



Association
Européenne
du Ciment
The European
Cement
Association

THE REACH MANUAL

Implementation of REACH in the Cement Industry

TABLE OF CONTENTS

I.	Introduction and Purpose of this Tool	4
II.	REACH Basics	6
III.	Registration (Articles 5 et seq. REACH).....	11
IV.	Pre-registration (Articles 28 et seq. REACH).....	13
V.	Multiple Manufacturers/Importers of Same Substance (Article 11)	16
VI.	Post-Registration Data Sharing / Data Compensation Rules	17
VII.	Specifics of Registration and Exemptions for the Cement Industry	18
	1. <i>Portland cement clinker and Portland cement</i>	18
	2. <i>Petcoke</i>	19
	3. <i>Coal, fuel oil, natural gas, raw and processed natural gas condensate, LPG</i>	19
	4. <i>Minerals, including limestone, and calcined minerals</i>	19
	5. <i>Waste</i>	20
	6. <i>By-products</i>	21
	7. <i>Granulated blast furnace slag</i>	21
	8. <i>Fly ash</i>	22
	9. <i>Gypsum</i>	23
	10. <i>Chromate reducers, grinding aids and other additives</i>	23
VIII.	Downstream User Requirements (Articles 37 et seq. REACH).....	24
IX.	Information in the Supply Chain (Articles 31 et seq. REACH)	25
X.	Record Keeping (Article 36 REACH)	26
XI.	Classification & Labelling.....	27
	1. <i>Classification of Substances – Existing System</i>	28
	2. <i>Classification of Preparations</i>	29
	3. <i>Labelling of Substances and Preparations</i>	30
	4. <i>GHS – Globally Harmonised System</i>	31
XII.	Safety Data Sheets	33
XIII.	Authorisation	35
XIV.	FEES	37
XV.	Marketing & Use Restrictions	38
XVI.	REACH Compliance Steps for Cement Companies	39
XVII.	Contract and Insurance Implications of REACH	41
	1. <i>Insurance</i>	41
	2. <i>Contracts</i>	41
XVIII.	REACH Company Chemical Inventory	42

XIX.	Substance Identity Cards	43
XX.	REACH Timelines	44
XXI.	REACH glossary and abbreviations used.....	45
XXII.	For Further Reference.....	47
	Annex: Guidelines for the safety data sheet for cement and clinker	48

I. INTRODUCTION AND PURPOSE OF THIS TOOL

REACH, the new directly applicable EU chemicals registration, evaluation and authorisation regime¹ was adopted on 18 December 2006 and came into force on **1 June 2007**.



As a service to its Members, CEMBUREAU has decided to publish this REACH MANUAL (the 'MANUAL'), which is intended to provide guidance to CEMBUREAU Member associations and cement producing companies on their coverage and compliance obligations under REACH.

In particular, the MANUAL provides recommendations and sets out conclusions with regard to the REACH obligations concerning the most important categories of raw materials, fuels and products used and produced by the cement industry, namely:

- Portland cement clinker and Portland cement
- Petcoke
- Coal, fuel oil, natural gas, raw and processed natural gas condensate, LPG
- Minerals, including limestone, and calcined minerals
- Waste
- By-products
- Granulated blast furnace slag
- Fly ash
- Gypsum
- Chromate reducers, grinding aids and other additives

The MANUAL also provides several useful technical tools for companies' compliance efforts, namely:

- [Guidelines for the safety data sheets for Portland cement clinker and Portland cement \(Annex\)](#)
- [Guidance on pre-registration for materials in the cement value chain](#)
- [Substance identity cards \(work in progress\)](#)
- ["REACH basics" PowerPoint presentation](#)
- [Legal opinion on the interpretation of "importer"](#)
- [Legal opinion on REACH and "waste and recovered substances"](#)
- [Sample REACH inventory](#)

The MANUAL does not deal with substances that are exclusively used in the production of concrete, nor does it specifically deal with the issues related to substances in articles (eg for pre-cast concrete or plasterboard products).



For any questions and comments regarding this Manual, or if you encounter REACH issues which CEMBUREAU might deal with on behalf of its Members, please contact

Inneke CLAES

**Issues Manager
CEMBUREAU**

E-mail: reach@cembureau.eu

¹ <http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2007:136:SOM:EN:HTML>

Disclaimer

This document intends to provide guidance to CEMBUREAU Member associations and cement companies in order for them to assess their obligations under the REACH Regulation. Whilst the content of this document has been drafted with the support of external legal counsel, it is for informational purposes only and does not constitute and/or replace specific legal advice or opinion.

Please note that this manual contains a number of links to the CEMBUREAU/*Cimeurope* REACH implementation website. This website is only accessible to CEMBUREAU members. Other persons interested parties can obtain access from the *Cimeurope* website www.cimeur.com.

II. REACH BASICS

REACH is the abbreviation for the new EU regulatory regime for the registration, evaluation, restrictions and authorisation of chemicals.

Whereas under the previous EU chemicals legislation, only new (post 1981) chemical substances needed to be registered, and risk assessments on existing chemicals were conducted based on a priority list, under REACH

- **Every substance manufactured or imported in the EU above 1 tonne must be registered by the entity that imports or manufactures it, unless it is exempt from registration.** This applies both to substances manufactured or imported by cement companies, as well as to substances supplied to cement companies, or sold to customers and other entities by cement companies. Substances delivered to the cement industry must be registered by the suppliers.

Note: Each separate legal entity within a group needs to fulfil the REACH requirements individually (e.g. individual registration or pre-registration of a substance). However, implementation of REACH can be coordinated at group level and registrations can be conducted jointly for the same substance. Although, even in that case, certain information must be submitted individually, legal entity by legal entity.




