



# **REACH Rubber Industry Manual**

**EC. Reg. 2006/1907**

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# 1 INTRODUCTION

The aim of this guidance document is to outline the requirements the Reach Regulation could put on the rubber companies in function of the different roles rubber companies might have in REACH.

The document has been created for HSE managers, product designers, product safety managers and engineering manufacturers of rubber articles.

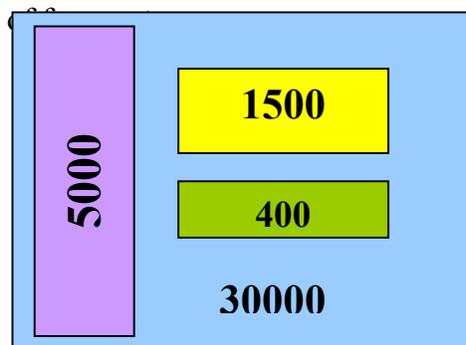
These guidelines are based on the analysis of the text of REACH Regulation as published on the 30<sup>th</sup> of December 2006<sup>1</sup> in combination with the guidance so far developed by the authorities (RIPs – REACH Implementation Projects) and based on the interpretation of these documents by ETRMA staff and Experts. Some of these references may be modified so users are encouraged to check for later versions of this guide. This document can be in fact considered as a living document which will be developed along the time line of REACH implementation.

This document should not be used as a substitute for the applicable rules as defined in the regulation (CE) N° 1907/2006.

## 1.1 MEANING OF REACH

REACH is the new EU chemicals policy, which is build up out of

- **Registration**
- **Evaluation**
- **Authorisation**
- **Restrictions**



*Number of substances expected to be involved.*

The provisions of the REACH regulation will apply to all substances manufactured or imported in a volume totalling above 1 tonne/year per producer or importer of the substances that are placed on the market on their own in the form of preparations or in articles.

<sup>1</sup> [http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l\\_396/l\\_39620061230en00010849.pdf](http://eur-lex.europa.eu/LexUriServ/site/en/oj/2006/l_396/l_39620061230en00010849.pdf)

**Registration:** under the Registration producers and importers of substances have the obligation to register all substances placed on the market in quantities exceeding 1 tonne per manufacturer/importer per year<sup>2</sup>. Safety use of the chemicals placed on the market has to be demonstrated.

**Evaluation:** Evaluation is split up in two blocks:

- *Dossier evaluation*, which is not more than a checking procedure on whether the submitted registration dossier is complete or not;
- *Substance evaluation*, which is fairly comparable to the current system of Risk Assessment.

**Authorisation:** so-called substances of very high concern (SVHC), will only be allowed to be produced and used by companies if an authorisation is obtained. Here it should be born in mind that a authorised use of a chemical might be subject to strict conditions and will be limited in time. The final aim of the REACH regulation is that these substances will be replaced by safer alternatives.

**Restrictions:** This part acts as a general ‘safety net’, where any substance may be subject to restrictions (e.g. banning, or allowing particular uses under specified conditions), regardless of whether they are subject to registration or not. The restrictions process enables risk reduction measures to be introduced across the Community where they are shown to be necessary. For this part the initiative will be lying with the Authorities (Member States, Commission or Agency).

This guidance focuses on registration and authorisation requirements, as those are the areas where industry has the responsibility to initiate the actions and need to comply with specific requirements.

## 1.2 RESPONSIBILITIES UNDER REACH

The obligation to register the substances lies with the producer or importer of the substance (on their own, in preparation or in articles), who has the obligation to register the substance for own use(s) as well as for the uses he intend to place the substance on the market.

A Downstream User (DU) has the right to assist in the preparation of a registration dossier and he also has the right to inform his supplier in writing of his use. The supplier has to take into account his use on the condition the DU is supplying sufficient information on his use and / or further downstream uses to enable the supplier to prepare an exposure scenario as part of the suppliers chemicals safety assessment.

The supplier does however have the right not to include a certain use for reasons of protection of human health or the environment on basis of an assessment. In this case he will have to inform the agency and his downstream users for the reason thereof and shall not supply the Downstream users with that substance without including the reasons why this specific use is not supported via

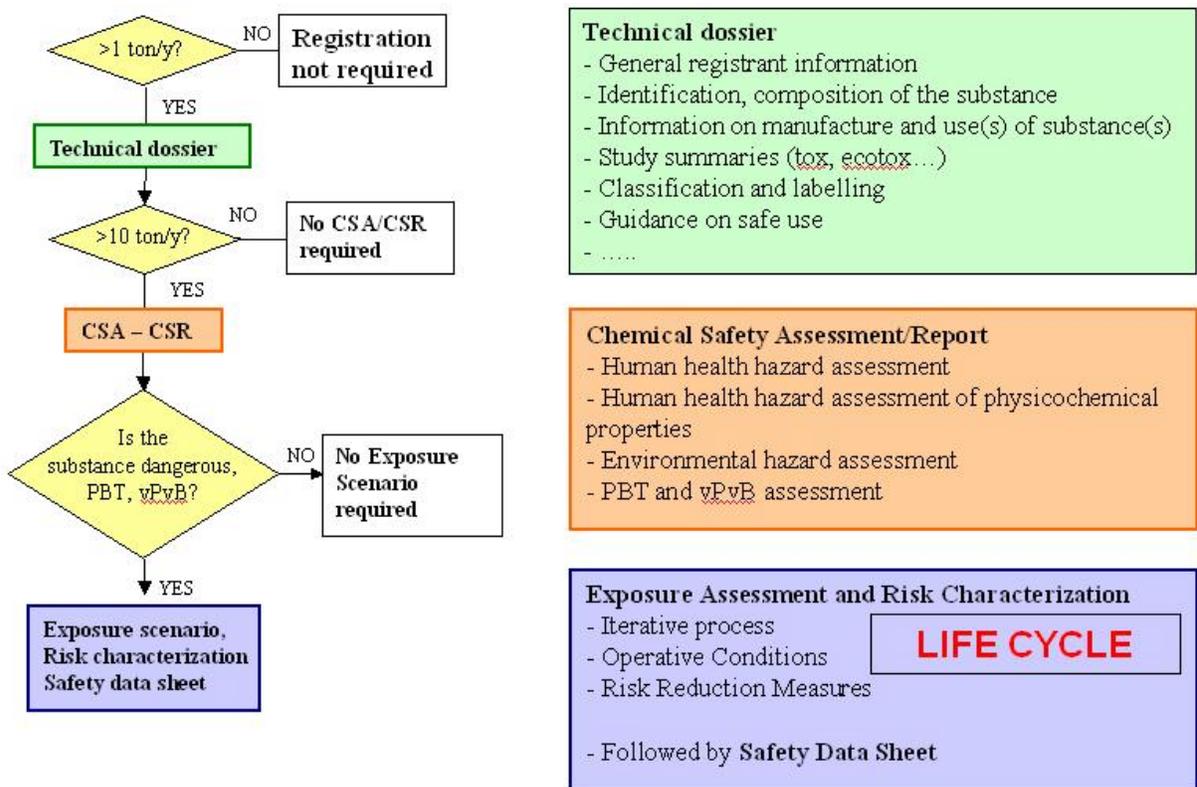
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<sup>2</sup> Means per calendar year, unless stated otherwise; for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be

the information in the Safety Data Sheet (SDS) or the via the alternative information when a SDS is not required.

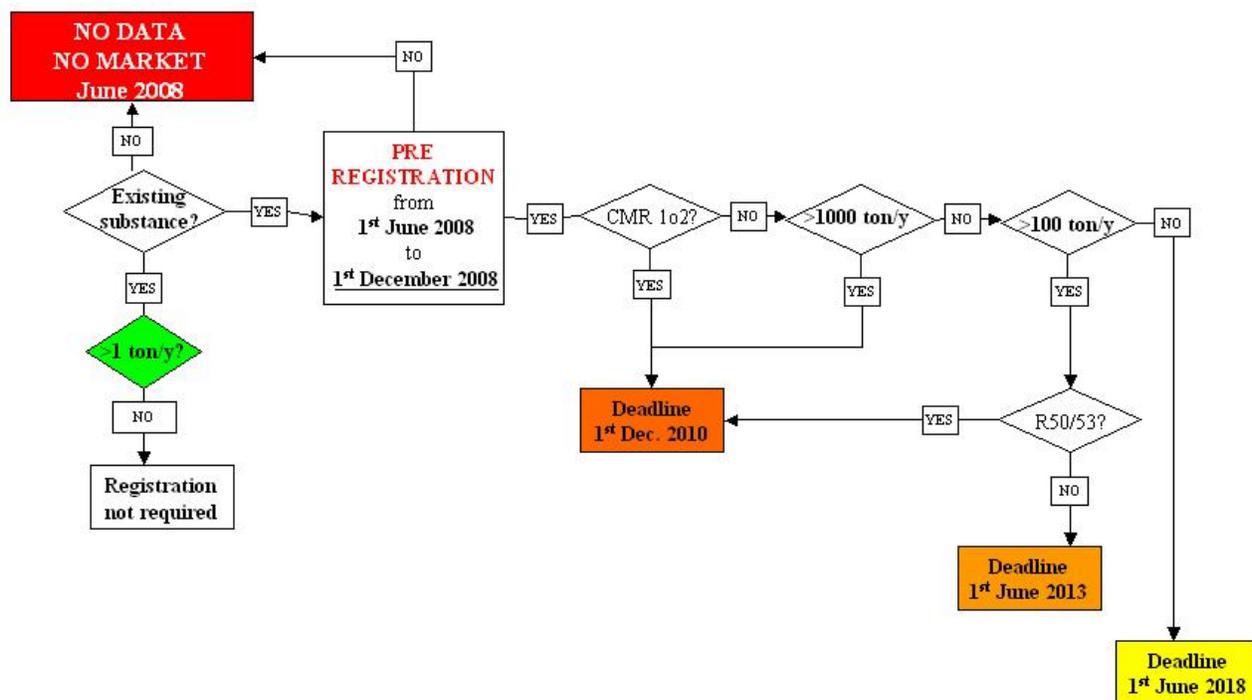
### 1.3 REQUIREMENTS ASSOCIATED TO THE REGISTRATION

The requirement associated to the registration vary in relation to amount and type of substances to be registered. The following flow charts helps to understand the information to be collected and the analysis to be performed.



## 1.4 DEADLINES

As far as the Registration requirements are concerned, a distinction is first made between new and phase-in (existing) substances. For phase in substances the registration will be spread over an 11 year-period.



### 1.4.1 Deadline for new substances

The registration duties for **new substances** or substances that have not been pre-registered (after pre-registration deadline has passed) will apply independently of the volume from 1<sup>st</sup> of June 2008.

