

Guidance document for implementing REACH in aluminium plants

Disclaimer

This guidance document is addressed to EAA members active in the aluminium sector (manufacturing, fabricating, recycling, converting), and has been prepared by the EAA REACH Task Force. The document focuses, in a concise manner, on the main legal requirements under REACH, which apply to aluminium plants/companies. The main scope is to help locations to understand their role and duties and to provide some specific model templates for letters and inventory data collection.

EAA does not take any legal responsibility on this document.

This document is not replacing the need to have a more in-depth understanding of REACH and the applicable Reach Guidance documents issued by EU authorities. If you have further questions, please contact Eirik Nordheim at nordheim@eaa.be

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1. INTRODUCTION

a. What is REACH

REACH stands for the **R**egistration, **E**valuation, **A**uthorisation and **R**estriction of **C**hemicals, and represents the new EU-wide legislation for dealing with chemicals. It entered into force on 1 June 2007 (Regulation N° 1907/2006 from 18 December 2006).

REACH requires manufacturers/importers of chemicals into the EU to register all existing and future substances with the European Chemicals Agency (ECHA). Without such a registration, substances cannot, in theory, be placed/ used on the EU market. REACH replaces over 40 existing Directives and regulations on chemicals legislation in EU.

Its main purpose is to protect the human health and the environment through better and earlier identification of the properties of chemical substances. To this objective, manufacturers and importers of chemicals in the EU must provide information on the properties of their substances. This information will form the basis for advice on safety measures.

One of the fundamental differences between existing EU chemicals laws and REACH is the involvement and legal requirements for downstream users.

b. Scope of REACH

REACH focus is on chemical substances. REACH is very wide in its scope and is addressing all **substances** whether manufactured, imported, used as intermediates or placed on the market, either on their own, in preparations or in articles.

Waste is specifically exempted.

Member States may exempt substances used in the interests of defence. Other substances are exempted from parts of REACH, where other equivalent legislation applies. Examples of this are pharmaceuticals, cosmetics and food contact articles. Some substances, listed in Annex IV and V of the REACH regulation, are exempted only from the requirement of registration

2. ROLES

a. Roles under REACH

According to REACH, aluminium industry/locations can play several roles in the regulation, the term “chemical” should in fact be interpreted as “substance” (in whatever form considered, on their own, in a preparation or in an article– with some limitation). For definitions of substances and preparations, see Annex 1.

The REACH Regulation makes a distinction between several roles in the supply chain of substances on their own, in preparations or in articles, connected to the activities of a company. The obligations you have to fulfil depend on your role. The role you should identify here is the role you have for a given substance. Note that a company/plant can have different roles for different substances.

EAA members (Aluminium locations) can have one or more of the following roles:

Are you a manufacturer?

A manufacturer under REACH means any natural or legal person established within the Community who manufactures more than 1 tone per year of a substance (either in its own or in preparations) within the Community.

If you manufacture your substance in the European Economic Area (EEA) (EU 27 Member States and Norway, Iceland and Liechtenstein) then you have the obligations of an EU manufacturer. The preparation of the registration documents necessary as EU manufacturers of aluminium metal, oxide and hydroxide is undertaken by the Aluminium REACH Consortium. However, it remains the obligation of each manufacturer to actually register substances produce in quantities over 1 tone per year.

Are you an Importer?

An importer means any natural or legal person established within the Community who is responsible for import.

Import means the physical introduction into the customs territory of the Community. Importers of a substance either on its own or in a preparation in quantities over 1 tone per year shall register manufacturer.

If a non-EU manufacturer decides to appoint an “only representative” in the EU, this only representative will take over all obligations of the importers (see Article 8 (2)). This means that you will not have to register your substance, even if you are importing it from a non-EU manufacturer. Instead you will be considered a downstream user.

Special cases cover

- Recycled or recovered substance
- Re-imported substances

As a general rule these do not need to be registered.

Are you a Downstream User?

According to REACH, *Downstream User (DU)* 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 professional activities. A distributor or a consumer is not a downstream user”.

A 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 utilization”.

Examples:

As far as the aluminium industry is concerned, the production of hydrate, aluminium oxide and aluminium metal, irrespective of physical form is production of chemicals. The use of hydrate in pharmaceuticals, oxide in refractory products and aluminium in further fabrication like extrusion is downstream use.

The production of an extrusion or a coil from rolling is downstream use, the storage and distribution of this by a stockist is distribution and the further use of this profile to manufacture an article is downstream use.

Special situations

Are you a Producer or Importer of Articles?

Some aluminium plants will be producers of articles. This does not require any special measures apart from the exposure scenarios relevant for all plants. In rare cases plants may be importers of articles. This does not require any special measures apart from two cases:

- 1/ The article contains a substance which is intend to be released under normal conditions of use
- 2/ The article contains Substances of Very High Concern (SVHC) in concentration above 0.1%

There can be several DUs and distributors as part of the supply chain before an article reaches the final consumer.

b. A summary of main cases is reported below.