- CEMBUREAU has undertaken a preliminary analysis of the main component substances used and produced in the cement industry as to their legal status under REACH. This analysis is set out in the table below and more in depth in section VII.
- Substances present in articles manufactured by cement companies are subject to notification if they are contained in the articles above 0.1% by weight and are either carcinogenic (1 and 2), mutagenic (1 and 2), toxic to reproduction, PBT, vPvB or endocrine disruptors or of “equivalent” concern (and if they are identified as such in a so-called ‘candidate list’).
- There will be an obligation to communicate upstream (towards suppliers) and downstream (to customers) on substances by means of safety data sheets (SDS) and chemical safety reports as the case may be.
- Substances considered as particularly dangerous and entered into a list will be subject to authorisation and possibly to marketing and use restrictions ([click here for a first candidate list](#)).



- **The classification & labelling of all substances (including those below 1 tonne as well as dangerous substances not subject to registration) must be communicated to the European Chemical Agency Inventory by 1 December 2010 latest.**
- The REACH Regulation applies in all 27 EU Member States. The EEA joint committee adopted REACH on 14 March 2008 and hence REACH also applies in the EEA-EFTA countries Iceland, Liechtenstein and Norway. This means that legal entities in the EEA-EFTA countries are to be considered as EU manufacturers and importers and that they will also pre-register substances and take part in the pre-SIEFs and SIEFs. Switzerland, the fourth EFTA member country, is preparing to adapt its own chemicals legislation to REACH.

Please note:



Clinker is a substance (not an intermediate) and is exempt from REACH registration. It must be classified and labelled and an SDS must be provided. This classification and labelling must be notified to ECHA at the latest by 1 December 2010. CEMBUREAU can undertake this classification and labelling (C&L) notification on behalf of cement producers.

Cement is a preparation. As a preparation, cement is not subject to REACH registration. Cement must be classified and labelled. Because it is a preparation, no C&L notification to ECHA is necessary. An SDS, possibly with exposure scenario must be provided. (see Annex). The existing chromium VI restrictions continue to apply.

It is expected that there may be shifts in supply, production, and sales caused by REACH. Early REACH planning will assist companies in taking the necessary compliance steps and making strategic decisions. Contracts may have to be revised and adjusted accordingly.

Table 1: REACH basics for each of the material streams in the cement value chain

Material Number substance identity card	REACH requirements							Role cement company	Actions cement company
	Reg	Auth	Restr	C&L	C&L notif	SDS	e- SDS		
Portland cement clinker T12439	N	N	N	Y	Y	Y	N	Manufacturer or importer	No pre-registration (or registration) Notification of C&L (can be done by CEMBUREAU) SDS if put on the market
Portland cement T12440	N	N	Y	Y	N	Y	Y	Manufacturer or importer	Provide SDS if put on the market Adapt SDS once registration of components is done
Aluminous cement clinker -	N**							Manufacturer or importer	EINECS: 266-045-5 CAS number 65997-16-2 Will not be pre-registered, not covered by CEMBUREAU
White cement clinker -	N*							Manufacturer or importer	No pre-registration (or registration) Not covered by CEMBUREAU
Petroleum coke T12441	N**	N	N	N ¹	N ¹	N ¹	N	Importer	Strategic pre-registration (probably no registration)** Notification of C&L (can be done by CEMBUREAU) ¹ SDS if put on the market ¹
								Downstream user	No actions
Minerals occurring in nature not chemically modified, eg limestone T12442	N	N ²	N	N ²	N ²	N ²	N	Manufacturer or importer	No pre-registration (or registration)
								Downstream user	No actions
Granulated blast furnace slag ³ T12444	Y	N	N	Y	Y	Y	Y	Downstream user	Check that supplier will register the substance
								Manufacturer or Importer	Pre-registration and registration Notification of C&L (can be done by CEMBUREAU) SDS if put on the market
Waste in clinker production ³ T12445	N	N	N	N	N	N	N	Customer Importer?	No actions under REACH, falls under waste legislation

** Exemption from registration to be confirmed in the final version of the guidance document on Annex V, expected after January 2009

¹ Pending results of tests to assess the classification of petroleum coke (done by CONCAWE)

² Depends on properties of the material. If it meets classification criteria as dangerous then notification of C&L; SDS needed when put on the market

³ Check against national legislative framework

Reg Registration

C&L Classification and labelling

SDS Safety data sheet

Auth

C&L notif

e-SDS

Authorisation

Notification of C&L to ECHA

Extended SDS, includes exposure scenarios

Restr Restriction

Material Number substance identity card	REACH requirements							Role cement company	Actions cement company
	Reg	Auth	Restr	C&L	C&L notif	SDS	e- SDS		
Bottom ash-boiler slag ³ in clinker T12468	N	N	N	N	N	N	N	Customer Importer?	No actions under REACH, falls under waste legislation
Waste in cement production ³ T12467	Y	??	??	??	??	??	??	Manufacturer or Importer	Pre-registration No registration if the cement company can use the exemption from registration for recovered substances
								Downstream user (MS where is not a waste)	Check that supplier will register the substance
Fly ash ^{3,4} in cement T12446	Y	N	N	N	N	N	N	Manufacturer or importer	Pre-registration No registration if the cement company can use the exemption from registration for recovered substances
Waste gypsum ³ in cement -	Y	N	N	N	N	N	N	Manufacturer or importer	Pre-registration No registration if the cement company can use the exemption from registration for recovered substances, to checked if same substance as gypsum which will be registered
FGD gypsum and anhydrite T12447	Y	N	N	N	N	N	N	Manufacturer or importer	Pre-registration and registration
								Downstream user	Check that supplier will register the substance
Calcined minerals T12452	N	N ²	N	N ²	N ²	N ²	N	Manufacturer or importer	If not chemically modified: no pre-registration (or registration) If chemically modified: pre-registration and registration
								Downstream user	If not chemically modified: check that supplier fulfilled requirements for uncalcined mineral If chemically modified: check that supplier will register the substance
Silica fume T12450	Y							Downstream user	Check that supplier will register the substance

² Depends on properties of the material. If it meets classification criteria as dangerous then notification of C&L; SDS needed when put on the market

