

REACH pre-registration and registration requirements for imported alloys

June 2008



This leaflet is intended to be a faithful summary of the 'Guidance on Pre-registration and Registration for Metallic Alloy Manufacturers and Importers' prepared by the European Industry Metallic Alloys Group (EIMAG) in September 2007. The full version containing additional information on this topic is available at: www.reach-metals.eu

REACH is the new EU chemicals legislation that will manage the safe use of chemicals throughout their entire life cycle. The system consists of four pillars: Registration, Evaluation, Authorisation and Restriction of Chemicals.

It will apply to all substances - on their own, in preparations and in articles that are manufactured in or imported into the European Economic Area (EEA)¹ in quantities of 1 tonne or more per year. REACH will require substances within the scope of the regulation to be registered in order to have the right to place them on the EEA market. Pre-registration and registration will apply directly to metals, metal compounds on their own as well as when they are incorporated in alloys manufactured, used and imported into the EEA. The requirements do not apply to minerals, ores and ore concentrates as long as they are not chemically modified².

The majority of metals are placed on the market as metallic alloys³. Recital 31 of the REACH regulation recognises that metallic alloys are special preparations, as their properties, behaviour, and characteristics are different from those of the constituent substances.

Metallic alloys can be manufactured by different manufacturing routes, but the two most common methods are:

Melting

Where metals and other substances are melted and mixed together (there is no intentional chemical reaction between the substances); and

Smelting

Where one or more ores or ore concentrates are heated and reduced (i.e. chemically modified) by e.g. aluminino-carbon-silico thermic reduction - to manufacture and mix the metals in one step, or by electrolysis. Examples of smelted alloys are ferro-alloys, master alloys and mischmetal.

The aim of this leaflet is to inform importers on:

- the pre-registration and registration requirements to be fulfilled for substances in alloys or for the alloy itself when considered as a multi constituent substance (MCS)
- the consequences of not complying with the REACH regulation for alloys that are imported into the EEA.

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2. Pre-registration requirements



2.1 Who can pre-register?

As the pre-registration and registration of the substances in the alloy or the MCS (alloy as such) has to be made by a legal entity established in the EU, the pre-registration and registration requirements related to imported alloys can only be fulfilled by:

The importer of the alloy

In this situation, the importer should properly identify the non-EEA manufacturer of the alloy, obtain all the necessary information, and proceed with pre-registration and subsequently the registration; or

The Only Representative (OR) of the non-EEA manufacturer of the alloy

If the non-EEA manufacturer decides to appoint an 'Only Representative' (OR), then the alloy importers will be considered as the downstream users (DU) of that OR under REACH; consequently they are not required to pre-register and later register the substances in the alloy or the MCS.

The OR will be fully responsible for pre-registration and registration as they assume the full responsibility and liability of the importers on behalf of the Non-EEA manufacturer.

The Non-EEA manufacturer is obliged to:

- inform all the importers in the supply chain that an OR has been appointed
- provide the OR with up to date info on:
 - list of EU importers covered
 - the volumes imported.

The OR has to be able to document to enforcement authorities at request, which importers he covers at EU and MS level. This information also includes data on the volume covered per importer, but it is not required to be submitted to the European Chemicals Agency (ECHA).

2.2 What should be pre-registered?

There are two options for fulfilling pre-registration requirement for alloys.

Preparations route

Pre-register each individual substance within the alloy (Article 28). In line with Article 6 of the Regulation, any manufacturer or importer of an alloy will be required to pre-register all⁴ the individual substances that are present in the alloy in total quantities of more than 1 tonne per year, independent of the concentration in which they are present in the alloy. The pre-registrant will then be listed on the Substance Information Exchange Forums (SIEF) for each one of the pre-registered substances.

Multi Constituent Substance (MCS) route

Pre-register the (smelted) alloy as a multi-constituent substance. Those alloys which are manufactured through intended chemical reactions could be considered as multi-constituent substances⁵ under REACH. Each alloy can then be pre-registered as a substance on its own. This route applies only to alloys which:

- are formed by a chemical reaction (smelted alloys); and
- are listed on the EINECS or whose constituents are listed on the EINECS.

Only the 'preparations' route is applicable to melted alloys. For smelted alloys, the 'preparations' or the 'Multi Constituent Substance' route can be followed.

