

EUROPEAN ASSOCIATION OF PUMP MANUFACTURERS  
ASSOCIATION EUROPÉENNE DES CONSTRUCTEURS DE POMPES  
EUROPÄISCHE VEREINIGUNG DER PUMPENHERSTELLER



**Guideline for the application of  
EC-Regulation 1907/2006/EC**

**REACH**

**(Registration, Evaluation and Authorization of CHemicals)**

**Version : May 2010**

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## **Foreword**

EUROPUMP is the European Association of Pump Manufacturers. EUROPUMP consists of seventeen national industry associations of pump manufacturers in Europe : PROFLUID (F), Asociacion Espanolo (E), ASSOPOMPE (I), BPMA (UK), CPMA (CZ), AGORIA (B), FMWI (A), TIF (FIN), DK Pumps (DK), Holland Pomp Groep (NL), NVS (N), RPMA (RUS), SWEPUMP (S), GR Union of Greek Metal Industries (GR), VDMA (D), SWISSMEM (CH), SPP (P), POMSAD (T), BPMA (UK). Within the EU, the member associations represent more than 400 enterprises with a collective annual production worth more than 6 billion €.

This EUROPUMP-Guideline has been established by EUROPUMP Technical and Standard Commissions, from existing tools :

- VDMA : Information for Downstream users of substances and preparations in the capital goods industry
- FIM : Reading guide
- Orgalime : Practical guide for downstream users, articles producers and articles importers
- PROFLUID : Application guide for Pumps, Compressors and Valves

This Europump REACH Guide is a free guide that intends to assist users in providing information concerning REACH. While it attempts to provide accurate information, we make no warranty or representation of any kind with respect to the information included herein or its completeness or accuracy. We are not responsible for any action taken as a result of relying on or in any way using information contained in this guide and in no event shall be liable for any damages resulting from reliance on or use of this information. We also make no representations as to the accuracy of the information provided in any of the guides linked to this one and obviously cannot be responsible for any information contained in those guides. Users should, as with all information or reference material, use their own best judgment as to the usefulness and accuracy of any information presented. This Guide could contain inaccuracies, and changes to the information contained herein may be made at any time.

## 1. Introduction

Pump manufacturers, being downstream users of chemicals, need to be aware of how the directive is applicable. The aim is to clarify the requirements and present different possible solutions and offer support in answering essential questions.

The new REACH Chemicals policy is the most ambitious piece of legislation since the establishment of the EU. No other draft legislative proposal has ever had such an impact across all economic sectors of the manufacturing industry or has been so controversially and emotionally discussed as REACH. Since a wide range of chemicals are used in the capital goods industry, environmental and health protection is traditionally of paramount importance. This new chemicals directive contains 849 pages and is described and explained in approx. 12000 pages of implementation guidelines. The question is how can companies that are not chemical specialists deal with the new law and ensure compliance with all the requirements stipulated by REACH?

**This brochure is intended to provide our member companies with a tool that, while it cannot fully describe and explain REACH, offers a basis for taking the initial steps in order to successfully implement REACH within a company.**

### European Chemicals Agency

The European Chemicals Agency (ECHA – <http://echa.europa.eu/>) is a central authority that will be newly established on the basis of REACH and will be based in Helsinki, Finland.

The tasks of this agency include:

- establishing, administrating and managing a data base for operating the REACH system as well as developing tools (software) and guidelines for the implementation and monitoring of the requirements that REACH places on industry.
- Receiving the documents required for registering and evaluating substances as well as conducting and coordinating the registration and evaluation processes.

The data contained in the substance data base concerning all substances and preparations to be registered should be made available to the public unless such data is declared confidential on sound and reasonable grounds.

Any interested party anywhere in the world can thus obtain an overview of the chemicals that are used in the European economic zone and/or contained in products manufactured in that zone and adjust their consumption patterns accordingly at their own discretion.

