propylene is not regarded as an intermediate or as a monomer.

2.2 Polymer

A polymer is a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units.

In accordance with REACH (Article 3(5)), a polymer is defined as a substance meeting the following criteria:

- (a) Over 50 percent of the weight for that substance consists of polymer molecules (see definition below); and,
- (b) The amount of polymer molecules presenting the same molecular weight must be less than 50 weight percent of the substance.

In the context of this definition:

- A "**polymer molecule**" is a molecule that contains a sequence of at least 3 monomer units, which are covalently bound to at least one other monomer unit or other reactant.
- A "**monomer unit**" means the reacted form of a monomer substance in a polymer (for the identification of the monomeric unit(s) in the chemical structure of the polymer, the mechanism of polymer formation may for instance be taken into consideration).
- A "**sequence**" is a continuous string of monomer units within the molecule that are covalently bonded to one another and are uninterrupted by units other than monomer units.

This continuous string of monomer units can possibly follow any network within the polymer structure.

- "**Other reactant**" refers to a molecule that can be linked to one or more sequences of monomer units but which cannot be regarded as a monomer under the relevant reaction conditions used for the polymer formation process.

These definitions are exemplified in Example 2.

Whenever it is not scientifically possible to establish whether the substance falls under the definition of polymer or identify the chemical structure of the monomer units or any other unit as well as their concentration in the substance, the substance can be regarded as a UVCB substance, i.e. substance of Unknown or Variable composition, Complex reaction products or Biological material (see [Guidance on substance identification](#)). In this case the registration of the substance itself can be submitted (see the [Guidance on registration](#)).

2.3 Manufacture of polymer

Any legal or natural person established within the Community, who manufactures a polymer substance, or isolates a polymer substance in its natural state, is a polymer manufacturer (Article 3(8) and 3(9)).

It should be highlighted that polymers may be synthesised not only from the polymerisation of monomers, but also from other processes such as the chemical post-modification of polymer substances. Examples of such post-modification reactions include polymer curing, polymer functionalisation via grafting, and controlled polymer degradation such as visbreaking.

Example 2 : Example illustrating the definitions of section 2

To illustrate the definitions given in **Section 2.1 and 2.2**, let us consider a polymer forming reaction taking place when ethylene oxide is reacted with phenol.

Figure 3 represents the different molecules susceptible to be formed upon completion of this ethoxylation-type of polymerisation reaction.

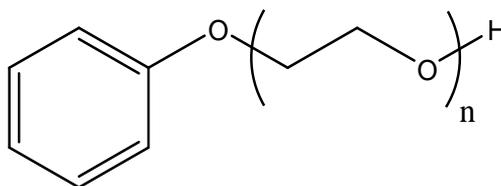


Figure 3: ethoxylated phenol (n is an integer, $n \geq 1$)

The **monomer unit** is in this case the opened epoxide $-(\text{CH}_2-\text{CH}_2-\text{O})-$

Phenol acts as the initiator of the ethoxylation reaction, and must be regarded as an "**other reactant**" since it cannot react with either itself or an opened epoxide.

The molecule depicted in **Figure 3** would therefore qualify for the definition of "**polymer molecule**" whenever $n \geq 3$.

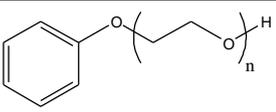
The ethoxylated phenol substance thus manufactured must be regarded as a **polymer** if both following conditions are met:

(a) Over 50 weight percent of the substance consists of polymer molecules, i.e. molecules depicted in figure 2 and for which $n \geq 3$)

(b) None of the polymer molecules having the same molecular weight represent 50 weight percent or more of the substance.

In **Table 1** three different compositions of the ethoxylated phenol substance are considered. For each example, the weight percent of every molecule present in the substance is reported.

Table 1 Molecular composition of 3 examples of ethoxylated phenol substances.

|  | Example 1 | Example 2 | Example 3 |
|---|-----------|-----------|-----------|
| n=1 | 0% | 40% | 5% |
| n=2 | 10% | 20% | 10% |
| n=3 | 85% | 15% | 20% |
| n=4 | 5% | 12% | 30% |
| n=5 | 0% | 8% | 20% |
| n=6 | 0% | 5% | 10% |
| n=7 | 0% | 0% | 5% |
| Sum | 100% | 100% | 100% |

In Example 1, the substance consists of 10% ethoxylated phenol with $n=2$, 85% with $n=3$ and 5% with $n=4$. Since this substance comprises 85 weight percent of the same polymer molecule ($n=3$), it does not meet the definition of polymer. Therefore, it should be considered as a standard substance.