Process step	Activity with respect to use of chemical Substances	Role under REACH	Possible examples in the process chain
All locations	Utilization of substances supplied from EU market	DUs	Lubricants, fuel, cleaning agents
All locations	Utilization of substances imported by location	Importer	Alumina Alloy components
Refinery	Producer of Substance	Manufacturer	Al ₂ O ₃ , Al (OH) ₃
Smelter (pot)	Producer of substance	Manufacturer	Al metal
Cast House in a smelter	Producer of substance	Manufacturer	Al Metal
	Producer of Alloy	DU of Alloy components	
Cast House Downstream	Producer of alloys from metal supplied from EU market	DU of Al and alloy components	
	Importer of waste scrap to produce metal /alloy	DU of Alloy components and Al metal	
	Importer of Metal (ingot/ slabs) from outside EU – if the supplier has no representative in EU	Importer	
Rolling or Extruder	Use of Al from EU market to produce coils/sheet	DU of Al and Alloy components	Note: Distinction article/ preparation to be fixed

3. OBLIGATIONS

a. Manufacturers/ Importers of substances or substances in preparation

An M/I should register connecting to the applicable existing consortium. An indication of the process to follow would be:

- 1/ Consider what substance the site is importing (say as an example Al metal)
- 2/ Confirm it is an importer (i.e. see if the supplier has a EU representative who will register)
- 3/ Consolidate quantities by the applicable Legal Entity (who is the registering entity)
- 4/ Pre-register for the imported quantities
- 5/ Register in due time or withdraw if in the meantime the "exporting supplier" has nominated an EU representative (in this case shall the cost to consortium should be part of the consortium agreement).

If a site imports an Alloy, it should contact all consortia for the various components, (say Al, Mg, and Cu etc). Consortia related to impurities have not to be contacted since the impurities don't have to be registered. Moreover, all the components in the alloy (except the impurities) should be pre-registered.

b. Downstream User

In most cases, aluminium plants are downstream users (DUs) of several chemicals. DUs are a part of the supply chains and the nature of their obligations refer basically to Safe USE of the product (substance or preparation) and to communication. DUs' right and obligations can be classified in several categories:

- 1/ Direct responsibilities of DUs
- 2/ Communication up the supply chain
- 3/ Communication down the supply chain
- 4/ DU reporting obligations

1/ Direct responsibilities of DUs cover:

- Determine whether own use of a substance is covered by the exposure scenarios in the Safety Data Sheet (SDS) supplied by the manufacturer
- If not, DUs must, either change to a supplier that includes his use in the exposure scenarios in its SDS, or, in the cases required in Art. 37.4 of REACH perform a Chemical Safety Assessment (CSA) of the substances
- Apply operational conditions and Risk Reduction Measures (RMM) as indicated in the SDS
- Keep Chemical Safety Report (CSR) available and up-to-date
- Comply with any restrictions on the use of a substance
- Use authorised substances only within the conditions in the authorisation and notify the European Chemical Agency of this use
- Apply for authorisation of use for substances which may require this step

2/ Communication up the supply chain require:

- DUs have the right to make a use known to their supplier, for inclusion in the exposure scenarios (must supply sufficient information)
- DUs may provide any information to their supplier which could help with the registration process
- DUs must inform suppliers of any change in the appropriateness of risk reduction measures indicated in the SDS
- DUs must inform suppliers of any new information on the hazardousness of the substances purchased

3/ Communication down the supply chain require:

- DUs to prepare (when necessary) a SDS for dangerous preparations placed on the market and pass it on to customers
- DUs to be ready to provide SDSs at the request of their customers for non-hazardous preparations but which contain at least one hazardous substance

- When SDSs are not required, DUs to be prepared to provide basic information on the substance/preparation to customers

4/ DUs reporting obligations:

A Downstream user must report to the European Chemicals Agency if:

- The downstream user has to prepare his own chemical safety report due to use outside the exposure scenarios provided by the supplier
- His classification of a substance is different from that of his supplier

DUs are part of the chain to produce the exposure scenario and the final SDS (see Annex II).

The DUs has the **right** to identify his use of a substance to the manufacturer of a substance and to request that his use is included in the exposure scenario developed by the manufacturer, and thus in his registration dossier. If the DU does not do this, he must change to a supplier that covers the DU's use in the SDS, or, in the cases requested in art. 37. 4 of REACH provide his own Chemical Safety Report on any use of the substance that is not identified in the exposure scenario from the manufacturer.

DUs will receive the SDS from their supplier and need to check if their use of the substance is included in the exposure scenario.

