

## **New EU Chemicals Policy (REACH)**

As a rule, chemicals must only be manufactured and used in ways which do not lead to significant negative impacts on human health and the environment.

In contrast to so-called existing substances (i.e. chemical substances that were put on the market before 1981), so-called “new” substances (chemical substances placed on the market after 1981) must first be assessed and tested for potential risks to human health and the environment before being launched.

The majority of the chemicals currently on the market are existing substances. Consequently, the data available on existing substances does not suffice to make a statement on the impact such substances have on human health and the environment.

The REACH project has been launched to remove the distinction between existing and new substances.

For that reason, a fundamental reform of the European chemicals legislation has been introduced: REACH.

REACH stands for Registration, Evaluation and Authorisation of Chemicals.

The so-called REACH Regulation was published in the Official Journal of the European Union on 30 December 2006 as Regulation (EC) No 1907/2006 and came into effect on 1 June 2007.

REACH is based on the principle of individual responsibility. Following the motto “No data, no market”, the REACH Regulation provides that only such chemical substances may be placed on the market for which sufficient data on material properties such as toxicity, environmental properties etc. exist. The manufacturer and/or importer must collect the data required for assessment and pass on the data along the supply chain.

REACH covers absolutely all substances manufactured in or imported into the EU in quantities above one tonne per year.

These substances will have to be registered with the newly established European Chemicals Agency in Helsinki/ Finland.

### **1. Time Limits for Registration under REACH**

The requirements for examination of individual substances depend on the risks associated with the substances and the amounts marketed.

Until 01.12.2010    Registration of substances with volumes > 1000 t/a  
                          Registration of substances classified as R 50/53 and with volumes > 100 t/a  
                          Registration of category 1 and 2 CMR substances with volumes > 1 t/a

Until 01.06.2013    Registration of substances with volumes > 100 to 1000 t/a

Until 01.06.2018    Registration of substances with volumes 1 to 100 t/a

## **2. Exceptions**

Substances completely exempt from REACH include those manufactured or imported at under 1 t/a, waste, non-isolated intermediate products, radioactive substances, polymers, and substances in transit.

Substances exempt from registration include, without limitation, biocides, plant protection products, food additives, medicinal products and substances listed in Annex IV (e.g. water, sugar, ascorbic acid) and Annex V (e.g. natural substances that can be regarded as safe) of the REACH Regulation.

## **3. Pre-registration**

In order to be able to make use of the transitional period for the registration of substances, the relevant substances must have been pre-registered in the period from 1 June until 1 December 2008 (Article 28).

The preregistration phase has meanwhile been concluded. At the beginning of 2009, the European Chemicals Agency (ECHA) published the preregistrations that had been dealt with on their website and also named the substances, the EINECS and the CAS numbers (about 143,000 entries).

This preregistration did not entail any obligation to actually register the substance.

All manufacturers / importers who had submitted a preregistration for the same existing substance to the European Chemicals Agency were subsequently given access to the individual Substance Information Exchange Forums (SIEF) where they were to negotiate with the other potential registrants of the same substance as regards data sharing and joint registration.

## **4. Authorisation**

In addition to the general obligation to register substances amounting to more than 1 ton per manufacturer/ importer, the REACH Directive provides for the mandatory registration of Substances of Very High Concern (SVHC).

This registration constitutes special authorisation from the EU Commission to use an SVHC that is listed in Appendix XIV under certain conditions.

To be granted this authorisation, an applicant – either a company or an association – must apply for approval. Such an application for authorisation is normally submitted by the manufacturer of the substance.

For downstream users, this means that, from a certain date on, they will only be permitted to use the substance if authorisation has been issued to their supplier or if they themselves have applied for authorisation and this has been granted.

The downstream user is obliged to comply with the conditions defined in the authorisation. Additionally, the intended use of the substance has to be registered with the ECHA within three months of receipt of the first shipment of this substance (compare Article 66, Paragraph 1).

From 01/06/2011 on, manufacturers or importers of products must inform the ECHA if these products contain any SVHC substances from the so-called candidate list in a concentration of more than 0.1 mass percent (w/w) and is manufactured or imported in quantities of more than one ton per year by each individual producer or importer, as the case may be (compare Article 7, Paragraph 7 of the REACH Directive).

SVHC substances are ascertained and assessed in a multiphase process:

1. Identification as an SVHC substance and proposal by an EC member state or the EU commission / ECHA
2. Incorporation of the substance in the candidate list  
(A substance that has been included in the candidate list is in no way restricted by this)
3. Prioritisation of the substances on the candidate list  
(Recommendations planned by the Commission every two years)
4. Incorporation of substances in Appendix XIV of the REACH Directive with deadline according to Article 58 of the REACH Directive.

