EUROFER

REACH

Guidance for the European Steel Industry

Version 2.1

October 2008

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Preamble

REACH is the name given to the EU's Chemicals Policy that affects an estimated 30,000 chemical substances placed on the market in the EU. European steelmakers, steel processors, and importers are directly affected by this regulation because it encompasses metals and alloys (e.g. steels and their additives/coatings), solvents, cleaners, acids, alkalis, oils, lubricants, metalworking fluids (and their additives) as well as inorganic and organic chemical compounds.

Following a lengthy period of negotiation, the EU Regulation on the **R**egistration, **E**valuation and **A**uthorisation of **Ch**emicals (REACH) was adopted by the European Parliament and the Council of Ministers in December 2006. The provisions of this regulation came into force in June 2007. REACH is considered one of the most ambitious and biggest pieces of legislation in the European Union (EU). It will replace over 40 existing Directives and Regulations and create a single system for all chemical substances. As a Regulation, REACH is directly applicable in all member states.

Several REACH Guidance Manuals, the REACH Regulation itself and Commission websites providing the official REACH guidance documents have been used as source material in order to create this Eurofer REACH guidance, which will be updated on a regular basis.

If you have any further questions on the content of this document, please contact Danny Croon, EUROFER Reach Manager & Deputy Environment Director at +32 2 738 79 45; d.croon@eurofer.be ; or Tony Newson, General Manager – EUROFER Stainless Health & Environment at +32 2 738 79 44; t.newson@eurofer.be

Acknowledgement

Eurofer wishes to acknowledge that this REACH Guidance Manual has made extensive use of the content and structure of a similar steel-orientated manual produced by UK Steel-EEF for its members. Eurofer wishes to express its thanks to UK Steel-EEF for its generosity in allowing the use of their work in the development of a REACH Guidance Manual suitable for the European steel industry.

Important Notice

This industry guidance is intended as a supplement to the REACH Regulation and the official REACH Technical Guidance Documents published by the European Chemicals Agency (ECHA). It is provided as an advisory document and, as such, has no legal standing. Therefore, in conjunction with this guidance, users are advised to consult Regulation EC 1907/2006 (for the legally binding requirements of REACH) and the official REACH Technical Guidance Documents (for detailed information on REACH implementation). It may also be appropriate to seek independent legal advice on matters related to pre-registration and registration.

While every effort has been made to ensure the accuracy of this document, neither Eurofer nor the authors of this document accept liability for its content or for the use which might be made of the information herein.

1. Introduction to REACH

The purpose of the REACH Regulation (EC 1907/2006) "…is to ensure a high level of protection of human health and the environment, including the promotion of alternative methods for assessment of hazards of substances, as well as the free circulation of substances on the internal market while enhancing competitiveness and innovation". In order to achieve these objectives, REACH places the responsibility on industry to manage the risk of chemicals and to provide appropriate safety information to professional users and, where necessary, to consumers. Under the previous regime, the burden of proof was placed on governments in respect of the safety of substances and where unsafe to restrict their use. REACH covers all substances on their own, in preparations and in some articles.

Relevant definitions out of the REACH Regulation

Article 3.1: Substance: means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (e.g. pig iron, benzene, toluene, zinc, etc.);

Article 3.2: Preparation: means a mixture or solution composed of two or more substances (e.g. alloys, cutting fluid, lubricating oil, etc.); and

Article 3.3: Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition (e.g. cold rolled coil, pipe, tubes and tube fittings, etc,)

Under REACH, substances that are manufactured or imported in quantities above 1 tonne per year per manufacturer/importer will have to be registered. Currently, there are an estimated 30,000 substances in the EU market at volumes above 1 tonne. Unless an exemption applies, failure to register a substance prohibits its manufacture, import or use in the EU. Exemptions from the scope of REACH (e.g. waste) apply where other EU legislation provides a similar level of protection for human health and the environment. In addition, REACH Annexes IV and V as adopted in June 2008 entered into force in October 2008 and lists individual substances (e.g. argon, nitrogen, etc) and groups of substances (e.g. minerals, ores, process gases, etc) that are exempt from registration because their properties are well-known and they are deemed to cause minimal harm.

REACH consists of four main stages:

• **R**egistration – Importers and manufacturers of substances in quantities over 1 tonne per year must register their substance(s) with the new European Chemicals Agency (ECHA) based in Helsinki.

• **E**valuation – ECHA in conjunction with Member State competent authorities will review registration dossiers to determine the impact of substances on human health and the environment and, where necessary, they may request further information or testing.

• **A**uthorisation – SVHC, substances of very high concern, (i.e. carcinogens, mutagens, reproductive toxicants Category 1 & 2 and those harmful to nature classified R50/53) will require authorisation for each use.

• Restriction – Member State competent authorities may request restriction of the manufacture or use of a substance where there is an unacceptable risk to human health or the environment that needs to be addressed on a Community-wide basis.

Manufacturers and importers have certain duties to manage the risks posed by using chemicals. These include an obligation to:

- prepare risk assessments and to register their substances;
- provide appropriate safety information to downstream users and, for the more hazardous substances, to consumers; and
- pass information on chemical hazards and management techniques up and down the supply chain.

Downstream users of chemical substances:

- must apply the risk management measures identified by the supplier and communicated to them via Safety Data Sheets (SDS) and pass this information down the supply chain; and
- should make their suppliers aware of how they use each substance so that the supplier can include these uses in the risk assessment and risk management information in the SDS.

REACH contains a number of terms and definitions which are referenced throughout the document. A list of key definitions is provided in Annex I and a glossary of terms in Annex II of this Eurofer REACH guidance. Where possible, the key articles extracted from the REACH Regulation have been included as a further source of information. Useful web links are provided in Annex III of this guidance.

2. The REACH Process

2.1 Pre-registration

Pre-registration is one of the key stages of the REACH process, which takes place between 1 June 2008 and 1 December 2008. During this period, manufacturers and importers may in accordance with Article 28 provide the following information concerning the substances that they intend to register:

- The name of the substance;
- EINECS and CAS numbers of the substance or, if not available, other identity codes;
- The name and address of the potential registrant (i.e. manufacturer, importer or person representing them);
- The name of the contact person; and
- The envisaged deadline for the registration and the tonnage band.

Pre-registrants may, as a further option, provide any information that already exists regarding computer predictions of the toxicity of the substance (QSARs) or toxicological properties that are predicted by comparing the substance to ones with a similar chemical structure.

Pre-registration does not mean that there is an obligation to register the substance within the deadlines set for the relevant tonnage bands. However, manufacturers and importers who fail to pre-register will not be entitled to take advantage of the transitional periods for registration (i.e. they must cease manufacture, import and placing of their substance on the market unless a registration is made).

Pre-registration applies to "phase-in" substances (i.e. existing substances with EINECS and/or CAS numbers already placed on the EU market). Hence, manufacturers and importers of new substances and phase-in substances that are not pre-registered will be required to register, in full, 12 months after REACH enters into force (i.e. 1 June 2008).

Thus, any manufacturer or importer who fails to pre-register its "phase-in" substances will not be able to rely on support from Substance Information Exchange Forums (SIEFs), making registration of a substance potentially both onerous and expensive. Pre-registered information will only be available to those who have pre-registered the same substance (i.e. SIEFs). When pre-registering a "phase-in" substance, the manufacturer or importer can tick the option to be the SIEF formation facilitator. This option is available on a first come, first-serve basis.

De-activation of a pre-registerion of a substance is available closure of the pre-registration period.. After the pre-registration period has closed, the legal entity will become part of the SIEF – meaning its data-sharing obligations will be retained. However, a legal entity may indicate it no longer intends to register and it wishes to be a dormant SIEF members. This arrangement is to avoid that pre-registration simply to find out who else has pre-registered the same substance. A legal entity will be able to re-activate its pre-registration if it wishes to do so.

It is expected that some manufactures and/or importers may decide to withdraw substances from the market rather than undergo the burden of pre-registration and registration, while other manufacturers and/or importers with SVHC subject to an authorisation or with substances subject to restriction may also decide to withdraw from the market. For downstream users (DUs), this may necessitate seeking alternative suppliers or substances for product use.

