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EUROPEAN CHEMICALS AGENCY

GUIDANCE

# Guidance for monomers and polymers

April 2012

Version 2.0

Guidance for the implementation of REACH

| Version | Changes | Date |
|---|---|---|
| Version 0 | First edition | June 2007 |
| Version 1 | Section 2.2 - More explanations given on the definition of polymer (including different types of additives). Most of section 3.3 transferred to here.<br><br>Section 3.1 - Clarification of cases where the substance is used both as monomer and as intermediate under strictly controlled conditions.<br><br>Section 3.2.1.1 - Addition of a sentence to clarify that there is no need to register stabilisers<br><br>Section 3.2.1.2 - The section has been modified in order to reflect a proposal for solution for those substances already notified.<br>Section 3.2.1.3 - Some wording change for clarification that only the substance used for the modification of the natural polymer needs to be registered when ending up chemically bound to the polymer.<br><br>Section 3.2.1.4 - Need for update acknowledged.<br><br>Previous Section 3.3 - Deleted and mostly transferred to section 2.2. | 18/03/2008 |
| Version 1.1 | Section 3.2.1.2 - Based on the comments received from Ireland after the CA meeting in December 2007 some additional guidance on what needs to be done for notified polymers has been added (4 pages). | 27/05/2008 |
| Version 2.0 | Section 2.1 and 3.1 – Reference to monomers as intermediate reworded in order to be consistent with new clarification of intermediate definition.<br><br>Section 2.2 - Clarification of the definition of "unreacted monomers" which remains in the polymer's composition.<br><br>Section 3.2.1 – Clarification of registration obligations in regard to unreacted monomers according to article 6(1). The reference to Art.6(1) has been added throughout the document.<br><br>Section 3.2.1.1, 3.2.1.2 and 3.2.1.4 – Addition of the reference to late pre-registration possibility.<br><br>Section 3.2.1.3 – Amendment of the case of naturally occurring polymer to be consistent with the new agreed interpretation. | April 2012 |

| | | |
|---|---|---|
| | Section 3.2.4 – Amendment of the section on classification and labelling to bring it in line with the CLP regulation and its requirements.<br><br>Example 4 – Table indicating the quantities of substances ending up in the polymers amended.<br><br>Section 4.2.2 – Implementation of the reading of the Court Case C-558/07 and clarification on the calculation of the tonnage for registration purposes.<br><br>Example 5 – Amendment following implementation of the Court Case reading in the core text. | |

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**Guidance for monomers and polymers**

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# PREFACE

This document describes the specific provisions for polymers and monomers under REACH. It is part of a series of guidance documents that aims to help all stakeholders with their preparation for fulfilling their obligations under the REACH regulation. These documents give 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 have been drafted and discussed within the REACH Implementation Projects (RIPs) led by the European Commission services, involving stakeholders from Member States, industry and non-governmental organisations. The European Chemicals Agency (ECHA) updates these guidance documents following the Consultation procedure on guidance. These guidance documents can be obtained via the website of the European Chemicals Agency (http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach). Further guidance documents will be published on this website when they are finalised or updated.

This document relates to the REACH Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006[1]

1 Corrigendum to Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), establishing a European Chemicals Agency, amending Directive 1999/45/EC and repealing Council Regulation (EEC) No 793/93 and Commission Regulation (EC) No 1488/94 as well as Council Directive 76/769/EEC and Commission Directives 91/155/EEC, 93/67/EEC, 93/105/EC and 2000/21/EC (OJ L 396, 30.12.2006); amended by Council Regulation (EC) No 1354/2007 of 15 November 2007 adapting Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) by reason of the accession of Bulgaria and Romania (OJ L 304, 22.11.2007, p. 1).

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# 1. INTRODUCTION

Polymers are the material of choice in a vast range of applications such as packaging, building and construction, transportation, electrical and electronic equipment, agriculture, as well as in the medical and the sports sectors. The versatility of polymeric materials is due to 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 due to their high molecular weight, this group of substances is exempted from registration and evaluation under REACH. Polymers may however still be subject to authorisation and restriction.

Nonetheless, manufacturers and importers of polymers may still be required to register the monomers or other substances used 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, via 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 substance used as a monomer in the manufacturing of a polymer 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 may fulfil the conditions to benefit from the specific provisions for the registration of intermediates under REACH (see the Guidance for intermediates[2]). Otherwise, it will have to comply with all REACH requirements for a "normal substance" including registration requirements in accordance with Title II (see the Guidance on registration).