³ Check against national legislative framework

⁴ Calcareous fly ash will be pre-registered under the same EINECS and CAS numbers

Reg Registration

C&L Classification and labelling

SDS Safety data sheet

Auth Authorisation

C&L notif Notification of C&L to ECHA

e-SDS Extended SDS, includes exposure scenarios

Restr Restriction

Material Number substance identity card	REACH requirements							Role cement company	Actions cement company
	Reg	Auth	Restr	C&L	C&L notif	SDS	e- SDS		
Fe(II)SO ₄ T12456	Y	N	N	Y	Y	Y	Y	Downstream user Importer	Check that supplier will register the substance Pre-registration and registration Notification of C&L (can be done by CEMBUREAU) SDS if put on the market
SnSO ₄ T12457	Y	N	N	Y	Y	Y	Y	Downstream user Importer	Check that supplier will register the substance Pre-registration and registration Notification of C&L (can be done by CEMBUREAU) SDS if put on the market
Grinding aids – additives -	Y?	?	?	?	?	?	?	Downstream user	Check that supplier will register the substance or the substances in the preparation
Raw meal -	N							Manufacturer	Raw meal is a preparation, all the components in the preparation should comply with REACH
Coal T12443	N	N	N					Downstream user	No actions
Fuel oil -	Y	N	N					Downstream user	Check that supplier will register the substance
Natural gas -	N	N	N					Downstream user	No actions
LPG -	N	N	N					Downstream user	No actions

Reg Registration

C&L Classification and labelling

SDS Safety data sheet

Auth

C&L notif

e-SDS

Authorisation

Notification of C&L to ECHA

Extended SDS, includes exposure scenarios

Restr Restriction

III. REGISTRATION (ARTICLES 5 ET SEQ. REACH)

Any manufacturer or importer (each legal entity) of a substance, either on its own or in a preparation (mixture of substances), in annual quantities of one tonne or above (per manufacturer or importer), has to submit a registration to the new European Chemical Agency (ECHA), based in Helsinki, for its substance, unless the substance is exempt from registration.

Manufacture / importation may start three weeks after registration if no indication to the contrary is given by ECHA.

The obligation to register will apply in stages:

For new (as of 1 June 2008) substances above 1 tonne, it will apply as of 1 June 2008 (For new substances placed on the market between 1 June 2007 and 1 June 2008, the notification scheme under Directive 67/548 applies).

For existing (substances on EINECS) substances, the so-called phase-in substances, above 1 tonne, the obligation to register will also apply as of 1 June 2008 unless the producer/manufacturer participates in the so-called pre-registration (SIEF).

Substances that have been notified under Directive 67/548 (listed on ELINCS) are considered as registered as far as the original notifier(s) are concerned.

Manufacturers/importers participating in pre-registration can benefit from delayed timelines, namely

- **1 December 2010 for**
 - **carcinogenic, mutagenic and reprotoxic substances (Cat. 1 and 2);**
 - **R 50/53 substances above 100 tonnes annually;**
 - **other substances above 1000 tonnes annually.**
- **1 June 2013 for**
 - **other substances above 100 tonnes;**
- **1 June 2018 for**
 - **other substances above 1 tonne.**

A registration dossier has to contain (a) a **technical dossier**; and (b) a **chemical safety report** (see Annex I REACH for content). A chemical safety report is only required for substances at 10 tonnes or above annually per manufacturer / importer:

Technical dossier:

- identity of the manufacturer/importer;
- identity of the substance (see section 2 of Annex VI);
- information on manufacture and identified use(s) of the substance (Annex VI section 3);
- classification and labelling of the substance (Annex VI, section 4);
- guidance on safe use of the substance (Annex VI section 5);
- study summaries of the information derived from application of Annexes VII to XI;
- robust study summaries of information derived from application of Annexes VII to XI;
- indication which information above has been reviewed by an experienced assessor;
- proposals for testing where listed in Annexes IX and X;
- exposure information for 1-10 tonne substances (Annex VI, section 6);
- confidentiality request and justification therefore.

Chemical Safety Report:

See Annex I of REACH for content of the CSR.

IV. PRE-REGISTRATION (ARTICLES 28 ET SEQ. REACH)

Rather than registering substances on 1 June 2008, manufacturers and importers of existing substances can choose to participate in the so-called pre-registration. Manufacturers and importers of intermediates can also participate.

Pre-registration has a number of advantages but also certain disadvantages, namely:

Pros:

- benefit from a delayed registration deadline (3.5, 6 or 11 years);
- benefit from studies owned by competitors (participants in the substance information exchange forum (SIEF) or registrants);
- share the cost of generation of new data;
- participate in discussions on common classification & labelling and content of the registration dossier;

Cons:

- considerable resources to be dedicated to SIEF discussions;
- confidentiality and anti-trust concerns;
- additional costs (SIEF administration).

Pre-registration will be possible for a six-month period starting 1 June 2008 and ending 1 December 2008.

Therefore, companies wishing to participate in pre-registration have a very short time frame in which to take this decision and benefit from pre-registration. However, companies which manufacture/import substances for the first time after 1 December 2008, may still decide to join pre-registration at a later date (Article 28 (6)).

Pre-registration will work as follows:

- **In the June - December 2008 period, manufacturers and importers have to submit limited information to ECHA, namely**
 - **name of the substance/intermediate (Annex VI section 2), including EINECS and CAS number or, if not available, other identity codes;**
 - **name and address of company and contact person;**
 - **envisaged registration date depending on nature of substance and tonnage as of 2008 (2010, 2013, 2018);**
 - **names of substances for which the available information is relevant (QSARs, read-across, see Section 1.3 and 1.5 of Annex XI REACH).**

Pre-registration will be carried out in **two steps**:

- The company (legal entity) creates an account in REACH-IT, providing administrative information about the company, such as general contact information and billing information
- The legal entity pre-registers the phase-in substance using the username and password obtained when creating an account in REACH-IT

Two presentations from ECHA contain screen shots and explain in detail how the [account creation](#) and [pre-registration](#) work.