It is also anticipated that some downstream users may seek not to disclose their intended use to a manufacturer and/or importer and notify the use of a substance with ECHA directly, thus preserving the confidentiality of that commercial use.

2.2 Substance Information Exchange Forums (SIEFs)

On 1 January 2009, 1 month after the pre-registration phase has ended, the European Chemicals Agency (ECHA), which is responsible for coordinating registration at community level, will publish a list of the substances pre-registered on its website. The list will comprise only the names of the substances, including their EINECS and CAS numbers if available and other identity codes, and the first envisaged registration deadline. Any manufacturer or importer who pre-registers can expect to rely on support from SIEFs, which are to be formed by pre-registrants after the pre-registration phase ends.

In accordance with REACH Article 29, SIEFs will be formed by groups of producers, importers and downstream users of the same substance with the following aims:-

> (a) facilitate, for the purposes of registration, the exchange of specified information between potential registrants in order to avoid the duplication of studies; and
>
> (b) agree classification and labelling where there is a difference in the classification and labelling of the substance between potential registrants.

SIEF participants are obliged to provide other participants with existing animal studies, react to requests by other participants for information, collectively identify the need for further studies and arrange for such studies to be carried out. The sharing of test data on vertebrate animals is a mandatory requirement of REACH. Furthermore, in accordance with Article 11, REACH encourages SIEF members to make joint submissions of certain data via a Lead Registrant (to be appointed by the SIEF members). These provisions are intended to reduce the cost of registration and assessment of substances for individual legal entities. Detailed guidance on data sharing, the operation of SIEFs, the role of Lead Registrants and joint submissions are to be found on the ECHA REACH Navigator website. Furthermore, CEFIC published in June 2008 its guidance on SIEF Formation.

It is important to differentiate the legal status of SIEFs and consortia. SIEFs are a legal requirement and, as such, manufacturers and importers that have pre-registered "phase-in" substances will automatically be placed in the relevant SIEF(s). Later, other data holders (e.g. DUs, NGOs, universities, etc) may join the SIEF. For manufacturers ands importers that have pre-registered "phase-in" substances, participation in a SIEF is mandatory (unless specific criteria can be met). In contrast, membership of a consortium is purely voluntary and it should be noted that the REACH Regulation does not address the formation of consortia, although they are addressed

in the REACH guidance on data sharing. Consortia may be formed at any time during the REACH process (i.e. prior to, and after, pre-registration). Therefore, SIEF members may decide that it would be advantageous to form a consortium to share the cost of data gathering, testing and/or preparation of the Chemical Safety Report for their substance.

It is also important to note that a SIEF will only be formally established when its members have agreed and informed ECHA that they are manufacturers or importers of the same substance. Once again, the REACH guidance documents on substance identification and data sharing should be consulted in order to establish the "sameness" of the substance and rules for forming SIEFs. Each SIEF remain operational until 1 June 2018.

2.3 Registration

Registrations may be submitted to the ECHA from 1 June 2008, when the registration process commences. **If**, however, **a phase-in substance has been pre-registered in accordance with REACH Article 23, the transition period applies and registration is permitted in the following three stages based on the hazard and annual production tonnage manufactured in EU or placed on the EU Market per legal entity:**

 1 December **2010:** Registration deadline for:
- substances in quantities of 1000 tonnes per year and above;
- carcinogens, mutagens and reprotoxic substances (CMR category 1 and 2) above one tonne per year; and
- substances classified as very toxic to aquatic organisms (R50/53) above 100 tonnes per year.

 1 June 2013: Registration deadline for substances in quantities between 100 and 1000 tonnes per year.

 1 June 2018: Registration deadline for substances in quantities between 1 and 100 tonne(s) per year.

Legal entities (i.e. manufacturers and importers) may voluntarily register phase-in substances at any time between 1 June 2008 and the transitional deadlines listed above, **while new substances must be registered before being placed on the market.** In this respect, it is important to note that REACH Article 5 'No data, no market' states "…substances on their own, in preparations or in articles **shall not** be manufactured in the Community or placed on the market unless they have been registered…"

Users of this manual are recommended to consult the ECHA REACH Navigator website for detailed guidance on registration and its costs (the Commission Regulation on the fees and charges payable to the ECHA pursuant to the REACH Regulation was adopted in April 2008.

Information for registration purposes: technical dossier and chemical safety report

REACH Articles 6 (substances on their own or in preparations) and 7 (substances in articles) require manufacturers and importers to submit a 'technical dossier' for substances manufactured or imported in quantities of 1 tonne or more. For substances manufactured, imported, or used in quantities over 10 tonnes per year an additional more detailed Chemical Safety Report (CSR) is also required.

The technical dossier contains information on the properties, uses and on the classification of a substance as well as guidance on its safe use. Amongst other information, the CSR documents the assessments of the risks associated with the manufacture and all of the uses of the substance throughout the entire life cycle. Where appropriate, the CSR must also include a recommendation for the classification should the substance represent a hazard to human health and/or the environment in case it is Persistent, Bio-accumulative, Toxic (PBT) or very Persistent and very Bio accumulative (vPvB).

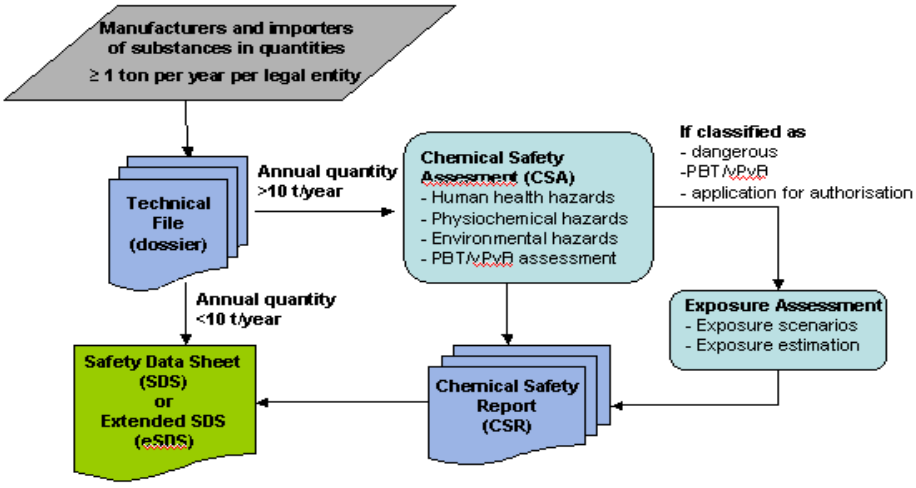
If the substance is assessed as hazardous (the substance meets the criteria for classification as dangerous in accordance with Directive 67/548/EEC or is assessed to be a PBT or vPvB or subject to authorisation), the CSR must also describe exposure scenarios for all 'identified uses' of

a substance throughout the entire life cycle (i.e. from the cradle to the grave) of the substance. Exposure scenarios include risk management measures (RMM) and operational conditions that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled. Information on the safe use of a substance within these categories must then be placed in an annex to the safety data sheet (SDS) and communicated down the supply chain.

Table 1 provides an overview of the information requirements of registration, making reference to relevant Articles in the REACH text.

Table 1: Information requirements for registration dossiers

Quantity manufactured/imported	Registration dossier requirement	Information required
>= 1 tonne	Technical dossier (Ref: Article 10)	• Identity manufacturer/importer • Identity substance and information on its manufacturing and use • Classification and labelling of the substance • Guidance on its safe use • Robust study summaries of the information on the intrinsic properties • Indication on whether the information has been reviewed by an assessor • Properties and eco/toxicological data as required • Exposure related information for the substance • Proposals for further testing, if relevant • Safety Data Sheets
In addition to the Technical dossier when > 10 tonnes	Chemical safety report (Ref: Article 14)	As above plus: • Chemical Safety Assessment • Hazard and classification of the substance, identification as PBT or vPvB if applicable. • If classified as dangerous (67/548/EEC), PBT/vPvB and/or application for authorisation, exposure scenarios, including risk management and operating conditions are required.