## 2. Scope

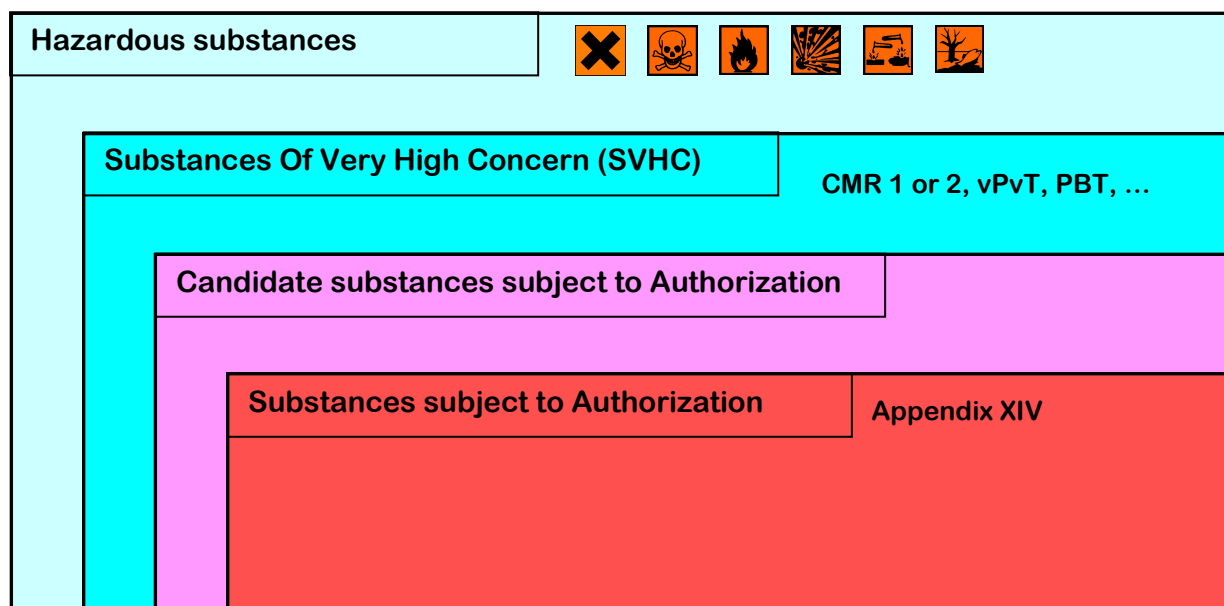
The 1907/2006/EC REACH Regulation was created in order to know and master the chemicals used and produced in Europe, to evaluate them and/or eventually decrease their uses. It concerns all chemicals, which can be :

### 2.1. Substances

A substance is any element from the Mendeleiev table (Copper, Iron, Nickel ...) or a non-polymerized chemical molecule (Ethanol, Benzene ...). They are all represented by a CAS number (Chemical Abstract Service) and a IUPAC name (International Union of Pure and Applied Chemicals).

➔ Substances concerned by REACH are all substances on the EU market, whatever their forms (liquid, solid, gas) for general people or industrials.

A classification of substances is made and highlights how hazardous the substance will be. The substances judged the most hazardous by the European Commission could be integrated into appendix XIV : in this case, they will need an authorization to be used.



### 2.2 Substances of Very High Concern (SVHC)

SVHC are substances known for being hazardous for health and environment, for example substances which are :

- Persistent, Bioaccumulable or Toxic : PBT
- Cancerogen, Mutagen, Toxic for reproduction : CMR(1 or 2)
- Very Persistent and Very Bioaccumulable : vPvB
- Endocrine disruptor

A SVHC can be integrated into the “List of candidate substances subject to authorization” (also called candidate list) if proposed by a member state. You can check which SVHC could be integrated into the candidate list on the ECHA website :

[http://echa.europa.eu/consultations/authorisation/svhc\\_en.asp](http://echa.europa.eu/consultations/authorisation/svhc_en.asp)

### 2.3. Substances subject to Authorization

Some substances issued from the candidate list will be officially included into the Annex XIV of the Regulation "Substances subject to Authorization". These chosen substances could be authorized by ECHA to be used, case by case, for a specific use and for a limited duration.

In January 2010, ECHA identified 14 priority substances studied for possible integration into Annex XIV. Later, other substances will be integrated into the candidate list, up to be studied and, eventually, be integrated into the Annex XIV. The candidate list should be reviewed maximum every 6 months at fixed dates.

As a living document, no definitive candidate list can be presented into this document. To consult the candidate list, you can refer to the ECHA website by following this link:

[http://echa.europa.eu/chem\\_data/authorisation\\_process/candidate\\_list\\_table\\_en.asp](http://echa.europa.eu/chem_data/authorisation_process/candidate_list_table_en.asp)

### 2.4 Preparations

A preparation is a mixture of two or more substances (liquid, solid or gas), in which a solvent or an excipient is eventually added. Preparations can directly be used (Varnishes, Lubricants, Paints, Glues ...) or after a physical and/or chemical transformation (Evaporating drying, Ingot, ...), but their chemical composition mustn't be affected by the transformation.