Further information on REACH-IT can be found [here](#).

Please see the presentation "[REACH – Basics](#)" for the steps following pre-registration and leading up to registration.

Notes

- The information provided for the pre-registration can be modified prior to the pre-registration deadline of 30 November 2008
- Substances for read-across: a link will be made between the pre-SIEF and SIEF of the pre-registered substance to the pre-SIEF and SIEFs of the substances for read-across and this might also mean a considerable additional workload. Careful consideration is essential when deciding whether or not to use this option
- If a company appoints a third party representative, this third party representative will be the company representative during the discussions in the pre-SIEF and the SIEF. The contact details of the company who appointed the third party representative will not be accessible to the other pre-registrants of the same substance. However, the company remains responsible for carrying out REACH duties
- Determining which legal entity is the importer is not always straightforward. [This document](#) gives some guidance on how to approach this.

After the 6-month pre-registration deadline expires, ECHA will publish the list of pre-registered substances.

Downstream users, and manufacturers/importers below 1 tonne, may join SIEFs, as may any third parties holding information on pre-registered substances. Downstream users could have an interest in joining SIEFs in order to monitor whether their suppliers (direct suppliers or those further up in the supply chain) support registration of substances used by downstream users. Third parties may have an interest in joining SIEFs if they have data available to be sold (if, for example, they ceased to manufacture a certain substance and are therefore not subject to registration under REACH) or if they may expect to start manufacturing or importing at a later stage and want to ensure that the SIEF would adequately protect their interests at that time.

Once a substance has been pre-registered, all pre-registrants (legal entities) will be automatically put in contact and discussions on the “sameness” of a substance can start in the so-called pre-SIEF. If an agreement is reached between all pre-registrants on the substance identity (and after the deadline for pre-registration), the potential co-registrants will enter the SIEF.

SIEFs must facilitate the exchange of information needed for registration (in particular to avoid the duplication of studies and animal testing) and must also facilitate agreements on classification and labelling. SIEF participants must provide other participants with existing studies, react to requests for information from other participants, collectively identify needs for further studies and arrange for them to be carried out. EACH SIEF will be operational until 1 June 2018 but cooperation between SIEF members may continue beyond this date on the basis of an agreement.

Article 30 of REACH contains complicated rules on data sharing and sharing the costs of such data which SIEF participants provide to each other for the purpose of registration. These rules differ depending on whether the studies in discussion involve vertebrate animals or not. The company in need of vertebrate animal studies is obliged to buy the studies or access to the studies from the study owner, if one exists. If no one owns a specific study, SIEF members must agree to share the cost of conducting such a new study equally. The company in need of a non-vertebrate animal study may choose whether to share the cost of an existing study or whether to conduct the study itself.

Data sharing/data compensation discussions (and related agreements or contracts) will concern each company needing to conduct studies for its own registration dossier, and each company owning studies needed by another company.

In addition to the Article 30 rules, it is expected that SIEFs will have to establish for themselves detailed operating rules (antitrust rules, confidentiality, administrative cost, administration etc.), since SIEFs will not be a formal forum managed by ECHA or by the Commission. The management can be provided by external consultants or by industry associations. The [Technical guidance document on data sharing](#) provides some guidance in this regard. In some industries, pre-SIEFs have informally been set up prior to June 2008.

CEMBUREAU can assist in the setting up of a SIEF, consortia or in contributions to SIEFs and consortia.



CEMBUREAU can also act as a third party representative for cement companies, representing them in the pre-SIEF and the SIEF discussions, eg for FGD gypsum.

V. MULTIPLE MANUFACTURERS/IMPORTERS OF SAME SUBSTANCE (ARTICLE 11)

When the same substance is manufactured/imported by several companies, Article 11 REACH requires that these companies submit certain registration information together (namely classification & labelling; study summaries; robust study summaries and proposals for testing; an indication of which information has been reviewed by assessor) through a so-called "lead registrant". The lead registrant must be one of the companies (or Only Representatives) in the consortium.



An industry association such as CEMBUREAU may not be a lead registrant.

Once this information is submitted, the other information required for registration may be submitted by each registrant separately (the registrants cannot submit joint information related to the identity of the substance and their identity and the individual uses and exposure scenarios).

As an exemption to the foregoing obligation to work together in the submission of a joint registration dossier, Article 11 (3) provides that each registrant may provide the information separately if (a) it would be disproportionately costly for him to submit this information jointly; or (b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and would likely cause him substantial commercial detriment; or (c) he disagrees with the lead registrant on the selection of this information. In these cases, however, an explanation must be given as to why the information is being submitted separately with the explanation being assessed by ECHA at the "dossier" evaluation stage.

Although the joint registration requirement applies formally to all registrations, in practice, it can be expected that joint registration would apply to registrations submitted by SIEF members only. Only SIEF members will know the identity of the other potential concomitant registrants. Subsequent registrants of the same substances or of new substances will not know in practice that another company intends to register at the same time, and concomitant registrations will be rare, hence registration dossiers would be submitted individually.

Joint registration after SIEFs have ceased to exist will probably also often take place in larger companies consisting of several legal entities that would each have to register their substances and would achieve cost reductions by registering through a single entity of the group, acting as "lead registrant".

Joint registration will be beneficial financially because reduced registration fees (see section XIV) will be applicable, and because it will reduce the bureaucratic burden on the participating companies. However, joint registration may also prove financially disadvantageous for smaller companies, which may be exposed to costs (administrative and other) supporting the registration of larger companies with broader tonnage ranges. Last but not least, companies have to be aware of potential confidentiality and anti-trust concerns when discussions take place in a SIEF.

VI. POST-REGISTRATION DATA SHARING / DATA COMPENSATION RULES

A company wishing to register a substance that has already been registered by another registrant (individual or group of companies acting through a “lead registrant”) must contact the previous registrant and agree to buy access to studies that it lacks for its own registration dossier (Article 27).