### 1.4.2 Deadline for existing substances

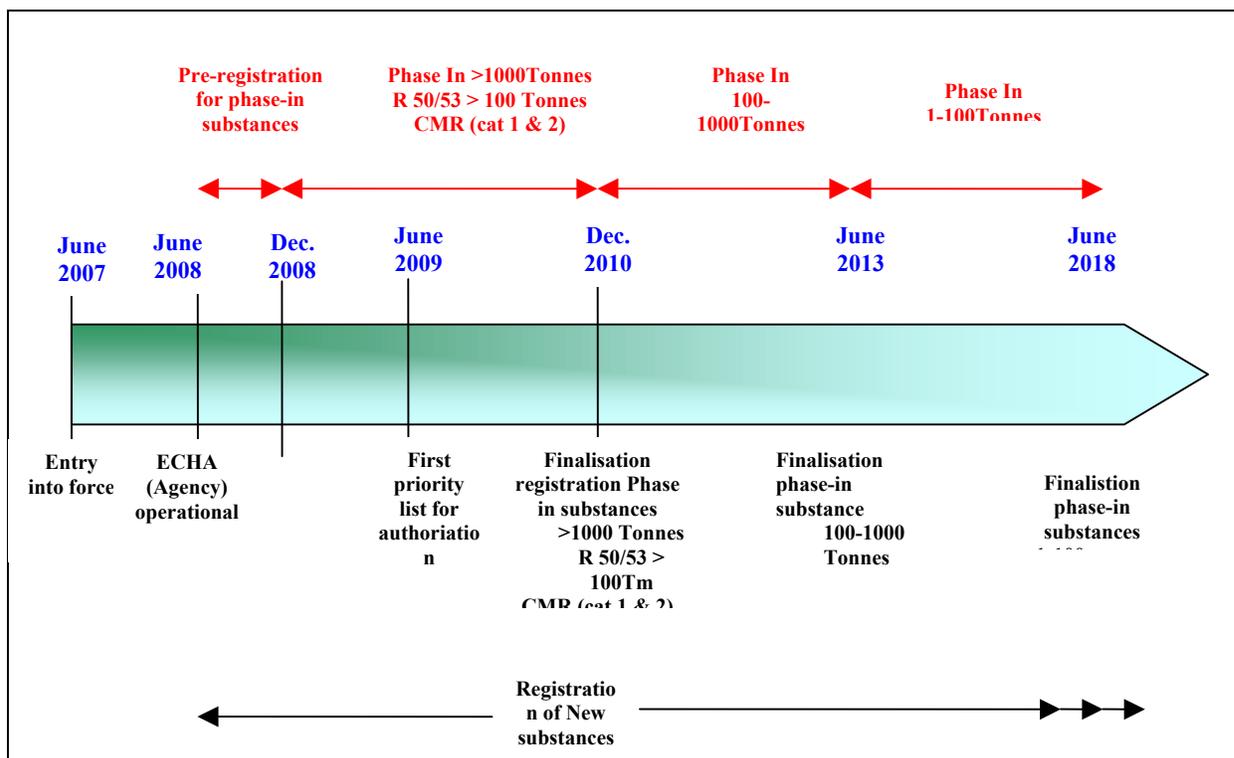
For phase-in (existing) substances the registration will be spread over an 11 years-period, according to the following criteria and timing:

- **1<sup>st</sup> December 2010:** Substances placed on the market in volumes of 1000 or more tonnes/year/producer or importer Substances classified as carcinogenic, mutagenic or toxic to reproduction Category 1 & 2 above 1 tonne/year/producer or importer. Substances with a R50/53 classification placed on the market at least once in quantities of more than 100 tonnes/ year/ producer or importer.
- **1<sup>st</sup> June 2013:** Substances placed on the market in volumes of 100 or more tonnes/ year/ manufacturer or importer:

- **1<sup>st</sup> June 2018:** Substances placed on the market in volumes of one tonne or more per year per producer or importer.

The above stepwise approach is valid on the condition that the substances have been pre-registered in the period between 1st of June 2008 and 1st of December 2008. By 1st of January 2009, the Agency will publish a list of the Pre-registered substances on their website.

Remark: The fact that a substance has been pre-registered does not mean that the pre-registrant is obliged to actually register the substance.



## 1.5 SUBSTANCES AND PREPARATIONS

Even looking at the definitions, a substance is fairly simply defined, in practise it is however much more complicated as no substance is 100% pure. The following conditions can actually exist:

**Main constituent:** A constituent, not being an additive or impurity, in a substance that makes up a significant part of that substance and is therefore used in substance naming and detailed substance identification.

**Impurity:** A constituent present in a substance, as produced. It may originate from the starting materials or be the result of secondary or complete reactions during the production process. Although impurities are present in the final substance, they were not intentionally added.

**Additive:** Substances that have been intentionally added to stabilize the substance, but in the guidance document these are considered for registration purposes as impurities.

In line with the above definitions and existing guidance documents, a (mono-constituent) substance is a substance in which one main constituent is present at a concentration of at least 80% (w/w) and which contains up to 20% (w/w) of impurities.

A preparation could be considered as a chemical product that is a mixture consisting out of more than one main constituent (not reacting and stable in normal conditions).

In addition to the legal text the guidance document currently in preparation in RIP 3.10 is also introducing other concepts extending the original definition.

The first concept concerns the case of multi constituent substances. These are defined as substances that feature several main constituents present at concentrations generally in the range  $\geq 10\%$  and  $<80\%$  (w/w). A multi-constituent substance is named as a “mixture” of two or more main constituents. If a multi-constituent substance is manufactured, the multi-constituent substance needs to be registered and can be tested as a substance as such. This could be considered as an option for “fairly” simple preparations that are imported into the EU.

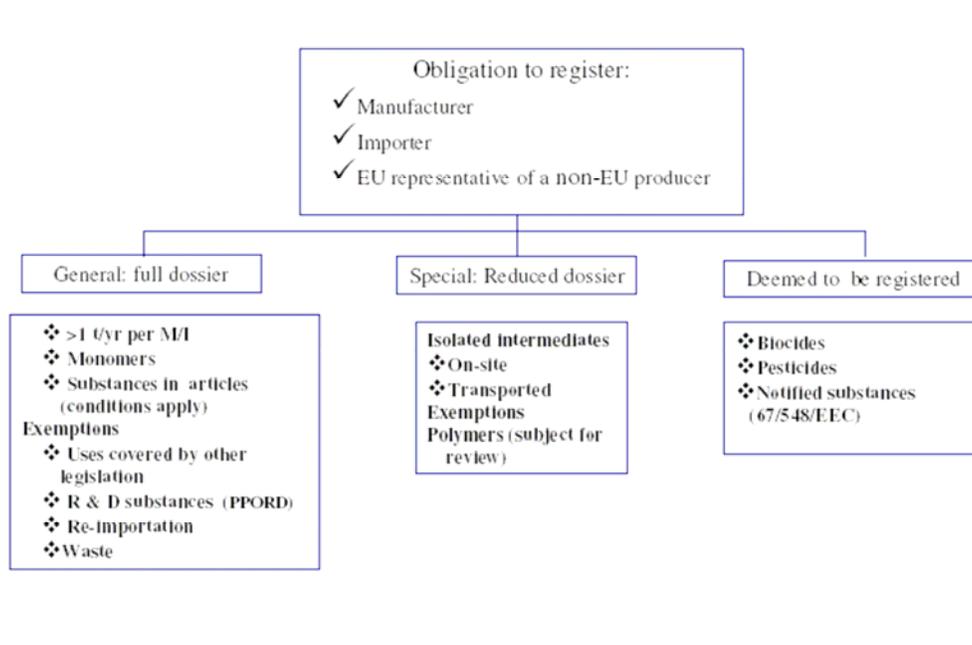
Examples:

Mixture of alkylated phenols (Cas N° 68610-06-0)

Mixture of Bis(3-triethoxysilyl)tetrasulphide (Si69) with Bis(3-triethoxysilylpropyl)tetrasulphane (Cas N° 40372-72-3)

## 2 EXEMPTIONS

In the following paragraphs we outline which substances are entirely or partly exempted from the registration requirements in REACH and further down we will also discuss for which substances special provisions are applicable.



### 2.1 EXEMPTIONS FROM THE DUTY TO REGISTER

The entire, or a substantial part of the REACH Regulation, according to Article 2 will amongst others not apply to:

- ✓ **Waste** as defined in article 3 of Directive 2006/12/EC.

However, producers of chemicals have the duty to assess in their CSA and report in their CSR the impact of their substances on human health and the environment as a consequence of the disposal of industrial waste as well as end-of life products. Additionally, it is clearly stated by the Commission that waste operators have no duty to communicate information up the supply chain as this would be difficult to organise in practice due to the disruption of the communication chain for end-of-life products;

- ✓ Specific uses of substances, preparations in articles when this is deemed necessary in the **interest of defence**, these types of exemption might be granted by Member States.

- ✓ The substances included in annex IV, as they are considered to **cause minimum risk due to intrinsic properties** and the fact that sufficient information is already available. These include certain types of oils and their extracts and physically modified derivatives, such as Sunflower oil, Soybean oil, safflower oil, linseed oil, corn oil, Castor oil, rape oil, etc.
- ✓ Substances covered by annex V, as registration is deemed inappropriate or unnecessary for these substances and their exemption **will not interfere with the objectives of this regulation**, these include:
  - Substances that are the result from a chemical reaction occurring upon end use of other substances, preparations or articles and which are not themselves manufactured, imported or placed on the market.
  - Substances which are not themselves manufactured, imported or placed on the market and which result from a chemical reaction that occurs when:
    - (a) a stabiliser, colorant, flavouring agent, antioxidant, filler, solvent, carrier, surfactant, plasticizer, corrosion inhibitor, antifoamer or defoamer, dispersant, precipitation inhibitor, desiccant, binder, emulsifier, de-emulsifier, dewatering agent, agglomerating agent, adhesion promoter, flow modifier, pH neutraliser, sequesterant, coagulant, flocculants, fire retardant, lubricant, chelating agent, or quality control reagent functions as intended; or
    - (b) a substance solely intended to provide a specific physicochemical characteristic functions as intended.
  - Substances occurring in nature, if they are not chemically modified and if they are not meeting the criteria for classification as dangerous of Directive 67/548/EC.
- ✓ Substances on their own or in preparations, that have been registered, exported from the Community by an actor in the supply chain and **re-imported** into the Community by the same or another actor in the same supply chain who shows that:
  - (i) the substance being re-imported is the same as the exported substance;
  - (ii) he has been provided with the information in accordance with an SDS or equivalent information when no SDS is required relating to the exported substance.
- ✓ Substances, on their own, in preparations or in articles, which have been registered under REACH and which are **recovered** in the Community if:
  - (i) the substance that results from the recovery process is the same as the substance that has been registered.

- (ii) he has been provided with the information in accordance with an SDS or equivalent information when no SDS is required relating to the exported substance.

✓ **Polymers** (limited to Registration and Downstream user requirements)

## 2.2 SUBSTANCES THAT ARE ALREADY DEEMED TO BE REGISTERED

As outlined in article 24, new substances that were notified under the new substances provisions of Directive 67/548/EC shall be regarded as registered and these substances will be given a registration number by 1<sup>st</sup> December 2008.

However, when the quantity of the notified substance is reaching the next tonnage band one will have to submit the information required in line with the new tonnage band as well as all information for the lower tonnage band.

## 2.3 SPECIAL PROVISIONS

There are a number of cases where special provisions will apply; these will be shortly outlined in the following paragraphs.

## 2.4 POLYMERS

Although polymers are at this moment exempted from the REACH registration and evaluation provisions as outlined in Art 2 (9), they remain subject to the authorisation and restriction provisions.

<i>How are <b>polymers</b> covered by REACH?</i>	Registration	Evaluation	Authorisation	Restriction
	No	No	YES	YES
<i>How are <b>monomers</b> covered by REACH?</i>	Registration	Evaluation	Authorisation	Restriction
	YES	YES	YES	YES

In line with the definition of a polymer as outlined in article 3 (5), a polymer is a substance consisting of molecules characterized by the sequence of one or more types of monomer units, where these molecules must be distributed over a range of molecular

weights and where the difference is mainly attributed to the differences in the chain lengths. Therefore, a substance must meet the following two conditions in order to be considered a polymer:

- ✓ Over 50% of the substance must consist of polymer molecules with a chain length of at least three monomer units that are covalently bonded to at least one other monomer unit or other reactants; and
- ✓ The amount of polymer molecules with the same molecular weight cannot exceed 50%. (this could affect the consideration of certain resins, that could be considered as polymers, that have a very narrow weight distribution )

Manufacturers or importers of polymers have the obligation to register the monomers and other substances, even in the form of monomer units chemically bound to the polymer (e.g. initiators, cross-linking agents, stabilizers), when the following conditions are met:

- ✓ They are present in the polymer in concentrations of 2% weight by weight (w/w) or more; and
- ✓ Their volume is exceeding 1 tonne/ year / producer or importer; and
- ✓ The monomers have not been register (for that use) by an actor up the supply chain. The term “up” the supply chain means that it will have to be registered for that use by a supplier up in **your** supply chain.

