



## REACH Industry Preparation Letter No 5

March 2007

### Table of content

1. <a href="#"><u>Summary of the Compromise</u></a>	<a href="#"><u>p. 2</u></a>
2. <a href="#"><u>Reach Awareness Workshop III and IV</u></a>	<a href="#"><u>p. 4</u></a>
3. <a href="#"><u>Standard Questionnaires for communication along the supply chain</u></a>	<a href="#"><u>p. 5</u></a>
4. <a href="#"><u>Registration of Monomers and Related Considerations for Polymers</u></a>	<a href="#"><u>p. 6</u></a>
5. <a href="#"><u>Ethylene as an Example for Pre-Registration under REACH</u></a>	<a href="#"><u>p. 10</u></a>
6. <a href="#"><u>Overview of the REACH Implementation project 3-10 (RIP 3.10)</u></a>	<a href="#"><u>p. 21</u></a>

#### Disclaimer

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## 0. Distribution policy

This newsletter will be circulated to Cefic member companies and organisations only. Member organisations are then free to distribute the contents further to their own members. Companies and organisations who subscribe to ReachCentrum will be able to access the same information via the ReachCentrum website.

## 1. Summary of the Compromise

The following document details the compromise recently agreed between EP, Council and Commission under the so called “trialogue”. The key issues discussed are listed below with a summary and details of the outcome.

### ➤ Duty of care

A new recital has been introduced (and not an article) to explain that the concept of the duty of care is something implicit in the duties under REACH.

### ➤ Animal welfare

Basically two new concepts have been introduced:

- Testing proposals will be open for comments. These comments have to be based on scientifically valid information and have to be sent in 45 days.
- The Commission after consultation with other stakeholders can make proposals to modify the test methods (under the new comitology procedure)

### ➤ Comitology

The new comitology procedure (Council Decision 2006/512/EC of 17 July 2006 amending Council Decision 1999/468/EC of 28 June 1999), recently adopted, has been introduced for certain decisions under REACH, instead of the “normal” comitology procedure. In cases where this new comitology procedure applies, the European Commission has to send its draft decision, after consultation with the Member States, to the EP and the Council which are entitled to stop the implementation measure within a deadline of 3 to 5 months, as the case may be.

This will result on the following:

- The clear separation of powers between Commission, Council and EP is compromised.
- Detailed scientific questions are exposed to political discussions
- The comitology procedure takes longer.
- Legal remedies are shortened.

## ➤ Agency

Several changes have been agreed. To highlight that in relation with the composition of the Agency's management board (art. 78.1), the EP can appoint two independent people, and as a consequence there is no balance in the representation of involved parties.

## ➤ Communication of information

- Safety data sheets will have to be provided for substances listed in the candidate list for authorization.
- New duty to communicate information on substances in articles.
- The Agency will provide guidance on how to communicate risk information to the public.

## ➤ Registration/data sharing

- First deadline for registration of phase-in substances has been extended 6 months (3.5 instead of 3 years).
- Intermediates are clear phase-in substances.
- No need to perform a CSR for substances between 1-10 tonnes but this will be revised by 7 years after REACH entries into force.
- Data protection has been extended 2 years (12 instead of 10 years).
- All potential registrants, downstream users, third parties, those having submitted information on biocides or plant protection products and those registrants who have submitted a registration for a phase-in substance before the deadline of 11 years are participants of the SIEF.
- The proposal from the Council common position on the reprotox test (Annex VIII) remains and this will be only reviewed after 12 years REACH entries into force.

## ➤ Authorisation, including substitution

- Substances will get an authorization if the risk is adequately controlled (threshold limits can be calculated) but a substitution plan (including a timetable for proposed actions by the applicant) will have to be submitted, when a suitable alternative is available, as part of the authorization dossier.
- Suitable alternative includes two aspects amongst others:
  - Reduction of the overall risks to human health and environment.
  - It has to be technical and economic feasible for the applicant.
- The duration of the time-limited review for an authorization will be determined on a case by case basis and the substitution plan will be taken into account.
- Whenever a suitable alternative becomes available a substitution plan has to be submitted or updated.

- The analysis of alternatives has to include information about any relevant R&D activities by the applicant, if appropriate.
- The criteria for identification of PBTs (Annex XIII) will be reviewed by 18 months after REACH entries into force in accordance with the new comitology procedure.

### ➤ Intellectual property rights

- Information on precise use of intermediates is confidential.
- Provided a justification is submitted and validated, the trade name of substance can be kept confidential as well as the IUPAC name for a dangerous non phase-in substance for a period of 6 years.

## 2. REACH Awareness Workshop III and IV

The Cefic REACH Implementation group organized its third and fourth REACH Awareness workshop at the Sheraton Brussels Airport hotel. Both workshops were organized back to back to the REACH IT workshops. There were about 135 participants in both Awareness workshops and many of them also attended the REACH IT workshops.

The first part of the workshop III held on Sept. 20th, 2006 was dedicated to give an update of the REACH legislation process, followed by presentations on RIP 3.2, RIP 3.3, Intermediates, Polymers, Preparations and Consortia. In the afternoon session there were two industry presentations by members of Industry on how they prepare for REACH.

Workshop IV, held on Jan 24th, 2007 was dealing with the REACH compromise, an extensive example on pre-registration, RIP 3.10 and RIP 3.3, Monomers, communication up and down the supply chain, data sharing and joint submission of data. There were also two presentations by distributors on how they are preparing for REACH.

Participants were asked to fill in an evaluation form. From the reactions we received we can conclude that we are meeting the expectations. Also the combination with the REACH IT workshop was well received. Some suggestions were made to go into more depth for specific subjects and also to come with more practical examples. The organizers will try to adapt the formula in that way.

Next REACH Awareness workshop V is scheduled for 23 May and will again be back to back to the REACH IT workshop (24 May).

### 3. Standard Questionnaires for communication along the supply chain<sup>1</sup>

REACH requires extensive communication between the different actors in the supply chain. This refers e.g. to the exchange of information on use and exposure between downstream users and manufacturer or importer.

Use and exposure information is critical for substance registration by the manufacturer or importer since substances will be registered according to their uses. If a manufacturer or importer is unaware of a use then that use may not be covered in the manufacturer's or importer's registration. Exposure information related to specific uses is needed for a risk assessment of the uses. Therefore users should provide use and exposure information to their suppliers. If use and exposure information is not provided, the specific use may not be registered by the manufacturer or importer. In that case the Downstream User should make his own CSA/CSR for his own use and notify the Agency accordingly.

This REACH industry preparation letter provides examples of standard questionnaires for suppliers and downstream users to communicate information necessary for the implementation of REACH. This facilitates the harmonized collection of use and exposure information from downstream users, whilst determining the intentions of suppliers to submit their substances for (pre-registration). In order to enable individual companies to prepare themselves for REACH communication these draft questionnaires can be used. However since RIP 3.2-2 (Guidance on generating CSR) is not finished yet, and the outcome of it may change these questionnaires in details, it is recommended to use the standard questionnaires for **your own preparations now and not to start sending it out before June 2007** (RIP 3.2-2 guidance available).

For downstream users, information on the availability of substances under REACH is of vital importance. This requires effective communication between downstream users and manufacturers or importers to determine the intention to pre-register and subsequently to register substances.

With respect to registration, it is in the interest of the downstream user to know at the earliest possible date whether his specific use(s) will be covered.

It is essential for the supplier be informed about the downstream applications of the respective substances at the earliest possible date in order to be able to generate the required chemicals safety report for the identified uses. In case a downstream user would like to keep his use confidential and make his own use known directly to the Agency, this information would also be valuable for the supplier.

The use of these questionnaires is optional; however, adoption of a standard format simplifies the process for all involved. Communication can also be pursued by other means, such as supplier-customer meetings.