Here again, much like in the SIEF, the potential registrant must obtain access to vertebrate animal studies but may choose whether or not to approach the previous registrant for non vertebrate animal studies.

REACH allows the two companies to agree on the data sharing and data compensation freely.

However, in the event of a disagreement, REACH default rules apply. These rules (Article 27 (5) to (7)) allow the ECHA to permit the potential registrant to refer to the studies submitted in previous registrations upon proof of payment of a proportional share of the cost. The previous registrant has the right to obtain compensation in national courts for an equal share of the cost if it provides the potential registrant with a physical copy of the full study report.

VII. SPECIFICS OF REGISTRATION AND EXEMPTIONS FOR THE CEMENT INDUSTRY

The cement industry will, for the time being, be able to benefit from a number of exemptions from the whole of REACH (see waste below) or from the REACH registration obligations (revised Annexes IV and V).

The substances listed in Annex IV are exempt from registration, evaluation and downstream user requirements "as sufficient information is known about these substances that they are considered to cause minimum risk because of their intrinsic properties" (Art 2.7 (a)).

For the substances in Annex V: "registration is deemed inappropriate or unnecessary [...] and their exemption [...] does not prejudice the objectives of this Regulation" (Art 2.7 (b)).

Article 138 (4) REACH requires the European Commission to carry out a review of Annexes IV and V (exemptions from registration) by June 2008 under the comitology procedure with scrutiny. The review has been completed and the [revised Annexes IV and V](#) were published in the Official Journal on 9 October 2008. The European Commission also issued a [draft guidance document for Annex V](#) which is expected to be officially adopted soon.

The section below gives a summary of the registration requirements for the most important material streams in the cement value chain. It is based on both the draft proposal for Annex V and the draft guidance document.

As the substances on the revised Annex IV and V lists are only exempt from certain REACH requirements (registration, evaluation and downstream user requirements), the other REACH obligations, such as classification and labelling, notification to ECHA C&L Inventory, information in the supply chain and, potentially, authorisation are still applicable.

1. Portland cement clinker and Portland cement

Portland cement clinker is a multiconstituent substance and it is exempt from registration as it is part of the list in Annex V.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".

The entry "cement clinker" on Annex V.10 also covers white cement clinker and hence this type of clinker is also exempt from registration.

It is the opinion of the companies producing aluminous cement clinker, that this other type of cement clinker is also covered by the entry "cement clinker" on Annex V.10 and hence is exempt from registration.

In the draft Commission guidance document on Annex V of REACH, both the EINECS entries "Portland cement, chemicals" and "Cement, alumina, chemicals" are mentioned and thus both types of cement clinker are exempt from registration. This needs to be confirmed when the final version of the guidance document will only be available.

Portland cement is a preparation and thus not subject to registration. The components in the preparation cement (constituents in the terminology of the standard EN 197-1:2000) have to be registered, unless they are exempted as in the case of, for example, cement clinker or natural gypsum.

2. Petcoke

Petcoke (petroleum coke, a carbonaceous solid derived from oil refinery cracking processes) often used as fuel in the cement industry.

In the existing chemicals inventory EINECS, three EINECS and CAS numbers exist for three types of petcoke.

EINECS		CAS
265-080-3	coke petroleum	64741-79-3
265-209-3	coke petroleum recovered	64743-04-0
265-210-9	coke petroleum calcined	64743-05-1

Only petcoke with EINECS number 265-080-3 ("coke petroleum") is used as a fuel in the cement industry.

Petcoke is not as such mentioned in Annex V but the draft guidance document for Annex V mentions that the entry V.10 "coke" also covers "coke petroleum" with EINECS number 265-080-3. This would mean that the petcoke used in the cement industry is exempt from registration.

However, as the final version of the guidance document will only be available in October 2008, this exemption can only be confirmed then.

However, given that the guidance document is not officially published by ECHA and will not be published before the pre-registration deadline; and given the "disclaimer" on the European Commission's website (http://ec.europa.eu/enterprise/reach/com_reviews_en.htm) ***it is recommended that cement companies who import petcoke into the EU + Iceland, Liechtenstein and Norway, pre-register it. This is a precautionary measure aimed at providing legal certainty for cement companies.***

This is in line with the recommendation from CONCAWE to its members.

3. Coal, crude oil, raw and processed natural gas, natural gas condensate, LPG, process gases and components thereof

These materials are all exempt from REACH registration because they are listed in Annex V. 7 or V.10.

4. Minerals, including limestone, and calcined minerals

Minerals occurring in nature and not chemically modified are listed in Annex V.8 and are thus exempt from registration.

Most of the raw materials used for cement production, e.g. natural gypsum and limestone, are minerals, are not chemically modified and are therefore exempt from REACH registration.

A manmade mineral is not exempt from registration. Only the naturally occurring form is exempt. This means that, for example, manmade forms of gypsum as FGD gypsum need to be registered (please see below the entries on by-products and on gypsum).

With regard to calcined minerals, the European Industrial Minerals Association, [IMA-Europe, follows the following interpretation:](#)

“Some forms of calcination are not considered as a chemical modification and hence the mineral resulting from this operation is still exempt:

- The calcination process results in the removal of impurities,
- The calcination process results in the removal of water (i.e. free and structural water),
- The calcination process results in a physical mineralogical transformation,
- The calcination process leaves the chemical composition (with the exception of water and impurities) unaffected

All calcined minerals produced by other types of calcination involving chemical modification are not exempt from registration. They are to be considered as different substances from the uncalcined minerals.”

The above does not apply to cement clinker which is exempt from registration through its entry in Annex V.10 of REACH.

A link needs to be made between hydrated and anhydrous form of a mineral. The hydrated form of a substance is covered by the registration of the anhydrous form (Annex V.6). This is of importance for manmade minerals, eg gypsum.