In Example 2, only $15+12+8+5=40$ weight percent of the substance consists of polymer molecules, i.e. molecules for which $n \geq 3$). For this reason, example 2 does not qualify for the criteria of polymer definition either. Therefore it should also be considered as a standard substance.

Example 3 meets the definition of a polymer since $20+30+20+10+5=85$ weight percent of the substance consists of polymer molecules (i.e. molecules for which $n \geq 3$), and none of the different constituent are present at concentrations above 50 weight percent, each constituent having a different molecular weight.

3 TASKS AND OBLIGATIONS

3.1 Manufacture/import of monomers

Manufacturers or importers of monomers have to register their monomers in accordance with the normal registration obligation laid down in Article 6 of REACH. Although monomers are by definition intermediates, these substances cannot be registered in accordance with the provisions which normally apply to on-site or transported isolated intermediates (Article 6(2)) (note however that the provisions of Articles 17 and 18 apply for the other substances used in the manufacture of

the polymer, provided those other substances meet the conditions of those Articles (see the [Guidance for intermediates](#))).

If a natural or legal person manufactures or imports a substance to be used both as a monomer and as non-monomeric intermediate, he needs to submit one “standard” registration dossier according to Article 10. If part of the tonnage manufactured or imported is for a use as non-monomeric intermediate and is handled under strictly controlled conditions, this tonnage will not need to be taken into account for the information requirement of the registration dossier. Nevertheless the use as intermediate should be documented in the dossier, including the volume manufactured or imported for this purpose. For instance, if a manufacturer manufactures 11 tonnes/year of a substance, of which 2 tonnes/year are for use as monomer and the remaining 9 tonnes/year is a non-monomeric intermediate handled under strictly controlled conditions, the registration information requirements for that substance is based on the 2 tonnes/year.

Monomers are by definition intermediates. These substances therefore cannot be subject to authorisation under REACH for the use as monomers in polymerisation reactions.

The manufacturer or importer of a monomer substance has otherwise the same obligations under REACH as for any standard substance: general rules on restriction, information down the supply chain and classification and labelling therefore apply.

3.2 Manufacture/import of polymers

3.2.1 Registration obligation

3.2.1.1 General situation

Polymers are exempted from the provisions of Title II of REACH on registration (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:*