→ The precise composition of a preparation is often protected by a industrial secret or a patent.

### 2.5 Articles

An article is a piece whose function is more defined by its shape, surface design, than by its chemical composition. Mechanical equipments are usually articles, built from the assembly of components which are articles too. Those components are made by machining of preparation or raw materials, and are assembled incorporating substances or preparations, like grease or glue.

The table below describes some examples from substances to articles in typical mechanical processes.

Process step	Articles : Examples	Preparations : Example	Substances contained in Articles or Preparations
<b>Casting Forging</b>	Pump casing Pump casting Bearing housing	Cast iron Steel Stainless steel Copper-tin alloy Copper-zinc alloy Zamak (Zinc injection)	Aluminium Silver Arsenic Cadmium Carbon Cobalt chloride Chromium Copper Di-butyl phtalate Tin Iron Magnesium Manganese Nickel Phosphore Silicon Urethane Zinc
<b>Stamping Bar stock</b>	Steel sheet Copper-zinc alloy bar		
<b>Machining</b>	Copper-tin alloy Copper-zinc alloy stator Pump shaft	Lubricant	
<b>Assembly</b>	Stainless steel spring Elastomer diaphragm Steel screw Silicone gasket	Adhesive Grease	
<b>Coating Paint</b>	Coated impeller	Paint Adhesive Varnish Degreasing agent Chemical or electrolytic solution	

### 3. Excluded equipment

- **Substances not concerned by REACH** (*Article 2.1 of the regulation*)
  - Radioactive substances (96/29/Euratom)
  - Substances under customs control
  - Non-isolated intermediate products
  - Transport of dangerous substances
- **Substances considered as already registered** (*Article 2.4*)
  - Substances concerned by Directive 67/548/EEC "new substances"
  - Substances used in phytosanitary or biocide products
- **Substances exempt from registration** (*specific exemptions*)
  - Substances in medical products for human or veterinary use (*Article 2.3*)
  - Substances used as food additives (*Article 2.3*)
  - Substances used as flavourings (*Article 2.3*)
  - Substances used for feed or fodder (*Article 2.3*)
  - Polymers (*Article 5.3*)
  - Substances used in the scope of research and development activities (exempt for 5 years) (*Article 7*)
  - Isolated intermediates (*Article 2.5*)
  - Substances appearing in Appendix IV and V
- **Dangerous substances in articles whose release is unintentional** (notification, registration upon request of the Agency), except if the substance is included into the candidate list (art. 7.2).

### 4. Possible roles

The requirements of REACH depend of the role of the company. A company can have several different status.

- **Manufacturer:** any natural or legal person established within the European Community who manufactures a substance.
- **Producer of articles:** Any natural or legal person who manufactures or assembles an article within the Community.
- **Importer:** Any natural or legal person established within the Community who imports a substance therein.
- **Distributor:** Any natural or legal person established within the Community who only stores or places on the market a substance on its own or in a preparation for third parties. This includes retailers.
- **Downstream user:** Any natural or legal person established within the Community other than a manufacturer or importer, who uses a substance, either on its own or in a preparation, in the course of its industrial or professional activities.  
NB : A distributor or a consumer is not a downstream user.



## 5. Schedule of implementation

### 5.1. Key dates and deadlines

<b>1<sup>st</sup> June 2008 – 1<sup>st</sup> December 2008</b> Pre-registration phase of substances (mandatory to benefit from transition periods for registration)
<b>1<sup>st</sup> June 2008 – 30<sup>th</sup> November 2010</b> Registration of : <ul style="list-style-type: none"> <li>- CMR – Category 1 and 2 <math>\geq</math> 1 T/year per manufacturer/importer</li> <li>- Substances very toxic for aquatic organisms <math>\geq</math> 100 T/year per manufacturer/importer</li> <li>- All substances <math>\geq</math> 1000 T/year per manufacturer/importer</li> </ul>
<b>From 1<sup>st</sup> June 2011</b> Notification of substances in articles, 6 months after they have been included into the candidate list
<b>1st June 2008 – 31<sup>th</sup> May 2013</b> Registration of : Substances $\geq$ 100 T/year per manufacturer/importer
<b>1<sup>st</sup> June 2008 – 31<sup>th</sup> may 2018</b> Registration of : Substances $\geq$ 1 T/year per manufacturer/importer

### 5.2. Key dates for downstream users

There are some important dates and deadlines of great relevance to downstream users if they are to comply with the new legislation. The above condensed chart provided an overview of the most important dates. The table below provides an overview of the most important tasks and their corresponding deadlines.