5. Waste

Article 2.2 REACH² provides that “waste, as defined in Directive 2006/12/EC of the European Parliament and of the Council of 5 April 2006 on waste, is not a substance, preparation or article within the meaning of Article 3 of this Regulation.” **Accordingly, REACH does not apply to waste.** This makes sense, because waste is subject to strict rules under the waste legislation.

For **waste materials**, the situation is complicated and these materials need careful consideration. The situation can be different in **different Member States**. Some materials are considered to be waste in some Member States while at the same time they are considered as products in another Member State or region; or some waste streams are even considered as a product depending on the industry processing the material, eg they are a product when being processed by a cement company. Therefore, the below given **recommendations should be checked against the national legislative framework**.

The European Commission or ECHA could not provide any clarification regarding materials which are considered waste in one country and a product in another. To avoid problems, those materials should be registered (and pre-registered) by the manufacturers or the importers in the countries where the materials are considered products. In general, it is therefore recommended that the cement companies who are considered as the manufacturers (or importers) of those non-waste materials, pre-register them.

Waste, used as alternative raw material or alternative fuel **to produce clinker** (hot part of the production process), will completely disappear in the process: a new substance clinker is produced from it (and from other input materials). Cement companies will thus have to apply the waste legislation and **REACH will not apply** to these waste materials.

Examples include: converter slag, other types of slag and ashes, industrial and other sludge, contaminated soils and similar, refuse derived fuel, old tyres, animal meal and similar, impregnated saw dust, solvents waste, oil and oily waste, photo water.

The “new” substances” manufactured from waste are subject to REACH.

For waste which is utilised in the preparation of cement (cold part of the production process), the following applies. When the **recovery process is completed** (ie cement is produced), the waste components of the preparation cement **cease to be waste** and hence fall **under the scope of REACH**. The cement company which is the legal entity owner of the material at the moment the material ceases to be a waste, needs to register it. The cement company can [Use](#) the exemption from registration for recovered substances (Art 2.7 (d))¹ if the substance has already been registered by somebody (not necessarily in the same supply chain) and if the cement company has access to the

² <http://europa.eu.int/eur-lex/lex/JOhtml.do?uri=OJ:L:2007:136:SOM:EN:HTML>

registration number and [SDS](#) or other equivalent information which has to be passed down the supply chain. The above also applies when a cement company imports waste into the EEA which is to be incorporated in the preparation cement. Examples of materials meant in this paragraph are fly ash and waste gypsum (not FGD gypsum which is a by-product).

The European Commission and the national helpdesks recommend companies to pre-register recovered substances, even though a registration afterwards will most probably not be necessary. However, industry has pointed out that this will serve no purpose and would only add to the administrative burden for companies.

In case of doubt, eg:

- If it is not clear if an outside EU producer/supplier will appoint an only representative
- If the supplier of a waste which is used in cement production, such as some types of industrial gypsum waste, will register it and it is not sure if the cement company will be able to use the exemption from registration for recovered substances

companies are recommended to pre-register (strategic pre-registration).

For more information, please consult the [CEMBUREAU legal opinion on REACH and recovered substances](#) and the [European Commission draft document on REACH and recovered substances](#).

6. By-products

It is noted under Annex V.5 of REACH, that **by-products, unless they are imported or placed on the market themselves**, are also **exempt from REACH registration**. However, unlike waste which is exempt entirely from REACH, by-products are only exempt from REACH registration.

However, the above rules may pose problems for **certain types of wastes that may be considered by-products by Member States rather than waste**. If they are considered by-products by Member States and are shipped by their manufacturers to cement kilns for use therein, they would have to be considered as “placed on the market themselves” and would therefore not be exempt from REACH, neither under the waste exemption nor under the by-products exemption.

Granulated blast furnace slag and FGD gypsum are considered as by-products at EU level³ if they can be used without further processing steps. They are thus subject to registration if they are placed on the market.

7. Granulated blast furnace slag

Blast furnace slag is produced in parallel with hot metal in a blast furnace. Iron and blast furnace slag emerge from the blast furnace as molten liquids. The blast is then air-cooled or granulated. According to figures from the sector organisation, none of it is land filled in the EU. 64% is used in cement production and 32.5% is used in road construction. Granulated and air-cooled blast furnace slag have a positive market price.

If it can be used without further processing steps it is considered as a by-product. If, in addition, it is placed on the market it becomes subject to registration (exemption of Annex V.5 no longer applies).

If the cement company buys granulated blast furnace slag which is a by-product, the cement company is a downstream user. In that case, the producer is responsible for the registration (and pre-registration). The cement company needs to ensure that his supplier will register the granulated blast furnace slag for use in cement.

³ European Commission communication on by-products: <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=COM:2007:0059:FIN:EN:PDF>

The case where the cement company buys liquid blast furnace slag and granulates it in an installation owned by the cement company which is located on the site of the blast furnace (iron producer) is more complicated as it is different in different Member States.

In countries where the liquid slag is a by-product, like in Germany, the cement company is in principle a downstream user and only carries out a physical transformation on the blast furnace slag.

In other countries as in France, the liquid slag is a waste. The cement company (or any other granulator) carries out a recovery operation and produces granulated blast furnace slag. Hence the cement company will need to pre-register the blast furnace slag, but will most probably not need to register as blast furnace slag will be registered by another actor.

Given that situation regarding the status of liquid blast furnace slag differs between Member States, Euroslag (European metallurgic slag producers) recommends that all slag treatment companies (not only cement companies) pre-register blast furnace slag as a UVCB substance under the EINECS entry:

Substance Name: Slags, ferrous metal, blast furnace

EC#: 266-002-0

CAS#: 65996-69-2

If the cement company acquires blast furnace slag with a waste status, the same applies as for other waste materials (eg fly ash) added to cement: the cement company carries out a recovery operation and needs to pre-register the material. Registration will most probably not be necessary if the exemption from registration for recovered substances can be used (same substance as already registered by another actor and access to information as registration number and SDS).