Potential candidates for authorisation procedures are substances which, due to subsequent or similar properties (compare Article 57 of the REACH Directive), are considered to be of particular concern:

- Carcinogenic, Category 1 or 2
- Mutagenic, Category 1 or 2
- Reprotoxic, Category 1 or 2
- Persistent, bioaccumulative and toxic acc. to Appendix XIII (PBT)
- Very persistent and very bio-accumulative according to Appendix XIII (vPvB)

An estimated 1,500 substances will in future be subject to authorisation due to being of very high concern.

The authorisation procedure is to be conducted independent of quantity thresholds!

Once a substance has been incorporated in Appendix XIV, deadlines and transitional provisions will be provided. These include the date up to which the substances may still be used without authorisation (the so-called "sunset date"), as well as the date by which applications for authorisation must have been received by the ECHA (at least 18 months before the deadline).

Once a substance has been incorporated as an SVHC substance in the ECHA candidate list (see No. 2 above) the following information requirements become mandatory according to Article 33 of the REACH Directive:

1. Every supplier of a product containing an SVHC substance from the candidate list in a concentration higher than 0.1 mass percent (w/w) is to provide the purchaser of this product with the information available to him to ensure its safe use, but must at least state the name of the relevant substance.
2. At the request of a consumer, any supplier of a product containing an SVHC substance from the candidate list in a concentration higher than 0.1 mass percent (w/w) has to provide the private end user of this product with the information available to him so as to ensure its safe use, but must at least state the name of the relevant substance.  
The pertinent information is to be provided, free of charge, within 45 days of receiving such a request.

## **5. Restriction**

Restrictions of marketing and use of hazardous substances and preparations have been laid down in Annex XVII of the REACH Regulation as of 1 June 2007. The already existing Directive 76/769/EEC has been revoked as of 1 June 2009.

The Commission will also incorporate new restrictions in Annex XVII based on the resolutions of a regulatory committee.

## **6. Chemical Safety Report/ Exposure Scenarios/ Safety Data Sheets**

A chemical safety assessment together with the relevant chemical safety report are prescribed for substances that have been classified as hazardous and are manufactured in quantities of 10 tons or more per year per registrant.

In the case of compounds that contain a substance classified as hazardous in a proportion that exceeds the scope of consideration and/or concentration restrictions, a chemical safety assessment must also be conducted if the manufactured or imported quantity exceeds 10 tons per year and registrant / importer.

The aim of the chemical safety assessment is to determine the conditions under which a substance can be used during its life cycle without causing any harm to people or to the environment.

The chemical safety report documents the assessment of the risk arising from a substance. An analysis of the exposure in the various applications of a substance is thus only required if a classification indicates a risk.

In the case of a hazardous substance, the registrant of quantities of the substance that exceed 10 t/a has to prepare an exposure scenario (ES) for each identified application to be covered by the registration. A description of the conditions for use (risk management measures - RMM) is to be included in the ES. The applications for the substances that are known to the registrant constitute the basis for the exposure scenarios.

These applications are to be described in a standardised form on the basis of five different categories (SU, PROC, PC, AC, ERC) from the ECHA Guideline R12 - "Use Descriptor System". In principle, the uses should be described as abstractly as possible and as accurately as necessary. As this may not always be possible in the first attempt, cooperative communication in the supply chain is more essential than ever.

These exposure scenarios including the applications are then forwarded together with the safety data sheet in line with REACH to the downstream user (= eSDS extended Safety Data Sheet).

Exposure scenarios only need to be attached to a safety data sheet, if required, in the case of used substances after the registration obligation for the relevant tonnage band has expired.

Since 01/06/2007, safety data sheets have had to meet the requirements of Appendix II of the REACH Directive.

According to EC Directive No. 453/2010, Appendix II was to be adapted to the provisions of EC Directive No. 1272/2008 (GHS-CLP) with effect as of 01/12/2010.

A further adaptation of Appendix II is to take effect on 01/06/2015 as the transitional regulations for mixtures set out in the CLP regulations expire on that date.

Even if no safety data sheet is required for a substance or mixture, the customer must still be provided with at least the registration number, any restrictions in use as well as any other available, pertinent information on the substance.

## **7. Duties of Downstream Users**

Downstream users use substances on their own, in mixtures, or for the manufacture of products.

Formulators of mixtures and manufacturers of products are subject to special duties under the REACH Regulation, in particular duties of information (safety data sheet etc.).