Deadline	Pending Task
Mid 2008	Pre – registration of the substances with the European Chemicals Agency is required, including the core information ( substance name, manufacturer). Deadlines for subsequent registration depend on volume of the produced /imported substances. None phase-in substances are generally subject to the REACH system
End of 2008	The pre-registration deadline expires . Phase –in- substances that have not been pre-registered are not eligible for the volume-based registration deadlines.
End of 2010	Expiration of the registration period for : <ul style="list-style-type: none"> <li>• CMR substances* in Category 1 &amp; 2 <math>\geq</math> 1t/y ,</li> <li>• R50/53 substances** &gt; 100 T/a and</li> <li>• Phase –in substances &gt; 1000 T/a</li> </ul> By this time, all SVHC that are imported , marketed or sold must be registered with the European Chemicals Agency ; registration must include the required classification and labeling. The same applies to hazardous substances contained in preparations. The Classification and Labeling Inventory that is thus created will be managed , maintained and published by the European Chemical Agency
Mid 2013	Expiration of the registration period for phase–in substances 100 -1000 T/a
Mid 2018	Expiration of the time registration for phase–in substances 1-100 T/a

\* CMR = Carcinogenic, Mutagenic and Toxic to Reproduction (See §2.2, page 5)

\*\* Risk phrases, defined in Annex II of the “Dangerous substances” Directive 67/548/EC

R50/53 = Very Toxic to aquatic organisms, may cause long term adverse effects in aquatic environments

## 6. Guidance notes for the Inventory of SVHC

Both manufacturers/importers (registrant) and downstream users can utilize the following procedure when preparing their substance inventory. The steps described in the procedure equally apply to manufacturers/importers and downstream users and are intended to be used as a guideline for preparing a substance inventory (which should be continuously updated).

**Step 1:** Check whether my articles contains SVHC

**Step 2:** Prepare a list of all chemical substances and preparations that are produced, marketed, imported or used in the company.

**Step 3:** Define the company status for each substance and each preparation subject to REACH : manufacturer/importer, dealer, retailer, downstream users, legal entity.

**Step 4:** Determine the category that each substance and preparation falls under :

- Manufactured by the company within the EU,
- Imported into the EU by the company, or,
- Purchased by the company from a supplier based within the EU.

**Step 5:** Determine which monomers are contained in the manufactured and/or imported polymers.

**Step 6:** Determine the respective annual volume for the manufactured or imported substances and preparations. In the case of preparations, this includes their composition, i.e. a listing of all substances contained in the preparation.

**Step 7:** Determine the CAS (Chemical Abstract Service) numbers of the manufactured or imported substances and the EINECS or ELINCS numbers.

NB: The CAS number does not always appropriately of sufficiently describe the substance as required by REACH.

**Step 8:** Identify the customers and suppliers and prepare a corresponding list according to substance and preparation.

**IN CASE WHERE ONLY THE DOWNSTREAM USER ROLE APPLIES: PLEASE GO DIRECTLY TO STEP 13.**

**Step 9:** Determine the intention of suppliers on the future of substances Continuation or shut down of the production.

**Step 10:** Determine whether the following information/documents are available for the substances and preparations :

- Information about relevant intrinsic properties,
- Data that could be used for waiving (see Column 2 of Annexes V to VIII and Annex IX in the REACH Regulation) : Internet link
- Relevant documents pertaining to costs for conducting studies and/or payments for jointly used/owned studies,
- The company's own data related to animal testing and experiments,
- Information on classification and labeling,
- Safety data sheet in compliance with existing legislation

While the safety data sheet is not a component of the registration dossier, it represents a key communication tool along the entire supply chain.

**Step 11:** Ensure that data/information which is the property of the company remains the property of the company.

**Step 12:** Determine which legal entity of the company group is concerned as the manufactured and/or importer of/for the respective substance/preparation.

**Step 13:** Compile all the information that is available in the company which regards the uses and exposures of the substances and preparations being used.