The DUs has the **obligation** to supply information, which can question the correctness of the RMM identified by the M/I. The DUs also has the obligation to implement the RRM indicated in the exposure scenario.

In these cases, consult REACH Guidelines or help desk.

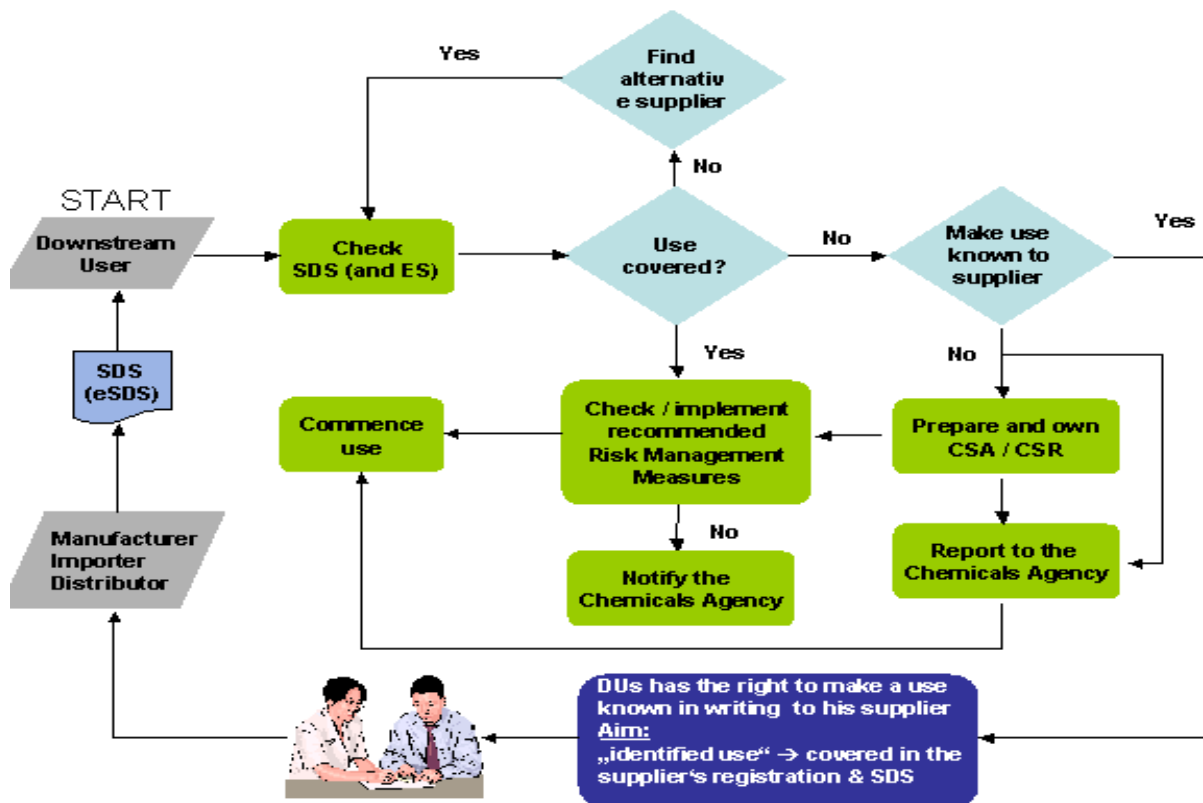


Figure 1: flowchart outlining Downstream User requirements

c. Producer or Importer of articles

- 1/ Any producer or importer of articles shall submit a registration to the Agency for any substance contained in those articles, if both the following conditions are met:
 - The substance is present in those articles in quantities totalling over 1 tone per producer or importer per year;
 - The substance is intended to be released under normal or reasonably foreseeable conditions of use.
- 2/ Any producer or importer of articles shall notify the Agency (in accordance with Article 7(4)), if a substance meets the criteria of SVHC (Article 57) and if both the following conditions are met:
 - The substance is present in those articles in quantities totalling over 1 tone per producer or importer per year;
 - The substance is present in those articles above a concentration of 0, 1 % weight by weight (w/w).

- 3/ Paragraph 2 shall not apply where the producer or importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal. In such cases, the producer or importer shall supply appropriate instructions
- 4/ Paragraphs 1 to 3 shall not apply to substances that have already been registered for that use.

4. OPERATIONAL RECOMMENDATIONS

The aluminium plants will be part of the chain of aluminium use and will benefit of the work done by the Aluminium Consortium.

If an exposure scenario is needed for aluminium, the Consortium intends to develop generic exposure scenarios to cover the main uses of aluminium and consider specific requests from DUs for additional exposure scenarios. This is delivered as part of the registration document and included with the SDS.

But the aluminium plants are also downstream users of a number of other substances and preparations.