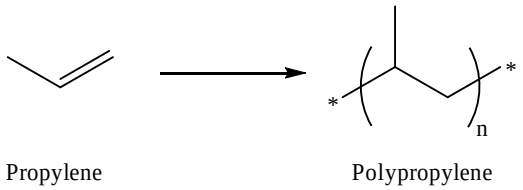
[2] All the ECHA Guidance Documents are available on the ECHA Guidance web page, in "support" section at: http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

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

**Example 1 Monomer definition: the propylene case**

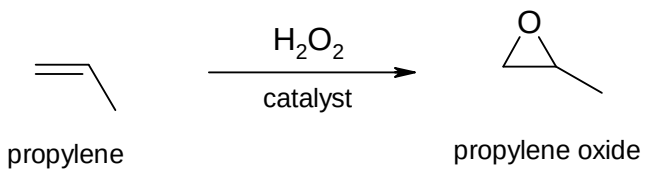
Propylene is to be considered as a monomer under REACH when it is used for the purpose of polymerisation process such as polypropylene manufacture, as illustrated in Figure 1:

**Figure 1: Propylene polymerisation**




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.

**Figure 2: Propylene epoxidation reaction**




Another example of the application of propylene is in its utilisation as fuel gas in certain industrial processes. In this specific case, propylene is regarded as neither an intermediate nor a monomer.

## 2.2 Polymer

A polymer is a substance consisting of molecules characterised by the sequence of one or more types of monomer unit. Such molecules must be distributed over a range of molecular weights. 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.

A polymer, as any other substance defined in Article 3(1), can also contain **additives necessary to preserve the stability** of the polymer and **impurities deriving from the manufacturing process**. These stabilisers and impurities are considered to be part of the substance and do not have to be registered separately. Stabilisers include, for example, heat stabilisers, anti-oxidants (both useful during extrusion) and light stabilisers (e.g. for preservation during use). Impurities are unintended constituents of the polymer such as catalysts residues. The quantities of a monomer substance which do not react during the polymerisation reaction and remain in the composition of a polymer are referred to as "unreacted monomers". Unreacted monomers in a polymer are also constituents of that polymer. Registration obligations linked to the presence of these unreacted forms are explained in sections 3.2.1 and 4.2.2[3].

Substances may also be added to improve the performance of the polymer even though they are not necessary for preserving the stability of the polymer. Indeed, substances are commonly added to a polymer for the purpose of adjusting or improving the appearance and/or the physico-chemical properties of the polymeric material. Examples of such substances include pigments, lubricants, thickeners, antistatic agents, antifogging agents, nucleating agents and flame retardants. When a polymeric material contains such substances it should be considered as a mixture or an article, as the case may be (see section 3.3). For such substances normal registration requirements apply (see the Guidance on registration)

Under REACH and in the guidance documents developed by the Commission and ECHA, only stabilising agents are considered as additives. Substances added to polymers to provide any function other than stabilisation are commonly called "polymer additives". However, for the purpose of this guidance, these substances are not referred to as additives.

When a given substance can be used both for preserving the stability of the polymer and for improving its performance (e.g. if the substance acts as a light stabiliser and a flame retardant), it is good practice to consider only the quantities necessary to preserve the stability of the polymer substance. The quantity of the substance that is not necessary to preserve the stability of the polymer cannot be regarded a part of the polymeric substance. It should be considered as another substance within a mixture. As such it may need to be registered.

[3] The approach suggested with regard to reacted and unreacted monomers and other substances follows the judgement of the European Court of Justice in EU Case C-558/07 of 07 July 2009 available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62007CJ0558:EN:HTML. See in particular paragraphs 20, 38 and 51 of the judgment.

Whenever it is not scientifically possible to establish either of the following:

i) whether the substance falls under the definition of polymer

ii) 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. A UVCB substance is a substance of Unknown or Variable composition, Complex reaction products or Biological material (see Guidance for identification and naming of substance under REACH. In this case the registration for 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 (thermal cracking).

**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 molecule likely to be formed upon completion of this ethoxylation-type of polymerisation reaction.

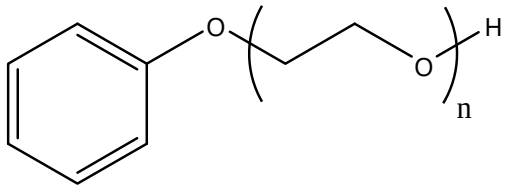



**Figure 3: ethoxylated phenol (n is an integer, n≥1)**

The monomer unit is in this case the opened epoxide -(CH2-CH2-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≥3.