The following standard questionnaires can be found in this issue:

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*1 The information contained in this questionnaire expresses only the intention of the questionnee and does not constitute a binding obligation. Whilst the information is provided in utmost good faith, no representations or warranties are made with regards to its completeness or accuracy and no liability will be accepted for damages of any nature whatsoever resulting from the use of or reliance on the information*

- Cover letter providing information how to use the standard questionnaires
- Part I: Questions from the customer to the supplier regarding pre-registration and registration intentions
- Part II: Questions from the customer to the supplier regarding use and exposure
- Part III: Questions from the supplier to the customer regarding use and exposure
- Annex providing information how to fill in part II and III questionnaires

The following points should be considered when using the questionnaires:

- The questionnaires offer the possibility to defer answering of a question to a later point in time. It is recommended to make use of this option in certain cases, until circumstances allow a proper assessment of the factors influencing the decision
- The part II and part III questionnaires employ the 'use and exposure matrix' approach in order to enable concise and effective communication regarding use and exposure, without the risk of disseminating confidential business information. However, in some cases, more comprehensive information on use and exposure may need to be exchanged.



Cover letter.doc



Part I Downstream user to Supplier.doc



Part II Downstream user to supplier.doc



Annex to Part II and III.doc



Part III Supplier to Down stream User.doc

## 4. Registration of Monomers and Related Considerations for Polymers

### *Polymers do not have to be registered under REACH, but...*

As the regulation has developed, it has become evident that polymers will not have to be registered under REACH, at least at the outset. This is confirmed in Article 2.9 of the final text of the REACH Regulation Number 1907/2006 of 18th December 2006. However, this does not mean that no actions are required by EU producers and importers of polymers. It should also be noted that polymers are not exempt from Authorisation and according to Article 138.2, polymers will be selected for registration in the future.

**Article 6.3** states that: Any manufacturer or importer of a polymer shall submit a registration to the Agency for monomers or substances which have not been registered by an actor **up the supply chain** if **both** the following conditions are met:

1. the polymer consists of >2% of such monomers, or substances in combined or reacted form (ie monomeric units and chemically bound substances)

**AND**

2. the total quantity of such monomers/substances based on polymer production, or importation  
is >1 metric tonne (MT) /annum.

This means that monomers (or the substances mentioned) need to be registered when manufactured or imported in the EU in quantities of >1MT/annum. Furthermore, monomers which are contained in reacted ie combined form in imported polymers also have to be registered if they are present in the polymer in reacted form at >2% **AND** they are imported in reacted form at >1MT/annum. It should be emphasised that these two criteria only apply to reacted monomers contained in combined form, not those that may be unintentionally present in free, unreacted form.

With respect to point 2 above, Article 3.30 explains that phase-in substances that have been imported or manufactured for at least three consecutive years, the annual quantities should be calculated on the basis of the average production or import volumes for the three preceding calendar years.

If a monomer is manufactured in quantities >1 MT/annum in the EU it must be registered, even if it is then exported. However, according to Article 2.7(c), importation of a polymer made from that same source of monomer would not trigger the need for a further registration of the monomer. This is true if the monomer has indeed been registered up the supply chain for use in the polymerisation. Companies should also check if other polymers involving same monomer are imported by the same entity. If relevant, the sum of tonnage for the same monomer should be made.

In conclusion, once REACH is enacted, companies involved with polymers, will have to ensure that the monomers they use are adequately registered, or exempt – or when importing polymers, consider the need to register the monomers themselves.

➤ **The Relationship between Monomers & Intermediates**

Chemicals used solely as monomers actually fulfil the definition of an intermediate, in that they are manufactured for, consumed in, or used for chemical processing in order to be transformed into another substance i.e. the polymer. Despite this, monomers are now separately defined in REACH in such a way that it appears to encompass just about any chemical which is employed in polymer production. The definition reads as follows:

*Monomer, means 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.*

According to Article 6.2, monomers are not associated with the reduced registration requirements outlined for intermediates in Articles 17 & 18 i.e. due to the Article 6.2 text, monomers are not treated like intermediates **for purposes of Registration**, but

they must be treated like any other substance in the registration phase. However, as no such text exists in Titles VI and VII, monomers will not need to be authorised as they may be considered to be intermediates, unless it is deemed to be necessary on a case-by-case basis.

### Examples

A co-polymer contains monomers A, B, C and D in reacted, i.e. combined form in the following % w/w quantities:

A = 75%

B = 21.5%

C = 2%

D = 1.5%

It must be emphasised that the above refer to monomers in reacted form, they are not residual quantities.

#### ➤ **Polymer is Produced in the EU**

Monomers A, B, C & D have been registered by the monomer producer, importer or his only representative (i.e. if the monomer is produced outside the EU).

Actions for the polymer producer: None required. However, a EU polymer producer needs to confirm that they are able to sustain the use of the monomers mentioned.

#### ➤ **Polymer is Imported into the EU**

##### Situation 1

None of the monomers are registered and the polymer is imported in quantities of <50MT/annum.

Actions for the polymer importer: Pre-register and register monomers A & B. However, there are no requirements to register C or D. Explanation: Although C is used at 2% if <50MT of the polymer is imported, then <1MT of the monomer is imported in reacted form. If >50MT of the polymer were imported, then monomer C would need to be registered.

##### Situation 2

None of the monomers are registered and the polymer is imported in quantities of >50MT/annum and <66.6MT/annum.

Actions for the polymer importer: Pre-register and register monomers A, B & C. However, there are no requirements to register D (because it is <1MT/annum and <2%).

##### Situation 3

None of the monomers are registered and the polymer is imported in quantities of >66.6MT/annum.

Actions for the polymer importer: Pre-register and register monomers A, B, & C. D does not require registration even though it is imported in combined form at >1MT/annum, as it is present in reacted form at <2%.

#### Situation 4

Monomers A and B are registered by the supplier of the monomers, who then exports the monomers to the polymer manufacturer located outside the EU. The polymer is then imported in quantities of >66.6MTe/annum.

Actions for the polymer importer: Pre-register and register monomer C. A and B have been registered up the supply chain and D does not require registration even though it is imported in reacted form at >1MT/annum, as it is present in reacted form at <2%.

#### Situation 5

A polymer, made from REACH registered monomers A and B, is exported to a non-EU polymer manufacturer, who then reacts the polymer with monomers C and D. The final polymer is imported in quantities of > 66.6MTe/annum.

Actions for the polymer importer. A and B have been registered up the supply chain. C must be pre-registered and registered. D does not require registration for the same reasons given in situation 4.

### ➤ **Integration with Current EU Legislation**

According to Article 24, substances (including monomers) notified in accordance with 67/548/EEC will be considered as registered under REACH.

For notified (ELINCS compliant) monomers, the question is, when will they be eligible for use in polymers, without these so called new polymers being subjected to the current New Substance Regulations? There are two potential dates, June 2007 or June 2008. If the latter, we could have a situation, whereby REACH is enacted but we still have to notify polymers. A ruling on this is being sought.

What will happen to polymers that have been previously notified polymer under the current legislation? As polymers are exempt from the registration process it seems that these will not be considered registered under REACH. However as in the future polymers may be selected for registration, (Article 138.2), this situation may change and so registrants should keep their documentation safe, (i.e. proof of notification and the supporting data) as it may well be needed for future regulatory action.

## 5. Ethylene<sup>2</sup> as an Example for Pre-Registration under REACH

The discussed scenario is totally fictitious and not related to any specific company. The scenario was developed to generically cover questions related to pre-registration.

The evaluation is based on the final REACH text, Regulation (EC) No 1907/2006, published in the Official Journal of the European Union on December 30, 2006.

### ➤ Scenario and assumptions

Ethylene is regarded as a substance within the definition given by REACH.

We realize that more complex substances exist; we may follow up in one of the next newsletters with a more complex example.

Only phase-in substances can be pre-registered. How to decide whether a substance is a phase-in substance was outlined in letter #4.

Ethylene is listed on the EINECS<sup>3</sup>; it is therefore a phase-in substance and can be pre-registered.

We consider a company with different locations that manufacture, import or use ethylene. We assume that the company has a clear picture of its organisation and structure in the sense of defining all the legal entities in each country:

- The holding company and the headquarters are located in Switzerland.
- The company has two legal entities in the EU (Germany, Belgium).
- The company has one legal entity outside the EU (Russia).