#### 2.4.1 Implications for rubber companies?

When acquiring your polymers from the EU market, the monomers and additives will automatically have to be registered by the suppliers or importers of the polymer and rubber processing companies will only have to deal with the normal downstream user obligations.

Where it will be a different story is when one is buying or preparing polymer based mixtures (e.g. premixed compounds, master batches, etc..) outside the EU. Where full registration duties will again fall on the rubber sector companies, unless it concerns a re-import of an EU produced substance or when the polymer producer appoints a sole representative as outlined in paragraph 3.3.3.

Remark: On the contrary to the special provisions that are foreseen for substances that have been notified under the provisions of Directive 67/548/EC, Notified polymers will not be exempted from monomer registration requirements unless that notification was performed for the monomers and its additives.

## **2.5 SUBSTANCES USED FOR PROCESS AND PRODUCT ORIENTED RESEARCH & DEVELOPMENT (PPORD)**

In line with the provisions of Article 9, substances (including intermediate substances), substances in preparations and substances in articles are exempted from the registration/notification duties (art 5, 6, 7, 17, 18 and 21) for a period of five years when they are used for product and process oriented Research & Development.

This exemption is applicable to the substances or preparations producers or importers or producers of Articles themselves or in the context of co-operations with listed customers and the exemption is limited uniquely to those volumes that are needed for the purpose of PPORD.

It will however be necessary to communicate the following information to the Agency:

- ✓ Identity of the producer/ importer or producer of the articles;
- ✓ The identity of the substance;
- ✓ The classification of the substance;
- ✓ The estimated quantities;
- ✓ The list of customers, including name and addresses.

The notification will need to be accompanied by a fee and a notification number will be appointed to the notification after the agency has evaluated the application and they might impose conditions to the use of the substance., such as:

- ✓ Only to be used by listed staff under clearly controlled conditions that assure the protection of workers
- ✓ It may not be made available to the general public
- ✓ The remaining quantities need to be re-collected for disposal after the exemption period.

Without any counter indications, one is allowed to use the substance two weeks after the notification.

The initial period of five years may be extended with a maximum of 5 additional years in case this can be justified on the basis of a Research & Development program. Additionally, the provisions of article 37 paragraph 4 section (f) is specifying that when a certain use is not covered by the CSA of the supplier a downstream user will not have to prepare his own CSA/CSR when he is using a substance for the purpose of PPORD on the condition that the risks to human health and environment are adequately controlled in accordance with workers protection and environmental legislation.

## **2.6 FOOD CONTACT MATERIALS**

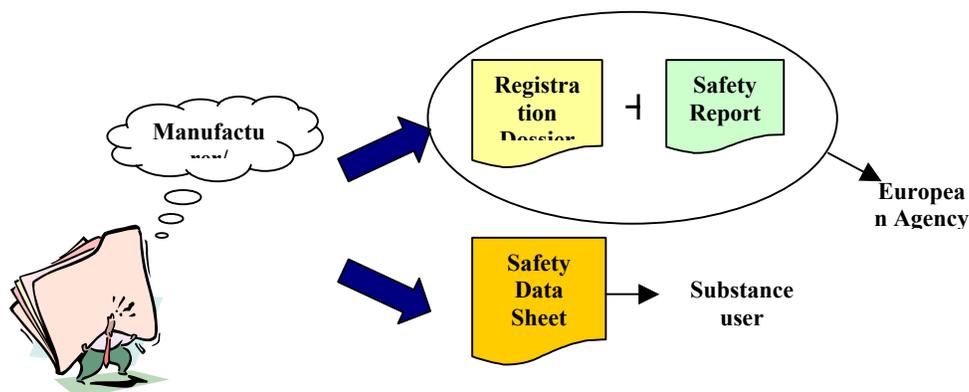
Although the chemicals used for the production of food contact materials like all other substances produced in quantities exceeding 1 tonne/ per year per producer or importer are subject to the REACH requirements. The chemical safety report, in line with the provisions of Article 14 paragraph 5, will not have to consider the risks to human health for food contact materials and articles that are within the scope of EC Regulation 2004/1935.

### 3 OBLIGATIONS FOR RUBBER PROCESSING COMPANIES

Tyre and Rubber Companies are mostly considered and actually act as downstream users of the chemicals industry, but taking into account the global nature of the Chemicals industry, Rubber companies might fall under the various roles:

- ✓ Downstream user of chemicals
- ✓ Producer and supplier of rubber compounds
- ✓ Importer of raw materials ( substances and preparations)
- ✓ Producer or importer of articles

The following chapter we will outline the main requirements each company has to comply with when acting under the REACH regulation in these different roles.



#### 3.1 ACQUISITION OF SUBSTANCES/PREPARATIONS VIA AN EU SUPPLIER.

When you are using chemicals acquired from EU suppliers (producer, importer or distributor), the duty to register the substance(s) is fully the supplier's responsibility. He has the obligation to submit a pre-registration and a registration dossier for all substances he places on the market in quantities exceeding 1 tonne/year and this for his own use(s) as well as for the downstream uses he intends to place the chemical on the EU market. Furthermore, the supplier has to perform a Chemical Safety Assessment (CSA) and document this in a Chemicals Safety Report (CSR), when the volumes of substances are exceeding 10 tonnes/year.

When the substance is meeting the criteria for the classification as dangerous, the CSA will also have to include:

- an exposure scenario for all identified uses of the substance and
- An impact assessment on human health and the environment during the entire life cycle of the substance.

As a downstream user you have the right to assist in the preparation of (parts of) the registration dossier of your supplier (e.g. Exposure scenario on your use), but no obligation.

In addition to the normal information contained in a safety data sheet, REACH will require a supplier to communicate the exposure scenario(s) as part of the *Extended Safety Data Sheet* (E-SDS).

This does however not mean that you will not have any obligations under REACH as a Downstream user and in the next paragraphs we will outline the requirements that have to met by downstream users. Nevertheless, the suppliers will not be able to meet their obligations without the assistance of their customers, as their assessments has to cover the entire lifecycle of the substances (Industrial use, service life and waste treatment). Under the obligation the obligation of the duty to communicate information up and down supply chain, the supplier has a right to ask for such information.

### **3.2 ASSESSMENT OF INFORMATION RECEIVED FROM YOUR SUPPLIER**

As a DU your main obligation will be to assess the information received from your supplier either the E-SDS unless an SDS is not required to be provided, you will have to assess if:

- ✓ your use is covered by the intended uses or use or could be considered to be covered by one of the use & exposure categories listed in the E-SDS
- ✓ you are at least implementing the risk reduction measures advised by your supplier.

The sections that are important to be checked are section 1.2; 2; 8 and 16 (Unsupported uses and Exposure scenario's)

### **3.3 INFORMATION TO BE COMMUNICATED TO THE SUPPLIER**

Downstream Users have the right to make a use of a substance or preparation known to their supplier(s) in writing with the aim of making it an identified use. By means of supplying sufficient information on your conditions of use to enable the Supplier to prepare an exposure scenario, or if appropriate a use and exposure category, for your use in his chemical safety assessment. this information has to include at least a brief, general description of the use.

 new substances, the supplier will have to take on board the notified intended use before he next supplies of the DU on condition that the request was made at least one month before the supply or within one month after the request, whichever is the latter.

For phase-in substances he will have to take on board the request before the registration deadline expires, on the condition that he has issued the request at least twelve months before the registration deadline.

Nevertheless, the supplier has the right after having assessed the use, not to include a certain use for reasons of protection of human health or the environment. He then will have the obligation to inform in writing both the Agency and the DU of the reasons for that decision and stop the supply of the substance/ preparation in question.

From a practical point of view, the following information is considered as necessary by the stakeholders experts that were involved in the development of the RIPs:

- ✓ General description of the use
- ✓ Situation of exposure (normal conditions of use, maintenance and cleaning)
- ✓ Conditions of use (Temperature, frequency of use, duration of use, concentration, physical form)
- ✓ Exposure estimation/ data
- ✓ Human health: dermal, oral, ingestion
- ✓ Environment: air, water, soil
- ✓ Sewage Treatment plant
- ✓ Waste treatment
- ✓ Implemented risk reduction measures

This type of information should cover the industrial use, service life and treatment of waste (Production and consumer products). In function of these requirements ETRMA is developing standardized templates to assist the companies to provide information to suppliers in a standardized manner. It will be in the interest of DU's to provide sufficient information on their use when this is needed in order to avoid that the supplier is making a decision against his interest.

### **3.4 CHEMICAL SAFETY ASSESSMENT (ART. 37)**

A Chemical Safety Report must be draw up by a downstream user if the use of the substance/preparation is not covered by the SDS (unless covered by the derogations in art. 37.4). This requirement will arise if:

- ✓ The DU does not inform the supplier of his specific use: an omission or for reasons of confidentiality;
- ✓ When the supplier doesn't support the DU "identified use"

In this case DU will have to prepare a chemical safety assessment for the use of a dangerously classified substance or PBT or vPvB substance. The scope of this CSA is limited to:

- ✓ Development of exposure scenario(s) for your use(s) not covered by the E-SDS received from your supplier and the uses you place the substance on the market (e.g. compounders);
- ✓ If necessary, a refinement of the hazard assessments from the supplier;
- ✓ Risk characterization for the new exposure scenarios.

Subsequently, the DU will have to prepare a CSR according to part B sections 9 and 10 from the format of the CSA in section 7 form annex I of the regulation text.

DU will not have to prepare CSA/CSR when:

- ✓ An SDS is not required, i.e. substance or preparation does not have to be classified as dangerous.
- ✓ A CSR is not required from your supplier, i.e. below 10 tonnes
- ✓ He uses the substance in quantities below 1 tonne/ year
- ✓ The substance is present in a preparation in quantities below the threshold values specified in Art 14 (2).
- ✓ He is using the substance for product or process oriented Research and Development (PPORD), on the condition that the risk to human health and the environment are adequately controlled in line with worker protection legislation.

According to Article 39 (1) a DU will have to meet the requirement outlined above at the latest 12 months after receiving a registration number from your supplier via the Safety data sheet.

### **3.5 DOWNSTREAM USER NOTIFICATION**

As outlined in article 38, you as a DU have to submit a so-called DU-notification to the Agency via the web oriented IUCLID V system, before you may commence or continue a use of a substance that has been registered by an actor up the supply chain in the following cases:

- ✓ You have performed your own CSA and prepared your own CSR. (cfr art 37(4));
- ✓ you are using the substance, on its own or preparation, in a quantity of less than 1 tonne per year or you are using the substance for PPORD, outside a recommended use or under confidentiality exemption;

According to Article 39 (2), you will have to comply with these provisions at the latest six months after receiving a registration number from your supplier via the Safety Data Sheet.

A DU notification to be submitted to the Agency must contain the following information:

- ✓ identity and contact details as specified in section 1.1 of Annex VI;
- ✓ registration number(s) referred to in Article 20(3), if available;
- ✓ identity of the substance(s) as specified in section 2.1 to 2.3.4 of Annex VI;
- ✓ identity of the manufacturer(s) or the importer(s) or other supplier as specified in section 1.1 of Annex VI;
- ✓ brief general description of the use(s), as specified in section 3.5 of Annex VI, and of the conditions of use(s);
- ✓ except where the downstream user is relying on the exemption in Article 37(4)(c), a proposal for additional testing on vertebrate animals, where this is considered necessary by the downstream user to complete his chemical safety assessment.

## 4 IMPORTING RAW MATERIALS FROM OUTSIDE THE EU

The chemicals market lies on a global stage and agreement between supplier and customer are strictly regulated by international trade rules. From a REACH standpoint, the actor responsible for the physical introduction of the chemicals in the EU market can be either the producer or the user of the chemicals.