## 7. Different scenarios

	<b>Substance</b>	<b>Preparation</b>	<b>Article</b>
<b>I import</b>	I am <b>Importer</b> of substances or preparations	I am <b>Importer</b> of substances or preparations	I am <b>Importer</b> of articles
	Ex : I import zinc	Ex : I import brass ingots	Ex : I import screws
	<b>n°1</b>	<b>n°1</b>	<b>n°2</b>
<b>I produce</b>		I am <b>Producer</b> of preparations (formulator)	I am <b>Producer</b> of articles
		Ex : Foundry	Ex : Assembly of a circulator
		<b>n°3</b>	<b>n°4</b>
<b>I use</b>	I am a <b>Downstream user</b>	I am a <b>Downstream user</b>	
	Ex : Foundry of DZR brass (or dezincification)	Ex : Lubricant	
	<b>n°5</b>	<b>n°5</b>	
<b>I distribute</b>		I am distributor of preparations	I am <b>Distributor</b> of articles
		Ex : Sale of glue on an own brand	Ex : Everybody
		<b>n°3</b>	<b>n°6</b>

### **N°1 : I am an Importer of substances or preparations**

➔ Does my non EU supplier have at least one representative in the EU?

If **YES**:

- This representative acts as an importer and may have to register all the substances,
- Check your use is covered.

If **NO**:

- I can check for alternative supplier in the EU who will register, or
- I act as importer and may have to register all the substances (single substances or contained in preparations) I import with a quantity more than 1 T/y.

### **N°2: I am an Importer of articles**

➔ I have to contact my suppliers to know whether their products contain candidate substances (SVHC).

➔ If there is a/several candidate substance(s), has it been registered for the use I make ?

If **NO**, and if the substance present in article is in quantity over 1t/y/importer, if it is intended to be released under normal and foreseeable conditions for use, I have to register the substance

If **there is a candidate substance**, with a concentration more than 0,1 % of the total weight of my article and if there is a risk of exposure to human and the environment during normal and foreseeable conditions for use including disposal, I will have to give sufficient information (at least the name of the substance) to use this article hazardless. I will also have 45 days to give this information to all customers who want it.

➔ I have to notify (= make the ECHA aware of) each candidate substance present in my article with a concentration more than 0.1% w/w and with a quantity more than 1T per year, if it has not already been registered for that use. The notification requirement will be applicable as from 1<sup>st</sup> June 2011.

**N°3 : I am a Producer of preparations (formulator)**

- If I produce a preparation from substances I import, I am an importer of substances, I thus follow the requirements of the point n° 1
- In all cases, I have to inform my customers of the risk of using my preparations. I give them exposure scenarios and Safety Data Sheets.

**N°4: I am a Producer of articles and/or I add substances**

The first question to ask is:

Did my supplier register the substance for that use? If not, is there any alternate supplier?

- If there is a candidate substance with a concentration more than 0,1 % of the total weight of my article, I will have to give the sufficient information (at least the name of the substance) to use this article hazardless. I will also have 45 days to give this information to all customers who want it.
- If my suppliers are on the European area, I have to contact them to know whether their products contain candidate substances.
- I have to notify (= make the ECHA aware of) each candidate substance present in my article with a concentration more than 0.1% w/w and with a quantity more than 1t per year, if it has not already been registered for that use. The notification requirement will be applicable from 1<sup>st</sup> June 2011.

**N°5: I am a Downstream user**

The first question to ask is:

Does my article contain Substances of Very High Concern? If yes:

- **Case 1 : I don't use candidate substance(s) subject to authorization**  
I do not have to register (I am not importer nor producer of substances), but I have to check that my suppliers have registered the substances I use for this use.
- **Case 2 : I use candidate substance(s) subject to authorization**  
I have to check whether my use has already been authorized by ECHA for a stakeholder within the supply chain of the product. If yes, I will have to notify this use (from 1<sup>st</sup> June 2011) at the latest 3 months after the first use.  
If the use of the substance has not been authorized, I do not have any other choice than substitute it by another non-candidate substance. If I can substitute it, I have to find a supplier authorized to sell this substance for this use. If I can't find him, I will be obliged to ask for an expensive authorization for using my substance.

**N°6: I am a Distributor of articles**

- I have to apply the same requirements than for a producer of articles.

## **8. Obligations of Downstream users**

### **8.1. What can and should downstream users of substances/preparations already be doing?**

In terms of the future handling of substances and preparations in companies, it is crucial to identify the significance of the individual substances in and for the company early on.