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

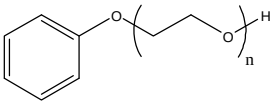
(a) Over 50 weight percent of the substance consists of polymer molecules, i.e. molecules depicted in
Figure 3 and for which n≥3)

(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 a 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≥3. For this reason, example 2 does not comply with the criteria for 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≥3) and none of the different constituents 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 substances used as monomers in the manufacturing of polymers 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)). However, Articles 17 and 18 (on intermediates) do apply for the other substances to be transformed into the manufactured polymer, provided those other substances meet the conditions specified in Articles 17 and 18 (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 a non-monomeric intermediate, a "standard" registration dossier, in accordance with Article 10, is required to be submitted. In this situation, where part of the tonnage is manufactured and used as a non-monomeric intermediate under strictly controlled conditions, the registrant can still submit one registration dossier covering the total tonnage. The information requirements for this registration dossier are based on the tonnage for non intermediate uses (including monomers used for polymerisation) and for intermediates not used under strictly controlled conditions. The part of the tonnage manufactured or imported for use as non-monomeric intermediate under strictly controlled conditions will not need to be taken into account for the information requirements of the registration dossier. Nevertheless, the use as an intermediate including the volume manufactured or imported for this purpose should be documented in the dossier. 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 for use as a non-monomeric intermediate handled under strictly controlled conditions, the registration information requirements for that substance will be based on the 2 tonnes/year. In addition, the 9 tonnes/year to be registered according to Article 17 or 18 should be documented in the registration dossier. The fees will be calculated independently for the use as an intermediate under strictly controlled conditions (fees for intermediates) and for the other uses (standard fees).

Substances used as monomers in the manufacturing of polymers are by definition intermediates. Therefore, they cannot be subject to authorisation under REACH for such use.

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 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 chemically bound to the polymer).

Furthermore, where the polymer includes, in its composition, unreacted monomer (or residues from any other substance within the meaning of Article 6(3)), the quantity of that monomer (or any other substance) also needs to be registered according to Article 6(1)[4]. This does not mean that an additional registration for the unreacted monomer is necessary. Both the reacted monomers and unreacted monomer should be covered in the same registration dossier for that monomer substance. This applies also to other substances within the meaning of Article 6(3).

In practice, 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

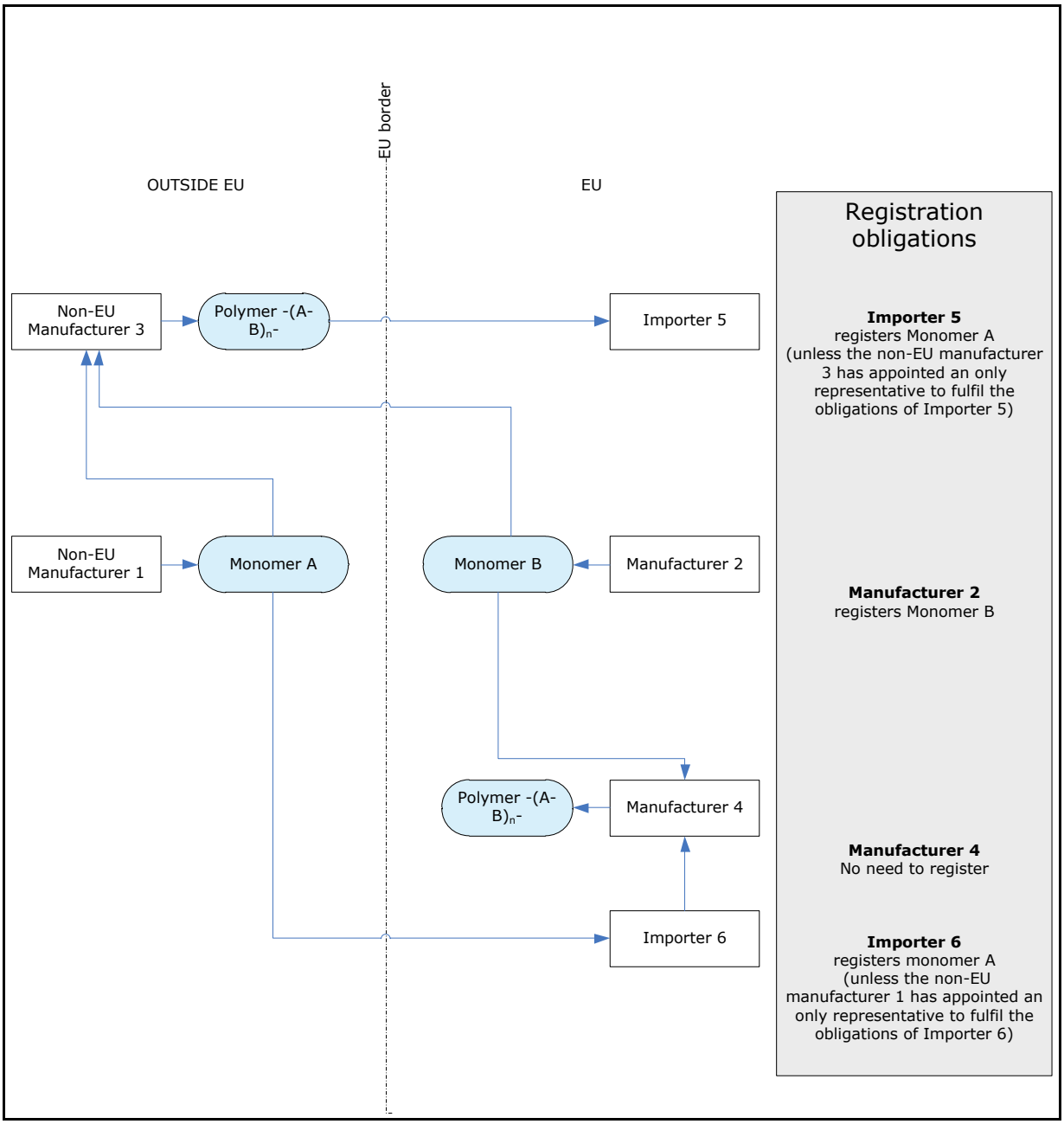
[4] For further information, please refer to the judgment of the European Court of Justice in EU Case C-558/07 of 07 July 2009 available at http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CELEX:62007CJ0558:EN:HTML. See in particular paragraphs 20, 38 and 51 of the judgment.