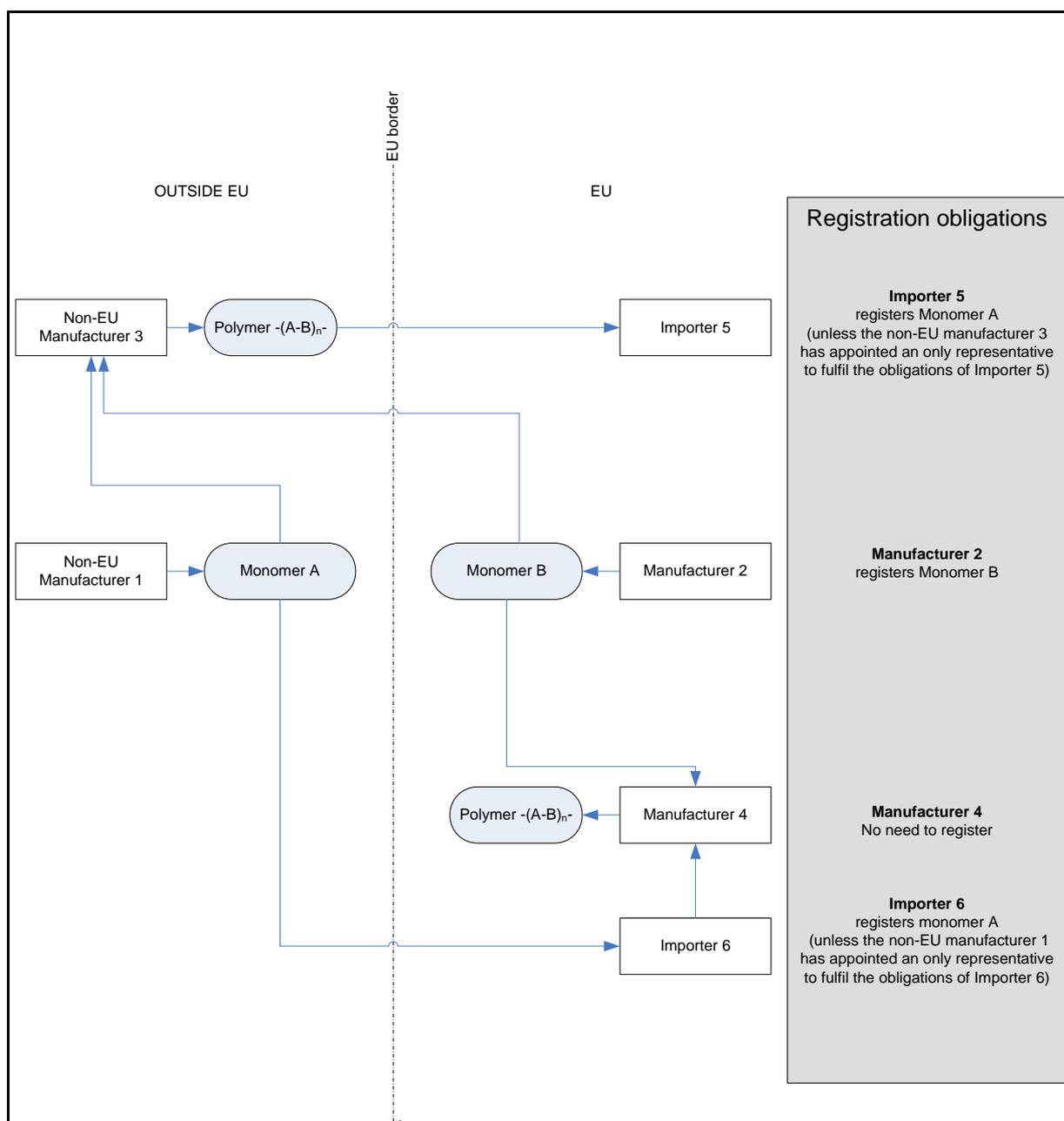
- (a) the polymer consists of 2% weight by weight (w/w) or more of such monomer substance(s) or other substance(s) in the form of monomeric units and chemically bound substance(s);*
- (b) the total quantity of such monomer substance(s) or other substance(s), i.e. the quantity of these substances ending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

Thus, 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 manufacturers of polymers, registration of the monomer(s) and any other substance(s) by their supplier(s) will mostly be the standard situation. However, for an importer of a polymer consisting of monomer(s) or other substance(s) fulfilling both the conditions (a) and (b) depicted 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 case only, 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 polymer manufacturer.

The registration requirements for the different actors in the supply chain are illustrated in Example 3.

Example 3 Registration obligations of the different actors of the monomer and polymer supply chains



With the purpose of establishing their obligations under REACH, and in order 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. Alternatively, this information may also be generated from the analytical methods specified in **section 4**.

Registration of the monomers and of the substances described above has to be prepared as for any other substances and guidance can be found in the [Guidance on registration](#). In Example 4, the considerations on the monomers or other substances to be made for the purpose of registration by the importer of a polymer are illustrated.

3.2.1.2 Case of a polymer notified in accordance with Directive 67/548/EEC

A manufacturer or importer of a polymer, who has carried out a notification of this polymer in accordance with Directive 67/548/EEC, does not need to register the monomer(s) or any other substance(s) meeting the conditions (a) and (b) of Article 6(3) if:

- he has already notified these monomers or other substances in accordance with Directive 67/548/EEC, or
- these monomers or other substances have already been notified by an actor up the supply chain in accordance with Directive 67/548/EEC (Article 24 of REACH), or
- these monomers or other substances have already been registered by an actor up the supply chain.

For all other situations, the Commission services are examining what needs to be done and the guidance will be updated as soon as possible.