When an alloy contains substances that were originally manufactured in the EEA but exported out of the Area, and then re-imported within an alloy, there is no need for the re-importer to register those substances again, as long as:

- (i) the substances have been registered before
- (ii) the re-importer can demonstrate that each substance is the same as the one which was registered and originates from the same batch, and
- (iii) the information specified in Articles 31 and/or 32 is made available and ensures a safe use of the substances in the alloy.

Until (i) can be confirmed, it is however recommended to pre-register each substance of the alloy⁶ as a precaution.

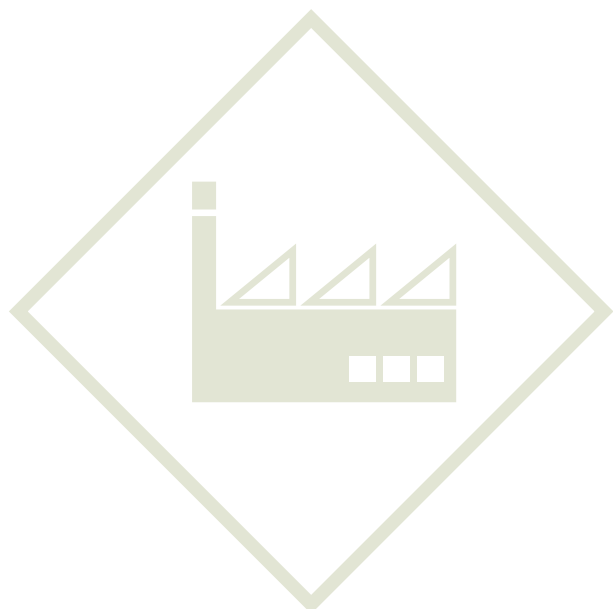
2.3 What should not be pre-registered?

Impurities⁷

The definition of a 'substance' in Article 3 of the REACH Regulation indicates that any impurities deriving from the process used for the manufacturing of the substance are part of the intrinsic constituency of a substance. Moreover, the guidelines of the ECHA on registration state clearly that only the substances intentionally added to a preparation need be registered. It can therefore be concluded, and this was recently confirmed by the EC at a stakeholder event, that impurities that are present in a preparation, such as an alloy, do not need to be pre-registered as a substance of the preparation⁸, unless intentionally added.

Alloys as articles

Pre-registration is not required when an alloy which is placed on the EEA meets the definition of an article⁹ from which substances are not intended to be released under reasonable and foreseeable conditions of use. The latter condition is likely to be the case for all alloys that can be regarded as articles¹⁰ under REACH.



3. Registration requirements



3.1 What to register and how?

Preparation of the registration dossier

In the event that the special preparations route is followed, the pre-registrant should prepare one registration dossier per individual substance.

In the event that both pre-registration routes are followed (in the case of smelted alloys), only one should be selected for the purpose of registration. The selection should be made by the potential registrant(s) based on the specific recommendations and agreements reached within the applicable SIEFs. The decision should not lead to lesser protection to human health and the environment.

Should the MCS route be chosen, the reasons supporting this decision must be documented. Choosing the MCS route requires the registration of the substance as manufactured. This means that the data requirements need to be met for the MCS as a substance on its own and all the relevant tests need to be performed on the MCS itself. However, there is no need to test the MCS if the hazard profile of the substance can be sufficiently described by the information of the individual constituents.

Preparation of the Chemical Safety Report (CSR)

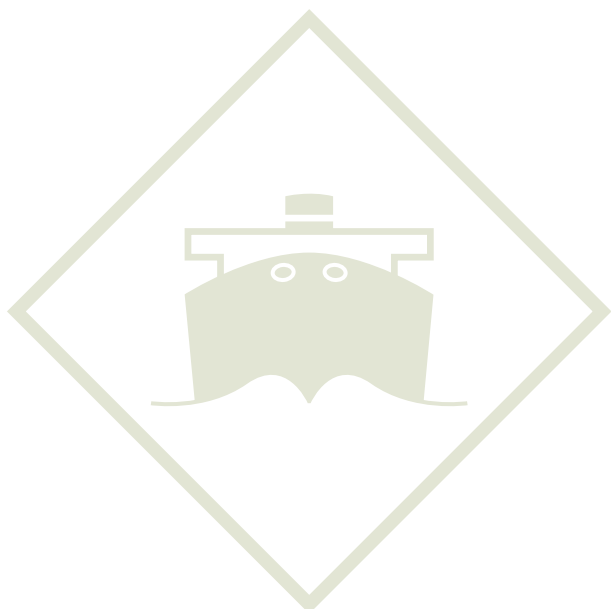
As alloys are regarded as special preparations, they require special methodologies for their assessment. As mentioned above, it has been recognised that alloys do present properties and

characteristics that are different from those of the substances they incorporate.