From a process point of view, we give the following operational recommendations:

We strongly recommend that each plant

- 1/ *Set up an inventory of all the substances and preparations they have on site and if they have SDS available for these (see Annex III for template). We also strongly recommend that plants check if they are importing any of these directly from outside the EU/EEA.*
- 2/ *To identify Substances of Very High Concern (CMR category 1 and 2, PBT, vPvB, endocrine disruptors), and also substances “critical” for their products or their processes, eventually not replaceable or of difficult supply.*
- 3/ *The DU should check if the products supplied (substance/preparation) are strategically critical for the production process and check if the supplier/manufacturer is taking any action under REACH to secure future supply and if the supplied product is potentially subject to use restriction, authorization or risk of future withdrawal from the market.*

Note: this is not a regulatory obligation but an important action from a business point of view.

- 4/ *Identify need of Pre-registration/Registration for manufactured or imported substances.*
- 5/ *To ensure that their own use of specific chemicals will be taken into consideration by the original manufacturers in their exposure scenarios and registration file, we strongly recommend that plants inform in writing their suppliers of their uses, at the earliest opportunity possible (see Annex IV for template letter).*
- 6/ *To establish a communication flow with down stream Customers and write to them to ensure them about our commitment to meeting our REACH obligations (see Annex IV for template)*

If the plant imports a substance or a preparation from outside the EU/EEA, the plant is responsible for the registration of the substance if they are imported in a quantity above 1 tone/year. The timeline and requirements depends on the quantity and properties of the substances see the enclosed diagram for further indication of this. The Aluminium Consortium is only concerned about the registration documentation for of aluminium hydroxide, aluminium oxide and aluminium metal, the actual registration for this and any other substance will be the responsibility of the plant/company.

The decision on how to carry out the above recommendations should be left to each EAA member.

At the time of writing this document, the EU Guidance Documents on how to develop exposure scenarios and on how to apply risk reduction measures (RRMs) has not been finalized yet. Therefore, this part of DU obligations is not covered by the guidance document.

If such a need is identified, the EAA REACH TF will continue to work on developing specific tools for helping the members in their implementation efforts, in particular with regard to application of RRMs.

Further information about user requirements is being developed as part of the RIP projects. These documents can be downloaded from <http://ecb.jrc.it/REACH/> or from http://echa.europa.eu/reach_en.html

An additional source of information is the national help desks set up by all EU Member States.

Annex I

REACH-relevant definitions

The definitions below are all taken from Article 3 of the REACH Regulation

Agency: means the European Chemicals Agency as established by this Regulation;

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;

- for aluminium we consider profiles from extrusion presses, coils from hot or cold rolling, cast pieces and everything downstream from this as articles.

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;

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;

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;

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 DU;

Import¹: means the physical introduction into the customs territory of the Community;

Importer: means any natural or legal person established within the Community who is responsible for import;

¹ When the EEA countries of EFTA include REACH in the EEA agreement, Norway, Iceland, and Liechtenstein will be considered countries of origin inside EU. As for Switzerland, Swiss authorities are at the present checking out how to handle the issue, avoiding new trade barriers and maintaining Swiss standards.

Intermediate: means 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"):

- 1/ *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 pipe work 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;
- 2/ *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;
- 3/ *transported isolated intermediate*: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

Manufacturer: means any natural or legal person established within the Community who manufactures a substance within the Community;

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;

Phase-in substance: means a substance which meets at least one of the following criteria:

- 1/ It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS²);

² EINECS substances are phase-in substances. ELINCS substances are substances to which the REACH Regulation directly applies and are as such non phase-in substances.

- 2/ 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;
- 3/ 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: 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;

Polymer: means 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:

- 1/ 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;
- 2/ 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;

Preparation: means a mixture or solution composed of two or more substances;

Producer of an article: means any natural or legal person who makes or assembles an article within the Community;

Registrant: means the manufacturer or the importer of a substance or the producer or importer of an article submitting a registration for a substance;

Site: means a single location, in which, if there is more than one manufacturer of (a) substance(s), certain infrastructure and facilities are shared;

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;

Use: means any processing, formulation, consumption, storage, and keeping, treatment, filling into containers, transfer from one container to another, mixing, and production of an article or any other utilisation;

The definitions below are relevant for this guidance and are mainly provided by CEFIC

Authorisation: is required for each use of a substance belonging to specific groups, i.e. substances of very high concern – **CMRs** category 1 and 2 (carcinogenic, mutagenic or toxic to reproduction), **PBT** (persistent, bio accumulative, toxic), **vPvBs** (very persistent and very bio-accumulative) and other substances identified as causing serious and irreversible effects on humans and the environment. *(Definition provided by CEFIC).*