3.2.1.3 Case of a naturally occurring polymer or a chemically modified naturally occurring polymer

A manufacturer or importer of a naturally occurring polymer is exempted from any registration provisions under Title II, provided that the polymer fulfils the definition of a naturally occurring substance and that the polymer has not been chemically modified and does not meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC (see Article 2(7)(b) and Annex V(8)). Under these circumstances, he does therefore not need to identify the monomers or any other substances constituting the building blocks of the polymer.

If, on the other hand, a naturally occurring polymer has been chemically modified and/or meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC, the manufacturer or importer of this polymer will have to make the registration of the monomers or any other substances in accordance with Article 6(3). The naturally occurring monomers or any other naturally occurring substance do however not need to be registered unless they meet the criteria for classification as dangerous in accordance with Directive 67/548/EEC (see Article 2(7)(b) and Annex V(8)) or they have been chemically modified. Whenever it is not scientifically possible to identify and quantify the building blocks of such substance of polymeric origin, the substance itself can be regarded as a UVCB substance (see **section 2.2**).

3.2.1.4 Case of a recycled polymer

Companies undertaking recovery of polymer substances from waste are exempted from the obligation to register the monomer(s) or any other substance(s) meeting the criteria of Article 6(3) in the recycled polymer, provided that these substance(s) constituting the recycled polymer have been registered (Article 2(7)(d)).

It is worth noting that this exemption does not require the substance to have been registered by an actor in the same supply chain. Therefore, it is sufficient that a registration was made for the substance, either by an actor in the same supply chain or by a company in another supply chain.

Further information on the registration obligations is provided in section 1.6.4.5 of the [Guidance on registration](#).

Note that if the monomer or any other substance is a phase-in substance, it is recommended that the recycler of the polymer pre-registers that substance in order to benefit from the transitional provisions laid down in Article 23 and eventually be later on exempted from the registration requirements if another pre-registrant registers the substance.

3.2.2 Application for authorisation

Polymers may be subject to authorisation under REACH. Further details on application for authorisation are available in the [Guidance on authorisation application](#).

3.2.3 Compliance with restriction

The monomers, any other substances used to manufacture the polymer and polymers may all be subject to restrictions. Details on the scope of the restrictions are available in Annex XVII (restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles).

Restrictions on a monomer only apply to polymers if the concentration of the residual monomer exceeds specific concentration limits listed for the monomer in Annex XVII.

3.2.4 Classification and labelling

The importer or manufacturer of a polymer has to classify and label the polymer, and, if it is classified as dangerous according to Directive 67/548/EEC and if the polymer is put on the market on its own or in a preparation above the concentration limits specified in Directive 1999/45/EC, where relevant, which results in the classification of the preparation as dangerous, he must notify the Agency. This notification has to be done by the 30th November 2010 if the polymer is already on the market or, from the 1st December 2010 onwards, as soon as the substance is put on the market (Articles 112(b) and 116, see also the [Guidance on C&L notification](#)). The classification of the polymer could, in particular, take into account the classification of the free monomers or other substances, using the Directive 1999/45/EC criteria.

A manufacturer or importer of a polymer has to classify those monomer substances that he is registering, as part of the technical dossier (see Article 10(a)(4)).

3.2.5 Information down the supply chain

The manufacturer or importer of a polymer must provide his customer(s) with a safety data sheet (SDS) of the polymer if this substance meets the criteria for classification as dangerous, PBT or vPvB or if it is listed in the candidate list of substances to be subject to authorisation (Article 31). If the SDS is not required, but the polymer is subject to either authorisation or restriction, or if relevant information about the polymer necessary to enable appropriate risk management is available, the supplier must nonetheless provide that information to his customer(s), together with details of any eventual authorisation granted or denied in his supply chain (Article 32).

In either case, the information in the supply chain needs, where relevant, to take into account the information generated on the monomer substance or any other substance. This is in particular relevant to consider for the presence of unreacted monomer substances.

Example 4 : Example on the identification of the monomer substances and other substances to be registered by an importer of polymer

Company X established in the Community intends to import 50 tonnes per year of a resin manufactured from ethylene oxide, propylene oxide and glycerol. The substance has the following composition:

1.0wt% of glycerol chemically bound to the polymer

70.0wt% of polymerised ethylene oxide

26.5wt% of polymerised propylene oxide

2.5wt% unreacted glycerol

The structure of the polymer molecules is depicted in **Figure 4**.