Note: in the last version of the Commission-ECHA guidance document on REACH- waste/recovered substances, it is stated that recovered slags from the iron and steel industry are substances and not articles.

8. Fly ash

Fly ash is created in coal combustion and is considered by its producers as a “by-product” rather than a waste. CEMBUREAU is of the opinion that fly ash is a waste because some is disposed of as waste in landfills, parts of it generated in coal firing combustion installations must be stored during the cold season for potential use in the construction industry during the warm season, and hence its economically viable re-use cannot necessarily be considered a “certainty” in the case law of the European Court of Justice.⁴

When fly ash is recovered to produce cement, it becomes a product: when the recovery process is completed (ie cement is produced), fly ash ceases to be waste and hence enters the scope of REACH. It will in principle have to be registered by the legal entity owner of the material at the moment the material ceases to be a waste. The cement company can use the exemption from registration for recovered substances (Art 2.7 (d)⁵) if the substance has already been registered by somebody (not necessarily in the same supply chain) and if the cement company has access to the registration number and SDS or other equivalent information which has to be passed down the supply chain. The above also applies when a cement company imports waste into the EEA which is to be incorporated in the preparation cement.

For recommendations regarding pre-registration, please see above under section “5. Waste”.

In the countries where fly ash is considered as a product, the cement company will be a downstream user and needs to contact the supplier to make sure that he will register fly ash for use in cement. The producers of fly ash have indicated that they will register it.

⁴ For status of by-product vs waste, see above.

⁵ (d) substances, on their own, in preparations or in articles, which have been registered in accordance with Title II and which are recovered in the Community if:

- (i) the substance that results from the recovery process is the same as the substance that has been registered in accordance with Title II; and
- (ii) the information required by Articles 31 or 32 relating to the substance that has been registered in accordance with Title II is available to the establishment undertaking the recovery.

Furnace bottom ash is not allowed to be used in cement production (standard EN 197-1:2000 for the common cement types). It can be used for clinker production. Fly ash used in clinker production remains waste and does not need to be pre-registered/registered.

9. Gypsum

Naturally occurring gypsum is exempt from registration. Synthetic gypsum, eg FGD gypsum (flue gas desulphurisation gypsum) is not covered by any of the exemptions from registration. Cement companies producing GFD gypsum should therefore register it.

Under REACH, the hydrated forms of a substance are covered by the registration of the anhydrous forms. Hence, for the case of FGD gypsum, CaSO_4 should be registered. This registration will also cover the anhydrous form (anhydrite) as well as the semi-hydrates and hydrates, among which FGD gypsum and other types of industrial gypsum.

Anhydrite (CaSO_4) is only exempt from registration if it is obtained from naturally occurring gypsum.

[This Eurogypsum factsheet](#) describes the main types of gypsum used and produced in the EU.

10. Chromate reducers, grinding aids and other additives

Process chemicals used in cement production, including additives, agents, maintenance products, oils etc., chromium VI reducers (tin and ferrous sulphates) are subject to all REACH requirements unless any of the exemptions are applicable. They can be substances (ferrous and tin sulphate) or can be preparations. Cement companies usually do not import these products from outside the EU and are thus downstream users. The manufacturers of these materials are responsible for fulfilling the registration requirements.

One source of ferrous sulphate is the production of titanium dioxide. Ferrous sulphate from the production of titanium dioxide therefore could be either a by-product or a waste

The European Court of Justice has consistently held that the term “waste” has to be interpreted widely and that the notion of “by-product” should be limited to situations in which the re-use of goods, materials and raw materials “is not a mere possibility but a certainty without any prior processing and as an integral part of the production process.” Whether the ferrous sulphate from titanium dioxide production is used for chromium VI reduction without prior processing and with certainty will be a case-by-case individual decision. As ferrous sulphate is a valuable ingredient for cement necessary for chromium VI reduction and must be purchased by cement companies it is indeed arguable that ferrous sulphate is a by-product.

VIII. DOWNSTREAM USER REQUIREMENTS (ARTICLES 37 ET SEQ. REACH)

Applicable at the latest 12 months after receipt of the substance registration number supplied through the SDS⁶.

<p style="text-align: center;">Obligations</p>	<p>May provide information to assist in the <u>preparation of a registration</u></p> <p>May make a use known in writing with the aim of making this an "<u>identified use</u>"; must pass this information up the supply chain</p> <p>The company not including the use as identified must include the reasons for non-inclusion in the information within the supply chain and to Agency</p> <p>Identify, apply and, where suitable, recommend appropriate risk control measures</p> <p>Prepare Chemical Safety Report for uses outside exposure scenarios</p> <p>Report in certain cases (if downstream user has to prepare chemical safety report or is relying on exemptions) information to ECHA at the latest 6 months after first receipt of the registration number by supplier</p> <p>Notify use of substances in Annex XIV (list of substances subject to authorisation) within 3 months of their first receipt to ECHA</p>
---	---

⁶ This means that the obligations apply only after the supplier has registered the substance. This also means that these obligations do not apply during the pre-registration phase (downstream users may, however, communicate their uses to their suppliers beforehand).

IX. INFORMATION IN THE SUPPLY CHAIN (ARTICLES 31 ET SEQ. REACH)

Applicable as of 1 June 2007:

Safety Data Sheet requirements (for professional users)	Applies to dangerous substances and preparations, PBT or vPvB, other substances on "candidate list" supplied (for others upon request) To contain annex with exposure scenarios with related use and exposure categories
Information <u>down</u> the supply chain	By suppliers, if a safety data sheet does not have to be provided By producers or importers of <u>articles</u> to the recipient of the article, in relation to substances in the "candidate list" (liable for authorisation) at concentrations above 0.1% (at a minimum the name of the substance). This obligation shall extend to all professional and industrial users of articles, as well as consumers if they request it. (Requested information must be supplied within 45 days)
Information <u>up</u> the supply chain	By actors in the supply chain up to next actor and distributor

Information in supply chain when a SDS is not required:

- Registration number
- Details on authorisation
- Details on restrictions
- "Any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied"

This information is to be updated when new information becomes available and the updated information is to be sent to free of charge to customers who received the substance or preparation within the 12 preceding months.