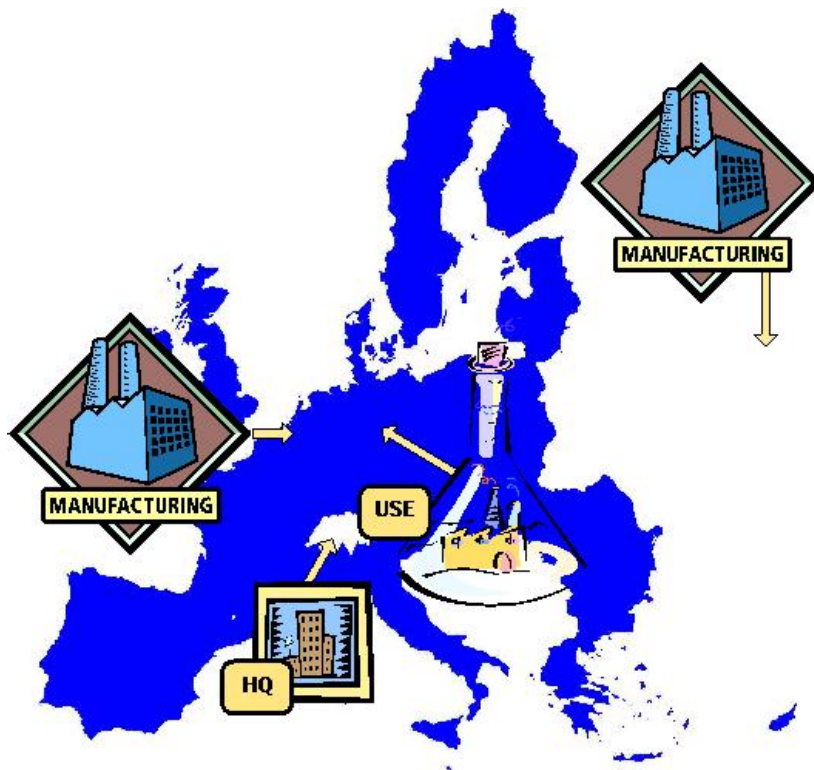
### **Step 1: Identify the roles of each legal entity under REACH**

Manufacturing of ethylene takes place in Belgium and Russia. The German legal entity is using but not producing ethylene. The suppliers of the German legal entity are the Russian and the Belgian legal entities.

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<sup>2</sup> Downstream uses for Ethylene can be found on the flowchart provided by APPE at <http://www.petrochemistry.net/flowchart/flowchart.htm>.

<sup>3</sup> The EINECS status can be checked at <http://ecb.jrc.it/esis/>



The first step when preparing for REACH is to identify the role of each legal entity under REACH because the obligations might differ.

Legal entity	Role in Supply Chain	Volume [tonnes/a]	Remarks	Role in REACH
Switzerland	holding company, Headquarters			none
Belgium	Manufacturer	1.000.000	sells the whole production to Germany	Manufacturer
Russia	Manufacturer	500.000	900 are sold to the German subsidiary	none
Germany	Importer for in total consumption of	900 1.000.900	from Russia from Belgium and Russia	Importer

### Step 2: Identify the legal entities that can pre-register

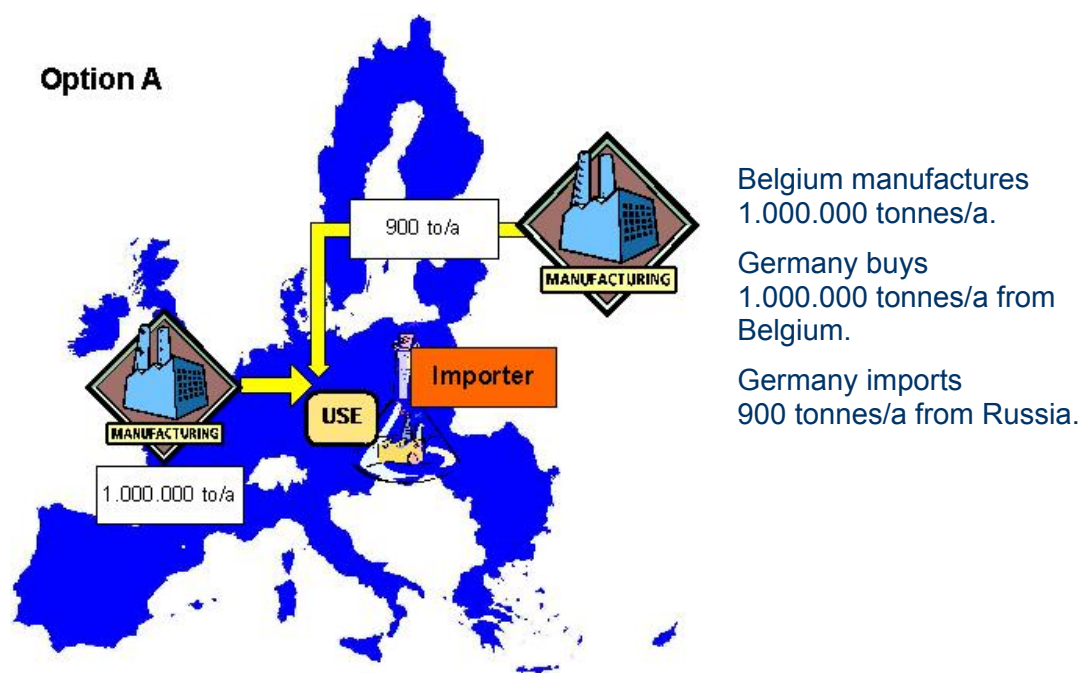
REACH requires manufacturers and/or importers (M/I) to register substances. M/I will be required to pre-register if they wish to benefit from the transitional periods for registration (3.5, 6, or 11 years, respectively).

Only M/I (in this example legal entities) established in the EU have obligations under REACH: The Belgian legal entity, as a manufacturer, and the Germany legal entity,

as an importer, are candidates for pre-registration of ethylene. Russia is not an EU country, so cannot participate directly in REACH. There is the possibility for companies based outside the EU to appoint an [only representative \(OR\)](#). The OR has to be based in the EU, will acquire the responsibility to fulfil the obligations of REACH for the non-EU legal entity.

REACH can drive strategic decisions to be taken by companies from the pre-registration phase. The following example will be used to illustrate the possible scenarios available to a fictitious organisation and will be refined further into different options A, B.1, and B.2.

- **Option A - Initial Scenario**



### Pre-registration possibilities

#### Belgium:

The Belgian legal entity is a manufacturer and can pre-register.

#### Russia:

Russia is not a member of the EU and therefore has no obligations under REACH thus no pre-registration activities in Russia are required.

#### Germany:

The German legal entity is importing from Russia and can pre-register. The volume bought from Belgium does not constitute an import within the meaning of REACH as Belgium is an EU country.

- **The Question of appointing a third party representative**

Article 4 provides for any M/I the possibility to maintain his identity undisclosed for confidentiality reasons within the pre-registration process. Article 4 of REACH states that "any M/I [...] may, whilst retaining full responsibility for complying with his obligations under this Regulation, appoint a third party representative for all

proceedings" under Pre-registration / Data Sharing involving discussions with other M/I. "In these cases, the identity of the M/I [...] who has appointed a representative shall not normally be disclosed by the Agency to other M/I".

In Option A of the given example, both the Belgian legal entity, as a manufacturer, and the German legal entity, as an importer, have the option to appoint a third party representative whilst retaining full responsibility for their obligations under REACH. Both legal entities would have to pre-register indicating that they want to use a third party representative.

Given the new legal environment under REACH it might be beneficial for the organisation to consider whether the German legal entity should be given the role as importer and all of the obligations this role will entail. Another possibility is encountered which generates two further scenarios:

- **Option B**

The Russian legal entity cannot be an importer under REACH because it is not based in the EU. In this example, the Russian legal entity decides to appoint an "only representative" (OR) to perform the pre-registration and registration activities in the EU on its behalf.

The OR would be regarded as the importer.