As previously stated, REACH requires manufacturers and importers to register substances on their own, in preparations and articles. **The following sub-sections provide specific guidance on the registration of substance on their own, in preparations and in articles.**

2.3.1 Registration of substances on their own

Integrated iron and steel producers are producers of pig iron and, therefore, a REACH registration will be required. Integrated steel producers with coke oven plants will be obliged to register any coke oven by-products (e.g. benzene, coal tar, toluene, etc) that are placed on the market. Many EU steel producers are also importers of metals for alloying and coating purposes (i.e. directly responsible for the import of metals), while others are downstream users of imported metals. Those directly responsible for the import of metals are required to register these substances.

The ECHA REACH Navigator website provides detailed guidance on the identification and naming of substances in REACH as well as guidance on registration of substances and intermediates[1].

2.3.2 Exemptions from registration

REACH Annexes IV and V as adopted in June 2008 entered into force in October 2008 and lists individual substances (e.g. argon, nitrogen, etc) and groups of substances (process gases, minerals and ores unless chemically modified) that are exempt from registration.

Annex IV "Exemptions from the obligation to register in accordance with Article 2(7)(a)" exempts a number of substances (predominantly food-related substances, but including inorganic elements of significance to steel producers) which "…are considered to cause minimum risk because of their intrinsic properties."

Annex V **"**Exemptions from the obligation to register in accordance with Article 2(7)(b) permits the following exemptions from registration:-

- Paragraph 7: "the following substances, which occur in nature, if they are not chemically modified: minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal."

- Paragraph 8: "Substances which occur in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).

- Paragraph 10: "the following substances if they are not chemically modified:
liquefied petroleum gas, natural gas condensate, process gases and components thereof, coke, cement clinker, magnesia."

> **Note:** While the substances listed in Annex IV and V are exempt from registration, they may still be subject to authorisation or restriction.

2.3.3 Registration of substances in preparations

REACH Article 6 requires the registration of substances in preparations when manufactured or imported in quantities greater than 1 tonne per year. [Preparations are defined as mixtures of substances and alloys are included in this definition]. However, this Article requires further explanation because, at first sight, it seems to imply that the substances in all alloys must be registered and this is an incorrect assumption.

1 See Annex I of this guidance for the types of intermediates. Non-isolated intermediates are exempted from registration. Isolated and transported isolated intermediates have limited registration requirements.

If a substance has already been registered and alloying is an identified use of the substance, then the alloy producer, as a direct downstream user of the substance, is not obliged to make a registration. This applies specifically to producers of melted alloys and the use of addition metals as inoculants in smelted alloys. ***In contrast, however, producers of smelted alloys (e.g. ferrochromium, ferronickel, etc) are obliged to register the substances in their alloys.*** This requirement arises from the fact that the smelting process transforms one or more minerals or ores into a metallic alloy (i.e. a mixture of metals or mixture of metal and non-metallic substances that did not previously exist). Therefore, according to the logic of REACH, the smelted alloy producer manufactures and places "new" substances on the market and hence registration of those substances is required.
The registration of the substances in smelted alloys is made still more complex by the REACH guidance on the identification and naming of substances, where the products of the smelting process meet the definition of a multi-constituent substance (i.e. they are the products of a chemical reaction). *Thus, there are two registration options*. Firstly, in accordance with Article 6, the individual substances in the smelted alloy may be registered and, secondly, the smelted product may be registered as a multi-constituent substance (i.e it would be treated as if it were a single entity, substance, and no longer regarded as an alloy).

Importers of alloys and, indeed, all preparations are, in accordance with REACH Article 6, obliged to register the individual substances in quantities greater than one tonne per year. Importers of smelting alloys may also consider the registration of these products as multi-constituent substances (MCS). However, the MCS registration route has attached to it significant implications with regard to the costs and the practicality of assessment.

EIMAG (European Metallic Alloys Group) has produced guidance on pre-registration and registration for manufacturers and importers of alloys that addresses these issues in detail. Users of this guidance are also recommended to consult the guidance on the identification and naming of substances provided on the ECHA REACH Navigator website, where the distinction between preparations and multi-constituent substances are clearly explained. EIMAG has also produced guidance documents on the assessment of preparations and special preparations (e.g. alloys) as well as the grouping of special preparations for assessment.

It has agreed that, as importers of ferroalloys and/or manufacturers of smelted alloys, Eurofer members will as a general rule register the individual substances in ferroalloys and other smelted alloys (i.e. treat them as preparations rather multi-constituent substances). We recommend the non-Eurofer members to do the same. It should be noted that REACH does not permit the registration of preparations.

2.3.4 Registration of substances in articles

Reach Article 7 details the 'registration and notification of substances in articles'. Once again, at first sight, the provisions of Article 7 (1) may seem to imply that the substances in all articles must be registered and, under Article 7 (2), that SHVC (substances of very high concern) in articles must be notified to ECHA. *However, if the substance has already been registered for that use and there is no intended release, the article producer or importer is <u>not</u> obliged to register the substance (Article 7(1)).*

Article 7 (1) requires producers or importers of articles to register any substance contained in those articles, if **both** the following conditions are met:

(a) the substance is present in those articles in quantities totaling over one tonne per producer or importer per year;

(b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.

It is also important to mention that "intended release" is defined as a release necessary in order that the article may function (e.g. the release of zinc from a sacrificial anode used for cathodic protection). Thus, corrosion and wear per se are not considered to be an intended release.

Article 7 (2) requires producers or importers of articles to notify the ECHA, if the article contains SHVC (a substance of very high concern) and if **both** the following conditions are met:

(a) the substance is present in those articles in quantities totaling over one tonne per producer or importer per year;

(b) the substance is present in those articles above a concentration of 0,1 % weight by weight (w/w).

Note: The ECHA guidance on the requirements for substances in articles provides a method of calculation for the SHVC content of an article which differs from that used in the EU Directives for End-of-Life Electrical & Electronic Equipments and End-of-Life Vehicles.

If the article producer or importer can demonstrate that there is no exposure to humans or the environment during normal and foreseeable conditions of use (including disposal), notification is not required. If these criteria met, article producers or importers are advised to record for future reference evidence to support these claims. However, where notification is required, the following information must be supplied:-

(a) the identity and contact details of the producer or importer;

(b) the substance registration number(s), if available;

(c) the identity of the substance;

(d) the hazard classification of the substance(s);

(e) a brief description of the use(s) of the substance(s) in the article(s);

(f) the tonnage range of the substance(s), such as 1 to 10 tonnes, 10 to 100 tonnes and so on.

Upon receipt of the notification, ECHA may decide to ask the producers or importers of articles to submit a registration, if **all** the following conditions are met:

(a) the substance is present in those articles in quantities totaling over one tonne per producer or importer per year;

(b) the Agency has grounds for suspecting that:

(i) the substance is released from the articles, and
(ii) the release of the substance from the articles presents a risk to human health or the environment;

(c) the substance is not subject to Article 7 (1).

From 1 June 2011, the measures related to Article 7 (2) apply 6 months after the substance enters the candidate list for Authorisation.

“Guidance on requirements for substances in articles” was released in May 2008 and can be found on the ECHA REACH Navigator website. This guidance has great significance for importers of metal semi-finished products. This is because the status of the product (i.e. whether it is regarded as a substance/preparation or an article under REACH) will determine the importer’s pre-registration strategy and, ultimately, the extent of his registration requirements. Thus, as preparations, metal semi-finished products would be subject to the requirements of Article 6. Whereas, metal semi-finished products meeting the definition of an article as well as the additional indicative criteria specified in the “guidance on requirements for substances in articles, would be subject to the less onerous requirements of Article 7. Eurofer developed a position paper on the borderline between preparations/articles for steel and steel products (see Annex V of this guidance) of which the aim is to present a global position to ECHA and the Member States.

2.3.5 Registration of recovered substances

Reach Article 2.7 (d) makes it clear that substances, on their own, in preparations or in articles, which have been registered and which are recovered in the Community are exempted from registration if **both** of the following conditions are fulfilled:

- the substance that results from the recovery process is the same as the substance that has been registered;

- the information required by Reach Articles 31 or 32 relating to the substance that has been registered is available to the establishment undertaking the recovery.

Eurofer is working on a European Steel agreement on scrap and REACH of which the aim is to have it recognised by ECHA and the Member States. The Commission (DG Environment/DG Enterprise), developed a paper on waste and recovered substances[2], including amongst others a paragraph on recovered metals.