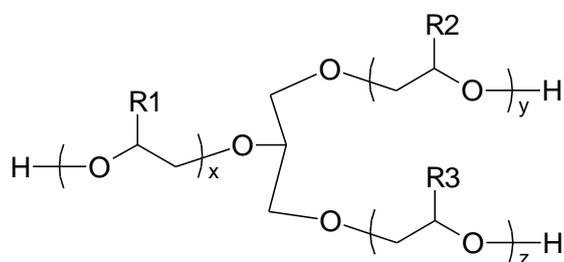


Figure 4: One representation of the general structure of the reaction product from glycerol, ethylene oxide and propylene oxide (x, y and z are integers, R1, R2 and R3 are H atoms or methyl groups).

Ethylene oxide and propylene oxide are both monomers, while glycerol acts as the initiator of the reaction and therefore is an "other reactant".

In **Table 2**, the composition of the polymer is reported:

Table 2 Polymer composition

| Substance | Type | Weight fraction in the polymer | Total quantity of unreacted+reacted substance |
|-----------------|----------------------------------|--------------------------------|---|
| Ethylene oxide | Polymerised monomer | 70.0 wt% | 35 tonnes |
| Propylene oxide | Polymerised monomer | 26.5 wt% | 13.25 tonnes |
| Glycerol | Other reactant, chemically bound | 1.0 wt% | 0.50 tonnes |
| | Other reactant, unreacted | (2.5 wt%) | + 1.25 tonnes =1.75 tonnes |

Provided that this substance falls under the definition of polymer, and unless ethylene oxide and propylene oxide have been registered up the supply chain, company X will be required to register both ethylene oxide and propylene oxide, since:

(a) The total quantity of ethylene oxide and, propylene oxide which was used and incorporated in the polymer chain constitute 35 and 13.25 tonnes respectively, and

(b) The manufactured polymer substance consists, respectively, of 70.0 and 26.5 wt% of ethylene oxide and propylene oxide monomer substance(s) in the form of monomeric units.

However, glycerol does not need to be registered, since the reacted glycerol accounts for only 1 weight percent of the polymer. The condition in Article 6(3)(a) is therefore not fulfilled

The unreacted glycerol as such does not need to be registered, as it is an impurity.

3.3 Formulation/import of polymer preparations

Substances are commonly added to polymer for the purpose of adjusting or improving the appearance and/or the physicochemical properties of polymeric material. Examples of polymer additives include pigments, lubricants, thickeners, antistatic agents, compatibilisers, antifogging agents, nucleating agents, flame retardants, etc.

In accordance with the REACH definition of a substance, any additive necessary to preserve the stability of a polymer substance is regarded as a constituent of that polymer (see Article 3(1) and the [Guidance on substance identification](#)). The quantity of any heat stabiliser, light stabiliser and/or antioxidant that is added to a polymer for the purpose of preserving its stability is therefore considered as part of the polymer substance. Consequently, the importer of a polymer containing an unbound heat stabiliser, light stabiliser and/or antioxidant does not need to register these stabilisers.

A polymer containing any unbound additive other than polymer stabilisers must however be treated as a preparation composed of the mixture of polymer substance and the additive substance. There is the general obligation to register the additive substance manufactured or imported on its own or in the polymer preparation (see the [Guidance on registration](#)) in quantities of at least 1 tonne per year.

3.4 Production/import of articles containing polymer substances

Polymer substances can either be part of an article, or constitute an article themselves. Articles made out of polymer substances are for instance plastic water bottles, plastic garden furniture, plastic bags, etc.

Special techniques, including injection moulding or extrusion, are utilised to give polymer substances a special shape. However, polymers which are given a special shape are not systematically regarded as articles, as the shape still has to determine the function of the polymeric material to a greater degree than does its chemical composition. For instance, thermoplastics are often extruded into pellets (pelletisation process) for the sole purpose of facilitating their further handlings. Pelletised polymer is therefore not regarded as an article.

The producer or importer of an article containing a polymeric substance is under no circumstances required to register the polymer, as polymers are exempted from registration. Articles 7(1) and 7(5) therefore do not apply for polymers in articles. The producer or importer of an article containing a polymeric substance has otherwise the same obligations under REACH as he would have for any other standard substance present in the article. Further information is available in the [Guidance for articles](#).