- **Option B.1:** The organisation appoints an external OR who is not part of the group of companies.
- **Option B.2:** The organisation appoints a legal entity within the group of companies as the OR for the Russian legal entity.

<p><b>Remark:</b> In the example outlined in this newsletter, we have decided that the Belgian legal entity will be appointed as OR. It should be kept in mind that the same duties could also be taken over by the German legal entity, which would then act not only on its own duty as an importer, but as the OR for all imports from the Russian legal entity into the EU.</p>
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- **The Question of appointing an "Only Representative" (OR)**

According to REACH, an importer "means any natural or legal person established within the Community who is responsible for import". A legal entity that is manufacturing outside the EU (in this example the Russian legal entity) therefore cannot be the importer within the meaning of REACH.

The importers are the EU based companies who buy from the non-EU manufacturer (in this example the German legal entity). A non-EU manufacturer can relieve his customers of the registration obligation by appointing an OR in the EU who will be responsible for fulfilling the importer obligations under REACH.

The representative could e.g. be:

- one of the company's already existing legal entities within the EU
- a newly setup office
- or a natural or legal person that is appointed.

The REACH regulation states in Art. 8 that "A natural or legal person established outside the Community who manufactures a substance [...] that is imported into the

Community may by mutual agreement appoint a natural or legal person established in the Community to fulfil, as his only representative, the obligations on importers under this Title." (Registration of Substances). "The representative shall also comply with all other obligations of importers under this Regulation."



The **Russian legal entity**, because it is not located in the EU, decides to appoint an "only representative" (OR) to fulfil all obligations under Title II "Registration of substances". The only representative can also pre-register for the Russian subsidiary. The OR will act as the importer and will have to fulfil all the legal obligations for importers under REACH.

The Swiss headquarters volunteer to act as the only representative, but the offer cannot be accepted because the only representative must be established in the Community (Art. 8, 1.).



In this specific example the most obvious approach is to appoint the Belgian legal entity as "only representative" for the Russian legal entity because Belgium being an EU manufacturer of ethylene can pre-register anyway.

In **all** cases the OR would need to have the required "sufficient background" in the practical handling of ethylene and the information related to ethylene (Art. 8, 2.). The Belgian subsidiary agrees to take over the task.

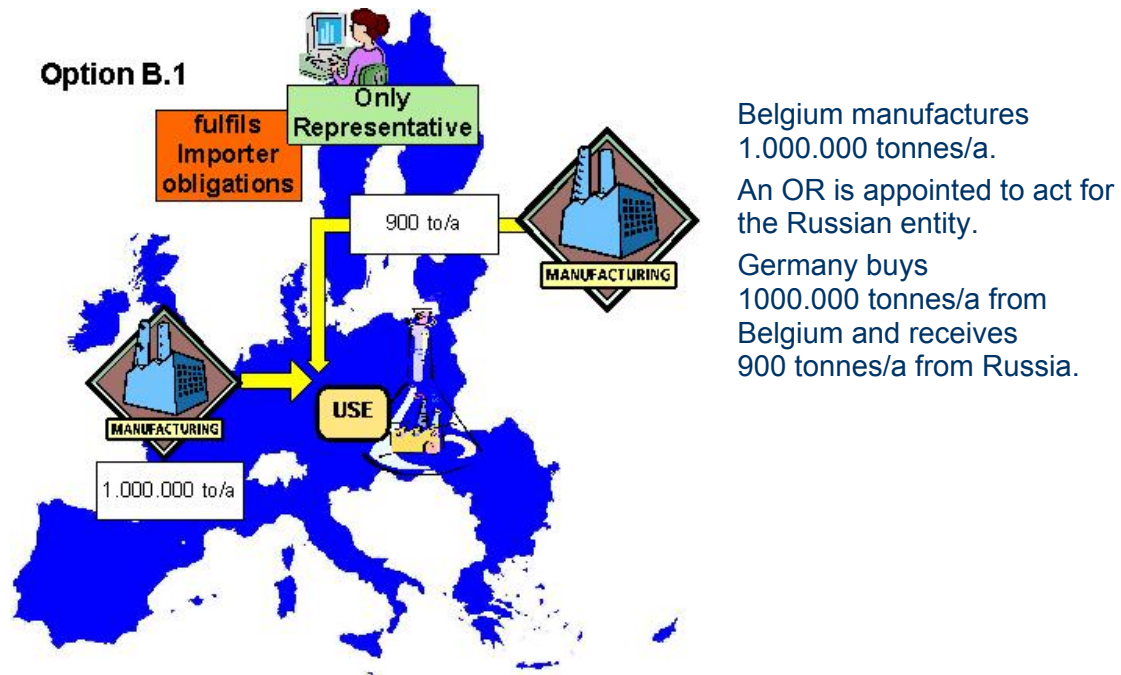
#### The requirements for appointing an "only representative" are fulfilled:

- Russian legal entity
  - is a legal person established outside the Community
  - manufactures a substance that is imported into the Community
- Belgian legal entity
  - is a legal person established in the Community
  - has agreed to act as only representative for Russia
  - has sufficient background (Art. 8, 2. requirements)
    - in the practical handling of ethylene and
    - the information related to ethylene

**Remark:** In our fictitious company, appointing the Belgian subsidiary as only representative for their Russian colleagues requires an additional project: A project group is given the task to ensure that the Belgian subsidiary is able to **comply with the additional requirements listed in Art. 8, 2.:** "keep available and up-to-date information on quantities imported and customers sold to, as well as information on the supply of the latest update of the safety data sheet". Because these activities are distributed widely within the company, experts from several departments within the fictitious company are needed, in our case IT (for interfaces with existing software), Sales (they know the customers), HazardComm (they update the MSDSs), and Print&Send (they distribute the MSDSs).

## Option B - Russian legal entity appoints Only Representative (OR)

### Option B.1: External OR (not part of the group of companies)



### Pre-registration possibilities

#### Belgium:

The Belgian legal entity is a manufacturer and can pre-register.

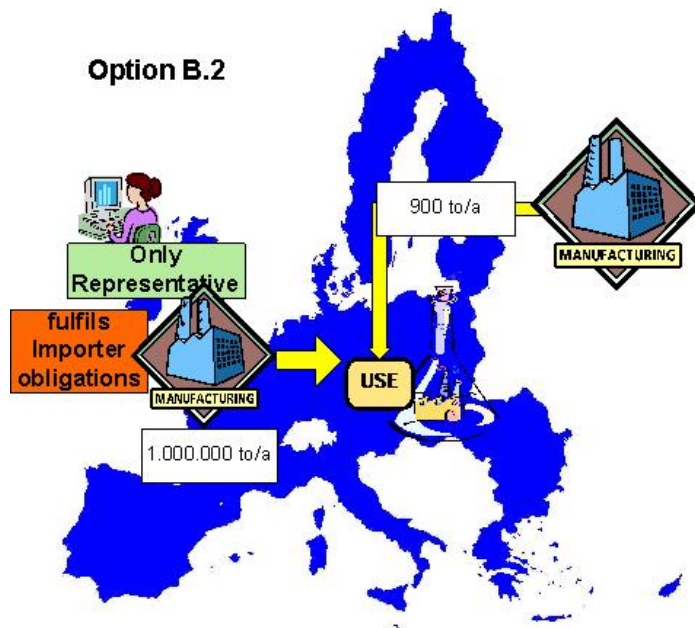
#### Russia:

The Russian legal entity cannot be an importer within the definition given by REACH, therefore it cannot pre-register directly. The OR that was appointed can pre-register. The OR could e.g. be an already existing legal entity within the EU, a newly setup office, or a natural or legal person that is appointed.

#### Germany:

The German legal entity does not need to pre-register (nor to register) ethylene as the German legal entity is not an importer in this scenario. Belgium and the OR will pre-register.

### Option B.2 - Company-Internal OR



Belgium manufactures 1.000.000 tonnes/a.  
 Belgium is appointed to act as the OR for the Russian entity.  
 Germany buys 1.000.900 tonnes/a from Belgium and receives 900 tonnes/a from Russia.