2.4 Downstream Users

REACH places obligations on Downstream Users (DUs), but these are less onerous than those applied to substance manufacturers and importers. Primarily, REACH obliges DUs to facilitate the communication of information up and down the supply chain.

For their own benefit, DUs need to communicate their uses of substances to their suppliers and ascertain whether suppliers intend to pre-register and register the substances in question. If the substance is to be pre-registered and later registered, it is necessary to determine whether the DU's uses are accepted as "intended uses" by the suppliers and, where appropriate, that they are addressed in the supplier's Chemical Safety Assessment of the substance(s). In accordance with their duty of care, suppliers may refuse to accept uses where risks cannot be adequately controlled. Supplier may also decide that, for commercial reasons, registration of the substance is not worthwhile. In which case, the DU must be prepared to seek new suppliers in anticipation that his current supplier(s) will withdraw from the market.

For business reasons, DUs may be reluctant to disclose (and, indeed, they may even be constrained from disclosing) their use(s) of a substance to their suppliers. Under these circumstances, DUs choose to notify ECHA and conduct their own Chemical Safety Assessment of their use(s) of the substance. If a DU selects this option, there is no necessity to submit either a registration or the Chemical Safety Assessment (CSA) to ECHA. However, the CSA must be recorded, retained for future reference and kept up to date.

DUs may provide exposure data related to their use of the substance(s) in order to assist their suppliers in preparing exposure scenarios and recommended risk management measures for inclusion in Safety Data Sheets (SDS). Whether or not the DU provides exposure data, the supplier will, where appropriate, generate exposure scenarios and risk management measures to ensure safe use of the substance(s) and the DUs are obliged to determine whether those recommendations are sufficient to ensure safety in their use(s) of the substance. If the DU applies more stringent risk management measures, then he is obliged to notify his supplier. The supplier is then obliged to review his risk management recommendations and, if necessary, introduce changes to the SDS.

The DU must apply the risk management measures identified by the supplier, communicated to them via Safety Data Sheets (SDS), and pass this information down the supply chain. They should also make the supplier aware of how their own DUs use the substance so that these uses can be included in the Chemical Safety Assessment and, where appropriate, in the risk management information in the SDS. Figure 2 provides a simple illustration of DU responsibilities.

Safety Data Sheets (SDS) are the primary tool for the transfer of chemical information up and down the supply chain. The provisions of the current Safety Data Sheets Directive (91/155/EEC) are carried over into the REACH, although this new Regulation brings some changes to the duties of suppliers of chemical substances in relation to SDS. These include:

- a CSR (for substances >10 tonnes per year and per producer);
- alteration of several SDS sections; and
- an e-mail address for the supplier.

2 Downloadable from the Eurofer website: www.eurofer.eu/index.php/eng/REACH

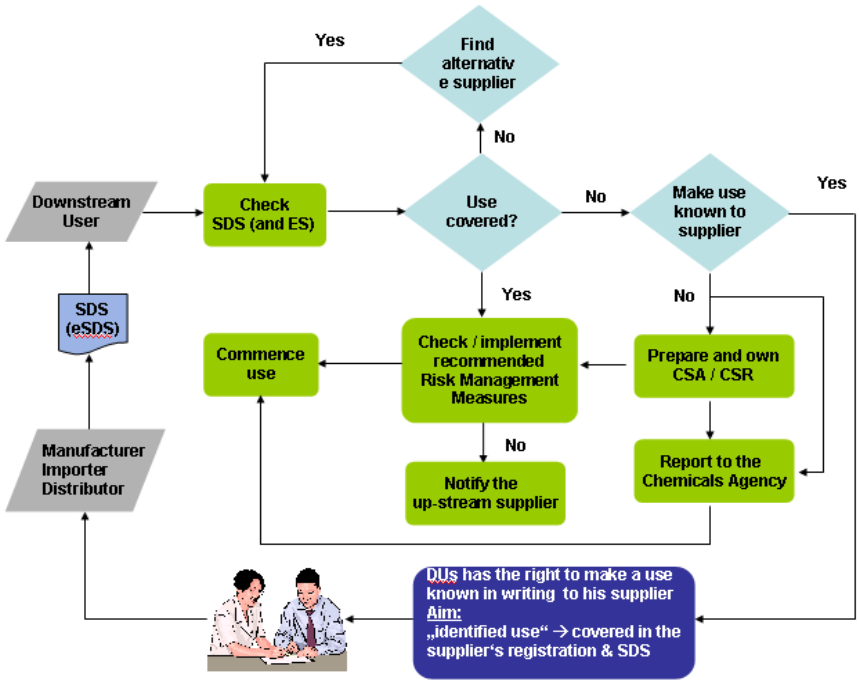


Figure 2 – Flowchart outlining Downstream User requirements

Existing SDS must be updated as more information relating to human health and the environmental properties of the substance becomes available as a result of the chemical safety assessment and, where appropriate, exposure scenarios must be annexed to the safety data sheet. Thus, SDS are required for substances that meet the criteria for classification as hazardous to human health and the environment (i.e. PBTs and vPvBs) or are included in the candidate list for authorisation.

All actors in the supply chain have a duty to pass updated SDSs down the supply chain. Indeed, whenever new information on hazardous properties and other information becomes available that alters the validity of the risk management measures in the SDS, this new information must be passed up and down the supply chain.

The Guidance document on "Downstream Users can be found on the ECHA REACH Navigator website.

2.5 Evaluation

ECHA and the Member State competent authorities will evaluate chemical registration dossiers. Each registration will be subject to an automated completeness check, while ECHA will undertake a compliance check of >5% of the registration dossiers to:

(i) assess whether the information provided by the industry is sufficient; or

(ii) that further information is necessary; if so, ECHA will publish the proposals for testing to allow third parties to submit data to minimise the need for animal testing.

REACH requires that Member States establish a competent authority to carry out in-depth evaluations on an agreed list of substances. These evaluations may lead to authorisation, substitution, restriction or no requirement for further action. Member States are charged with the responsibility for enforcement of REACH. Action in the European Court of Justice may be taken against legal entities where there is:

- The manufacture, import, sale, supply or use of substances without the appropriate registration;

- Use of a hazardous substance outside the terms of an authorisation or restriction;
- Failure to provide required information up and down the supply chain;
- Failure to comply with other duties regarding information;
- Failure to comply with the duty to apply recommendations; and
- Failure to comply with the duties to co-operate and to supply information.

2.6 Authorisation

REACH requires manufacturers and importers to apply for authorisation for each continued use of SVHC, Substances of Very High Concern [i.e. Carcinogens, Mutagens, Reproductive Toxicants (so-called CMR's); Persistent, Bio-accumulative, Toxic substances (PBT); very Persistent very Bio-accumulative substances (vPvB); and endocrine disruptors).

SVHC that meet the criteria for authorisation will be placed on a candidate list for inclusion in REACH Annex XIV. ECHA plans to publish the first list by the end of October 2008. ECHA must propose before 1st June 2009 a list of priority substances (10 substances) for inclusion into Annex XIV (authorisation). The second recommendation of priority substances to be included in Annex XIV will be made by 1st June 2011 (every second year). There are currently an estimated 900 SVHC and it is expected that REACH will identify a further 600 SVHC over the next 11 years. However, the authorisation process has a capability to handle only 20-25 SVHC per year and, therefore, the Commission will prioritise substances on the candidate list for authorisation. Once a decision has been made to include the substance in Annex XIV, ECHA will set a “sunset date” after which it will be illegal to use the substance unless a specific authorisation has been granted. An application for authorisation, for a particular use, must be submitted at least 18 months prior to the “sunset date”.

Authorisation for use will only be granted where there are no feasible economic substitutes and where the applicant can demonstrate adequate control of the intrinsic properties of the substance in accordance with the Chemical Safety Report. If adequate control cannot be demonstrated, an authorisation may still be granted if the socio-economic benefits outweigh the impact of the substance on human health or the environment and if there are no viable substitutes. Where authorisation is granted, it will be for a limited period and subject to the acceptance of a substitution plan.

Users of this manual are recommended to consult the ECHA REACH Navigator website for detailed guidance on authorisationand its costs. The Commission Regulation on the fees and charges payable to the ECHA pursuant to the REACH Regulation was adopted in April 2008.