It is therefore good practice to consider the following approaches when preparing a CSR for the registration dossiers:

- Special preparations approach:** When preparing the CSR for the purpose of registering each individual substance in the alloy, the exposure scenarios included in the CSR should reflect the use of the substance as an alloying element. The potential health and environmental impact of this use should take into account the effect of the substance in the alloy (for the purpose of the use in alloys) and the way the constituents are bonded in the chemical matrix of the alloy, rather than simply the effect of each substance on its own.
- MCS approach:** When the alloy is registered as a multi constituent substance, the health and environmental assessment of the alloy can consider the impact of the alloy as a whole (a substance on its own) or of its individual constituents.

Impurities do not need to be registered. However, impurities that are present in the substances of the alloy or the alloy itself in quantities above 0.1% (w/w), or less in cases where a lower limit is specified in Annex I of Directive 67/548/EEC (e.g. CdSO_4 0.01%), need to be taken into account in the CSR to demonstrate safe use.



3.2 Consequences of not pre-registering and registering

To miss the pre-registration deadline for the alloy, either as substances in a preparation or as a multi-constituent substance, means loss of access to the EEA market: *'no data, no market'*, i.e. no registration dossier, no imports.

Should a non-EEA manufacturer intend to legitimately market an alloy in the EEA after the pre-registration deadline without having pre-registered, they need to consider that:

- Registration requirements apply from 1 June 2008 (even if you may still pre-register until 1 December 2008).
- The importer or the OR of the non-EEA manufacturer will have to perform the registration before the import of the alloy can be continued beyond 1 June 2008.
- Manufacture, placing on the market and use of the alloy may be interrupted from 1 June 2008 until 3 weeks after completion of registration, during which the following processes must take place:
 - the inquiry process: to determine whether any other manufacturer(s) intend(s) to register the substances in the alloy or the alloy as an MCS. The required data are outlined in Article 26 § 1
 - submission of testing proposals for vertebrate animal studies that can not be performed with out prior consent of EChA
 - submission of the Registration dossier
 - completeness check of the registration dossier by the EChA.

Continuing to market or use an alloy without pre-registering, puts the manufacturer/importer and their clients at risk as marketing of the substance/alloy will be considered illegal and subject to enforcement measures for non compliance that are under development at Member State level.

Even if you do not pre-register, you are still bound to data sharing and joint submission of the core data set for the substance.

End Notes

¹ The EEA consists of the 27 EU member states, and Iceland, Lichtenstein and Norway.

² Minerals, ores and ore concentrates that have not yet been chemically modified do not need to be registered. Nevertheless, some materials that companies have traditionally referred to as 'ores' or 'concentrates' may not be legally recognised as such under REACH.

³ Alloy means a metallic material, homogenous on a macroscopic scale, consisting of two or more substances so combined that they cannot be readily separated by mechanical means.

⁴ Impurities do not need to be registered, also see section 2.3 for further clarification.

⁵ A multi-constituent substance is a substance defined by its composition, in which more than one main constituent is present in quantities between 10 and 80% (w/w).

⁶ When the MCS route is chosen, this is only valid if one pre-registers on basis of the individual substances of the alloy.

⁷ In the EChA guidelines on substances identification, an impurity is defined as an unintended constituent present in a substance as manufactured. It may originate from the starting material or as a result of secondary or incomplete reaction during the manufacturing process. While it is present in the final substance it was not intentionally added.

⁸ Care must be taken to fully document both the position taken regarding impurities and the rationale behind the decision to not pre-register the impurities contained in the alloy.

⁹ Article means an object which during manufacturing is given a special shape, surface or design which determines its function to a greater degree than its chemical composition.

¹⁰ For further guidance please refer to the EChA guidance document on substances in articles. This guidance contains an example for aluminium in which the borderline between a substance or preparation and an article is drawn. For other metals it remains a case-by-case interpretation, whose arguments and rationale should be fully documented.