- 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 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**



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. 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. Further guidance on this can be found in the Guidance on registration. Example 4 (section 3.2.5) illustrates the considerations to be taken into account by the polymer importer for the purpose of registration of the monomers or other substances.

Note that all the monomers and other substances which need to be registered can benefit from the extended deadlines for registration only if they have been **pre-registered between the 1st June 2008 and the 1st December 2008 or in accordance with the conditions set out in Article 28(6)[5].**

### 3.2.1.2 Case of a polymer notified in accordance with Directive 67/548/EEC[6]

Polymer substances notified in accordance with Directive 67/548/EEC are regarded as registered by the manufacturer or importer who submitted the notification (Article 24(1)). The registration requirements under Title II are therefore covered by the notification for the tonnage band for which the notification was made. Registration of the monomers or other substances from which the notified polymers are derived is not required[7]. As soon as the manufactured/imported quantity of polymer reaches the next tonnage threshold, the registration requirements (Title II of REACH) as described in this guidance should be followed for the monomer(s) or any other substance(s) meeting the provisions of Articles 6(1) and 6(3). By doing so, the registrant will update his registration dossier, according to Article 24(2).

**Information to submit for the update of the dossier**

As the situation is different from that for the usual update of registration dossiers (the substance identity is different, several dossiers can be submitted to replace one), specific practical mechanisms have been put in place so that notifiers of polymers are not disadvantaged compared to notifiers of other substances.

*For which substances does a registration need to be submitted as part of the update?*

The registrant has to identify which monomer(s) or any other substance(s) meeting the provisions of Articles 6(1) and 6(3) are concerned when he updates his dossier.

[5] For more information on the late pre-registration options, please consult the Guidance on data sharing on the ECHA Guidance website at http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

[6] In May 2008 additional details have been added to the Guidance Document starting from the last sentence of the first paragraph of section 3.2.1.2 until the end of section 3.2.1.2.

[7] However, manufacturers or importers of notified polymers can still use registration of monomers as one of the options to fulfil their obligations, as an alternative to updating a polymer dossier as described in this section.

*In which tonnage band should the monomers or any other substances meeting the provisions of Articles 6(1) and 6(3) be registered?*

For each monomer or other substance meeting the provisions of Article 6(1) and 6(3), the registrant should submit a registration dossier for the tonnage band determined by the new tonnage band of the polymer.

**Example**

An imported polymer P was notified in accordance with Directive 67/548/EEC for the 10-100 tonnage band. Polymer P is derived from 2 monomers, monomer A and monomer B. For the purpose of this example, we will consider that the quantity of monomer A used for the manufacture of 10 tonnes of polymer P is 2 tonnes and ends up in the form of monomeric units only.