When importing and using substances on their own or in preparations, the REACH requirements apply similarly as for manufacturers of substances based in the EU. This means that all substances that are placed on the market in quantities exceeding 1 tonne/year/Importer will have to be registered. For preparations, this concerns the substances intentionally added to the preparation/ mixture, but also the impurities when no cut-off levels are applicable.

The only situation where the registration duty is not required concerns re-imported substance, i.e. a substance that was initially produced in the EU and for which the information outlined in Art. 31 or 32 is available.

### 4.1 WITH THE “ONLY REPRESENTATIVE”

The first and definitely the easiest option is that your non-EU supplier appoints an “only representative of a non-Community manufacturer”.

In this case this natural or legal person, who is established in the EU, takes care of importer’s registration duties and you continue to be considered as a downstream. In this case, you only have to meet the “normal” Downstream User requirements outlined in the relevant chapters.

In this context it will again be important to have good contacts with your non EU suppliers in order to:

- ✓ encourage them to appoint a sole representative
- ✓ incorporate a clause in your purchasing contracts where your non- EU suppliers is contractually obliged to appoint a sole representative.

### 4.2 WITHOUT THE “ONLY REPRESENTATIVE”.

If none is appointed, you will have to assume the importer’s obligations, which means that a full registration for each substance place on the market (on its own or in a preparation) in volumes exceeding 1 tonne/year have to be performed. The registration will require you to perform the following tasks:

- ✓ Pre-registration (only phase-in substances)
- ✓ Participation to the SIEF
- ✓ Registration

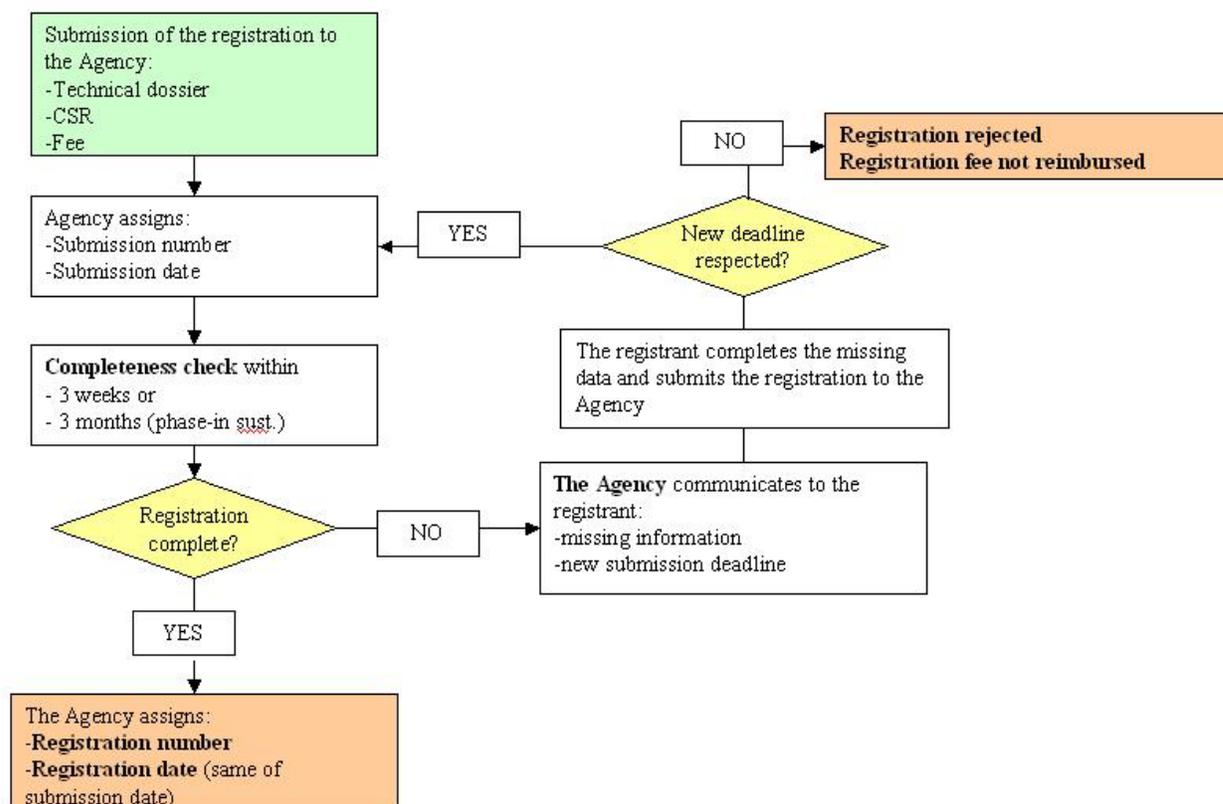
For preparations each ingredient of the preparation, which is meeting the registration requirement, has to be registered, unless the substance is present in the preparation in quantities lower than the lowest of the following limit values:

- ✓ applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC; or
- ✓ concentration limits given in Annex I to Directive 67/548/EEC; or
- ✓ concentration limits given in Part B of Annex II to Directive 1999/45/EC; or
- ✓ concentration limits given in Part B of Annex III to Directive 1999/45/EC; or
- ✓ concentration limits given in an agreed entry in the classification and labelling inventory established under Title XI of this Regulation; or
- ✓ 0,1 % weight by weight (w/w), if the substance meets the (e ) criteria in Annex XIII of this Regulation.

Additionally it will be worthwhile to check if the substance(s) you have to register are not benefiting from any of the special requirements that are outlined in Chapter 2.

## 5 REGISTRATION: PRACTICAL INFORMATIONS

This section contains practical information about the registration. In particular the following flow chart presents the main steps of the registration procedure.



### 5.1 PRE-REGISTRATION

The pre-registration is a facilitation given to the so called “phase-in” substances. This step is required in order to be able to benefit from the volume and hazard based phased in approach and has the aim to obtain information on who has the intention to register a certain substance with the aim of encourage stakeholders that intend to register the same substance to work together and avoid a duplication of work and specially to reduce testing. The requirements to fulfil are quiet simple and straight forward as the information that needs to be submitted is limited to:

- ✓ Name of the substance as specified in section 2 of Annex VI, including its EINECS and CAS number or, if not available, any other identity codes;
- ✓ Address and the name of the contact person and, where appropriate, the name and address of the person representing him in accordance with Article 4 as specified in section 1 of Annex VI;
- ✓ Envisaged deadline for the registration and the tonnage band;

- ✓ Name(s) of substance(s) as specified in section 2 of Annex VI, including their EINECS and CAS number or, if not available, any other identity codes, for which the available information is relevant for the application of sections 1.3 and 1.5 of Annex XI.

This information has to be submitted to the Agency (ECHA) via the IUCLID V web oriented tool.

The Pre-registration period will start on **1<sup>st</sup> of June 2008** and will end on **1<sup>st</sup> of December 2008**. After the Closing of the pre-registration period, the Agency will publish by **1<sup>st</sup> of January 2009** a list with the name of the substance, CAS N<sup>o</sup>, EINECS N<sup>o</sup>, other ID information and the envisaged registration deadline of all the substances that are pre-registered on their website. If a substance doesn't appear on the list published by the Agency, the DU may notify to the Agency of the use of the substance, so that the potential registrants can be informed.

Substances that are not pre-registered will not be able to benefit from the phased registration time table (transitional regime). These substances will need to be registered immediately.

The pre-registration is not a commitment to make a registration and does not guarantee the supply of the substance.

As all candidate registrant are known at the end of the pre-registration period, the Agency will set up a Substance Information Exchange Fora (SIEF) per substance where all pre-registrants and downstream users who have made available information to the Agency will be present.

## **5.2 SUBSTANCE INFORMATION EXCHANGE FORA (SIEF)**

The SIEF are hosted by ECHA. Their aim is to:

- ✓ facilitate, for the purposes of registration and with the aim to come to an agreed core data set for the intrinsic properties, this is also often discussed as being the One Substance One Registration (OSOR) approach on basis of the volume based information requirements outlined in annex VII-XI, via the sharing of:
  - Study summaries of the information derived from the application of Annexes VII to XI;
  - Robust study summaries of the information derived from the application of Annexes VII to XI, if required under Annex I;between potential registrants, thereby avoiding the duplication of studies ; and
- ✓ Share information on the data required by the registration procedures
- ✓ reach agreement on the classification and labelling of the substances

In this context participants "shall":

- ✓ Provide other participant with existing studies; and

- ✓ React to requests for information by other participants; and
- ✓ Collectively identify needs for further studies in the context to prepare the core data set on the intrinsic properties for the technical dossier; and
- ✓ Arrange for such test to be carried out jointly only once (only obligatory for vertebrate animal studies).

Each SIEF will be operational from December 2008 until at least 1<sup>st</sup> of June 2018.

### **5.3 DATA SHARING FOR PHASE-IN SUBSTANCES**

In context of avoiding duplication of testing a candidate registrant of a phase-in substance, a member of the SIEF shall enquire if the relevant study is available with other SIEF members before carrying out this test. In this context, the SIEF could be a major source of information as in order to be able to use the test data for the preparation of the registration dossier one needs to have an authorization to use the study data (either the (robust) study summary or the whole test report).

In case of test data being less than 12 years old, the owner of the data will have to be financially compensated for the use of the information on the basis of an agreement between the two parties.

Any study summary or robust study summary submitted in the framework of a registration under the REACH Regulation conducted more than 12 years ago, can be used by other registrants free of charge by any producer or importer.

#### **5.3.1 Which data have to be shared?**

If it concerns a test that involves *vertebrate animal studies* (VAS), he shall request that study to the owner, who has an obligation to share this study. If the study is less than 12 years old, he will be entitled to be financially compensated on basis of the proven cost of the study in question. In a first instance, it will be up to the different participants to reach a fair, transparent and non-discriminatory agreement on the sharing of the costs. If no agreement can be reached the cost shall be equally shared between the SIEF members. Subsequently the other SIEF members will be entitled to refer to the full study report within two weeks after receiving the payment.

In case of test data being less than 12 years old, the owner of the data will have to be financially compensated for the use of the information on the basis of an agreement between the two parties.

Although, the aim of the SIEF is to encourage the sharing of all test data, members of the SIEF are not obliged to share non-vertebrate animal studies. A SIEF member may ask for the owner of the study to be able to use the study against payment, but there are no legal obligations to share these studies. In this case the other SIEF members should proceed as if no data are available.

In case certain test data requiring testing for the preparation of the core data set are not available within the SIEF, the test should only be performed once by one agreed SIEF members acting on behalf of all others. All participants that need the study to meet their registration requirement will have to pay an equal share of the testing cost and have a right to receive the full study report.

### 5.3.2 Data allowed to be used

The data that can be used to full fill your registration duties can be of the following origin:

- ✓ In vivo test data
- ✓ In vitro test data
- ✓ (Q)SAR
- ✓ Read across data from other substances (if justifiable)
- ✓ Epidemiological data
- ✓ Data of the type mentioned above available in literature

Additionally, also data on use, exposure and risk reduction measures needs to be collected and in this case it can be based on pure measurement data or modeling data.