Note: Unlike the registration process where **s**ubstances manufactured or imported in volumes < 1 tonne do not need to be registered, there is no such volume based exemption for authorisation, restriction or the classification and labelling inventory.

2.7 Restriction

The Regulation also enables Member States to propose restrictions on the placement of substances on the market and their use(s) where there is an unacceptable risk to human health and the environment that needs to be addressed on a Community-wide basis. The restriction process applies to substances on their own, in preparations and articles. A restriction may be ‘partial’ (for specific uses) or ‘complete’. Either the national competent authorities or ECHA may prepare restriction dossiers.

Users of this manual are recommended to consult the ECHA REACH Navigator website for detailed guidance on restriction and its costs. The Commission Regulation on the fees and charges payable to the ECHA pursuant to the REACH Regulation was adopted in April 2008.,

2.8 Classification and Labelling of Substances

REACH requires registrants to assess substances and determine whether they meet the criteria for classification as hazardous to human health or the environment. Indeed, the technical dossiers to be submitted as part of the joint substance registrations will include, where appropriate, recommendations for classification and labelling.

In parallel to REACH, the EU plans to implement the Globally Harmonised System (GHS) for classification and labelling of substances and mixtures (preparations). The EU GHS will replace the classification and labelling provisions of the Dangerous Substances Directive (67/548/EEC) and the Dangerous Preparations Directive (99/45/EC). Eurofer will provide separate guidance when this important new legislation has been finalised and adopted under the co-decision procedure by the European Parliament and the Council of the European Union.

3. Application of REACH to the iron and steel industry

Eurofer's plans to host the Iron & Steel Cooperation Platform (including consortia for metallic iron and iron oxide) have been abandoned[3] in favour of working in smaller more manageable **clusters** based primarily on the iron and steel production routes/steel types.

The **clusters** consist of groups of steel producers with similar interests working together to implement REACH. The clusters that have so far been identified are as follows:

- Integrated iron and steel
- EAF carbon steel (+ Electrical steel producers)
- EAF stainless steel + EAF special and tool steel + Specialist iron-nickel alloys (S4A cluster)

Each **cluster** will map its uses of iron and steel, which will be used to generate a chapter concerning its uses of iron for the REACH Technical dossier. When the mapping is completed for all the clusters, a master map of uses will be made.

ArcelorMittal has indicated its willingness to act as Lead Registrant in the Fe SIEF and Corus has indicated its willingness to act as Lead Registrant for some iron oxides, while ThyssenKrupp is candidate to be proposed as Lead Registrant for the relevant steel slags.

In order to assist its members in their implementation of REACH and to overcome certain difficulties identified with the concept of working clusters, Eurofer has introduced its **REACH Forum** consisting of:

(i) **REACH helpdesk** for steel-related issues (via www.eurofer.eu)

(ii) **REACH Cluster WG** to provide an **internal** ongoing forum:
- For discussion of common issues and, where necessary,
- For the development of a European steel industry consensus on REACH-related issues,
- To prevent duplication of work,
- To identify existing data, and
- Highlight research and studies for cost sharing and/or that could be exchanged at a later date

(iii) **REACH Implementation WG** to provide an **external** ongoing forum:
- To act as a focal point for contact with external interests in iron and other steel-related consortia;
- For discussion of common issues with non-Eurofer interests in iron and steel and, where necessary, development of a global iron and steel industry consensus;
- To prevent duplication of work on iron and other steel-related substances;
- To identify existing data on iron and other steel-related substances; and
- Highlight research and studies for cost sharing and/or that could be bought/exchanged at a later date.

3 The International Pig Iron Association (IPIA) has established a REACH consortium (so-called Iron Platform) covering various forms of iron, iron oxide and inorganic iron compounds

In addition, Eurofer has been asked to undertake projects to gather existing human health and environmental data on iron on behalf of its members. These projects will include data concerning metallic iron, iron oxide and inorganic iron compounds. Meanwhile, Eurofer and the International Pig Iron Association (IPIA) signed with the consultancy firm ENVIRON the framework service agreement and project order. The submission date of the draft data gap analysis report is mid-January 2009 and, subject to mutual agreement, IUCLID compilation would be conducted during the period mid-January to mid-March 2009.

3.1 Registration in the steel sector

Steel alloys do not conform to either the definition of a substance or preparation (see Annex I). However, REACH recognises steels and other metallic alloys as 'special preparations'. In conjunction with the European Commission, EIMAG has developed guidance on the assessment of preparations and special preparations as well as guidance on grouping of special preparations. These documents will be uploaded onto the Eurofer website (www.eurofer.eu) when finalised.

Their status as special preparations means that the substances within steels and ferroalloys need to be registered, not the steels or ferroalloys themselves. In fact, REACH does not permit the registration of alloys. Examples of substances that may require registration by steelmakers and steel importers include: Fe, Si, Mn, P, S Ni, Cr, Mo, Cu, Sn, Al, etc.). Most substances that require registration by steel manufacturers and importers will fall into the highest tonnage band (i.e. over 1,000 tonnes per year), which requires a full REACH data set. These registrations must be completed before the 1st December 2010 deadline.

Steel and other metallic semi-finished products, require special consideration in order to define the point at which these products cease to be preparations and become articles. The guidance for substances in articles does not include a definition for semi-finished products. Instead, each industry sector has to apply the REACH definition of an article and additional indicative criteria given in the official guidance document to determine the point at which its substance or preparation becomes an article. "Guidance on requirements for substances in articles" was released in May 2008 and can be found on the ECHA REACH Navigator website. Eurofer developed a position paper on the borderline between preparations/articles for steel and steel products (see Annex V of this guidance) of which the aim is to present a global position to ECHA and the Member States.

> **Note:** Whatever the final decision concerning the status of steel semi-finished products, it must conform to the REACH definition of article and each steel producer must be able to demonstrate it has met its obligations under the REACH 'precautionary principle', or risk enforcement proceedings by the competent authority.

Eurofer is working on a European Steel agreement on scrap and REACH of which the aim is to have it recognised by ECHA and the Member States. The Commission (DG Environment/DG Enterprise), developed a paper on waste and recovered substances[4], including amongst others a paragraph on recovered metals.

In addition to the substances in steel, steel producers and importers may have obligations to register other substances. Steelmakers will have an obligation to register imported alloying additions and metals used for coating, certain refractories, other raw materials, process consumables and, if placed on the market, by-products. For example, ferric chloride produced during the pickling of steel with hydrochloric acid would require the steel producer to register the ferric chloride if it were to be placed on the market and sold as a product. Wherever a company identifies that it has a registration obligation, consideration should be given to joining a consortium for the substance in question. Contact details for relevant steel-related consortia can be obtained from the Eurofer website (www.eurofer.eu).

An EU master list of substances for (pre)registration has been established by Eurofer and, from that list, a common bulk pre-registration file was generated. This XML-file can be used by each Eurofer member to carry out a bulk pre-registration. Both files are available on www.eurofer.eu

4 Downloadable from the Eurofer website: www.eurofer.eu/index.php/eng/REACH

3.2 Authorisations in steel sector

Substances that may be required to be authorised in the steel sector include:

- Hexavalent chromium (Cr VI) compounds
- Soluble nickel compounds
- Benzene and some other coke oven by-products

In June 2008, ECHA launched the proposal for substances to be included in the first candidate list for Annex XIV substances, which will be made available by ECHA in October 2008. So far, issues for the steel industry would be: sodium dichromate, short chain chlorinated paraffins, benzyl butyl phthalate.

If a steel company is using a substance that meets the criteria for authorisation, this could have a significant impact on operational continuity. For example, the use of the substance could fail to secure authorisation or the conditions of use under the authorisation may be restricted or involve substantial exposure control costs. Alternatively, the substance might be withdrawn from the market and replaced with a less suitable and less effective substitute. Certain substances that may be liable for authorisation may be present only as minor constituents within essential process chemicals, such as rolling oils or coating line electrolytes. Great care is therefore needed to identify all uses of SVHC within a given operation, as withdrawal of even a minor constituent of a chemical formulation might compromise the entire formulation.