Evaluation: there are 2 types of evaluation

- 1/ *Dossier evaluation*: the Member State authorities can check the compliance of any registration dossier with the requirements of REACH and examine and endorse the testing proposals provided by the industry. *(Definition provided by CEFIC).*
- 2/ *Substance evaluation*: the Member State authorities are allowed to examine registration dossiers in order to evaluate whether a substance presents a risk to human health or the environment and to determine the need for possible authorisation or restriction of marketing and use. *(Definition provided by CEFIC).*

Legal entity: The term legal entity is used to refer to a “natural” or “legal person” having obligations under REACH. A “natural person” is a concept applied in many legal systems to describe persons who are capable and have the right to engage into contracts or commercial transactions. A “legal person” is a similar concept applied in many legal systems to refer to companies who have been endowed with legal personality by the legal system applicable to them and therefore are capable of carrying rights and obligations, independently of the people or other companies behind them. In other words the company usually has its own existence and it’s assets do not coincide with those of its owners.

(From RIP 3.1 Guidance on Registration)

LEGAL ENTITY

It should be noted that only a natural or legal person established in the European Union can be a registrant. Because Community law does not operate a complete harmonisation of civil and company law, it is the national law of each EU Member State which provides when one is faced with a natural or legal person. The following guidance may be useful:

Each legal entity established within the Community manufacturing or importing a substance is required to submit its own registration.

In the case of a company group which is composed of several legal entities (e.g. a parent company and its subsidiaries), each of those legal entities must submit its own registrations. However, they need to submit parts of the dossier jointly, as outlined in section on Joint submission of data by multiple registrants (see section 1.8.4). On the other hand, if one legal entity has two or more production plants which are not separate legal entities, then only one registration covering the different sites needs to be submitted by the legal entity.

Non-phase-in substance: a completely new substance that has neither been used nor registered in the market before the entry of force of REACH or put on the EU market after 1981 and listed in the European List of Notified Chemical Substances (ELINCS). Any non-phase-in substance must be registered before it can be used in a manufacturing process.

Notification: written information on the substance submitted by the manufacturer/importer to the European Chemicals Agency. (*Definition provided by CEFIC*).

Registration: for each substance produced or imported in quantities of 1 ton or more per year, manufacturers and importers must prepare a registration dossier to be submitted to the European Chemicals Agency (located Helsinki, Finland). (*Definition provided by CEFIC*).

ANNEX II

Duty to supply SDS and Exposure scenarios

There is a general duty for a manufacturer/importer to supply a SDS to his customers for all substances, which are classified according to the new Global Harmonised System (GHS) for classification and labelling (this new classification will replace the existing 67/548 and 1999/45 Directives).

If the substance is not classified and does not contain substances with EU workplace exposure limits above 1%, there is no general duty to supply a SDS, but downstream users can still request it, and we would recommend having an SDS in any case to describe general RMM for downstream users.

If there is a classification for the substance, either for human health or environment, then there is an obligation to develop exposure scenarios, and this is also where the DUs obligations come in.

The exposure scenarios under REACH are slightly different from the traditional exposure scenarios for risk assessment.

Under REACH, this is an iterative process, where in the first assessment it is possible to do a simple modelling using the established Derived No-Effect Level (DNEL) for human health endpoints and Predicted No-Effect Concentration (PNEC) for environment endpoints and compare this to modelled or measured exposure levels to see if there is any concern. If there is cause for concern, the exposure scenario is refined by better data for exposure and also introducing the normal risk management measures already in place, like ventilation hoods for dusty operations. The iteration can continue with increasing levels of refinement until a safe level is achieved, and the risk management measures needed identified. This will then be the final exposure scenario communicated to downstream users and with identification of the risk management measures needed as part of the final SDS.

Annex III

Substance inventory

A key step for downstream users to comply with REACH is to have a full overview of what substances/preparations the company uses or imports, including what substances in articles that the company uses or imports. Such a *substance inventory* or *inventory of purchased substances* will

- 1/ support companies in fulfilling their Downstream User obligations
- 2/ help Downstream Users to get an overview of the potential implications of REACH
- 3/ secure the necessary supply of substances/preparations

Establishing the inventory needs to be divided into two main steps

- 1/ Step 1: Before REACH enters into force or in the early stages of REACH implementation.
- 2/ Step 2: As REACH implementation is progressing the inventory can be extended to take care of additional information and requirements which only becomes available when registration and communication in the supply chain has started.

It is recommended to start filling in the template for the process chemicals, i.e. the chemicals which are directly used in your process, this should be followed by the imported chemicals and the chemicals of very high concern.

Annex III of this guidance is a proposal for how aluminium industry can organise a substance inventory. Each plant needs to check its own situation.

Substance inventory

Step 1 - recommended to be completed in the early stages of the REACH implementation.