### 5.4 TECHNICAL DOSSIER

Technical dossier that needs to contain the following information:

- (i) **Identity of the registrants** and sole representative (where relevant) (Name Company, address, telephone number, fax number, e-mail address, contact person, location of the registrants production and own production) as specified in section 1 of Annex VI;
- (ii) **The name of the substances** (IUPAC, trade names, usual names, abbreviations, EINECS, ELINCS, CAS number(s), other id code(s) (if available)) as specified in section 2 of Annex VI;
- (iii) **Information on the manufacture and use(s)** of the substance as specified in section 3 of Annex VI; this information shall represent all the registrant's identified use(s). This information may include, if the registrant deems appropriate, the relevant use and exposure categories;
- (iv) **Classification and labeling** of the substance as specified in section 4 of Annex VI;
- (v) **Guidance on safe use** of the substance as specified in Section 5 of Annex VI;
- (vi) **Study summaries** of the information derived from the application of Annexes VII to XI;
- (vii) **Robust study summaries** of the information derived from the application of Annexes VII to XI, if required under Annex I;
- (viii) **proposals for Vertebrate animal testing** where listed in Annexes IX and X;
- (ix) for substances in quantities of 1 to 10 tonnes, **exposure information** as specified in section 6 of Annex VI;

- (x) a request as to which of the information in Article 119(2) the manufacturer or importer considers should not be made available on the Internet in accordance with Article 77(2)(e), including a justification as to why publication could be harmful for his or any other concerned party's commercial interests.

## 5.5 CHEMICAL SAFETY ASSESSMENT (CSA)

In addition to the technical dossier a Chemical Safety Assessment (CSA) shall be performed and a Chemical Safety Report shall be completed for all substances that are placed on the market in quantities exceeding 10 tonnes per year per registrant. Unless:

- ✓ The substance is exempted from the registration duty or the substance is already regarded as registered.
- ✓ The substance is present in a preparation in concentrations below the lowest of the following:
  - the applicable concentrations defined in the table of Article 3(3) of Directive 1999/45/EC;
  - the concentration limits given in Annex I to Directive 67/548/EEC;
  - the concentration limits given in Part B of Annex II to Directive 1999/45/EC;
  - the concentration limits given in Part B of Annex III to Directive 1999/45/EC;
  - the concentration limits given in an agreed entry in the classification and labelling inventory established under Title XI of this Regulation;
  - 0,1 % weight by weight (w/w), if the substance meets the criteria in Annex XIII of this Regulation.

In line with Annex I, the chemical safety assessment for a substance will have to include the following steps:

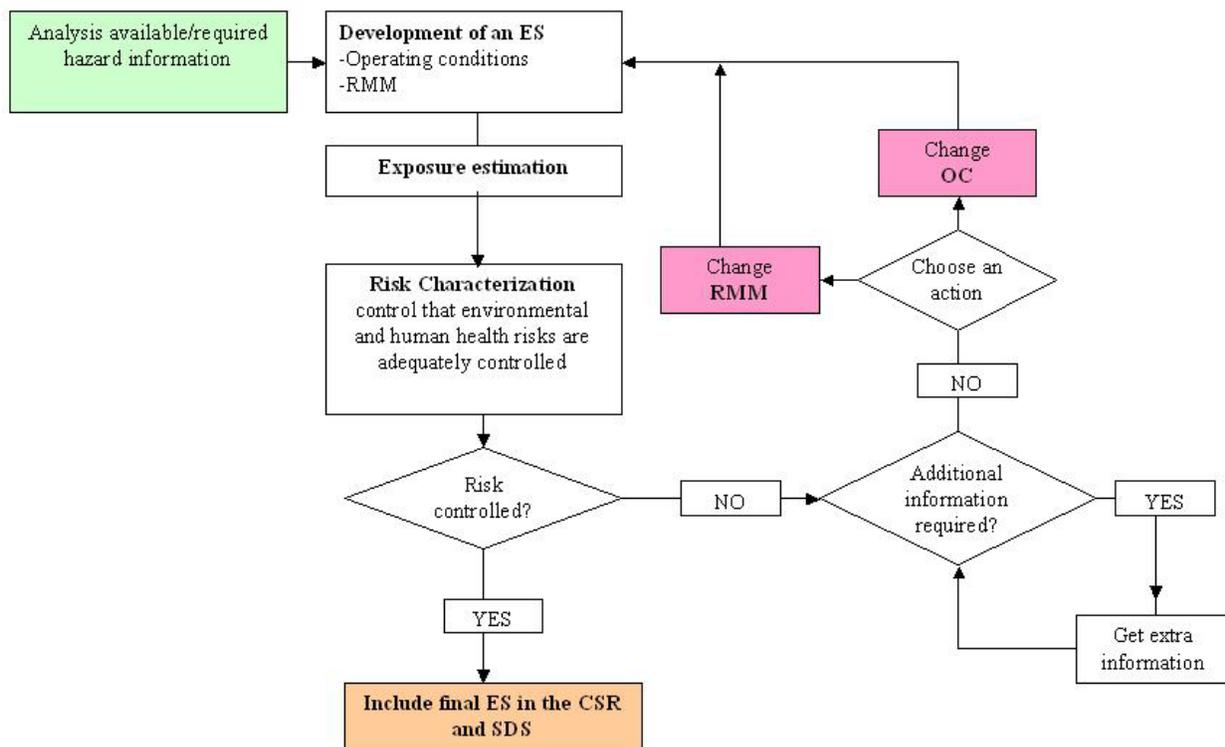
- ✓ Human health hazard assessment
- ✓ Physicochemical hazard assessment
- ✓ Environmental hazard assessment
- ✓ Persistent, bio-accumulative and toxic (PBT) and very persistent and very bio-accumulative (vPvB) assessment

When the above mentioned step leads to a conclusion that the substance meets the criteria for classification as dangerous according to Directive 67/548/EC or is assessed to be a PBT or vPvB substance, the chemical safety assessment also needs to include:

- ✓ An exposure assessment including the generation of an exposure scenario(s) and estimation of the exposures that needs to cover the producer or importers own use as well as the uses of his customers.
- ✓ A risk characterization

The registrant will have to identify and apply the appropriate risk reduction measures to adequately control the risks identified in the CSA and recommend them via the E-SDS (see section 4.3).

Any registrant required to conduct a CSA shall keep the CSR available and up to date.



CSA: Chemical Safety Analysis  
 CSR: Chemical Safety Report  
 RMM: Risk Management Measures  
 OC: Operative conditions  
 ES: Exposure Scenario  
 SDS: Safety Data Sheet

## 5.6 DIFFERENT STRATEGIES FOR THE REGISTRATION OF A SUBSTANCE

For the actual registration one has different options and you will have to weight of what will be the best option for your company. In the following paragraphs, we will outline the different possible options.

### 5.6.1 Individual registration

In this case you decide to register the substance on your own. You will have to prepare the full dossier on basis of the requirements outlined in the previous paragraphs, and which must contain the following parts:

- ✓ The technical dossier including the core data set information up to the level that this is required on the basis of the volume of the substance you are importing.
- ✓ The Chemicals safety assessment/ chemical safety report that may have to include the Exposure scenario's for your uses and/ or other downstream uses.

A manufacturer, importer or downstream user has the right to appoint an independent third party to take care about the following responsibilities:

- ✓ Joint submission of data via a consortium
- ✓ Data sharing provisions cover under title III
- ✓ Cost sharing discussions

This option is for instance useful when you want to remain anonymous with the aim of protecting confidential business information when you have a unique use of the substances, as long as the identity of the stakeholder is known to the Agency.

### 5.6.2 Joint registration

All companies that register the same substance can create a **joint registration**.

Consortia and other companies registering the same substance will automatically be put in contact with each other by the European Chemicals Agency own to the “substance information exchange forums (SIEF).

When creating a consortium, one of the registrant (lead registrant) submits the data that are allowed to be jointly submitted in respect to competition law, this concerns the following information:

- ✓ Classification & labelling information
- ✓ Study summaries of the information derived from the applications of annexes VII-XI.
- ✓ Robust study summaries of the information derived from the applications of annexes VII-XI.
- ✓ Proposals for testing required in line with annexes IX and X.
- ✓ Indication which of the above mentioned information has been assessed by a assessor (optional)

Additionally the registrant may freely decide to submit the following information jointly or separately:

- ✓ Identity of the registrant
- ✓ Identity of the substance
- ✓ Information on manufacture and use of the substances (i.e. identified uses and: or use & exposure categories)
- ✓ Exposure information on use between 1-10 tonnes/year

The following information will however always have to be submitted individually by each of the consortia members:

- ✓ Production capacities; and

- ✓ Production or sales volumes; and
- ✓ Import volumes; and
- ✓ Market shares.

The advantage of joining a consortium will be that one only has to pay for 1/3 of the registration fee, the sharing of the registration workload amongst the different members and if it is decided to hire consultants to be able to share the cost over the consortia.

It will also enable to reduce the number of tests on animals.

Both for the SIEF and a Consortium, the registrant is only required to comply with the information requirements for its tonnage band and therefore will not have to pay financial contribution to get information for additional test that are not required for its perspective.

For confidentiality reasons, it is possible to appoint a third party representative to accomplish the procedures requiring consultations with other manufacturers and importers.

## **5.7 DUTY TO ENQUIRE PRIOR TO REGISTRATION**

Instead of the pre-registration process, every potential registrant of a non-phase-in substance will have the obligation to enquire from the agency whether a registration has already been submitted for the same substance. For this purpose he is required to submit the following information:

- ✓ his identity as specified in Section 1 of Annex VI, with the exception of the use sites;
- ✓ the identity of the substance, as specified in Section 2 of Annex VI;
- ✓ which information requirements would require new studies involving vertebrate animals to be carried out by him;
- ✓ which information requirements would require other new studies to be carried out by him.

In response to his request the Agency will inform:

- ✓ If there are other candidate registrants or not;
- ✓ If the substance has been registered in the last 12 years, and if applicable inform the candidate registrant of the identity of the previous registrant together with the (robust) study summaries of submitted data. This situation could apply when you start you import after the phase-in deadline for your volume or when for instance a producer has decided not to register a chemical but he owns certain data on the substance in question.

## **5.8 SAFETY DATA SHEET**

Safety Data Sheets (SDS) will be the tool to pass on information from manufacturers/suppliers to downstream users. REACH establishes specific requirements for SDS in Art. 31 and Annex II. Some of these requirements were already known from existing EU legislation:

- ✓ The supplier of a substance or a preparation shall provide a safety data sheet in accordance to actual legislation.
- ✓ The SDS will be supplied in the official language of the Member State where the substance or preparation is placed in the market.
- ✓ A SDS will be provided free of charge on paper or electronically.

The new specific requirements are:

- ✓ If a Chemical Safety Assessment (CSA) has been performed for a chemical substance or a preparation, the information in the SDS has to be consistent with the information from the CSA.
- ✓ The SDS will contain 16 headings, as specified in Art. 31 of 1907/2006/EC regulation (See table below).
- ✓ The expose scenarios relevant to perform the CSA of the substance or preparation will come in an annex to the SDS together with the uses of the chemical substance or preparation.
- ✓ Any downstream user shall include relevant exposure scenarios and other relevant information when preparing its own SDS to make known to its supplier its identified use of the chemical substance or preparation, so that this information will be used by the supplier to perform a CSA.

In order to know if the specific use of a chemical substance is allowed, look at the Safety Data Sheet. A chemicals substance specific Safety Data Sheet (SDS) will be the tool to pass down information along the product chain.

The SDS will have to be provided in the official languages of the member state where the substance/ preparation is placed on the market and will have to be supplied free of charge. The supplier is obliged to provide an SDS in line with the above mention requirements at the first delivery in paper or electronic form and has the obligation to update the SDS without delay in the following cases:

- ✓ as soon as new information which may affect the risk management measures, or new information on hazards becomes available;
- ✓ once an authorisation has been granted or refused;
- ✓ once a restriction has been imposed.

Updated information will have to be provided also to all the customers you supplied the substances or preparation to within previous twelve months.

### Headings in the Safety Data Sheet

- 1 Identification of the substance/preparation and of the company/undertaking
- 2 Hazards identification
- 3 Composition/information on ingredients
- 4 First-aid measures
- 5 Fire-fighting measures
- 6 Accidental release measures
- 7 Handling and storage
- 8 Exposure controls/personal protection
- 9 Physical and chemical properties
- 10 Stability and reactivity
- 11 Toxicological information
- 12 Ecological information
- 13 Disposal considerations
- 14 Transport information
- 15 Regulatory information
- 16 Other information

## 6 REGISTRATION OF SUBSTANCE IN ARTICLES IMPORTED FROM NON-EU COUNTRIES

The provisions for substances in articles are outlined in articles 7 and 33 (4). In the following paragraph we will outline the respective requirements, what actions are expected to be met from the perspective of the rubber/tyre industry and by when these have to be met both by EU producers and importers of articles.