3.3 Downstream user activities in the steel sector

The first step for a DU is to coordinate existing information on the substances on their own, used in preparations or used in articles. It may be necessary to source this information from a number of different places within an organisation. This may include: chemical inventories gathered to meet the requirements of the Chemical Agents Directive or as part of the environmental management system; procurement databases; safety data sheets supplied that are supplied with substances and preparations, technical data sheets provided by suppliers and labels on packaging; risk assessments, etc.

When gathering this data there are a number of questions that should be satisfied, these include:

- In what quantities are these substances purchased?
- What is the ‘intended use’ of the substances and/or preparations purchased?
- Will the supplier register these substances?
- Are the substances manufactured or imported into EU?
- Does your organisation manufacture/import any substances?
- If so, would your organisation wish to register an ‘intended use’ confidentially?
- Which substances and/or preparations are critical to the business?
- Are any of the substances used SVHC?
- Will the SVHC used be subject to authorisation or restriction?
- Do substitutes exist for the SVHC used?
- Is your organization a DU?
- What data does your organization possess on the human and/or environmental exposure of the substances and/or preparations used that would aid the manufacturers’ and/or suppliers’ registration?
- Are there any confidentiality issues related to your use(s) of the substance or preparation?
- If so, does your organization wish to notify ECHA and conduct a CSA of those uses?

Manufacturers and importers may seek information from DUs in order to prepare their registration dossiers and to develop exposure scenarios. If a DU provides appropriate information to a manufacturer/importer to develop an exposure scenario (ES), then the manufacturer/importer is obliged to include that use in their registration dossier (unless the supplier can demonstrate that adequate control cannot be achieved by reasonable, cost-effective risk management measures and on this basis decides not support this use of the substance).

Where a supplier refuses to pre-register a particular substance use, the DU can express interest in the substance directly to ECHA. ECHA will publish this substance on its website and, on request from a potential registrant, ECHA will provide the DUs contact details.

For commercial reasons, a DU may decide to keep a substance's use confidential and not inform his supplier. Under these circumstances, the DU has an opportunity to notify ECHA and perform his own Chemical Safety Assessment for that use or those uses. However, this may be a costly and time consuming option to invoke.

Member State Competent Authorities and the European Chemicals Agency are anxious to ensure that Downstream Users do not pre-register substances unnecessarily. In case a DU plans to manufacture or import a substance at some indeterminate time in the future,he could establish production or secure an import and **apply as a latecomer** (i.e. make a late 'pre-registration', so long as they do so within six months of first manufacturing or importing the substance, and no later than 12 months before the relevant phase-in deadlines of 1 December 2010, 1 June 2013 and 1 June 2018). This option is detailed in the REACH Article 28(6).

It is important to note that some manufacturers and importers may decide not to register their substances. Withdrawal of substances from the market may be due to the high cost of registration or to the fact that certain substances may be subject to authorisation or restriction. Therefore, it is important that DUs engage with their manufactures/importers to understand their intentions with regard to compliance with REACH.

Annex I: REACH definitions

The following are just some of the key definitions which apply to REACH:

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;

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

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;

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;

Manufacturing: means production or extraction of substances in the natural state;

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

Import: 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;

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;

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;

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;

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"):

(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;

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

Registrant's own use: means an industrial or professional use by the registrant;

Identified use: means a use of a substance on its own or in a preparation, or a use of a preparation, that is intended by an actor in the supply chain, including his own use, or that is made known to him in writing by an immediate downstream user;

Restriction: means any condition for or prohibition of the manufacture, use or placing on the market;

Supplier of a substance or a preparation: means any manufacturer, importer, downstream user or distributor placing on the market a substance, on its own or in a preparation, or a preparation;

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;

Use and exposure category: means an exposure scenario covering a wide range of processes or uses, where the processes or uses are communicated, as a minimum, in terms of the brief general description of use;

Substances which occur in nature: means a naturally occurring substance as such, unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means;

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;

Alloy: means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means.

Annex II: Glossary of terms and abbreviations

Authorisation: Use-specific permission to use a substance of very high concern.

CAS number: Chemical Abstracts Service (CAS) numbers have been defined for substances to help in their identification.

CMR: Abbreviation for several groups of substance of very high concern, namely those which are carcinogenic (cause cancer), mutagenic (cause damage to genes) or reproductively-toxic (cause either a decrease in fertility or problems with development of the foetus). CMRs are classified in three categories according to the weight of scientific evidence of damages to human health. Only category 1 and 2 substances for which there is a high level of evidence of health damage to humans are subject to authorization under REACH.

CSR: For substances manufactured, imported, or used in quantities over 10 tonnes per year a Chemical Safety Report (CSR) is required in addition to the technical dossier for registration. The CSR documents the hazards and classification of a substance and the assessment as to whether the substance is PBT or vPvB. The CSR also describes exposure scenarios for specific uses of substances that are classified as dangerous or are PBT or vPvB substances.

Duty of care: The REACH official text clarifies in the recitals that the regulation should be implemented "in accordance with the duty of care". This obligation places a general responsibility on industry to avoid adverse effects on health and environment when manufacturing, importing, using or placing on the market chemicals.

ECHA: The European Chemicals Agency is responsible for the day-to-day management of REACH.

EINECS number: The European Inventory of Existing Commercial Chemical Substances. For each substance listed in the EINECS there is an identification code.

Endocrine disrupters: Substances of very high concern that mimic or inhibit the effects of hormones. They will be identified on a case-by-case basis and may become subject to authorisation. Many of these substances are also CMRs.

Exposure Scenario: An exposure scenario (ES) should address all identified uses of a substance through the lifecycle. An ES should be included as an annex in the manufacturer or importers SDS and communicated down the supply chain.

GHS: Globally Harmonised System for classification and labelling of chemicals, agreed under the auspices of the United Nations.

IUCLID: International Uniform Chemical Information Database. IUCLID 5 software systems are used for the registration of substances under REACH.

PPORD: Product and process oriented research and development is defined as any scientific development related to product development or the further development of a substance, on its own, in preparations or in articles in the course of which pilot plant or production trials are used to develop the production process and/or to test the fields of application of the substance.

PBTs: Substances of very high concern that are persistent (difficult to break down in the environment, e.g. by exposure to sunlight or micro-organisms in the soil), bioaccumulative (accumulate in our bodies and in animals' bodies, e.g. in polar bears) and toxic. Those substances may become subject to authorisation as a priority.

QSARs: Quantitative Structure-Activity Relationships. A modelling system used in the regulatory assessment of chemicals.

Registration: The first administrative step of REACH. Manufacturers and importers must submit information in a standardised format, to demonstrate that they know about the most important properties of their chemicals and that they are managing their risks adequately.

RIPs: REACH Implementation Programmes are technical guidance documents which aim to provide the necessary tools/information to ensure that the obligations and requirements of REACH are effectively administered.
SDS: Safety Data Sheets are one of the primary tools in hazard communication. They provide the user with the information needed to carry out a suitable risk assessment for their application.

SIEFs: Substance Information Exchange Fora, as outlined in Article 29 of the official text, allow groups of producers, importers and users of substances to join together and register a substance between them in a consortium.

SVHC: Substances of very high concern are:
- carcinogens (category 1 and 2)
- mutagens (category 1 and 2)
- substances which are toxic to reproduction (category 1 and 2)
- persistent, bio-accumulative and toxic substances (PBTs),
- very persistent and very bio-accumulative substances (vPvBs)
- substances identified from scientific evidence as causing equivalent concern to those mentioned above, for example substances which disturb the hormone system (endocrine disruptors)

Technical Dossier: Contains information on the properties, uses and on the classification of a substance as well as guidance on its safe use.

vPvB: Substances of very high concern that are very persistent (very difficult to break down), very bio-accumulative (very liable to accumulate in our bodies or in animals' bodies). Those substances are subject to authorisation.

Annex III: Useful web links

Eurofer: www.eurofer.eu/index.php/eng/REACH

European Chemicals Agency: (REACH and Guidance) http://echa.europa.eu/home_en.asp

European Chemicals Agency: (REACH Navigator and REACH Guidance): http://reach.jrc.it/

European Chemical Substances Information System: http://ecb.jrc.ec.europa.eu/esis/

European Commission's websites:
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

http://ec.europa.eu/enterprise/reach/index_en.htm

Eurometaux REACH Metals Gateway: www.reach-metals.eu/

Annex IV: REACH Technical Guidance

The following REACH technical guidance documents are available from the ECHA and REACH Navigator websites. These aim to provide the necessary tools/information to ensure that the obligations and the requirements of REACH are effectively administered.

