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.

In future, 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 be pre-registered in the period from 1 June until 1 December 2008 (Article 28).

Pre-registration takes place via REACH-IT at the European Chemicals Agency in Helsinki and must include:

- the name of the substance (including its EINECS and CAS numbers);
- the name and address of the pre-registering manufacturer and/or importer;
- the relevant tonnage band (average of the last three years);
- the name(s) of substances that allow conclusions to be drawn about comparable substances (in order to avoid animal testing and facilitate cost savings).

The Agency will by 1 January 2009 publish on its website a list of the names of the pre-registered substances, including their CAS and EINECS numbers.

Pre-registration does not result in any obligation to register.
Pre-registration is free of charge.
Therefore, it is recommended to pre-register as many substances as possible.

All manufacturers/importers who have identified the same existing substances for pre-registration with the European Chemicals Agency must participate in a so-called Substance Information Exchange Forum (SIEF).

4. Authorisation and Restriction

Approximately 1,500 substances (e.g. Category 1 and 2 CMR substances) are subject to authorisation, being substances of very high concern.

The authorisation procedure is carried out irrespective of volume thresholds.

Eventually, the Commission is going to publish a list of substances in Annex XIV that are subject to authorisation. The publication specifies a transitional period after which the substance may no longer be marketed or may be marketed only in accordance with the authorisation.

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 will be revoked as of 1 June 2009.

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

5. Duties of Downstream Users

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

Formulators of preparations 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 preparations 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/preparations:

- 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 (inlcuding < 1 t/a), provided that the use is not supported by the manufacturer/importer.

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

If a safety data sheet (SDS) is generated for a new product for the first time after 1 June 2007, the SDS must meet the new requirements of the REACH Regulation.
If a safety data sheet for an existing product is changed after 1 June 2007, it must also meet the new requirements of the REACH Regulation.

The extented safety data sheet (extSDS) is a safety data sheet that contains an exposure scenario in the annex.

The creation of an exposure scenario (ES) is mandatory in the following cases:
- a substance is manufactured/imported at quantities of ≥ 10 t/a (then a chemical safety report must also be created on the basis of the ES) and is classified as hazardous;
- a preparation contains a substance above the limit of consideration is classified as hazardous.

The applications of the substance known to the registrant form the basis of the exposure scenarios.

For existing substances, exposure scenarios (if any) will have be provided only after termination of the registration duty for the relevant tonnage band.

The results of the chemical safety report (mandatory for hazardous substances > 10 t/a) must also be incorporated in the safety data sheet which is to be submitted to the customer.

Where no safety data sheet is required, the customer must be provided with the registration number, information on the duty of registration, if applicable, information on any restrictions of use, and other relevant information available on the substance.

7. 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-helpdesk.de

www.reach-net.com

8. How does Alufinish implement the REACH Regulation?

Safety data sheets of products which Alufinish has brought to market after 1 June 2007 already comply with the REACH-regulation.

Safety data sheets of products which were on the market before 1 June 2007 will be gradually processed and adapted to the REACH requirements.
You can find this revised data sheets on our website under „download“.

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

At present we discuss with our suppliers which substances will be pre-registered or are not inteded for pre-registration.

The pre-registration stage will begin on 1 June 2008 and end on 1 December 2008.
Existing substances which have not been pre-registered may not be marketed any longer after 1 December 2008.

Until now all suppliers have signalised to pre-register all substances.

With a view to the actual registration stage effective from 1 December 2008, it must be agreed with the suppliers which use and exposure categories our raw materials and products are divided into.
Then it will be definitely decided, which substances/ primary products will furthermore be available and if this will have any influences on our products/ preparations.

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.

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

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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, Cypres, 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 the15 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.

VEK
Use and exposure category (Verwendungs- und Expositionskategorie).

REACH - Registration, Evaluation, Authorisation and Restriction of Chemicals

Regulation (EC) No. 1907/2006

Revised on: 2008-05-02

Preregistration
1 June 2008 until
30 November 2008

Alufinish will clarify the preregistration of all primary products with its suppliers.

Safety data sheets will be revised by and by according to REACH requirements.

No need for action for Alufinish customers.

1st Registration phase
1 December 2008 until
30 November 2010

Affected substances:
- Substances manufactured in the EC or imported, in quantities reaching 1.000 tonnes or more per year and manufacturer/ importer
- Substances classified as „N“ (dangerous for the environment) and R 50/53 and manufactured in the EC or imported, in quantities reaching 100 tonnes or more per year and manufacturer/ importer
- Substances classified as carcinogenic, mutagenic or toxic to reproduction (category 1 or 2) and manufactured in the EC or imported, in quantities reaching 1 tonne or more per year and manufacturer/ importer

In collaboration with its customers Alufinish will identify the products´ uses and exposure categories and will forward this data to the particular manufacturer.

Risk management measures defined by the manufacturer will be forwarded to the customers using safety data sheets.

2nd Registration phase
1 December 2010 until 31 May 2013

Affected substances:
- Substances manufactured in the EC or imported, in quantites reaching 100 tonnes or more per year and manufacturer/ importer

In collaboration with its customers Alufinish will identify the products´ uses and exposure categories and will forward this data to the particular manufacturer.

Risk management measures defined by the manufacturer will be forwarded to the customers using safety data sheets.

3rd Registration phase
1 June 2013 until 31 May 2018

Affected substances:
- Substances manufactured in the EC or imported, in quantites reaching 1 tonne or more per year and manufacturer/ importer

In collaboration with its customers Alufinish will identify the products´ uses and exposure categories and will forward this data to the particular manufacturer.

Risk management measures defined by the manufacturer will be forwarded to the customers using safety data sheets.