4 ANALYTICAL METHODS

In the following sections, brief account of available analytical methods which may be used by manufacturers or importers of polymeric substances to establish their obligations under REACH is provided.

4.1 Identification of polymer substances

The preferred method to identify whether a substance falls under the definition of a polymer is Gel Permeation Chromatography (GPC). Guidelines on the determination of the number average molecular weight (M_n) and molecular weight distribution using GPC are available in the OECD TG 118 (1996).¹ Whenever practical difficulties in using GPC are expected or encountered, alternative methods for the determination of the M_n are also listed in an annex to the OECD guideline.

4.2 Monomer/other reactant content in the polymer

4.2.1 Monomer/other reactant concentration

The monomer/other reactant concentration in the polymer as specified in Article 6(3)(a) does not refer to the weight by weight (w/w) content of the monomer substance and any other substance in the polymer substance, but to the weight by weight (w/w) content of the chemically bound monomer units (reacted form of the monomers) and other chemically bound substance(s) in the polymer substance. Note that the molecular weight of the monomer unit is not necessarily the same as the monomer itself, but can be lower. These considerations are illustrated in Example 5.

To determine the weight percent of monomer substance(s) or other substance(s) in the form of monomeric units or substances chemically bound to polymer molecules, several quantitative analytical methods are available, including for instance mass spectrometry, gas chromatography, infra-red spectroscopy and nuclear magnetic resonance spectroscopy.

¹ OECD Guidelines for the Testing of Chemicals are available on the OECD website at http://www.oecd.org/findDocument/0,3354,en_2649_34377_1_1_1_1_37465,00.html.

Alternatively, the weight percent of monomer units or any other substance chemically bound may be estimated from the recipe (amount of monomers or other reactant fed into the reaction vessel) and the quantity of unreacted monomers or other reactant that is present in the final polymer.

4.2.2 Monomer/other reactant tonnage to be considered for registration purposes

In accordance with condition (b) of Article 6(3), only the monomer(s) and any other substance(s) ending up in the final polymer, whether as chemically bound to the polymer or not, and for which the corresponding tonnage as reagents makes up 1 tonne or more per year are to be considered for an eventual registration. These considerations are illustrated in Example 4.

The tonnage of these monomers or other substances may be calculated from the amount of these substances fed into the reaction vessel, from which the amount of the substances eliminated throughout the process from the final polymer substance is deducted.

Example 5 : Simple illustration for the calculation of the monomer unit concentration and tonnage of monomer ending up in the final polymer as reacted or unreacted substance

133 tonnes/year of an alternating copolymer substance is manufactured by Company X from 90tonnes/year of monomer A and 50tonnes/year of monomer B.

The structure of the polymer is $-(A'-B')_n-$ where A' and B' are the monomer units of A and B respectively. Note that in this example both A' and B' have a lower molecular weight than their respective monomers.

In this particular example, purification of the polymer yields exclusively to the removal of 3tonnes/year of unreacted A and 4tonnes/year of unreacted B from the final polymer substance.

Analysis of the polymer showed the following composition:

- monomeric unit A': 85tonnes/year
- monomeric unit B': 40tonnes/year
- unreacted monomer A: 1tonnes/year
- unreacted monomer B: 2tonnes/year
- other impurities: 5tonnes/year.

The concentration of monomeric unit A' in the final polymer substance is $85/133 \times 100 = 64$ weight percent ≥ 2 weight percent (condition 6(3)(a) is fulfilled).

The concentration of monomeric unit B' in the final polymer substance is $40/133 \times 100 = 30$ weight percent ≥ 2 weight percent (condition 6(3)(a) is fulfilled).

Tonnage of monomer A ending up in the final polymer substance as reacted or unreacted monomer is $90-3=87$ tonnes/year ≥ 1 tonne/year (condition 6(3)(b) is fulfilled)

Tonnage of monomer B ending up in the final polymer substance as reacted or unreacted monomer is $50-4=46$ tonnes/year ≥ 1 tonne/year (condition 6(3)(b) is fulfilled).

The manufacturer will therefore have to register both monomers A and B, provided these substances have not been registered up the supply chain.