### 6.1 REGISTRATION OR NOTIFICATION?

In article 7 a first distinction is made between:

- ✓ Articles with substances intended to be released under normal and reasonable conditions of use
- ✓ Articles with substances not intended to be released.

For the first category, one is required to register the substances in question while for the second category a more limited notification will be required.

Some of the raw materials used for the production of rubber products/ tyres are already articles on their own, e.g. brass coated wire and textile fabric used as reinforcing materials. In order to be certain whether a raw material is an article or a preparation it can be useful to refer to the EC manual of decision ([http://ecb.jrc.it/DOCUMENTS/New-Chemicals/Manual\\_of\\_decisions.pdf](http://ecb.jrc.it/DOCUMENTS/New-Chemicals/Manual_of_decisions.pdf)), although there are a number of so-called borderline cases for which further guidance is currently under discussion between EC, MS and industry.

### 6.2 INTENDED RELEASE

According to the provisions of Article 7 paragraph 1, any producer or importer will have to submit a registration to the Agency for any substance contained in those articles for which both the following conditions are met:

- ✓ The substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year; and
- ✓ The substance is intended to be released under normal and reasonable conditions of use.

Unless the substance has already been registered for that use (cfr Art 7.6).

The requirements for the registration dossier are the same as for the production or import of substances. The deadlines for the registration of phase-in substances are also based on the amount of the substance put on the market per year. For new substances, the registration duty applies as of 1 June 2008. It is important to bear in mind that in order to benefit from the Phase-in provisions one has to pre-register the substances and a duty to participate in the SIEF.

## Which releases are to be considered as intended releases?

The release is essential for the end use function of the article or in other words without the release of the substances, the article would not work sufficiently. For example the release of ink from a felt tip pen.

A second valid definition includes the case where the release contributes to a minor function of the article, or, in other words, the release contributes to an 'added value' of the article, which is not directly connected to the end use function. For example the release of perfume for a perfumed eraser (function= to erase, added value/function for convenience= quality to smell good)

Other examples of articles with an intended release:

- ✓ Cleaning sponges contain detergents (release of the detergent)
- ✓ Refreshing napkin containing an eau de Cologne (release of eau de Cologne)
- ✓ substances from razors' lubricating strip

### 6.3 NON-INTENDED RELEASE

According to Article 7 paragraph 2 any producer or importer of articles has to submit a notification for those substances that meet the criteria for "substances of very high concern (SVHC)" and who are listed on the so-called "Candidate list" (first list to be published on the Agency website by **June 2009**), when the following conditions are met:

- ✓ The substance is present in those articles in quantities totalling over 1tonne per producer per year; and
- ✓ The substance is present in those articles in concentrations above 0,1% (w/w); and
- ✓ The producer or importer can exclude exposure to humans or the environment during normal and reasonable conditions of use, including disposal and the appropriate instruction to avoid this are communicated to the recipient of the article; and (cfr Art 7 (3)).
- ✓ The substance has not yet been registered for that use. (cfr. Art 7 (6)).

As a EU Downstream user of chemicals EU Article Producers will be compliant to REACH concerning the use of registered chemicals for the production of their articles. Therefore they, there use will already be covered in the registration dossier of their suppliers and they will be able to rely on the provisions outlined in Article 7(6), that the substances is already registered for that use.

For non-EU producers the impact of the notification requirements will be limited to those SVHC that are not used for that purpose by EU producers or SVHC that are not placed on the EU market for that specific use.

**The obligation to notify applies as from 1 June 2011. Whenever a substance is added to the candidate list, a period of 6 months is allowed for the notification of this substance.**

## **6.4 0,1 % RULE**

It has been confirmed that the 0,1% rule refers to the article as first placed on the EU market and not to the homogeneous parts.

## **6.5 NORMAL CONDITIONS OF USE**

This means the conditions associated with the intended end use function of the article and it might be easily deduced by applying common sense or from a user's manual or instructions of use.

## **6.6 REASONABLE CONDITIONS OF USE**

This means conditions of use outside the use originally intended by the article producer (normal use), but which may be foreseen because of the form, shape or function of that article. The following conditions could be considered as reasonably foreseeable:

- ✓ “Accidents of high likelihood”, e.g breakage of a fragile. These are considered as a worst-case situation.
- ✓ Uses that are not in accordance with the end use function, but which can be anticipated because the function and appearance of the article also suggest other uses than the intended ones.
- ✓ Extremely intense conditions of use

Excluding the following reasonably foreseeable conditions in situations of professional and industrial uses are:

- ✓ Uses, which are clearly and noticeably excluded by the article producer or importer. These should be considered as a deliberate use against the intention.
- ✓ Uses, which have been clearly advised to be avoided by means of product design or warning labels.
- ✓ Clear mis-use.

## **6.7 INFORMATION TO BE SUBMITTED FOR NOTIFICATION**

- ✓ Identity and contact details of the importer of the articles (cfr. Section of annex VI)
- ✓ Registration number(s) of the substance(s), if available (could be the case that the substances have been registered but not for use in articles – see point 5 previous paragraph).
- ✓ The identity of the substance (name, CAS, ...: cfr. Section 2.1 to 2.3.4 of annex VI)

- ✓ EU Classification of the substance(s) (cfr. Section 4.1 and 4.2 of Annex VI)
- ✓ A brief description of the use(s) of the substance(s) in the article as specified in section 3.5 of Annex VI and of the uses of the article.
- ✓ Tonnage range of the substance.

Whether a notification will be subject to a fee or not, remains to be seen as this is not explicitly mentioned in the Regulation's text although it could be reasonably expected.

In line with Article 7 (5), the Agency might require (to be read as a special procedure) an importer of articles (i.e. tyres) to register a substance that is not intended to be released, when the following conditions are met:

- ✓ substance is present in those articles in quantities exceeding 1 t/ importer
- ✓ the Agency has grounds to suspect that:
  - The substance is released (i.e. reasonable in the tyres case, even not intended)
  - The release of the substance (i.e. from the tyres) presents a risk to human health or the environment
- ✓ the substance hasn't been registered for that use.

From the perspective of a EU producer, the chances for having to perform such a procedure is limited to the cases when he is importing chemicals from outside the EU himself, as you are not allowed to use unregistered substances. While when his use is not covered, you only will have to prepare a downstream user CSA in line with Annex XII.

For non-EU producers or importers the Article 7(5) scenario might occur when it concerns an SVHC substances that is not (allowed to be) produced or used within the EU.

### **Timing**

First notifications are required by **1<sup>st</sup> of June 2011** and afterwards at least 6 months after the substance has appeared on the *candidate list*.

## **6.8 DUTY TO COMMUNICATE INFORMATION ON SUBSTANCES IN ARTICLES**

REACH also introduces some obligations for article suppliers to communicate information on the composition of the articles towards distributors, industrial & professional users as well as towards consumers. In both cases, the information to provided is limited to SVHC presence that have been identified on the *candidate list for authorizations* and which are present in the article in quantities exceeding 0,1% (w/w).

### **Duty to supply information to Distributors, Industrial or Professional users (article 33.1)**

Any supplier of articles containing SVHC in concentration exceeding 0,1% weight by weight (w/w) has the obligation to provide the recipient of the article(s) with sufficient information to allow a safe use of the article. The information should at least include the name(s) of the SVHC substance(s).

Apart from this minimum requirement, the format of the information has not been specified as it can be adapted to needs of the target receiver; it doesn't have to be exclusively in the form of a safety data sheet.

### **Duty to supply information to consumers (article 33.2)**

At request of the consumer, any supplier of an article containing SVHC in concentration exceeding 0,1% (w/w), must provide the consumer with sufficient information to allow the consumer to use the article in a safe way.

Also here the format for information supplying has not been specified and the only requirement that is laid down is that you have to provide as a minimum the name of the SVHC substance.

The information must be provided free of charge within a period of 45 days following the receipt of the request.

## 7 AUTHORIZATION OF SUBSTANCES

Substances of very high concern will be gradually included in Annex XIV of the REACH Regulation. Once included in that Annex, they cannot be placed on the market or used after a date to be set (the so-called “sunset date”) unless the company is granted an authorisation

The aim of the authorization provisions is to assure that the risk from substances of high concern:

- ✓ is properly controlled;
- ✓ these type of substances are progressively replaced by suitable and safer alternative substances or technologies, when they are economically and technically viable.

An authorization can be requested by a Manufacturer, Importer or Downstream user and is granted for (a) specific use(s) of a substance on its own or in a preparation or in an articles that may include his own uses as well as for the uses he intends to place the substance on the market. It should be highlighted that the grouping of substances and/ or uses is allowed.

### 7.1 SUBSTANCES SUBJECTED TO AUTHORISATION

The SVHC, likely to be included in annex XIV following the procedure that will be outlined in the next paragraph, are those meeting the following criteria:

- ✓ The classification as Carcinogenic substances Category 1 & 2 of Directive 67/548/EC.
- ✓ The classification as Mutagenic substances Category 1 & 2 of Directive 67/548/EC.
- ✓ The classification as Toxic for reproduction Category 1 & 2 of Directive 67/548/EC.
- ✓ The criteria set out in Annex XIII (REACH text) persistent, bioaccumulative and toxic for reproduction (PBT).
- ✓ The criteria set out in Annex XIII (REACH text) very persistent and very bioaccumulative (vPvB).
- ✓ Substances of equal concern, such as:
  - Endocrine disruptors
  - PBT or vPvB, that are not meeting the annex XIII criteria
  - Substances for which there is scientific evidence of probable serious effects to human health or the environment and give rise to an equivalent level of concern as the substances listed in the previous bullet point and that will be evaluated on a case-by –case basis.

### 7.2 AUTHORIZATION NOT REQUIRED

In line with the provisions outlined in article 56 (1) and (2), you will not have to request an Authorization, in amongst others the following conditions:

- ✓ You are using the substances for a particular use and within the conditions for which an authorization has been requested and granted by an actor up in your supply chain.
- ✓ Your use of the substance or the use for which it has been put on the market has been exempted from the authorization requirement in Annex XIV itself in accordance with Article 58(2); or
- ✓ The substance is present in a preparation in a concentration of:
  - Less than 0,1 % (w/w) for PBT, vPvB substances and substances of equal concern.
  - For the other substances subject to Authorization, below the lowest concentrations limits specified in Directive 1999/45/EC or Annex I of Directive 67/548/EC which result in their classification as dangerous.
- ✓ The substance has been exempted from the authorization requirements in annex XIV, when used for PPORD, although in this specific case extra limitation on the amount that can be used may be imposed, or
- ✓ The substance is subject to authorization only because it meets the criteria for CMR (Cat 1 & 2) or is a substance of equal concern only because of human health aspects and is used in food contact materials that fall under EC Regulation N° 1935/2004, or
- ✓ The date of entry into force of the authorization hasn't yet been reached, this date is also called "sunset date", or
- ✓ The sunset date has been reached and an application has been submitted as required 18 months before the entry in to force of the authorization, but a decision on the application for authorization has not yet been taken.

### **7.3 AUTHORIZATION GRANTED BY THE COMMISSION**

An authorization will be granted for those uses of a substance for which it can be demonstrated via the CSR that the risks arising for the intrinsic properties of the substance to human health and the Environment are adequately controlled.