The ECHA website contains 5 main elements:

About REACH
gives an overview of the processes foreseen by REACH, its scope and the main obligations of the actors involved in REACH

- **Navigator**
  is an IT-tool to help industry determine its obligations under REACH

- **Guidance documents**
  provides the Guidance Documents on REACH processes and methods, to be used by industry and authorities.

- **Formats**
  contains the key templates that industry and authorities can use in the context of REACH (e.g. format for Chemical Safety Report, format for Substance Evaluation Report, formats for Annex XV dossiers)

- **Legislation**
  contains different legislative texts related to EU chemicals policy, in particular the **REACH Regulation** in all official languages of the EU

Guidance mainly for Industry Use

Guidance on registration

Guidance on pre-registration

Guidance on data sharing

Guidance for intermediates

Guidance for monomers and polymers

Guidance on Scientific Research and Development (SR&D) and Product and Process Oriented Research and Development (PPORD)

Guidance on Classification and Labelling notification

Guidance on requirements for substances in articles

Guidance for Downstream Users

Guidance on the preparation of an application for authorisation

Guidance on the different methods under REACH

Guidance for identification and naming of substances in REACH

Guidance on how to comply with the provisions of the new Regulation on Classification, Packaging and Labelling of substances and mixtures

Guidance for the preparation of the Chemical Safety Report

Guidance on information requirements under REACH

Guidance on Socio Economic Analysis

Guidance on priority setting for evaluation

Guidance on IUCLID

Annex V: EUROFER position papers[5]

EUROFER position paper[6] determining the borderline between preparations/articles for steel and steel products

Background

Regulation (EC) No 1907/2006 of the European Parliament and of the Council of 18 December 2006 concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH), is a regulation on substances[7]. *Unless exempted from scope or from registration in accordance with Annex IV or V, substances on their own or in preparations[8] are always subject to registration when manufactured in, or imported into, the EU.*

Substances on their own and in preparations in the form of , or contained in, articles produced in or imported into the EU are subject to registration only if they are intended to be released under normal or reasonably foreseeable conditions of use and if this use of the respective substance have not been registered before in the Community.

This paper establishes the borderline between steel alloys (preparations) and steel products in the form of articles. In this paper, it will be shown that *slabs, bars, billets and blooms* made of steel alloys[9] have article status under REACH. The argumentation has been developed in close co-operation with the International Iron and Steel Institute (IISI) and is supported by the global steel industry in so far it applies to European law. Furthermore, this paper is based on a legal opinion received from the law firm “Mayer Brown International LLP”.

Main Steel process stages

There may be up to four main stages in steel processing. Overall, the first three stages are aimed to change and/or refine the shape and size of the material to progressively bring it closer and closer to its final main shape, as illustrated in the flow diagram on page 5 of this position paper.

Stage 1: cast ingots

In the first stage, liquid steel is poured into moulds having the shape and surface appropriate to the subsequent processing regardless of the chemical composition. The shape generally resembles a truncated pyramid or truncated cone, but cast ingots with additional shapes are also produced. Trade literature and standards[10] makes a distinction between cast slab ingots of rectangular cross section of width twice the thickness or over, and other cast ingots having a cross section that may be square, rectangular (of width twice the thickness), polygonal, round, oval or shaped according to the profile to be rolled.

EN 10079 gives the following definition for cast ingots: products obtained by pouring liquid steel into moulds of a shape appropriate to the subsequent processing into semi finished products, or flat or long products, generally by hot rolling or forging

Stage 2: semi-finished products

The second stage is reduction or pressing at primary/roughing mills or reducing press facilities. The cast ingots are heated to make them "workable" and are then rolled/forged to obtain semi-finished products with different shapes and sizes. These vary depending on the technical specifications set by

5 Will be made available in this guidance and on Eurofer REACH website by the end of October/early November 2008

6 Dated 26 September 2008, forwarded to ECHA

7 Definition of **substance** out of the REACH Regulation (Article 3 (1)): 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

8 Definition of **preparation** out of the REACH Regulation (Article 3 (2)):means a mixture or solution composed of two or more substances

9 Definition of **alloy** out of the REACH Regulation (Article 3 (41)): means a metallic material, homogenous on a macroscopic scale, consisting of two or more elements so combined that they cannot be readily separated by mechanical means

10 EN 10079:1992 E, "Definition of steel products"

the customer, which include strict requirements on other external characteristics of the products, such as precise length, width, thickness and surface. Trade literature and standards[11] classify these semi-finished products according to their specific shape into 4 main categories, as follows:
- Slabs: a long, thick, flat piece of steel, with a rectangular cross-section;
- Bloom: a long piece of steel with a square cross-section;
- Billet: like a bloom, but with smaller cross-section;
- Other semi-finished products (of circular cross-section)[12]

These products may also be obtained through continuous casting of liquid steel, which includes support during solidification and cutting to length as final stages of the continuous casting production process. In certain cases, these products do not need further processing and have an end-use function, e.g. slabs for the defence industry, counterweights for cranes. The continuous casting process provides substantial added value to semi-finished steel products and requires use of sophisticated and expensive production equipment.

EN 10079 gives the following definitions for various semi-finished products:

- semi finished products of square cross section: semi finished products with sides of 50 mm and over, generally described as blooms if the sides are greater than 200 mm, or as billets if smaller

- semi finished products of rectangular cross section: semi finished products of cross section area 2 500 mm^2 or over of width up to twice the thickness, generally described as blooms if the cross section is greater than 40 000 mm^2, or as billets if smaller

- flat semi finished products: products of thickness generally 50 mm or over of width twice the thickness or over, generally described as slabs

- round semi finished products: continuously cast or forged semi finished products of circular cross section

- blanks for section: semi finished products intended for the manufacture of sections that have been performed for that purpose

Stage 3: refined semi-finished products
The next stage is reduction at special mills, during which the specific shape, size and surface of the semi-finished products (e.g. slabs, blooms, etc.) is further refined to varying degrees, which in certain cases is the final shape, e.g. sheets, which only need cutting and other minor processing not affecting the general shape. Again, the products obtained from this processing stage are classified according to their general shape into flat or long products and, within these two main categories, into further sub-categories, according to their specific shapes and other technical specifications.

Stage 4: final steel products
In the final stage, the products are given the end-use shape through light processing, which does not affect the general shape of the refined semi-finished products. Examples of final products obtained from processing of coils and sheets are welded pipes, cans, car bodies or car parts such as doors and bonnets, household appliance frames, doors and other parts.

Fulfilment of article definition under REACH

In Article 3 (3) of the REACH regulation the *definition for an article is given: 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 an object to be considered an article, the following conditions should be fulfilled:
The shape, surface or design of the object must:
- be obtained during production and be special;
- be relevant for the function of the object;
- be more important for the function than the chemical composition of the object.

11 EN 10079:1992 E, "Definition of steel products"

12 E.g. machined and dressed ingots

Products obtained from **Stages 2 and 3 fulfill** the article definition. Below are the arguments in support of this conclusion.