Downstream users who manufacture substances or introduce substances as such into mixtures are subject to the duties for manufacturers/importers of substances (e.g. duty of registration). A re-importer is considered a downstream user.

Every actor in the supply chain has the following obligations when using substances/ mixtures:

- To verify if the use and exposure categories (UEC) listed in the safety data sheet consistently comply with the conditions of use.
- To verify if their own risk management measures (RMM) comply with the supplier's recommendations as laid down in the safety data sheet.
- To report to the supplier if the RMM allocated to the UEC element is unsuitable or inappropriate for controlling a risk.

If the use of the downstream user is not covered by the exposure scenario (ES) communicated by the manufacturer/importer together with the safety data sheet or by the use and exposure category (UEC) communicated, the downstream user must either produce and make available a chemical safety report (CSR) of his own or cease to use the relevant substance.

This does not lead to any duty of registration with the resulting fees.

The duty to notify the Agency thus exists for downstream users of hazardous substances regardless of the volume used (including < 1 t/a), provided that the use is not supported by the manufacturer/importer.

## **8. How does Alufinish implement the REACH Regulation?**

Our safety data sheets are being adapted successively to the provisions of the new Appendix II of the REACH Directive since 01/12/2010. The current safety data sheets can be accessed on our website under "Download".

The substances and mixtures used by our company were recorded taking into account the classification under hazardous substances legislation and the relevant tonnage band.

To ensure compliance with the duty to provide information within the supply chain, we have a personal contact person at each of our supplier companies as a REACH representative.

All our suppliers have confirmed the preregistration of the substances purchased by us.

During the registration phase itself, we are coordinating with our suppliers regarding the application and exposure categories in which our raw substances and products are classified.

Working in close contact with our suppliers, we are in a position to make sure that our customers' applications are also communicated to the manufacturers and importers of the substances and are consequently taken into consideration when being registered as so-called identified uses.

If it becomes apparent that products have to be changed or that production has to be discontinued altogether, we will of course inform the customers affected as soon as possible.

## **9. Further Information on REACH on the Internet**

On the Internet, you can find a large number of useful helpdesk offers such as:

<http://reach.bdi.info>

[www.reach-clp-helpdesk.de](http://www.reach-clp-helpdesk.de)

[www.reach-net.com](http://www.reach-net.com)

[www.baua.de](http://www.baua.de)

---

If you have any questions on the implementation of REACH or require detailed information, please contact:

Angela Walber  
Head of QEHS  
Quality, Environment, Health and Safety  
Management representative

Phone: +49 2632 9297-24

Fax: +49 2632 9297-18

E-mail: [angela.walber@alufinish.de](mailto:angela.walber@alufinish.de)

## **Glossary and Abbreviations**

### **Chemical Safety Report**

The Chemical Safety Report (CSR) contains the Chemical Safety Assessment that has to be carried out for all registered substances manufactured or imported by the registrant at quantities of 10 t/a or above.

### **Chemical Safety Assessment**

All substances subject to registration require a Chemical Safety Assessment (CSA) and a Chemical Safety Report (CSR) if the registrant manufactures or imports the substance at 10 t/a or above. The Chemical Safety Assessment must be performed either for each substance on its own or in a preparation, or for a group of substances.

### **CMR**

= Carcinogenic, Mutagenic or Toxic for Reproduction Chemicals classified under Directive 67/548/EEC

### **CSA**

= Chemical Safety Assessment

### **CSR**

= Chemical Safety Report

### **Distributor**

According to para. 14 Art. 3, “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.”

### **Downstream User**

According to para. 13 of Art. 3 “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 [...] shall be regarded as a downstream user.” Abbreviation: DU

### **EINECS**

= European Inventory of Existing Commercial Substances

Substances placed on the market in the European Economic Area between 1 January 1971 and 18 September 1981.

### **ELINCS**

= European List of Notified Chemical Substances

ELINCS contains new substances that were and are registered in accordance with Directive 67/548/EEC (dangerous substance directive) after finalisation of the EINECS list (18.09.1981). The list is continuously updated.

### **ESDB**

= Extended Safety Data Sheet

a safety data sheet extended by an annex to the exposure scenario

### **Existing substance**

According to Art. 2 (1) h) of Directive 67/548/EEC a substance listed in the European Inventory of Existing Commercial Substances – EINECS. This Inventory was amended by Corrigendum 2002/C 54/08 (OJ EU C 54/13 of 1 March 2002). The term “existing substance”, however, is not explicitly used in the Directive.