The authorization will only be granted after taking into account the opinion of the Committee for risk assessment and might be subject to conditions, and the following known aspects shall be taken into account:

- ✓ All discharges
- ✓ Emissions
- ✓ Losses
- ✓ Risk from diffuse or wide-dispersive uses

Unless it concerns the following substances:

- ✓ CMR (Cat 1 & 2) or substances of equal concern for which no threshold can be determined; and
- ✓ For substances that meet PBT or vPvB criteria; and
- ✓ Substances of equal concern that have PBT or vPvB properties

For these substances an authorization will only be granted if:

- ✓ Socio economic benefits from the use of the substance outweigh the risks to human health or the environment; and
- ✓ No suitable alternative substances or technologies are available.

Prior to the granting of an authorization these aspects will be evaluated by the Committees for risk assessment and socio-economic analysis on ground of the following information:

- ✓ The risks posed by the substance taking into account the appropriateness and, effectiveness of the implemented risk reduction measures;
- ✓ The socio-economic benefits from the use and the potential implications of a refusal as demonstrated by the applicant in the submitted dossier;
- ✓ The alternatives analysis or substitution plan submitted by the applicant as well as the comments from third parties;
- ✓ The available information of the risk to human health or the environment of the potential alternatives, this will include:
  - The potential reduction of overall risk that could be obtained
  - The technical and economical feasibility of the alternatives

## **7.4 DURATION OF THE AUTHORISATION**

In line with article 60, an Authorization will only be valid for a certain period of time that will be determined on a case-by-case basis, after which it will be subject to a review taking into account all the aspects mention in paragraph 5.4.

The granted authorization will specify the following:

- ✓ The person to whom the authorization is granted
- ✓ The identity of the substance(s)
- ✓ The use(s) it covers
- ✓ Any conditions that are imposed in the authorization
- ✓ The time limited review period
- ✓ Any monitoring arrangements

The authorization will be valid until the commission decides to amend or withdraw the Authorisation in the context of a review. The holder of the Authorization will have to submit a review report at least 18 months before the expiry of the review period

An authorization may be reviewed at any time, if:

- ✓ The circumstances of the authorization have changed and therefore would effect the risk to human health or the environment or the socio-economic impact; or

- ✓ New information on possible substitutes becomes available, or
- ✓ When an environmental quality standard referring to the EU IPPC Directive (Dir 96/61/EC) is not met; or
- ✓ The environmental objective of article 4(1) of water framework Directive (Dir 2000/60/EC) for the relevant substance are not met.

In this case the Commission will set a reasonable deadline by which the holder of the authorization may submit further information.

In case of serious and immediate risk to Human Health or the environment, the Commission has the right to suspend the authorization effective immediately pending a review.

## **7.5 REQUIRED INFORMATION FOR THE APPLICATION DOSSIER**

There are two ways to apply for an authorisation :

- By demonstrating that the risk from the use of the substance is properly controlled throughout its entire life cycle (article 60.2);
- By demonstrating that the socio-economic advantages provide a greater benefit than the risks to human health or the environment arising from the use of the substance and that there are no suitable alternative substances or technologies (article 60.4).

The application dossier for a first application shall include the following information (article 62.4):

- ✓ The identity of the substance(s), as referred to in section 2 of Annex VI;
- ✓ The name and contact details of the person or persons making the application;
- ✓ The use(s) for which the authorisation is being requested;
- ✓ The CSR (unless already submitted as part of the registration);
- ✓ an analysis of the alternatives considering their risks and the technical and economic feasibility of substitution and including, if appropriate information about any relevant research and development activities by the applicant;
- ✓ a substitution plan with an action timetable-

In the case of a request for an authorisation based on a socio-economic advantages provided by the use of the substance or if a substitute has been identified, the dossier must also contain:

- ✓ a socio-economic analysis conducted in accordance with Annex XVI;
- ✓ a justification for not considering risks to human health and the environment arising  
either from:
  - emissions of a substance from an installation for which a permit was granted in accordance with Directive 96/61/EC; or
  - discharges of a substance from a point source governed by the requirement for prior regulation referred to in Article 11(3)(g) of Directive 2000/60/EC and legislation adopted under Article 16 of that Directive.

An application for an authorisation shall be accompanied by the fee required in accordance

with Title IX. A reduced fee is set for SMEs.

## **7.6 OBLIGATION ASSOCIATED TO THE USE OF AUTHORIZED SUBSTANCES?**

When you are using a substance for which an authorization for your use has been granted up your supply chain, you will have to notify the Agency **within three months after the first supply** of the substances that you are using it.

The Agency will create and keep up to date a register of Downstream users who have made a notification in line with the previous paragraph that will be accessible to the Competent Authorities of the Member States.

When placing on the market an authorized substance or a substances in a preparation. Both the holder of the Authorization as well as the Downstream users, that is using a preparation for an authorized use, will have to include immediately the authorization number on the label of the substances or the preparation. This will apply independently of the requirements and obligations of Directive 67/548/EC and 1999/45/EC, such as e.g. the labelling exemption for preparations that are placed on the market in a massive form.

## 8 RECOMMENDED ACTIONS

In the following paragraphs, you will find some practical advices that could assist you to successfully implement REACH in the most efficient manner. Where in the first place it would be best to appoint one person as a coordinator for the REACH project within your company that acquire sufficient knowledge and that could function as a contact point to supplier, customers and authorities.

### 8.1 INVENTORY OF CHEMICALS YOUR COMPANY IS USING

Although depending on the internal organisation (e.g. usage of an SAP system) this might look like a big of work to be done, but it will definitely serve your company on long term. Here below you can find a summary of the information that could be interesting to be gathered in such an inventory:

#### **Chemicals used within your company**

- Name of the substance (chemical and or commercial names)
- Cas Number
- ⊖ Information on classification and labelling
- Is the substance to be considered as a “critical substance” (SVHC, indispensable in the manufacturing process, supplied by a limited number of supplier, ...)
- Annually Purchased volumes (best average over e.g. the past three years)
- Identities of the supplier(s) and whether they are based within the EU or Not
- Check which substances you import directly without the involvement of an EU based sales office (if applicable)

This type of information will help you to estimate the impact of REACH on your company and give you indication, which actions you will need to take. Additionally, it might assist you in making strategic choices for the (re-) development of products.

In this context ETRMA has assembled an inventory of rubber chemicals where useful information may be found. Additionally, a list of EU suppliers of rubber chemicals was assembled.

### 8.2 COMMUNICATION WITH SUPPLIERS

With the aim of optimising the use of your resources in order to comply with REACH, the key to a successful implementation of REACH will lie in the contacts with your suppliers in order to streamline your actions in two areas:

#### **Information to be received from your suppliers:**

- Are they going to (Pre-)register the chemicals you purchase from them? If yes by when?

- Which uses are they going to register?
- Do they intend to take into account the special characteristics of rubber preparations?
- What kind of information are they expecting from your side in order to be able to take your use into account?
- For non-EU suppliers, do they intend to appoint an only representative?
- For substances of very high concern, are they going to continue to supply these substances, will they apply for authorisation if necessary and will they include certain Downstream uses? if any which?

#### **Information to be supplied to your suppliers?**

- Information required for the industrial use towards different end-points
- Information on the Service life of the Articles
- Information on the impact of the disposal at the end-of-life of the substance/ preparation or article.

It will be important to assess what type of information you have readily available for the different parts of the life-cycle, either via internal information, sector information, etc. As far as missing information is concerned it might be interesting option to acquire such information jointly via the national or EU trade association.

In this context ETRMA has developed a template with the information that could be required from the supplier side that will be made readily available to the members, which could facilitate the communication with the suppliers and assure that rubber companies are communicating information in a harmonised manner towards their suppliers. Currently work to establish contact with suppliers is ongoing to assure that the template is meeting the suppliers information requirements without having to fill x formats of questionnaires

In order to assure that your suppliers will take your use into consideration it could be useful to incorporate in the “general terms and conditions of purchase”, their commitment to take your use into account and obliging them to provide you with the information in writing.

### **8.3 COMMUNICATION WITH YOUR CUSTOMERS**

This communication could be helpful for two reasons:

- To acquire information on the use of your products (articles and/ or compounds) as also your customers might have an amount of information readily available on how they use your articles or compounds and how they are used afterwards and or disposed of.
- To avoid that they are going to demand excessive or confusing amount of information on article composition that might require you to reveal confidential business information, e.g. in the Automotive supply chain via the IMDS system.

## 8.4 FOLLOW-UP ON THE PROGRESS ON THE REACH IMPLEMENTATION

It will also be important to check a number of sources for information to follow-up on the REACH implementation, such as:

- the pre-registration inventory, to check if the substances you use are indeed pre-registered.
- the candidate list for substances subject to authorisation to check:
  - If certain of the substances, you use might require you to obtain an authorisation either via your supplier or yourself and by when this will be required?
  - In order make some strategic choices whether to continue the use of a certain substance or to check for alternative substances in due to time?

An outlined timeline giving you an overview of the different deadlines is reported in Annex V, while the already foreseen revisions of the regulation are included below:

Review date	Ref. To legislation	Subject
Entry into Force	Dir. 91/155/EC	Provisions requiring a Safety Data sheet for Dangerous Substances and preparations Amending Dir 88/379/EC
June 2008	Dir 93/105/EC	Directive specifying the technical dossier requirements for the notification of new polymers according to 67/548/EC requirements
	Dir 2000/21/EC	Directive Specifying that Plant protection and Biocidal Substances are exempted from the notification procedure under Dir 67/548/EC
	EC Reg. 793/93	Regulation containing the Provisions for the Risk assessment of existing substances
	EC Reg. 1488/94	Regulation laying down the provisions for the assessment of the risk to Human Health and the Environment in accordance with EC Reg 793/93
Aug 2008	Dir 93/67/EEC	Directive laying down the provisions for the assessment of the risks to human health and the environment for new substances notified under 67/548/EC
June 2009	Dir 76/769/EC	Restrictions on the marketing and use of certain dangerous substances and preparations

## 8.5 CASE STUDY ON HOSE LINING COMPOUND

We are going to work out the Reach application on a rubber blend designed for the manufacturing of a hose lining. The two actors in this example are the rubber blender and the Article manufacturer. The base compound used for this example is showed in the next table.