- Their shape and/or surface is given during production and is/are regarded as "special".
  These products are produced by specialised factories at the order of the customer. They have different dimensions and technical characteristics, which depend on the specific needs of the customer placing the order. Their surface is developed during production ensuring that the end product requirements are obtainable. Surface defects in the primary products cannot be eliminated in later process stages and therefore the surface finish of the primary product is fundamental to achieving the customer requirements.
- The shape and/or surface is relevant to the function of the object.
  Products intended for further processing are given their specific shape, surface and size to allow production of a specific category of products, whose shape overall reflects that of the intermediary product used for their production. This is also the reason why their shape is important for both the producer and the customer. A customer buys slabs to produce flat steel products, whereas billets and blooms are ordered and purchased for use in the production of long products. From a different perspective, it is worth noting that, unlike steel electro slag remelting electrodes, none of these products, are intended for remelting, during which their main structure and shape would be destroyed. This is further evidenced by the semi-finished products referred to in stage 2 above, where the surface also plays a role and where the degree of refinement of the shape is lighter, showing a strong correlation with the products obtained from them in terms of shape and surface.
- The shape is more important for the function than the chemical composition
  Steel is produced in different grades and these play an important role for the product appearance, characteristics and expected performance. These requirements are achieved on a worldwide basis by national, European and, to a lesser degree, International standards for steel compositions. The chemical composition is established while the steel is in the molten state and, once solidified, the chemical composition is fixed. Therefore, for the products after solidification, the shape and dimensions and surface of these products determines their function to a greater degree than their chemical composition. As indicated above, the function of the (refined) semi-finished products is to provide the bulk structure and main shape of the final products that will be obtained from them. Although the function of the product depends on the chemical composition, this is accessory to that of the shape and surface in that it only confers the products specific physical properties required for it to meet the customer expectations for instance in terms of mechanical properties (hardness, rigidity, resistance to wear, etc.). Furthermore, the mechanical properties are function of both chemical composition (which is fixed upon solidification) and thermo-mechanical treatment. Thus, the shape[13] and design of the steel semi-finished product, irrespective of the chemical composition, determines the facility that can be used for further processing and it also determines the final steel product.

ECHA guidance for articles dated May 2008

The ECHA guidance for articles contains in appendix 3 an example shown for Aluminium products. At the bottom of page 83 of this guidance, the following is mentioned: "Similar raw material type in the form of metal and alloy semi-finished products as *coil and profile (both articles in the example of Aluminium processing on page 82)* are: bars, blanks (e.g. cut, machined, pressed, etc), coil (coated and uncoated), extrusion profiles, films and filaments, foil and ribbons, forgings, plate, pipe and tube (cast, seamless and welded), pipe and tube fittings, sintered semi-finished and final products, sheet and strip (coated and uncoated), stampings, wire rod and wire (coated and uncoated).
At the bottom of page 85 of the guidance, the following is mentioned: "Similar raw material types as *the aluminium alloy cast piece (an article in the example of Aluminium processing on page 82)*: castings (e.g. centrifugal, die, investment, sand, etc), continuous cast shapes (e.g., bars, billets, blooms, rounds, slabs).

As such, the ECHA guidance acknowledges the position of the Iron & Steel industries expressed in this position paper on the borderline between preparations/articles for steel and steel products.

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13 Flat products (e.g. sheet, coil, plate etc.) and long products (e.g. bars, wire rod etc.)

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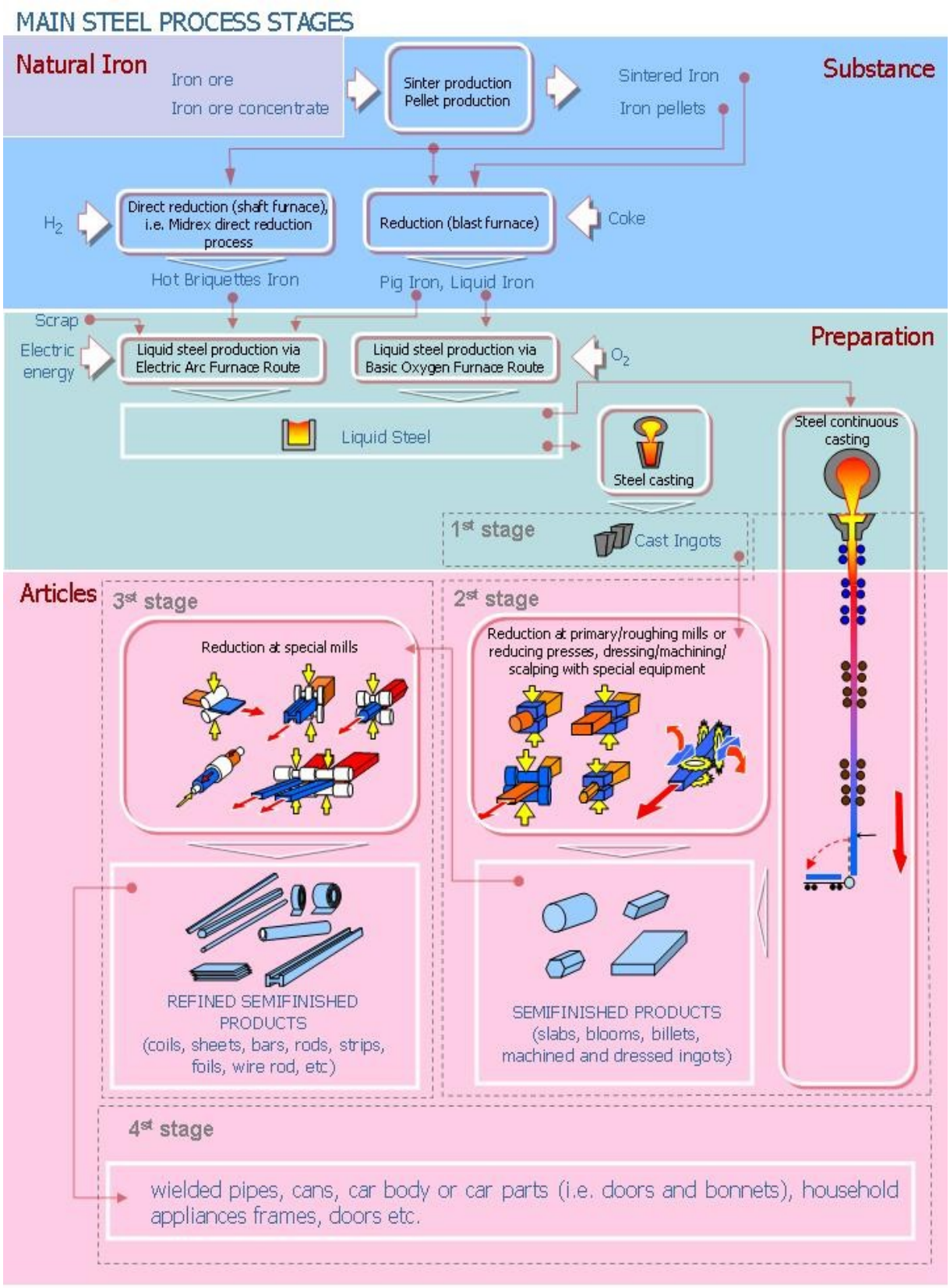

"Scrap" can either be a waste or a preparation. In the case of waste, it is out of the scope of REACH. In case of a preparation, its substances are exempted from registration in accordance with Article 2(7)(d) of 1907/2006/EC (REACH Regulation)

Annex VI: Case studies

1) On the borderline between preparation/article, developed by UK Steel-EEF

Keith Lloyd is a HS&E Manager at a UK steel processing company that manufacture 'merchant bar' from steel 'billet', supplied from Spain, Norway and Turkey. Keith has been charged with ensuring the company's compliance with REACH and has undertaken some background reading on this complex subject. He understands his obligation as a downstream user for the substances/preparations the company uses as part of its manufacturing process. However, he remains confused as to whether the semi-finished (as-cast) steel he uses as a raw material is considered a preparation or article under the requirements of REACH.

Keith understands that if the large quantity of billet his company is supplied (>30,000 tonnes) is determined a preparation he would be subject to register the iron and non-ferrous metals within the steel he 'imports'. He recognises that the obligation to register would only extend to the steel imported from Turkey, not from within the EU (Spain) and European Economic Area (includes EU 27 and Norway, Iceland, Lichtenstein). If the billet was considered an article then no registration would be necessary.

Having contacted his national association (UK Steel) Keith discovers that the European Iron and Steel Federation's (EUROFER) position on this issue is that all semi-finished and final steel products (i.e. Slab, Bloom, Billet, machined and dressed ingots) are articles, and are therefore exempt from the requirements of registration. This position, which is supported by the global steel industry in so far it applies to EU law, was determined from the European Chemical Agency's "Guidance on substances in Articles", where it can be clearly argued that semi-finished steel products have a special shape, surface, or design which determine their function to a greater degree than their chemical composition.

This position assumes that semi-finished steel products are re-shaped into finished steel products. No where in the manufacturing chain is the semi-finished product re-melted (i.e. back to a preparation). Were this to happen then the article-article chain would be broken and registration obligations may apply. The position also recognises that only machined and dressed ingots satisfy the definition of an article. Cast ingots are considered preparations.