**Pre-registration possibilities**

**Belgium:**

The Belgian legal entity is a manufacturer and an 'only representative' (importer) at the same time and can pre-register.

**Russia:**

As Russia is not a member of the EU and the Russian subsidiary cannot be the importer into the EU within the definition given by REACH, no pre-registration activities in Russia are required.

**Germany:**

The German legal entity does not need to pre-register (nor to register) ethylene, as the German legal entity is not classified as an importer anymore. Pre-registration will be done by Belgium acting as a manufacturer and as the OR at the same time.

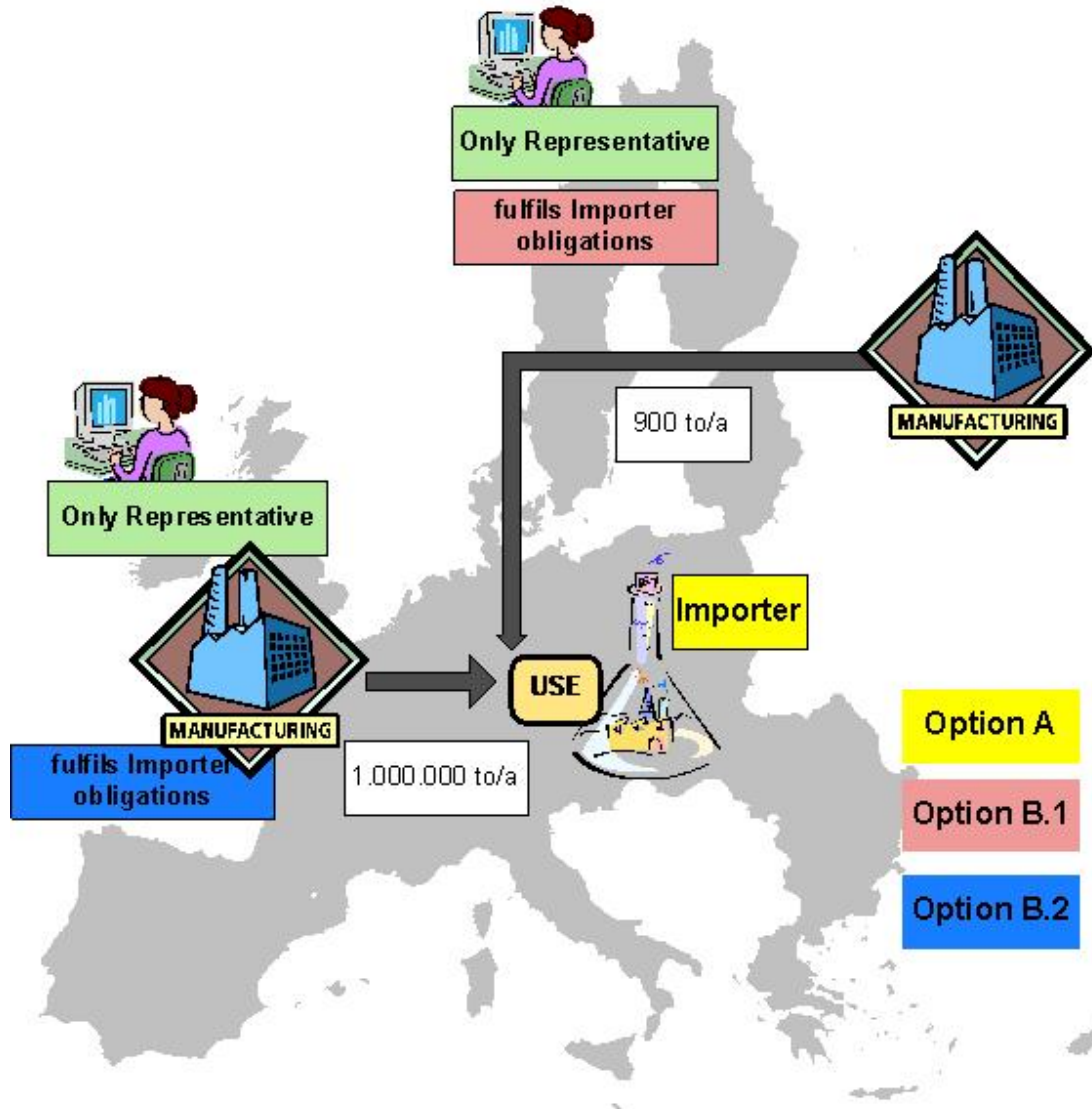
**Remark:** In this example, we have decided that the Belgian legal entity will be appointed as OR. If the German legal entity were appointed as OR, it would have to pre-register the volume imported from Russia.

**Summary of Pre-registration Possibilities in the three legal entities**

Option	Belgium (B)	Russia (RUS)	Germany (D)
A	manufacturer	non-EU manufacturer	Importer
	manufactures 1.000.000 tonnes/a	manufactures 500.000 tonnes/a sells 900 tonnes/a to D	buys 1.000.000 tonnes/a from B  buys 900 tonnes/a from RUS (relevant for importer status)

Option	Belgium (B)	Russia (RUS)	Germany (D)
	Pre-registration	No REACH obligations	Pre-registration
<b>B.1</b>	manufacturer	non-EU manufacturer	downstream user
	manufactures 1.000.000 tonnes/a	appoints external OR in EU	buys 1.000.000 tonnes/a from B  buys 900 tonnes/a from Russia
	pre-registration	pre-registration by OR	no pre-registration required
<b>B.2</b>	manufacturer, OR	non-EU manufacturer	downstream user
	manufactures 1.000.000 tonnes/ acts as OR for 900 tonnes/a from Russia	appoints internal OR in EU	buys 1.000.000 tonnes/a from B  buys 900 tonnes/a from Russia
	pre-registration	pre-registration by OR	no pre-registration required
			<b>Remark:</b> If the German legal entity was appointed as OR, it should pre- register.

The following figure is intended to exemplify who has to fulfil the importer obligations in each of the scenarios A, B.1, and B.2.



**Remark:** In the example outlined in this newsletter, we have decided that the Belgian legal entity will be appointed as OR. If the German legal entity was appointed as an OR, it would fulfil the importer obligations.

**Step 3: Information needed for pre-registration**

The REACH text requires the information given in the left column of the tables below for pre-registration.

No specific format is required for data submission in pre-registration.

### Data submission by the Belgian subsidiary (all Options)

Data required for pre-registration	Data from the Belgian Subsidiary
Name(s) in the IUPAC nomenclature or other international chemical name(s)	ethene <sup>4</sup> , Ethylene
Other names (usual name, trade name, abbreviation)	bicarburetted hydrogen, Elayle
EINECS number if available and appropriate	200-815-3
CAS number if available	74-85-1
CAS name if available	Ethene
Other identity code (if available)	not applicable
name of the potential registrant	The Belgian Subsidiary
address	Antwerp Belgium
name of the contact person	Jan Doe
name and address of the third party representative where appropriate	none
envisaged deadline for the registration	entry into force + 3,5 years
Tonnage band	> 1000 tonnes
substance(s) which you intend to use for read-across approach or (Q)SAR <sup>5</sup>	none

**Remark:** In case the OR takes over *all* obligations of importers under the REACH regulation (Art. 8.2), the Belgian legal entity needs to submit *two* pre-registrations: one for their own manufactured volume as in the example given above, an additional one for the purpose of acting as an OR.