Under REACH, the registration obligations for the 10-100 tonnes tonnage band of the polymer are covered by the notification and the Agency will provide the notifier with a registration number by 1 December 2008 (Article 24(1)). As soon as the tonnage of the polymer reaches the next tonnage band, i.e. a tonnage within the 100-1000 tonnage band, the registration dossier needs to be updated.

Nevertheless, as P is in the 100-1000 tonnage band, it is possible to consider that 20 to 200 tonnes of A might need to be registered. It is therefore up to the registrant to decide whether he wants to register A in the 10-100 tonnage band or in the 100-1000 tonnage band.

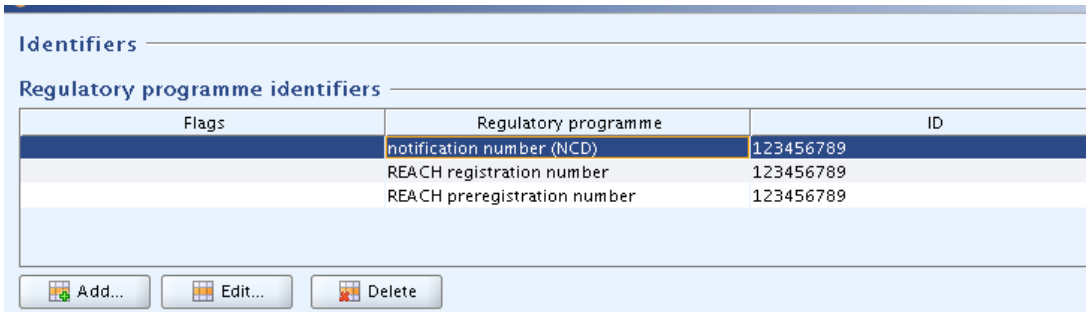
- if he registers in the 10-100 tonnage band, he will have to submit the information required for this tonnage band (annex VII and annex VIII information). If his import of polymer increases above 500 tonnes, he will then need to update his registration dossier for A, as A would be in the 100-1000 tonnage band.
- if he registers in the 100-1000 tonnage band he will need to submit additional information (annex IX information in addition to annex VII and annex VIII information) but will not need to update his dossier until he imports more than 5000 tonnes of the polymer, as only then A would be in the >1000 tonnage band.

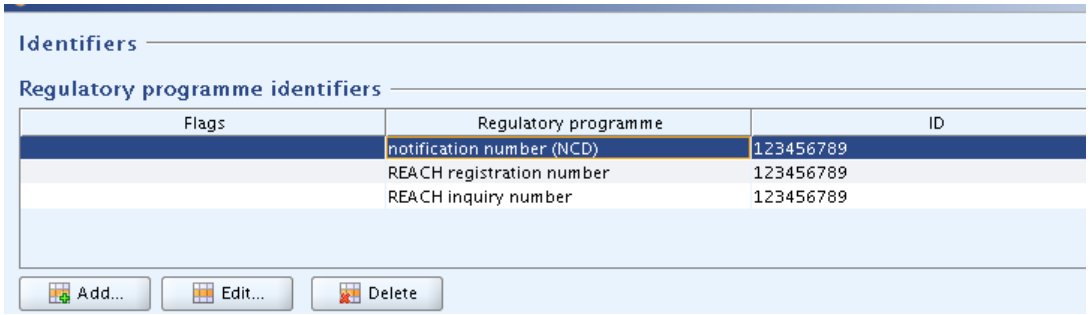
Similar considerations also need to be taken into account for the monomer B from which polymer P is derived.

*How can a registrant make clear to ECHA that his new registration dossier is an update of the previous "polymer registration dossier"?*

When preparing their registration dossier for the monomers and any other substance meeting the provisions of Articles 6(1) and 6(3), the registrant should:

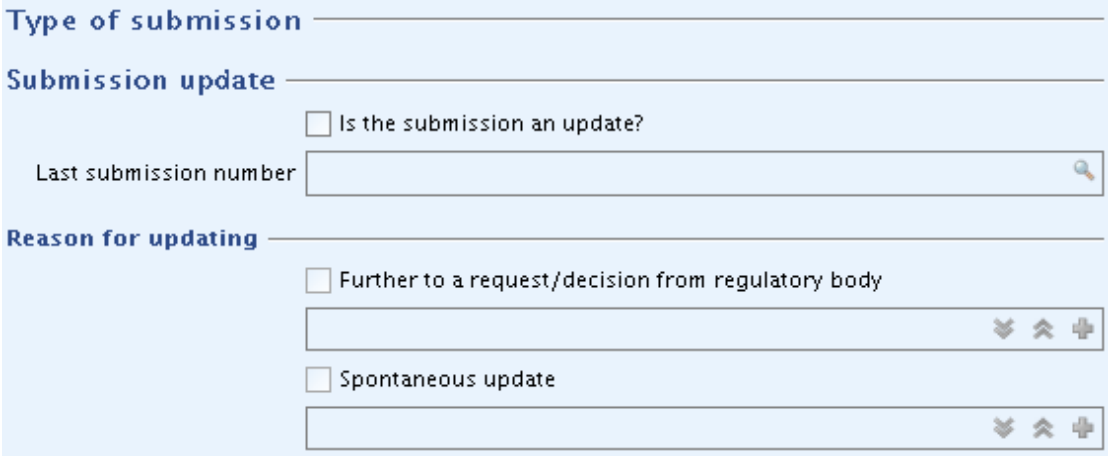
- in section "1.3 identifiers" of his dossier make a reference to:
  - the notification number under Directive 67/548/EEC
  - the registration number of the polymer provided by the Agency, if the dossier is submitted after December, 1st 2008
  - the pre-registration or inquiry number for the substance




- in the same section (1.3), add a justification letter as an attached document in the information section of each dossier. It is important that the registrant submit the following information to the Agency in the aforementioned submission letter:
  - The identity of each of the monomers and other substances which fulfil the provisions of Articles 6(1) and 6(3), according to section 2 of Annex VI, including their EC and CAS number, if available.
  - The respective tonnage of the monomers and other substances, determined on the basis of the tonnage of the notified polymer considered for the update of the registration
  - The tonnage band for which the monomers and other substances will be registered
  - The former tonnage band of the polymer (notification tonnage band)
  - The tonnage of the polymer considered for the update of the registration
  - Indication of whether these monomers and other substances are phase-in substances and whether they have been pre-registered.

**<u>Important note</u>**: when a dossier is submitted for the first time for a monomer or another substance included in a notified polymer, the submission shall be made as an initial one. Consequently, in the IUCLID 5 dossier template, the checkbox "Is the submission an update?" should **not** be ticked and the last submission number should **not** be provided.




**When should the registration dossiers for the monomers and any other substances meeting the provisions of Article 6(1) and 6(3) be submitted?**

All monomers and any other substance(s) which should be registered have to be registered before the polymer is imported at a tonnage which exceeds the notification. If some of these substances are phase-in substances, they can benefit from the special transitional regime for phase-in substances (see the Guidance on registration) only if they have been **pre-registered between 1 June 2008 and 1 December 2008 or late pre-registered according to Article 28(6)[8].** If some of these substances are non phase-in substances or non pre-registered phase-in substances then an inquiry will be required before submitting the dossier (see the Guidance on registration).

**Fees to be paid for the first update of the dossier**

Pursuant to Article 24(2) and 22(5) the basic fee to be paid for the update of a dossier will correspond to the fee payable for an update of the tonnage range of the notified polymer. This fee is payable for the submission of the first monomer registration dossier submitted in relation to the update of the tonnage range of the notified polymer. No separate update fee is payable for any of the other monomer registration dossiers that are submitted as part of this "initial update" of the tonnage range of the "notified polymer".

Nevertheless, this procedure can only be based on the information submitted by the registrant in his "justification letter".

However, a fee will be charged for each item in the monomer registration dossiers for which confidentiality is requested.

**Joint Submission**

Joint submission provisions apply in this case as for any other registration. Guidance can be found in the Guidance on registration and in the Guidance on data sharing.

**Subsequent updates**

For subsequent updates of the registration dossiers for monomers or any other substance which has been registered, the standard rules for the submission of updates will be applied.

[8] For more information on the late pre-registration options, please consult also the Guidance on Data sharing on the ECHA Guidance website at http://echa.europa.eu/web/guest/guidance-documents/guidance-on-reach.

#### 3.2.1.3 Case of a natural polymer or a chemically modified natural polymer

Natural polymers are understood as polymers which are the result of a polymerisation process that has taken place in nature, independently of the extraction process with which they have been extracted. This means that natural polymers are not necessarily 'substances which occur in nature' when assessed according to the criteria set out in Article 3(39) of the REACH Regulation.

Following Article 2(9) of REACH, any polymer meeting the criteria of Article 3(5), whether natural polymers or not, does not have to be registered. This exemption from registration includes natural polymers which are chemically modified (e.g. post-treatment of natural polymers).