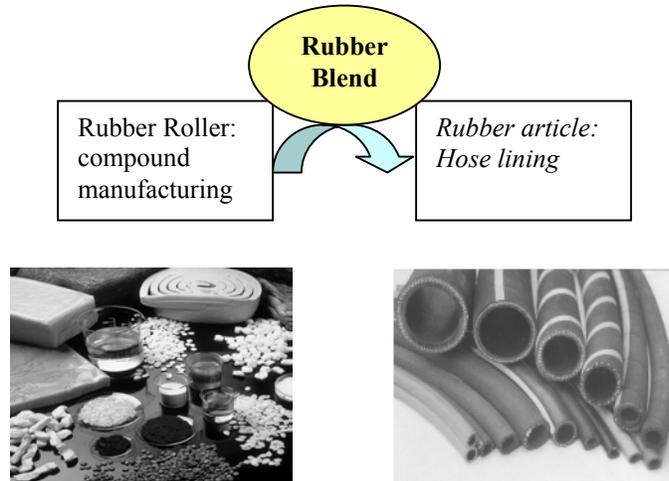


TABLE 1: BASE COMPOUND FOR THE HOSE LINING

Ingredient	phr	%	CAS Number	Risk Phrases
NBR, 34 % ACN	100	34	----	-----
Zinc oxide	5.0	1,7	1314-13-2	N R50-53
MT N-990	70.0	23,8	1333-86-4	-----
Silica	35.0	11,9	310-127-6	Reach exempted Annex V.7
HAF N-30	35.0	11,9	1333-86-4	-----
TMQ	1.0	0,34	26780-96-1	-----
Stearic acid	1.0	0,34	57-11-4	Reach exempted Annex IV
DOP	30.0	10,2	117-81-7	Rep.Cat2; R60-61; T R60
Aliphatic aromatic resin	10.0	3,4	----	-----
TMTD	2.0	0,68	137-26-8	Muta.Cat.3; R68 Xn R20/22 Xi R36/37 R43 N R50-53
MBTS	1.0	0,34	120-78-5	Xi R31 R43 N R50-53
Emulsion plasticizer	2.0	0,68	----	-----
Phtalic anhydride	0,8	0,27	85-44-9	Xn R22 Xi R37/38-41 R42/43
Insoluble sulphur	0.75	0,25	7704-34-9	-----
Tot.	293.55	100		

## Duties for the actors

### Rubber Blender

5. Receives from chemicals suppliers Safety Data Sheets with Exposure Scenarios if needed (ES for dangerous substances).
6. Check the information received in the E-SDS, to see if your use is covered and/ or you are at least implementing the advised risk reduction measures
7. If the blender imports directly substances outside the EU, then see point 3.4.3 in this guide for more details
8. Implementation of safety measurements to control risks.
9. As DOP it is a substance meeting the criteria of a substance of very high concern. You might have to obtain an authorisation and your downstream uses, unless your supplier has already obtained an authorisation for your use. In any case you will have to notify the Agency that you are using the substance
10. As you are placing the compounds on the market, you need to check if the compounds need to be classified as dangerous according to Dir.99/45/CE. For this example, the blend may impair fertility due to the DOP and it is an R52-53 Preparation, harmful to aquatic organisms, may cause long term adverse effects in the aquatic environment.
11. A [Safety Data Sheet](#) is needed for the preparation.
12. If the volume of the substance is exceeding 10 Tons/y, then a Downstream [Chemical Safety assessment](#) is needed. If DOP concentration is 10,2 %, this means that with a manufacturing volume of 98 Tons of this blend, a CSA would be needed. The blender has to provide enough information to the DOP , ZnO, TMTD and MBTS suppliers about how are these chemicals used in the process.

### Article manufacturer

1. Receives from blender supplier a Safety Data Sheet with Exposure Scenarios for the preparation.
2. Check Implementation of safety measurements to control risks.
3. Possible notification of DOP if it is used above 1 Ton/year and if the substance has not been yet registered for that use.
4. The article contains a substance of very high concern, DOP in a concentration above 0,1%. There is a duty to communicate information:
  - a. To distributors, industrial or professional users. The article supplier has to provide information including at least the name of the DOP.
  - b. To consumers. At request of the consumer, the article provider must provide information to allow a safe use of the article.

## ANNEX I: Definitions (art. 3 of REACH)

- 1) **Substance:** means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition;
- 2) **Preparation:** means a mixture or solution composed of two or more substances;
- 3) **Article:** means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;
- 4) **Producer of an article:** means any natural or legal person who makes or assembles an article within the Community;
- 5) **Polymer:** means a substance consisting of molecules characterized by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:
  - a. a simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
  - b. less than a simple weight majority of molecules of the same molecular weight. In the context of this definition a "monomer unit" means the reacted form of a monomer substance in a polymer;
- 6) **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;
- 7) **Registrant:** means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;
- 8) **Manufacturing:** means production or extraction of substances in the natural state;
- 9) **Manufacturer:** means any natural or legal person established within the Community who manufactures a substance within the Community;
- 10) **Import:** means the physical introduction into the customs territory of the Community;

- 11) **Importer:** means any natural or legal person established within the Community who is responsible for import;
- 12) **Placing on the market:** means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;
- 13) **Downstream user:** means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a preparation, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user;
- 14) **Distributor:** means any natural or legal person established within the Community, including a retailer, who only stores and places on the market a substance, on its own or in a preparation, for third parties;
- 15) **Site:** means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;
- 16) **Actors in the supply chain:** means all manufacturers and/or importers and/or downstream users in a supply chain;
- 17) **Agency:** means the European Chemicals Agency as established by this Regulation;
- 18) **Competent authority:** means the authority or authorities or bodies established by the Member States to carry out the obligations arising from this Regulation;
- 19) **Phase-in substance:** means a substance which meets at least one of the following criteria:
- (a) it is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS);
  - (b) it was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;

- (c) it was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this;
- 20) **Notified substance:** means a substance for which a notification has been submitted and which could be placed on the market in accordance with Directive 67/548/EEC;
- 21) **Product and process orientated research and development:** means any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance;
- 22) **Scientific research and development:** means any scientific experimentation, analysis or chemical research carried out under controlled conditions in a volume less than 1 tonne per year;
- 23) **Use:** means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation;
- 24) **Registrant's own use:** means an industrial or professional use by the registrant;
- 25) **Identified use:** means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;
- 26) **Full study report:** means a complete and comprehensive description of the activity performed to generate the information. This covers the complete scientific paper as published in the literature describing the study performed or the full report prepared by the test house describing the study performed;
- 27) **Robust study summary:** means a detailed summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an independent assessment of the study minimising the need to consult the full study report;
- 28) **Study summary:** means a summary of the objectives, methods, results and conclusions of a full study report providing sufficient information to make an assessment of the

relevance of the study;

- 29) **Per year:** means per calendar year, unless stated otherwise, for phase-in substances that have been imported or manufactured for at least three consecutive years, quantities per year shall be calculated on the basis of the average production or import volumes for the three preceding calendar years;
- 30) **Restriction:** means any condition for or prohibition of the manufacture, use or placing on the market;
- 31) **Supplier of a substance or a preparation:** means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;
- 32) **Supplier of an article:** means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market;
- 33) **Recipient of a substance or a preparation:** means a downstream user or a distributor being supplied with a substance or a preparation;
- 34) **Recipient of an article:** means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers;
- 35) **SME:** means small and medium-sized enterprises as defined in the Commission Recommendation of 6 May 2003 concerning the definition of micro, small and medium-sized enterprises;
- 36) **Exposure scenario:** means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;
- 37) **Use and exposure category:** means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;
- 38) **Substances which occur in nature:** means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

- 39) **Not chemically modified substance:** means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;
- 40) **Alloy:** means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

**ANNEX II: Criteria for PBT and vPvB substances** (Annex XIII of REACH)

Criteria	PBT		vPvB	
<b>P</b>	Half life water	Fresh or estuarine	> 40 Days	>60 days
		Marine	> 60 days	
	Half life Sediments	Fresh or estuarine water	<del>&gt;180 days</del> 120 days ?	>180 days
		Marine	<del>&gt;120 days</del> 180 ?	
Half life Soil -		>120	> 180 days	
<b>B</b>	Bioconcentration Factor (BCF)		> 2000	>5000
<b>T</b>	Chronic NOEC, LC50 or EC 50		< 0,01 mg/L	
	<i>Carcinogens &amp; mutagens (cat 1 &amp;2) and Reprotoxic (Cat 1,2 &amp;3)</i>		R45, R46, R60, R61, R62	
	Chronic Toxicity		T, R48 or Xn, R48	

## **ANNEX III: Useful information sources and contact information**

### **Interesting websites**

- ✓ Portal website to EC REACH navigator on REACH, this webpage is the Agency future webpage where you can find general guidance on REACH and its requirements.
- ✓ ECB webpage on RIP projects, this webpage contain the final documents from the REACH Implementation Projects.
- ✓ DG Enterprise REACH website: website of Directorate-general Enterprise of the European Commissions.
- ✓ DG Environment REACH website: website of DG Environment of the European Commission.
- ✓ REACH start page: An internet site with may interesting links on REACH
- ✓ REACH E-learning tool

### **EU helpdesks**

DG Enterprise REACH helpdesk network (coordinated by the Agency)

European Chemical Agency (ECHA) helpdesk

### **Member state Helpdesks (non-exhaustive list)**

In line with article 124 of the Regulation, the Members states have an obligation to set up REACH help desks. Below you find an overview of the helpdesks that are already operational

#### **Belgium**

Email: [reachinfo@economie.fgov.be](mailto:reachinfo@economie.fgov.be)

Tel: + 32 (0)800 12 033

Fax: +32 (0)2 277 53 04

#### **Bulgaria**

#### **Denmark**

#### **Finland**

A helpdesk is currently under preparation, in the mean time questions in respect to reach can be addressed to the following e-mail addresses ( [reach@sttv.fi](mailto:reach@sttv.fi) and/ or [reach@ymparisto.fi](mailto:reach@ymparisto.fi))

**France**  
**BERPC**

[www.reach-info.fr](http://www.reach-info.fr)

**Germany**

**Ireland**

Tel.: +353 (0)1890 289 389; or  
email [reachright@hsa.ie](mailto:reachright@hsa.ie)

**Luxemburg**

CRTE : Centre de ressource des technologies pour l'environnement  
Contact: Mrs Caroline Fedrigo [caroline.fedrigo@tudor.lu](mailto:caroline.fedrigo@tudor.lu)  
Tel.: +352 (0)42 59 91 600

**The Netherlands**

**Poland**

**Sweden**

**United Kingdom**

**ETRMA REACH contact**

ETRMA at [technical@etrma.org](mailto:technical@etrma.org)

**National association REACH contact points**

Belgium	Federplast Contact:
Finland	Rubber Manufacturers Association of Finland (RMAF) Contact:
France	SNCP Contact: <a href="mailto:thomas.evrard@lecaoutchouc.com">thomas.evrard@lecaoutchouc.com</a>
Germany	WDK Contact:
Italy	Federazione Gomma Plastica Contact:

The Netherlands: NVR  
Contact

Portugal: APIB  
Contact

Spain: Consorcio  
Contact

Sweden: SGI  
Contact

UK: BTMA  
Contact

### **Sector groups & others (non-exhaustive list)**

ACEA (European car manufacturers)

Cefic ( European Organic chemicals industry council)

ERCA (European rubber chemicals association)

Orgalime (European Engineering industry association)

### **Others**

BDI (German industry association) (in German only)

## **ANNEX IV: ETRMA Member Associations**

### **Belgium**

FEDERPLAST  
Diamant Building  
B- Bd A. Reyerslaan 80  
1030 Brussels  
Tel: +32 2/238 98 04  
Fax: +32 2/238 99 98  
Url:  
<http://www.fedichem.be>

### **France**

SNCP  
60 rue Auber  
F-94408 Vitry sur Seine  
Cedex  
Tel: + 33 1/49 60 57 57  
Fax: +33 1 46 70 97 74  
Url:  
<http://www.lecaoutchouc.com>

### **Germany**

WDK  
Zeppelinallee 69  
D-60487 Frankfurt am Main  
Tel: +49 69 / 79 36 - 0  
Fax: +49 69 / 79 36 - 175  
Url: <http://www.wdk.de>

### **Italy**

FEDERAZIONE GOMMA  
PLASTICA  
Via San Vittore, 36  
I-20123 Milano  
Tel: +39 02/43 92 81  
Fax: +39 02/43 54 32  
Url:  
<http://www.federazionegommaplastica.it/>

### **The Netherlands**

NVR  
Postbus 420  
NL- 2260 AK Leidschendam  
Tel: + 31 70/44 40 660  
Fax: + 31 70/44 40 661  
Url: [www.vereniging-nvr.nl](http://www.vereniging-nvr.nl)

### **Spain**

CONSORCIO  
C/Sirio, 18  
E – 28007 Madrid  
Tel: +34 91/445 84 12  
Fax: +34 91/447 81 11  
Url :  
[www.consorciocaucho.es](http://www.consorciocaucho.es)

### **Sweden**

SIG  
Box 5501  
SE-114 85 Stockholm  
Tel: +46 8/783 86 00  
Fax: +46 8/663 63 23  
Url:  
[www.plastkemiforetagen.se](http://www.plastkemiforetagen.se)

### **Portugal**

APIB  
Rua Eduardo Torres nº 1734  
Rc. Dto, Senhora da Hora  
P - 4460-299 Matosinhos  
Tel: +351 22/9 373 994  
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# ANNEX V: REACH Project Management