Listing substance/preparations purchased								Supplier information			Substance information				
Product trade name	SDS	Substance or preparation	Composition	CAS	EINECS/ELINCS	Chemical (IUPAC) name	Annual tonnage used	Name	In/not in EU	Will supplier register substance	Use	Confidential use	Alternatives	Classification	High concern substances
1)	2)	3)	4)	5)	6)	7)	8)	9)	10)	11)	12)	13)	14)	15)	16)

Example of an inventory table under step 1:

The red boxes indicate information that will require follow-up (further checking or action); see recommendations on the next pages.

Listing substance/preparations purchased								Supplier information			Substance information				
Product trade name	SDS	Substance or preparation	Composition	CAS	EINECS/ELINCS	Chemical (IUPAC) name	Annual tonnage used	Name	In/not in EU	Will supplier register substance	Use	Confidential use	Alternatives	Classification	High concern substances
	No		Known				< 1		In EU	No		No			Yes
	Yes		Unknown				1-10		In EU			Yes	No		No
	Yes		Known				10-100		In EAA			No			No
	Yes		Known				100-1000		China			No			No

Step 2 – additional columns - recommended to be completed when registration and communication in the supply chain has started under REACH.

Use covered	RMMs implemented	Subject to authorization	Subject to restriction
1)	2)	3)	4)

Guidance for completing a Substance Inventory

Step 1

1/ **Product**

Trade name or trivial name of the purchased product (substance or preparation).

2/ **SDS**

Is SDS available, yes or no? If no, check with supplier. SDS is usually the main source of information available to identify the chemical composition of a product (see item 4 - composition).

3/ **Substance or preparation**

Is the purchased product a substance or a preparation? (See definitions in Annex I).

4/ **Composition**

In case of preparation, is the chemical composition known, yes or no? If yes, list all substances and their CAS number in column 5 and their EINECS/ELINCS number column 6. If no, check with supplier. It is necessary to know the composition of preparations purchased to fulfil all obligations under REACH. This will be especially important if you import preparations from outside EU, because this places registration obligations on you as an importer (see also item 10).

5/ **CAS number**

A CAS number, or Chemical Abstracts number, is a single and unique number allocated any chemical substance.

6/ **EINECS/ELINCS**

EINECS (European Inventory of Existing Chemical Substances) is a list of all chemicals substances placed on the European market between 1971 and 1981. All substances in this list have a number starting with 2 or 3. EINECS listed substances produced in quantities over 1 tone per year are the so called 'phase-in substances'.

ELINCS (European List of Notified Chemical Substances) is a list of all new substances placed on the European market after 1981. These are the so called non-phase in substances for which REACH applies immediately. These substances are considered as already registered since they have been subject to testing requirements in line with REACH since 1981.

7/ **Chemical name**

CAS number and EINECS/ELINCS number is sufficient to precisely identify a substance, but it is recommended to add the names of substances in the substance inventory for communication purposes. IUPAC (International Union of Pure and Applied Chemistry) provides the most precise substance terminology.

8/ Annual tonnage

What are the annual quantities used of the chemical product (per legal entity)? Information on tonnages used is important because volumes decide registration deadlines for phase-in substances, which in turn are decisive for communication obligations in the supply chain and other DU obligations related to registered substances.

9/ Suppliers

Who is the supplier, name (and address)?

10/ In/not in EU

Do you buy the product within EU-27 or outside, yes/no or both? Note that if a non-EU manufacturer has not appointed an EU representative for registrations you are considered as the importer and must take care of the registration yourself.

11/ Will supplier register substance?

Will supplier register the substance and thus be able to continue the supply, yes or no? This is important to secure your supply of substances and preparations. If no, you could try to identify alternative suppliers, or ask the supplier to assist in the preparation of a registration (see also item 14 - alternatives). Note that DUs may notify the Agency of interest in substances that are not pre-registered.

12/ Use

Define your identified use of the substance (default categories of identified uses will be established). All identified use of substances shall be reported to your supplier in order for him to prepare exposure scenarios.

Note that the supplier is not *obliged* to include your use(s) in the registration/exposure scenario. If that is the case, you may find a supplier who provides an exposure scenario covering your use; you can do the chemical safety assessment, compile a chemical safety report and notify the Chemicals Agency; or you can change your conditions of use to comply with your supplier's exposure scenarios.

13/ Confidentiality

Do you want to keep your use confidential, yes or no? Be aware of the fact that if you keep your use confidential you yourself needs to do the chemical safety assessment and compile a chemical safety report and notify the Chemicals Agency.

14/ Alternative

Are there any alternatives on the market for the actual chemical product, yes or no? In case you identify a risk for a chemical substance or preparation not being supplied (from *any* supplier) it is important to check out if there any alternatives. Such alternatives can be another substance/preparation which gives the same functionality or another process where the substance/preparation is no longer needed. If you can't find any alternatives which are accepted for use at your plant, the product is probably *critical*. Lack of alternatives may cause problems in case of disappearance from the market or subject to large price increases.