Monomer substance(s) and other substance(s) ending up in the form of monomeric units and chemically bound substance(s) in natural polymers can, for practical reasons, be treated as "non-isolated intermediates" and do not have to be registered.

In the case of chemically modified natural polymers, the building block monomer substance(s) and other substance(s) in the form of monomeric units and chemically bound substance(s) similarly originating from the natural polymers can also, for practical reasons, be treated as "non-isolated intermediates" and do not have to be registered. However, any monomer substance or any other substance (within the meaning of Article 6(3)) used for the modification of the natural polymer and meeting the provisions of Article 6(1) and 6(3) needs to be registered accordingly, unless it has been registered up the supply chain. These registration obligations apply provided the chemically modified natural polymer itself meets the Article 3(5) polymer definition.

Whenever it is not scientifically possible to identify and quantify the building blocks of a substance that is under consideration as to whether it is a natural polymer or not, this substance must instead of a natural polymer be regarded as a UVCB substance (see **section 2.2** for further information) that therefore has to be registered.

#### 3.2.1.4 Case of a recycled polymer

Companies undertaking recovery of polymer substances from waste during which these substances cease to be waste are exempted from the obligation to register the monomer(s) or any other substance(s) meeting the provisions of Articles 6(1) and 6(3) in the recycled polymer. This exemption applies provided that these substance(s) constituting the recycled polymer have been registered and the information on the registered substance is available to the company undertaking the recovery (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 for recycled or recovered substances is provided in the Guidance on Waste and recovered substances.

If the monomer or any other substance is a phase-in substance, it is recommended that the recycler of the polymer pre-register that substance in order to benefit from the transitional provisions laid down in Article 23 even if later on that substance is exempted from the registration requirements by virtue of the fact that another pre-registrant registers the substance. Although the pre-registration period as well as the first deadline for late pre-

registration have already passed there is still the possibility to benefit from late pre-registration for first time manufacturers and importers of recovered phase-in substances on their own or in a mixture or in the context of articles under certain conditions, as foreseen in Article 28(6) of REACH.

The Commission is currently working on the development of End of Waste criteria which will help to identify for different major waste types when obligations under the Waste Framework Directive cease and obligations under REACH apply. This will also cover the issue of recycling of polymer waste. After finalisation of the review, this guidance document may be updated accordingly.

### 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 the preparation for an application for authorisation.

### 3.2.3 Compliance with restrictions

The monomers, any other substances used to manufacture a polymer, and polymers themselves 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, mixtures and articles).

Restrictions on a monomer apply to polymers only if the concentration of the unreacted monomer in the polymer 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 in accordance with Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures (CLP). Also, if the polymer is classified as hazardous and if it is put on the market on its own or in a mixture above the concentration limits specified in the CLP Regulation or in Directive 1999/45/EC, where relevant, resulting in the classification of the mixtures as hazardous, he must notify the Agency (see CLP Article 39(b))[9]. This notification has to be done within one month after the substance is placed on the market (CLP Article 40).

The classification of the polymer should, in particular, take into account the classification of all its constituents, such as unreacted monomers. These constituents in fact should be taken into account for classification of the polymer. This means that the same classification methods as for mixture should be applied to polymer substances. For more information please refer to the Guidance on the Application of the CLP criteria available on the ECHA Guidance website.

A manufacturer or importer of a polymer has to classify those monomer substances that he is registering in accordance to the CLP Regulation. The classification should be included in the technical dossier (see Article 10(a)(4) of REACH).

[9] Note that from 1 June 2015 the classification of mixtures according to the criteria and concentration limits of the CLP Regulation becomes legally binding.

For further information on notification requirement in accordance with the CLP Regulation, please refer to Practical guide no.7, available on the ECHA website.

### 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) for the polymer if this polymer 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). According to Article 32, 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.

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

**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:

2.0 wt% of glycerol chemically bound to the polymer

70.0 wt% of polymerised ethylene oxide

25.5 wt% of polymerised propylene oxide

2.5 wt% unreacted glycerol

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

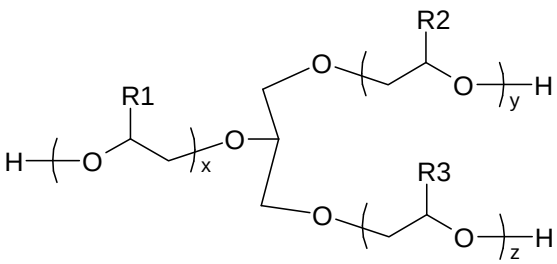



**Figure 4: One representation of the general structure of the reaction product from glycerol, ethylene oxide and propylene oxide (x, y and z are integers, R1, R2 and R3 are H atoms or methyl groups).**

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

The composition of the polymer is given in Table 2.