### **Exposure Scenario (ES)**

According to para. 37 of Art. 3, “the set of conditions 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”. Abbreviation: ES

### **GHS**

= Globally Harmonized System of Classification and Labelling of substances and preparations

### **Identified use**

According to para. 26 of Art. 3 “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”.

### **Importer**

According to para. 11 of Art. 3 “any natural or legal person established within the Community who is responsible for import”.

### **Intermediate**

According to para. 15 of Art. 3 “a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as synthesis):

- a) non-isolated intermediate: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
- b) on-site isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an) other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;
- c) transported isolated intermediate: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites.”

### **Manufacturer**

According to para. 9 Art. 3 “any natural or legal person established within the Community who manufactures a substance within the Community”.

### **New substance**

Substances that are not existing substances according to Article 2 (1) h) of Directive 67/548/EEC.

### **No-Longer Polymers**

A substance which was considered to be a polymer until the early 90ies (following the 7th amendment to directive 67/548/EEC). Since the term “polymer” was defined more precisely under chemical law, some substances that were classified as polymers until then are no longer to be regarded as such (hence the name “no-longer polymer”). Next to lists of substances identified by EINECS or ELINCS codes, another list was therefore established for no-longer polymers. The substances in this list were allocated no-longer polymer numbers. These numbers are seven-digit numbers of the type XXX-XXX-X. The list begins with number 500-001-0. Abbreviation: NLP

### **Non-Phase-in substance**

A substance which is not a phase-in substance, i.e.

- a) it is not listed in the European Inventory of Existing Commercial Chemical Substances (EINECS),
- b) the manufacturer or importer cannot prove that he did not, in the 15 years preceding the entry into force of REACH (on 1 June 2007), place the substance on the market in the European Union (in accordance with the membership status as of 1 May 2004: Austria, Belgium, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Lettland, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Slovakia, Slovenia, Spain, Sweden, United Kingdom); and
- c) it was not (with the exception of polymers) registered in a country of the European Union (membership status as of 1 May 2004) before 1 June 2007 in accordance with Directive 67/548/EEC.

### **Phase-in Substance**

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.

### **Placing on the market**

According to para. 12 of Art. 3 “means supplying or making available, whether in return for payment or free of charge, to a third party. Import into the customs territory of the Community [...]”

### **Polymer**

According to para. 5 of Art. 3 “a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. 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.”

### **Preparation**

According to para. 2 of Art. 3 “a mixture or solution composed of two or more substances”. This definition is contained in directive 67/548/EEC. As a result of the introduction of the GHS (Globally Harmonized System), preparations will be renamed “mixtures”. The definition will then be amended by the (implicitly assumed) half sentence “... that do not react with one another”

### **Producer of an article**

According to para. 4 of Art. 3 “any natural or legal person who makes or assembles an article within the Community”.

### **R 50/53**

Risk Code: Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment.

### **Registrant**

According to para. 7 of Art. 3 “the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance”.

**RIP**

REACH Implementation Project Information on the current status of the project is provided by the ECB (European Chemicals Bureau, an institution of the Commission European Union located in Italy).

**RMM**

= Risk Management Measure

**SDS**

Safety data sheet

**SIEF**

= Substance Information Exchange Forum

Under REACH (Art. 29), a forum for the exchange of information on substances established after pre-registration of phase-in substances. Participants of a SIEF consist of all manufacturers/importers of an identical substance. The aim of SIEF is to avoid multiple execution of trials.

**Substance**

According to para. 1 of Art. 3 “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”.

**Substance, hazardous**

Highly hazardous substances include:

- a) CMR substances: Substances that are carcinogenic, mutagenic or toxic to reproduction.
- b) PBT substances: Substances that are not broken down in the environment, accumulate in humans and animals, and are toxic (substance with persistent, bio-accumulative and toxic properties).
- c) vPvB substances: Substances that are not broken down and accumulate in tissue (very persistent and very bioaccumulative substances)
- d) Other substances of similar concern, e.g. hormone disrupting (endocrine) substances

**Supplier of an article**

According to para. 33 of Art. 3 “any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market”.

**Supplier of a substance or a preparation**

According to para. 32 Art. 3 “any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation”.

**Substances which occur in nature**

According to para. 39 of Art. 3 “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.”

**Use, identified/supported**

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 and that is covered in the safety data sheet communicated to the downstream user concerned.

**Undesirable/unsupported use**

Use by downstream users which the registrant advises against.

---

**THE BRIGHT ALTERNATIVE FOR  
SURFACE TREATMENT**

---



**VEK**

Use and exposure category (Verwendungs- und Expositionskategorie).