### Data submission by the external OR for the Russian subsidiary (Option B.1)

Data required for pre-registration	Data submitted for the Russian Subsidiary
Name(s) in the IUPAC nomenclature or other international chemical name(s)	ethene, Ethylene
Other names (usual name, trade name, abbreviation)	bicarburetted hydrogen, Elayl
EINECS number if available and appropriate	200-815-3
CAS number if available	74-85-1
CAS name if available	Ethene
Other identity code (if available)	not applicable
name of the potential registrant	Best Consultant Services
address	Anywhere European Union
name of the contact person	Olaf Doesson
name and address of the third party representative where appropriate	None

<sup>4</sup> [http://www.acdlabs.com/iupac/nomenclature/93/r93\\_684.htm](http://www.acdlabs.com/iupac/nomenclature/93/r93_684.htm)

<sup>5</sup> cf. newsletter #3, 4,4 Grouping of Substances

Data required for pre-registration	Data submitted for the Russian Subsidiary
envisaged deadline for the registration	entry into force + 6 years
Tonnage band	100 - 1000 tonnes
substance(s) which you intend to use for read-across approach or (Q)SAR	none

#### Data submission by the German subsidiary (Option A)

Data required for pre-registration	Data from the German Subsidiary
Name(s) in the IUPAC nomenclature or other international chemical name(s)	ethene, Ethylene
Other names (usual name, trade name, abbreviation)	Aceten, Ethen
EINECS number if available and appropriate	200-815-3
CAS number if available	74-85-1
CAS name if available	Ethene
Other identity code (if available)	not applicable
name of the potential registrant	The German Subsidiary
address	Frankfurt Germany
name of the contact person	Johannes Doemann
name and address of the third party representative where appropriate	none
envisaged deadline for the registration	entry into force + 6 years
Tonnage band	100-1000 tonnes
substance(s) which you intend to use for read-across approach or (Q)SAR	none

**Remark:** In case the German legal entity is appointed as OR for the Russian legal entity in option B.2, the German legal entity needs to submit a pre-registration for the purpose of acting as an OR in this scenario.

#### Step 4: Submit the data

Pre-registration data can be submitted online via the internet at the Agency's website. Although not yet finalised, current work in progress at the Commission shows three different options to submit Pre-Registration data to the European Chemicals Agency (ECHA):

- Enter Pre-Registration data manually into the entry mask to be provided on the Agency's website
- If Pre-Registration data has been gathered / stored in IUCLID5, submission may be triggered from this system by creating a XML data file which will be compliant with the Agency's predefined standard template.
- If Pre-Registration data has been collected in another system, submission may be created from that system as long as it will be compliant with the Agency's predefined standard template.

#### **Questions companies need to answer for themselves**

- Are the roles of each legal entity under REACH clearly defined?
- Do you need an "only representative"? Who can fulfil the obligations? How are you going to manage complying with the requirements listed in Art. 8, 2?
- Which substances do you intend to use for read-across approach or (Q)SAR?
- What is your strategy regarding substance definition (RIP 3.10)?

## **6. Overview of the REACH Implementation project 3-10 (RIP 3.10)**

### **Technical Guidance for the Identification & Naming of Substances in REACH**

#### **➤ INTRODUCTION**

RIP 3.10 Technical Guidance Document (TGD), although not a legally binding document, addresses the methodology on the identification, naming and reporting of a chemical substance within the framework of REACH.

RIP 3.10 consists of 9 sections of in-depth text and definitions to explain to manufacturers and importers how to establish the chemical identity of their substances within the context of REACH. A key element of this guidance is how to name the substance, which is required for the first critical regulatory action, pre-registration. Additional substance identification parameters required for Registration are also covered. RIP 3.10 also gives guidance as to when substances may be regarded as equivalent, which is an essential principle for the process of registration, enquiries relating to non-phase-in substances, data sharing and for SIEF formation. This newsletter provides a brief summary of this guidance.

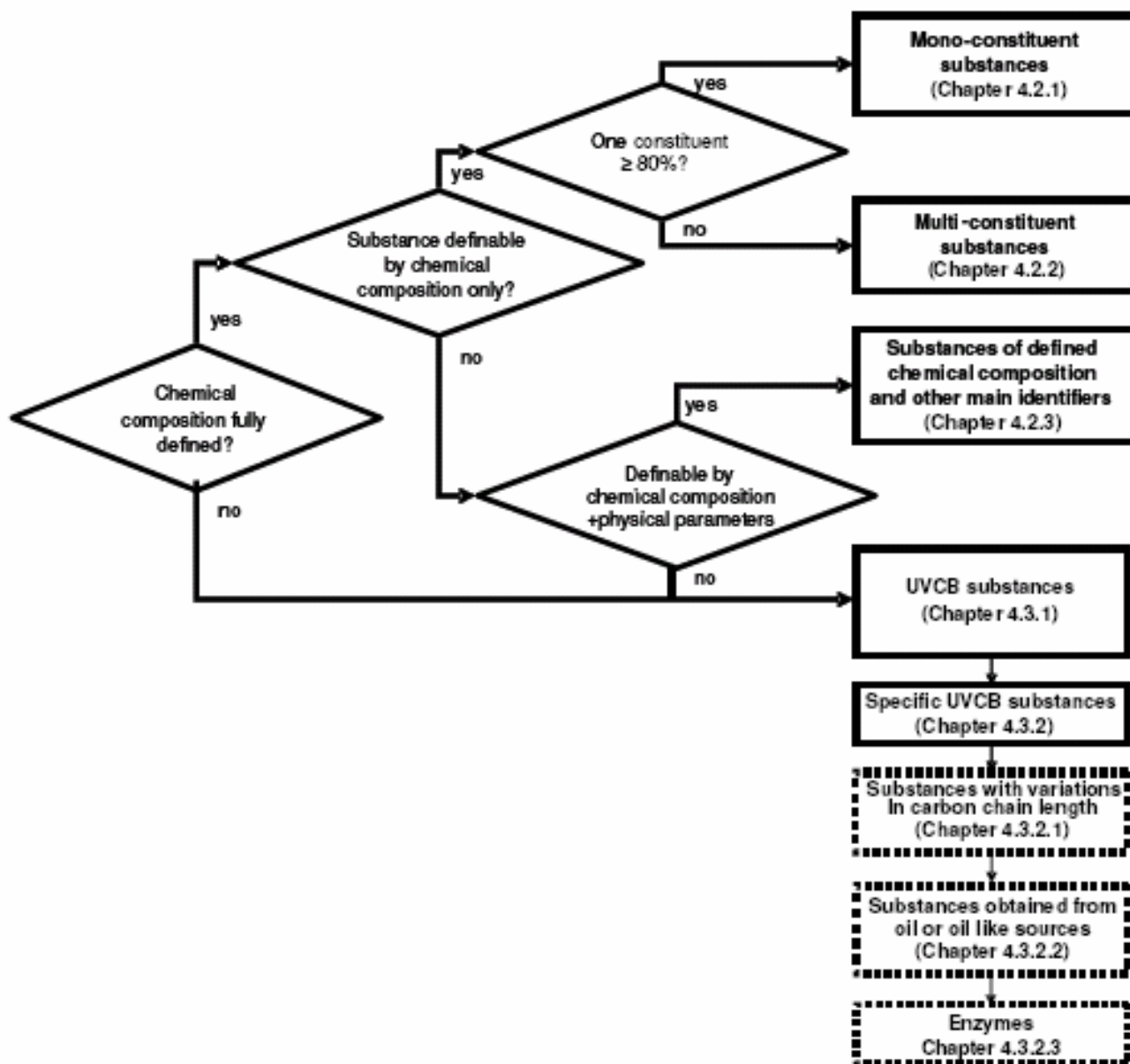
Note that RIP 3.10 is still in draft form, having been sent for consultation in the Technical Committee on New and Existing Substances (TC NES) in July 2006. The draft has been discussed in the TC NES meeting on 22-24 Nov 2006, where the ECB took over the task of preparing revised text proposals for some items still under discussion. Aspects of the guidance are still under consideration by the Commission Working Group.

#### **➤ SUBSTANCE DEFINITION**

There are two main groups of substances in RIP 3.10:

- 1) "Well defined substances": Substances with a defined qualitative and quantitative composition that can be sufficiently identified according to the parameters of REACH Annex VI point 2. The composition of well defined substances is expressed as typical concentration values or ranges.
- 2) "Poorly defined or variable substances": Substances that cannot be sufficiently identified as above. These substances are often referred to as substances of Unknown or Variable composition, Complex reaction products or Biological materials (UVCB Substances).