Downstream users of substances and preparations should also be prepared for the implementation of REACH. For this reason, it is advisable to already start preparing a comprehensive financial and human resources plan with regard to implementing REACH and acquiring any know-how that may be needed to manage the requirements stipulated by REACH.

If not already in place, a substances and preparations inventory of all substances handled in the company should now be prepared. Please note that in the case of preparations, the individual substances must be analyzed.

The following aspects should be taken into account:

- Identification of the company's role under REACH: manufacturer/importer, distributor, downstream user.
- Production volumes quantities used and application conditions (substances, preparations).
- Compilation of safety-relevant information about the substances and preparations used.
- Compilation of all collected data (substance properties and exposures).

The main requirement for downstream users is to manage and handle chemical substances and preparations in such a way that does not pose a risk to human health or the environment. The supplier provides the downstream user with a safety data sheet (if a substance is classified as hazardous) or at least general information about safe management and handling, precisely detailing first aid measures and substance disposal in addition to safe handling instructions. The downstream user must comply with the precautions for the safe management and handling of substances, called "risk reduction measures"

The safe management and handling of a chemical substances described in the safety data sheet may refer to certain uses that are listed in detail. In that case, downstream users are only allowed to utilize the substance for those uses that are explicitly listed in the manufacturer's safety data sheet as supported uses or intended uses. Downstream users are obliged to identify whether their use of the substance is listed in the chemical safety report as a "supported use".

If the use is not indicated on the safety data sheet, there are two options:

- The downstream users notifies the manufacturer in advance about the intended use of the substance - if applicable, the manufacturer then includes this use in its chemical safety report and lists it on the safety data sheet.
- The manufacturer has misgivings about the inclusion of a use because he does not regard it as being safe for human health and the environment. In this case, he can classify this use as "use advised against" on the safety data sheet. In this case, or if the downstream user has misgivings about communicating its own use to the manufacturer due to a possible disclosure of trade secrets, the downstream user does not require the manufacturer to indicate the use and the downstream user can then prepare a chemical safety report on his own, if applicable. In this case, the downstream user has to develop his own risk reduction measures, implement the according recommendations, communicate them to his customers and submit a corresponding notification to the European Chemicals Agency.

## 8.2. Duty to inform

In addition to implementing proper risk management measures, the duty to communicate extensive information is the most challenging and essential task facing downstream users.

Downstream users must communicate information to their customers and, in some cases, to their suppliers as well.

Any information pertaining to the safe management and handling of substances, whether indicated on the safety data sheet or prepared by the downstream user, must be communicated to the customers so that they can also initiate the required measures.

The duty to communicate information pertaining to, at least, safe management and handling also extends to substances that do not require a safety data sheet because they are not classified as hazardous or do not meet the PBT (persistent, bio-accumulative and toxic) or vPvB (very persistent and very bio-accumulative) criteria.

If a customer is supplied with a preparation that contains at least one substance classified as hazardous, he must be provided with a chemical safety report upon request.

Downstream users can communicate the use of a substance to their suppliers. If they themselves possess sufficient information or experience in managing and handling individual substances which might facilitate the supplier in classifying or registering a substance, they can provide their suppliers with said information or forward any information provided by their customers. This also applies to information that might be available or obtained at a later date in the future.

## 8.3. Preparing a chemical safety report

Ideally, downstream users do not have to prepare a chemical safety report on their own. Only in cases where the supplier's safety data sheet does not list a use among the supported uses, does the downstream user need to undertake this task. The easiest scenario is when the downstream user communicates its own intended use to the manufacturer, who in turn includes it in a new safety data sheet.

If it is not in the company's interest, however, to communicate the use to the manufacturer or if the manufacturer's safety data sheet classifies this use as an "undesirable use": the downstream user must prepare its own chemical safety report.

However a chemical safety report is not mandatory if:

- a safety data sheet is not required for a substance or preparation (i.e., the substance/preparation is not classified as hazardous),
- the manufacturer does not have to prepare a chemical safety report since the company produces an output volume of less than 10 tons per year)
- the downstream user uses less than 1 ton per year of the substance or preparation,
- the exposure scenarios described in the safety data sheet are implemented,
- the substance is solely used for research purposes, or
- the concentration of a substance in a preparation remains below certain limits.