15/ **Classification**

Are the substances classified according to Directive 67/548/EEC? This information is given in the SDS. Harmonized classifications of substances are given here:

<http://ecb.jrc.it/classification-labelling/>. Information on classification is important in order to apply the appropriate Risk Management Measures (RMM) communicated in SDS, and to report sufficient information to registrant on downstream use for substances that are dangerous/PBT/vPvB.

16/ **High concern substances**

Is the substance CMR category 1 or 2, PBT, or vPvB (see definitions in Annex I) High concern substances will require authorization for use, and are the ones that have the highest potential to disappear from the EU market or to be severely restricted to just a few uses.

Step 2

1/ **Use covered**

Check if your use is covered in the registration by your upstream suppliers, yes or no? This should be communicated to you in the new SDS. (See also item 13 in Step 1 - confidentiality).

2/ **RMMs implemented**

Are all the recommended RMMs that are communicated to you in the SDS implemented, yes or no? If the answer is no, all deviations should be listed. Note that it is legally binding for DUs to apply the operational conditions and RMMs recommended in the SDS, and that you need to notify the Chemicals Agency about any deviations from the recommended RMMs, with a justification.

3/ **Subject to authorisation**

Is the substance subject to authorisation, yes or no? If you use substances subject to authorisation you need to notify the European Chemicals Agency.

4/ **Subject to restriction**

Is the substance subject to any restrictions, yes or no? A substance on its own, in a preparation or in an article that are subject to restriction shall not be used unless it complies with the conditions of that restriction.

Annex IV

Template of letter to suppliers

EARLY COMMUNICATION to CUSTOMER

Dear Customer.....,

We are referring and drawing your attention on the new chemicals legislation that has just entered into force across Europe on June 1st, 2007.

This legislation, known as REACH Regulation (EC) No 1907/2006 (Registration Evaluation Authorization and Restriction of Chemicals) will have a significant impact on a wide range of industries, including our own.

The regulation is complex and is affecting all manufacturers, importers and downstream users in the European Union, and is requiring their joint collaboration across the supply chain.

It is essential for users of substances to know if suppliers (Manufacturer/Importer) will register the substances they require – in order to confirm that these substances will be available in the future and their specific uses will be covered by a registration.

It is also essential for manufacturers/importers to be informed about downstream applications as well as use and exposure information for the respective substances in order to be able to incorporate them in the required chemical safety report.

We (*name of Company*) are committed to meeting our legal obligations under REACH, as a manufacturer / importer / downstream user and have started preparing for it.

However, as related important technical details – e.g. guiding documents (RIPs) are still under development – and some financial elements e.g. registration costs are not available yet, we cannot yet fully assess the impact of REACH on our product portfolio.

We would like to ensure you that, as a supplier of the following product:

Substance: Name (Aluminium metal, Al Oxide, Al Trihydrate)

Preparation: Name / Trade name (.....)

Alloy: (.....)

Article: (.....)

1. We are going to pre-register manufactured or imported substances in order to benefit from the transitional periods provided by the pre-registration under REACH
2. We are going to register manufactured or imported substances
3. We will check among our suppliers, or any party up the supply chain, their willingness to undertake the responsibility of pre-registration and registration of the applicable substances in order to grant our supply to you.



If you consider that any product(s) we supply to you is a very critical component in your operations, we would be happy to discuss this with you in more detail. (OPTIONAL)

It is not the intention of this letter to request data at this stage, as some technical guidance (e.g. on how to apply REACH to alloys) and specific formats are still under development, however we anticipate the need of a future close information flow, up and down the supply chain.

We intend to provide information on exposure scenarios and possible risk reduction measures related to the supplied substances for uses known to us in order to ensure safe handling and use of our products.

We will need from you a check of actual conditions of use and updating information where applicable, in order to pass them up the supply chain as needed to our raw material suppliers. Meanwhile if you have any question on REACH implementation we provide you with a company contact.

Yours sincerely,

.....

Company Name:
Date:
REACH contact person: Name: Position: Tel: Fax: E-mail:

Early communication to Suppliers

Dear

Re: Future information requirements related to REACH.

We would like to bring to your attention the importance of the new chemicals legislation that will enter into force across Europe on 1st June 2007. This legislation, known as the REACH Regulation (EC) No 1907/2006 (Registration Evaluation Authorisation and Restriction of Chemicals), will have a significant impact for a large number of industries, including ours.

During the legislative process, the chemical industry continuously expressed a general concern about the potential for some chemical substances to be withdrawn from the European market as a consequence of REACH, and the impact this may have for downstream users. As a downstream user, we strongly share this concern.

All substances manufactured and/or imported in quantities above 1 tone/year, even if only supplied in mixtures or preparations, will need to be registered under REACH.