Below is an explanation of the process with references to the RIP 3.10 sections:



## Substances of well defined composition

Substances of well defined chemical composition are named according to their main constituent(s). Registrants should aim to account for 100% of the composition by showing typical concentration(s) and/or concentration range(s), as verified by the analytical information. For registration purposes each constituent<sup>6</sup> requires a

<sup>6</sup> The following definitions are useful for understanding the text which follows:

complete chemical specification (or “identification”); this includes such parameters as molecular and structural formula. Impurities present at a concentration  $\geq 1\%$  w/w are included in the substance identification in all cases, but if they are relevant to the substance classification they should be included even if they are present at  $< 1\%$ . Impurities should be identified by at least one of: chemical name<sup>7</sup>, CAS and EC number and/or molecular formula.

There are 2 distinct types of substance of well defined composition.

### 1) Mono-constituent substances

A mono-constituent substance has one constituent present at a concentration  $\geq 80\%$  (w/w), and which thus could contain up to 20% (w/w) of impurities. Naming is based on the main constituent only.

#### Examples

Main constituent	CAS number	EC number	Content (%)	Impurity	Content (%)	Registered substance name
m-xylene	108-38-3	203-576-3	99	o-xylene	1	m-xylene
o-xylene	95-47-6	202-422-2	81	m-xylene	19	o-xylene

#### **Deviation from the 80% naming rule has to be justified; possible examples are:**

- If the constituent is  $< 80\%$  but the substance can be shown to have similar physico-chemical properties and the same hazard profile as other mono-constituent substances with the same identity that fulfil the 80% rule.
- The range of concentrations for the main constituent overlaps the 80% threshold and the main constituent is only occasionally  $\leq 80\%$ .

Guidance about describing mono-constituent substances in IUCLID 5 is given in Chapter 8.2.1 of RIP 3.10. Note that RIP 3.10 also gives detailed conventions for naming alkyl groups, isomers, salts etc.

### 2) Multi-constituent substances

Substances that are less than 80% pure are defined as multi-constituent substances.

A multi-constituent substance consists of more than one main constituent present at concentrations of  $\geq 10\%$  and  $< 80\%$  (w/w).

A multi-constituent substance is named as a mixture of the main constituents.

- 
- Main constituent: A constituent that makes up a significant part (generally  $\geq 10\%$ ) of a substance and is therefore used in the substance naming and identification.
  - Impurity: An unintended constituent present in a substance as produced, for example as a result of secondary or incomplete reactions. By definition, an impurity can only be present at  $< 10\%$ .
  - Additive: A substance intentionally added to stabilise another substance.

<sup>7</sup> As a general rule (applicable to mono- and multi-constituent substances and UVCBs) the name should be given in English Language using IUPAC nomenclature. Other internationally accepted designations can be additionally given.

### Example

Main constituent	Content (%)	Impurity	Content (%)	Registered substance name
m-xylene	50	p-xylene	5	Mixture of m-xylene and o-xylene
o-xylene	45			

Guidance, how to describe multi-constituent substances in IUCLID 5, is given in Chapter 8.2.2. of RIP 3.10.

### **The concept of manufactured multi-constituent substances**

***Note that this aspect of RIP 3.10 is still under review, but is included here to update you on this potentially important subject***

During the time of EINECS reporting, the rules declared that: Mixtures obtained as a result of a chemical reaction and placed on the market without separation can be reported as such or by reporting separately the individual constituents if known. Therefore, under the current Directive 67/548/EEC a marketed multi-constituent substance could be considered EINECS compliant, if all its constituents were listed on EINECS.

The interpretation of the RIP 3.10 draft published in July 2006 was that REACH requires registration of the manufactured substance. According to this interpretation, if a multi-constituent substance is produced, it has to be registered as such (and is not covered by registration of the individual constituents).

### Example

A one-pot esterification reaction between two carboxylic acids and one alcohol yields two esters (both present at <80%):

Reactants			Products		
Name	CASRN	EC #	Name	CASRN	EC #
Octanoic acid	124-07-2	204-677-5	2-heptyloctanoate	55193-32-3	259-519-8
Hexanoic acid	142-62-1	205-550-7	2-heptylhexanoate	6624-58-4	229-582-6
Heptan-2-ol	543-49-7	208-844-3			

Under the current regime this reaction product is considered in compliance by virtue of both esters being listed on EINECS. Under the RIP 3.10 draft proposal the substance that would need to be registered is "Mixture of 2-heptyloctanoate and 2-heptylhexanoate", rather than the two individual esters.

This aspect of the RIP 3.10 draft is still under review and it is likely that registrants will ultimately have the choice to register either the reaction product as a whole, or the individual reaction products (constituents) within the mixture. The Commission proposal in the TC NES meeting of 22- 24 Nov was that registration usually should be according to the multi-constituent approach, but the registration approach of

individual constituents could be used, if justifiable. The over-riding factor in the choice of registration route should be the avoidance of extra animal testing or having a “more efficient situation(i.e. avoiding numerous registrations of substances which consist out of the same constituents)” when registering the individual constituents. We will report the final outcome of this review in a future newsletter.

There is no need to test a multi-constituent substance as such if its hazard profile can be sufficiently described using existing information about the individual constituents. If this information does not exist, then there are two options: 1) test the multi-constituent substance as such, or 2) test each of the individual constituents. Option 2 is only possible if no extra animal testing is involved (this could be the case, for example, if a registrant has several multi-constituent substances which contain the same constituents but in different combinations and/or proportions). Again details of option 2 are still under review.

Note that reference can be made to the EINECS listings of the individual constituents to demonstrate the phase-in status of a multi-constituent substance (mixture of the two esters in the above example), and to facilitate the formation of appropriate SIEFs. Also note that the registration of a multi-constituent substance does not cover the individual constituents; if they are also made separately they require their own registrations.

It is important to distinguish between multi-constituent substances and preparations. A preparation is formed when more than one component substance is physically mixed together. In this case each component substance has to be registered by its manufacturer / importer.

### **Poorly Defined or Variable substances**

A lot of chemicals derive from processes where several raw materials will react to form the intended resulting substance.

Due to the nature of the raw materials, their impurities, the processes (main reaction and side reactions) and the final refining techniques the substances may consist of several constituents. In some cases it will not be possible to differentiate between a real constituent and an impurity.

The same applies to products of natural origin, where the composition varies because of region, weather conditions or purification methods.

Other biological materials will be difficult to describe with formulas, molecule structures and CAS numbers.

Due to their very nature, it is more difficult to identify UVCB substances by their chemical composition. An in-depth analysis is provided in section 4.3 of RIP 3.10.

In the group of UVCBs we will find most mineral oil distillates, reaction & refinement products of complex chemicals, most chemicals of biological sources, reaction products of those, enzymes etc. etc.

### **Naming of UVCB Substances**

Naming should be in the order of source and then process(es): those of biological source by the name of the species, and those of non-biological source by the starting materials. Processes should be identified by the type of chemical reaction, if synthesis is involved, or by the refinement step, e.g. extraction, fractionation etc.

EINECS, ELINCS, NLP or IUPAC descriptions are preferred, but have to be supplemented by additional process, origin or refinement information in certain cases.

### Substance Identification for UVCB

This is based on the chemical name, source, process and specification and by the other information specified in REACH Annex VI point 2. This could also include, generic chemical composition, chromatographic, or other type of fingerprint, physico-chemical properties, Colour Index or other recognised nomenclature.

For UVCB substance all known constituents  $\geq 10\%$  should be specified and all constituents that are relevant for classification must be specified.

Unknown constituents should be identified at least by a generic description of their chemical nature.

RIP 3.10 provides detailed guidance for 4 sub-groups of UVCB substances, based on process and chemical type, namely: synthetic biological; synthetic chemical or mineral; refinement biological and refinement chemical or mineral.

### Examples of UVCBs:

1. A reaction product could look like:

*Fatty acids, coco, compds. with diethanolamine*

EC 263-153-4	CAS: 61790-63-4	Condensation product of coco fatty acids and diethanolamine
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Known constituents:

Fatty acids, coco, compds. with diethanolamine	EC 263-153-4	CAS: 61790-63-4	>80%	typical 88%
Coco fatty acid	EC: 262-978-7	CAS: 61788-47-4	<10%	typical 7%
Glycerol	EC: 200-289-5	CAS: 56-81-5	1 - 5%	typical 2%
Diethanolamine	EC: 203-868-0	CAS: 111-42-2	1 - 5%	typical 3%.