If none of these points apply, however, the downstream user is required to prepare its own chemical safety report; in this case, the risks to human health and the environment arising from a substance must be assessed and, if applicable, exposure scenarios must be developed (Annex XI of the directive: "General Provisions for Downstream Users to Assess Substances and Prepare Chemical Safety Reports").

If he writes a chemical safety report, a downstream user is responsible for its content, which must include any use made by the customers (similar to the inclusion of an intended use in the manufacturer's safety data sheet) and the report must be continuously updated. Moreover, a notification indicating the identity and uses of a substance must be submitted to the European Chemicals Agency.

If, in the course of preparing a chemical safety report, a downstream user reaches conclusions that differ from the results of the manufacturer regarding the classification of a chemical substance, both the Chemicals Agency in Helsinki and the manufacturer must be notified of this fact.

#### 8.4. Documentation information on exposure

An exposure scenario is a document explaining how a substance is used during the manufacturing process, by giving the risks of use and the safety measures. It has to be realized for substances classified as dangerous or as PBT/vPvB and manufactured or imported at more than 10 tons per year.

According to the common position of the Council, information on exposure - in the form of use and exposure categories, among other things must be provided when registering substances with a production volume of **1 to 10** tons per year.

The following structure provides possible approaches to describe the individual use categories.

##### Industrial use

- Facilities with technical risk reduction measures
- Organizational measures for occupational safety and environmental protection
- High level education, qualification and training of employees
- Monitoring of technical and personal safety measures

##### Commercial use

- Organizational measures for occupation safety and environmental protection
- Education and qualification of employees at varying levels
- At minimum, use of personal safety equipment

##### Consumer use

- At a maximum , gloves and protective goggles as safety equipment
- No experience and very limited skills in handling substances

##### Types of industrial and commercial use

- Use in a closed system
- Isolated use in or on a matrix
- Use at few locations ( non –dispersive)
- Widespread use ( dispersive )

## **9. Consequences of non-compliance**

### **9.1. Discontinuation of substances**

If a manufacturer or importer does not register a substance or preparation or fails to ensure the safety of a substance for certain applications, and if the downstream user is not able or willing to support the registration by the manufacturer or importer or is unable to undertake the registration on its own accord, such a substance or preparation will most likely be discontinued on the market. This commercial deselection of substances and preparations will lead to a streamlining of the article portfolio for substances and preparations available on the market, in turn requiring the manufacturers of preparation to reformulate their articles, which changes their intrinsic properties. Further along the value-added chain, certain article properties or effects of the respective formulations can thus no longer be guaranteed – or only guaranteed to a limited extent – which can potentially have a significant impact on production conditions, where such operating resources and materials are needed.

### **9.2. Disclosure of proprietary company know-how**

To ensure the future availability of a substance on the market and that this substance be implemented according to its intended use, the registrant must be aware of the said intended use in order to be able to cover and include that use in the registration documents as supported use. Of course, this requires communication of the corresponding information to upstream stages of the value-added chain.

Information can be communicated within the scope of SIEFs (Substance Information Exchange Forums). However, access to the SIEFs for the purpose of collecting information required for registration necessitates disclosure of proprietary company know-how. Unfortunately, the participants have only very limited veto rights with regards to preventing their company and article information from being published on the Internet by the Chemicals agency. This communication and disclosure of data and applications are in line with one of the key messages of REACH: no data – no market.

### **9.3. Additional resources required**

Unfortunately, the majority of downstream users do not meet the requirements stipulated by REACH, so that in most cases, the activities necessary to implement REACH can only be realized with additional expense and personnel. Moreover, the sometimes very specific know-how needed for the implementation of REACH will often require the added expense of an external source.

### **9.4. Discrimination of product manufacturers within the EU**

Currently, Article 7 (about registration and notification) does not sufficiently address compensation for the deterioration of the competitive position of article manufacturers within the EU as compared to importers outside of the EU, which REACH will inevitably cause. In contrast to articles manufactured in the EU, which include only “REACH-compliant” substances and preparations, imports are not affected in terms of their manufacturing routes and production processes. REACH only examines and regulates substances whose release from products is intentional or foreseeable.



## Appendix : Flow chart “EU Chemicals Policy - Applicability Check”

This flow chart can be used to determine whether REACH is applicable to a company. Whilst this does not guarantee actual applicability or non-applicability, the questions listed can help identifying initial indicators of company’s own role in REACH.