Moreover, all substances meeting the criteria for “phase-in” substances (i.e. existing substances on the market today) should be pre-registered in order to benefit from the transitional periods provided under REACH. The pre-registration will be completed between 1st June 2008 and 1st December 2008.

We, therefore, ask you, as our supplier of important raw materials, to communicate with us on your considerations for subjecting all these substances to the pre-registration and registration requirements of REACH.

While it is your decision whether or not to register a particular substance, we need to know such decisions well in advance, as they are likely to directly impact our business planning, and potentially that of our customers. Indeed this is also outlined in Recital (55) of REACH which states that *“Such information should be provided to a downstream user sufficiently in advance of the relevant registration deadline if the manufacturer does not intend to register the substance, in order to enable the downstream user to look for alternative sources of supply.”*

Any potential withdrawal of a substance from the market is likely to disrupt the whole supply chain. It is, therefore, of utmost importance that every party along this chain brings its substances to the pre-registration, thereby enabling the maximum use of the transitional periods allowed under REACH.

Your earliest response in this regard is therefore essential.

Yours sincerely,

.....

Detailed communication to Supplier

Purchasing department Dear Supplier

As you are aware, the **REACH** Regulation (EC) No 1907/2006 (Registration, Evaluation and Authorisation of Chemicals) has entered into force across Europe on June 1st 2007.

All substances manufactured and/or imported in quantities ≥ 1 ton/year, even though only supplied in mixtures or preparations, will need to be registered under REACH. All substances meeting the criteria for "phase-in" substances should therefore be pre-registered in order to benefit from the transitional periods provided by pre-registration under REACH. Pre-Registration will have to be completed by the end of December 2008.

REACH implies a potential risk for some chemical substances to be withdrawn from the European market.

To enable our company, to be fully prepared for REACH, we would like to know if your company intends to pre-register and register the substances in the product(s) that you manufacture and / or import into the European Union, and supply to us. In addition we would like to know if your company plans to include the use by our company of any of these substances in your registration.

We therefore would like to obtain a written statement from you, as our supplier of important products, indicating that:

Concerning the Product(s) (trade Name):

- a) You are going to PRE_REGISTER under REACH all substances included in these products that you manufacture or import in the EU.
 - Yes No Too early to decide. Reply probably by.....
- b) You are going to REGISTER under REACH all substances included in these products that you manufacture or import in the EU.
 - Yes No Too early to decide. Reply probably by.....
- c) In case you as well have to rely on raw material shipments by your suppliers, you will ensure that they will be informed accordingly, so they can behave in the same way.
 - Yes No Too early to decide. Reply probably by.....
- d) In case any party up the supply chain is not intending to pre-register, you will inform us; as early warning is critical for our own planning. Any gap will affect our own business as well as the business of our customers
 - Yes No Too early to decide. Reply probably by.....
- e) You have all the relevant information about the use by our company of your product
 - Yes No Too early to decide. Reply probably by.....

- f) You plan to include the use by our company in your registration.
 Yes No Too early to decide. Reply probably by.....
- g) You will inform us in case any Substances of Very High Concern (SVHC) components above 0,1% w/w are contained in the mentioned product and/or you envisage any risk for this product(s) in relationship to possible withdrawal from the market or restriction in use.
 Yes No Too early to decide. Reply probably by.....

Please provide also the name of a contact person within your company for REACH (Name, Position, Phone number, E-mail)

Your earliest response in this regard is therefore essential.

If you need additional clarification on pre-registration and registration or any other issue on REACH, please contact us.

Thank you in advance for your answer,

Yours sincerely,

.....

Company Name:
Date:
REACH contact person:
Name:
Position:
Tel:
Fax:
E-mail:

Annex V

Useful links

1. CEFIC. <http://www.cefic.org/Templates/shwStory.asp?NID=29&HID=441>
2. EuroMetaux. <http://www.eurometaux.org/content/default.asp>
3. European Chemicals Agency (ECHA). http://ec.europa.eu/echa/home_en.html
4. European Commission. http://ec.europa.eu/enterprise/reach/index_en.htm
5. REACH-IT & Informatics provided by the European Chemicals Bureau (ECB).
http://ecb.jrc.it/reach-it_informatics/
 - IUCLID5. <http://ecbwbiu5.jrc.it/>
 - REACH Implementation Projects (RIPs).
http://ecb.jrc.it/home.php?CONTENU=/DOCUMENTS/REACH/RIP_FINAL_REPORTS/
6. National helpdesks on REACH
 - Belgium.
https://portal.health.fgov.be/portal/page?_pageid=56,5920388&_dad=portal&_schema=PORTAL
 - Norway. http://www.sft.no/artikkel_____39876.aspx
 - UK. <http://www.hse.gov.uk/reach/>