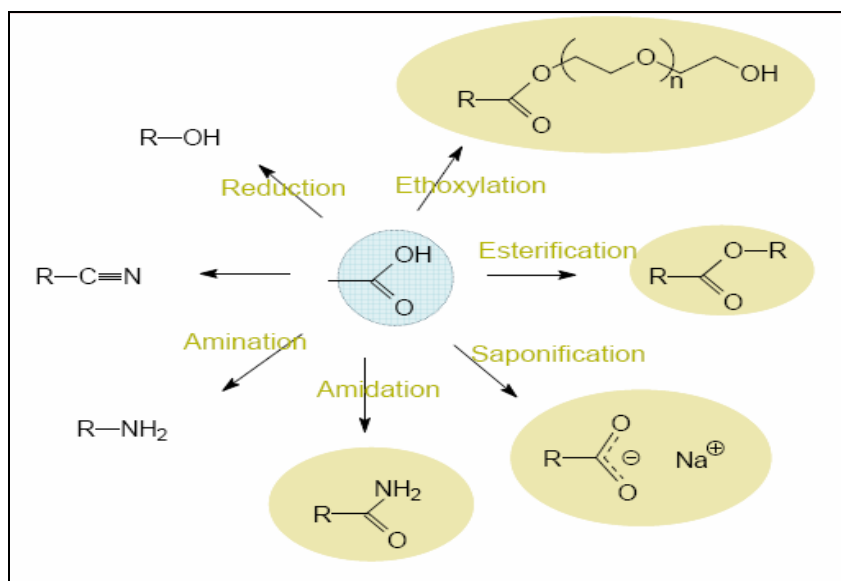
This product consists of various amides formed from various fatty acids which are present in the coconut oil.

The ratio of these fatty acids in the coco nut oil varies already.

The fatty acid mixture which is used for the production still contains traces of glycerol or even coconut oil, which will form part of the final product.

The chemical reaction, condensation, will not be 100%, so traces of the fatty acids, diethanolamine and glycerol will remain in the final product as well.

The condensation product will consist of various fatty acid amides and other esters of fatty acids with diethanolamine. The exact composition varies!



In terms of read-across information, there are at least 3 other CAS/EC numbers related to similar or identical (as far as UVCBs can be identical) substances:

EC: 274-305-4, CAS: 70084-81-0; Fatty acids, coco, esters with diethanolamine

EC: 270-430-3, CAS: 68440-04-0; Fatty acids, coco, reaction products with diethanolamine

EC: 271-657-0, CAS: 68603-42-9; Amides, coco, N,N-bis(hydroxyethyl)

and even:

EC: 232-483-0, CAS: 8051-30-7; Coconut oil, reaction products with diethanolamine.

In the pre-registration submission it is possible to mention alternative CASRN and closely related substances that could potentially be relevant for SIEF formation.

## 2. Another example is solvent naphtha:

*Solvent naphtha, light, aromatic*

EC:265-199-0	CAS: 64742-95-6	Solvent naphtha (petroleum), light arom. A complex combination of hydrocarbons obtained from distillation of aromatic streams. It consists predominantly of aromatic hydrocarbons having carbon numbers predominantly in the range of C8 through C10 and boiling in the range of approximately 135°C to 210°C
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Known constituents:

Propylbenzenes	EC: 202-704-5 & 203-132-9	CAS: 98-82-8 & 103-65-1	4 - 8%
1,2,4-trimethylbenzene	EC: 202-436-9	CAS: 95-63-6	25 - 40%
1,3,5-	EC: 203-604-4	CAS: 108-67-8	9 - 15%

trimethylbenzene			
Ethylbenzene	EC: 202-849-4	CAS: 100-41-4	0,1 - 1%
Xylene (mixture of isomers)	EC: 215-535-7	CAS: 1330-20-7	1 - 15%
Toluene	EC: 203-625-9	CAS: 108-88-3	0,1 - 0,5%
Benzene	EC: 200-753-7	CAS: 71-43-2	< 1 ppm

### 3. A botanically-derived (and refined) product:

#### *Turpentine oil*

EC: 232-350-7	CAS: 8006-64-2	Any of the volatile predominately terpenic fractions or distillates resulting from the solvent extraction of, gum collection from, or pulping of softwoods. Composed primarily of the C <sub>10</sub> H <sub>16</sub> terpene hydrocarbons: alpha-pinene, beta-pinene, limonene, 3-carene, camphene. May contain other acyclic, monocyclic, or bicyclic terpenes, oxygenated terpenes, and anethole. Exact composition varies with refining methods and the age, location, and species of the softwood source.
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Typical composition of turpentine oil (known constituents):

alpha-pinene	EC: 201-291-9	CAS: 80-56-8	60 to 80%
beta-pinene	EC: 204-872-5	CAS: 127-91-3	0 to 35%
other terpenes and resinous by-products			5-20%

### **Analytical information for Well Defined and UVCB substances**

Irrespective of the type of substance, certain analytical data has to accompany any level of Registration:

- Sufficient spectral data (such as UV/Vis, IR, NMR, mass spec.) to confirm the substance identity and structure
- Chromatography to determine the purity profile (composition).

### **Criteria for deciding if substances are the same**

This is crucial for data sharing in the SIEF and the registration process and is described in detail in RIP 3.10 section 5. The following summarises some of these aspects. The principles covered up to this point in the newsletter play an important role in determining whether or not substances from different manufacturers or importers can be regarded as the same. Under REACH the same substance may include the various grades of a production process with varying amounts of different impurities. However, to be considered equivalent, substances should contain the

same main constituents. When the impurity profiles from various manufacturers or importers differ, expert judgement will need to be applied in order to decide if these differences affect whether test data from one can be used by other SIEF members. Substances which are not deemed to be the same may be regarded as similar enough still to enable data sharing. Other than giving some examples of equivalence/non-equivalence, no further guidance is given in RIP 3.10, which implies that the final decision rests with SIEF members based on expert judgement. Putting aside purity considerations, which are the main driving force in determining equivalency, the following examples are given for guidance:

- In general the so-called “80%-rule” for “mono-constituent substances” should be applied. No differentiation is made between technical, pure or analytical grades of the substances.
- Hydrates and water free substances shall be regarded as one substance.
- Substances with chiral centres are regarded as a racemate (mixture of the two isomers) in the absence of any indication to the contrary.
- Alkyl derivatives which are specified for example, iso, neo, branched etc are not considered the same as those substances for which that particular specification does not apply.
- Acids or bases and their salts are different substances. This also applies to different salts of the same acid or base.
- Branched vs. linear or saturated vs. unsaturated versions of otherwise identical substances are deemed to be different.

### Reference substances in IUCLID 5

RIP 3.10 Chapter 8 gives guidance on how to identify substances in IUCLID 5 software, and, amongst other things, it explains the concept of Reference Substances. These are “building blocks” for substances, and can be main constituents, impurities or additives. They are created by the user and are stored in a central inventory (or library). They are retrieved when required to populate the full composition of a substance. The benefit of this approach is to avoid repeated entry of the same identity information when a constituent, impurity or additive occurs in different substances.

#### Example

In the examples of mono- and multi-constituent substances on preceding pages, m-xylene, o-xylene and p-xylene could each be entered into IUCLID 5 as reference substances.

Information that can be stored for each Reference Substance includes:

- CAS number & name
- EC inventory information (from a read-only downloadable database)
- IUPAC name or UVCB substance name
- Synonyms

- Formula, SMILES code, structure
- Molecular Weight

Only identity information, not hazard / test data, is stored for Reference Substances.

Note that a Reference substance is not necessarily the same thing as a “pure chemical listed on EINECS”.

#### Example

The multi-constituent substance “mixture of 1,2-dimethyl benzene, 1,3-dimethyl benzene and 1,4-dimethyl benzene” could itself be a Reference Substance, and used as a building block for variants with different impurities.