**Table 2 Polymer composition**

| Substance | Type | Weight fraction in the polymer | Quantity of substance ending up in the polymer |
|---|---|---|---|
| Ethylene oxide | Polymerised monomer | 70.0 wt% | 35 tonnes |
| Propylene oxide | Polymerised monomer | 25.5 wt% | 12.75 tonnes |
| Glycerol | Other reactant, chemically bound | 2.0 wt% | 1 tonnes |
| | Other reactant, unreacted | 2.5 wt% | 1.25 tonnes |

Provided that this substance falls under the definition of a 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 12.75 tonnes respectively, and

(b) The manufactured polymer substance consists, respectively, of 70.0 and 25.5 wt% of ethylene oxide and propylene oxide monomer substance(s) in the form of monomeric units.

In addition, glycerol also needs to be registered. The quantity of this substance to be covered by the registration is the overall quantity of glycerol used which ends up chemically bound or unreacted in the polymer.

## 3.3 Production/import of articles containing polymer substances

Examples of articles composed of polymer substances are plastic water bottles, plastic garden furniture and plastic bags.

Special techniques, including injection moulding or extrusion, are used to give polymer substances a special shape. However, polymers which are given a special shape are not automatically 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. In this case, polymer pellets are therefore not regarded as articles.

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 to 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 on requirements for substance in articles.

# 4. Analytical methods

The following sections briefly describe some of the available analytical methods which may be used by manufacturers or importers of polymeric substances to establish their obligations under REACH.

## 4.1 Identification of polymer substances

The preferred method to determine 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)[10]. 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. Rather, it refers 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. It should be noted 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.

There are several quantitative analytical methods available 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. Examples of these methods are mass spectrometry, gas chromatography, infra-red spectroscopy and nuclear magnetic resonance spectroscopy.

Alternatively, the weight percent of monomer units or any other chemically bound substance may be estimated from the amount of monomers or other reactant fed into the reaction vessel and the quantity of unreacted monomers or other reactant that are 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), the monomer(s) and any other substance(s) ending up chemically bound to the polymer and for which the corresponding tonnage as reagents makes up 1 tonne or more per year are to be considered for registration under Article 6(3). Furthermore, the quantities of unreacted monomer or any other substance (within the meaning of Article 6(3)) present in its unreacted form as part of the polymer also need to be registered according to Article 6(1). For each monomer substance and any other substance, the quantity to be registered should therefore correspond to the cumulated tonnage of the

[10] 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.

substance ending up in the polymer in its reacted or unreacted form. This aggregated volume is therefore that which should be used in the single registration for that monomer or other substance. Should the registration according to either Article 6(1) or 6(3) not be individually required, the registrant does not need to add up the corresponding quantity to the tonnage to be registered. All these considerations are illustrated in Example 4 on page 20 and in Example 5.

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 : 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 90 tonnes/year of monomer A and 50 tonnes/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.

Analysis of the polymer showed the following composition:

- monomeric unit A': 85 tonnes/year (equivalent to the use of 87 tonnes/year of monomer A)
- monomeric unit B': 40 tonnes/year (equivalent to the use of 42 tonnes/year of monomer B)
- unreacted monomer A: 1 tonne/year
- unreacted monomer B: 2 tonnes/year
- other impurities: 5 tonnes/year.

The concentration of monomeric unit A' in the final polymer substance is 85/133x100= 64 weight percent i.e. ≥ 2 weight percent (condition 6(3)(a) is fulfilled).

The concentration of monomeric unit B' in the final polymer substance is 40/133x100= 30 weight percent i.e. ≥ 2 weight percent (condition 6(3)(a) is fulfilled).

Tonnage of monomer A ending up in the final polymer substance as reacted monomer is 87 tonnes/year i.e. ≥ 1tonne/year (condition 6(3)(b) is fulfilled).

Tonnage of monomer B ending up in the final polymer substance as reacted monomer is 42 tonnes/year i.e. ≥ 1tonne/year (condition 6(3)(b) is fulfilled).

The manufacturer will therefore have to register both monomers A and B according to Article 6(3), provided these substances have not been registered up the supply chain. Furthermore, pursuant to Article 6(1) of the REACH Regulation the quantities of unreacted monomers A and B will also need to be registered and therefore should be added up to the overall quantities of reacted monomer to be registered. The quantities of substance A and substance B to be registered therefore are 87+1=88 tonnes/year and 42+2=44 tonnes/year, respectively.

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