4. Key deadlines



4.1 Pre-registration

As most or all metals or metal compounds are existing substances, the manufacturers of alloys are able to benefit from the phase-in provisions, on condition that a pre-registration is performed between 1 June and 1 December 2008.

4.2 Registration for non phase-in or non pre-registered phase-in substances

The deadline for registration of non-phase-in substances or phase-in substances for which a pre-registration will not be submitted was the 1 June 2008. The only cases where this would be applicable are:

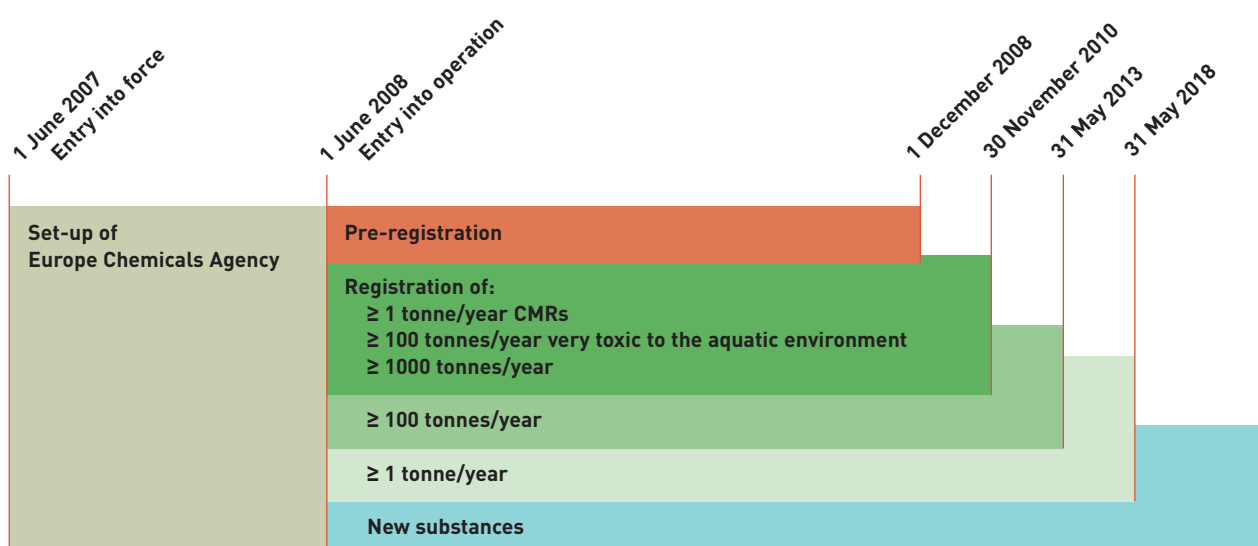
- Preparations route: in the event not all substances in the alloy are phase-in substances.
- MCS route: in cases where the MCS or not all the constituents in the alloy have an EC-number.

4.3 Registration for pre-registered phase-in substances

The pre-registrant will be able to benefit from a transitional period allowing them to prepare a registration dossier and submit it to the EChA by the deadlines specified in Figure 1 below as a function of the manufactured volume and the classification of the substance.

Additional information on metals consortia, the latest information from EC and EChA, guidance and REACH activities in the metals industry can be found on the REACH metals Gateway (www.reach-metals.eu).

Figure 1: Overview of the pre-registration and registration timelines



Eurometaux

Eurometaux constitutes the interface between the European non-ferrous metals industry and the European authorities and international or intergovernmental bodies. It is committed to establishing dialogue with the latter in order to ensure early consultation in all fields of policy and legislation that may affect industry and to asserting the sector's views and positions in this respect. It asserts the contribution of the European industry and its products to sustainable development, as well as this industry's views and positions, whenever the opportunity to do so arises across all sectors of society.

www.eurometaux.org

ICMM

The International Council on Mining and Metals (ICMM) is a CEO-led industry group that addresses key priorities and emerging issues within the industry. It seeks to play a leading role within the industry in promoting good practice and improved performance, and encourages greater consistency of approach nationally and across different commodities through its association members and member companies. ICMM's vision is for a respected mining and metals industry that is widely recognized as essential for society and as a key contributor to sustainable development.

For further information on industry initiatives on hazard and risk assessment, including MERAG and HERAG, visit: www.metalsriskassessment.org

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