Please note:

Employers have to provide access to SDS and other supply chain information to workers.

X. RECORD KEEPING (ARTICLE 36 REACH)

- Assembly and keeping of all information required to carry out duties under REACH for at least 10 years after last manufacture, import, supply or use;
- This obligation is transferred in case of company transfer/cessation upon successor;
- Obligation upon manufacturers, importers, downstream users and distributors.

XI. CLASSIFICATION & LABELLING

Classification and labelling of substances and preparations must be conducted by qualified and trained experts in cement companies. If in-house expertise is not available, external experts should be approached. Classification and labelling will ultimately determine the marketability of products as well as potentially increase obligations under REACH (e.g. advanced registration deadlines, restrictions, authorisations).

Set out below are the basic legal principles of classification and labelling.

The classification of substances and preparations in the EU under REACH is based on Directives 67/548⁷ (substances) and 1999/45⁸ (preparations).

The European Commission plans to replace the current classification and labelling system by the Globally Harmonised System (GHS) (see below) in due course, preferably simultaneously with the entry into effect of the REACH requirements regarding the notification of the classification and labelling of substances. The current system of classification and labelling of substances and preparations will continue to exist in parallel to the new GHS system for a number of years once the GHS is adopted in the EU (for more details, please refer to the [CEMBUREAU guidelines on safety data sheets for cement](#)).

Manufacturers, importers and distributors of substances (self-)classified as dangerous have to provide professional users with safety data sheets at or before the first delivery of the dangerous substance/preparation under Art 31 of REACH and in line with the detailed rules set in Annex II of REACH.

With [this link](#), you can access the IUCLID⁹ dataset on Portland cement identifying the existing data on this product

According to the [EN standard 197-1:2000](#) there are 27 types of common cements which can be put into 5 [general categories and three strength classes](#)

Under REACH, cement is a preparation and cement clinker is a substance. Both should be covered by appropriate SDS and adequate classification and labelling if they are placed on the market. [Recommended harmonised templates for the SDS for cement and clinker](#), taking into account the requirements of REACH and with a recommendation for their classification, have been developed by CEMBUREAU (see Annex).

(Self-)classifications in certain danger categories (carcinogen category 1 and 2, mutagens cat. 1 and 2, reprotoxic cat. 1 and 2) may trigger the REACH authorisation requirements, because substances so

⁷ In the form of its Seventh Amendment: Council Directive 92/32 amending for the seventh time directive 67/7548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; OJ L 154 of 1992. http://ec.europa.eu/environment/chemicals/dansub/consolidated_en.htm

⁸ Directive 1999/45/EC concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations; OJ L 200 of 1999. <http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=CONSLEG:1999L0045:20070601:EN:PDF>

⁹ IUCLID is the software program set up by the OECD on data on large volume chemicals

classified qualify for entry into Annex XIV of REACH (list of substances subject to authorisation). Hence, (self-) classification is an important exercise and its impact should not be underestimated.

Also under REACH, two additional obligations apply:

First, for substances subject to registration, the hazard classification will have to be submitted in the registration dossier (Article 10 (a) (iv) REACH). In the case of phase-in substances, the SIEFs shall agree on classification and labelling of the substance in question if there is a difference in opinion on the classification and labelling of a substance among the potential registrants.

Second, under REACH manufacturers and importers have to notify the hazard classification of substances and the corresponding hazard label to the new classification and labelling inventory (the 'Inventory') held by ECHA under Article 114 REACH. The obligation to notify the classification of substances to the Inventory also applies to substances exempt from registration (such as non-chemically modified minerals) provided they are (self-) classified as dangerous.



CEMBUREAU can notify the classification and labelling of clinker on behalf of its members.

If manufacturers or importers of the same substance arrive at a different classification of the same substance, Article 113 of REACH requests them to make every possible effort to come to the same classification.

If manufacturers/importers cannot come to a common entry, ECHA will record this separately under Article 114 (2) (c) REACH. There are no direct consequences from inconsistent entries.

However, Article 115 REACH provides that harmonised classification and labelling at Community level shall 'normally' be added to Annex I of Directive 67/548 for carcinogens, and also for other effects on a case-by-case basis if justification is provided demonstrating the need for action at Community level - provided a Member State submits a proposal to ECHA for a harmonised classification and labelling (to be subsequently adopted by Commission Decision through comitology).

We would expect that if manufacturers/importers of a substance cannot come to a common classification, in particular in cases where individual manufacturers/importers classify a substance as a carcinogen contrary to others, such 'need for action at Community level' is established.

The classification of preparations does not need to be notified to the new ECHA Inventory.

1. Classification of Substances – Existing System

Under Directive 67/548, substances are defined in Article 2 (1) (a) as "*chemical elements and their compounds in the natural state or obtained by any production process, including any additive necessary to preserve the stability of the products 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.*"

According to Article 4, substances shall be classified on the basis of their intrinsic properties according to the 15 danger categories listed in Article 2 (2) (danger categories: explosive, oxidizing, extremely flammable, highly flammable, flammable, very toxic, toxic, harmful, corrosive, irritant, sensitizing, carcinogenic, mutagenic, toxic for reproduction, dangerous for the environment).

Impurities shall be taken into account in the classification as far as their concentration exceeds the concentration limits either listed in Annex I or in Article 3 of Directive 88/379 on preparations (now Article 3 (3) of Directive 1999/45).

According to Article 6 of Directive 67/548, manufacturers, distributors and importers of dangerous substances which appear in the EINECS but which have not yet been introduced into Annex I (list of harmonised classifications), shall be obliged to carry out an investigation to make themselves aware of the relevant and accessible data which exist concerning the properties of such substances. On the basis of this information, they shall package and provisionally label these substances according to the rules in, among others, Annex VI.

The general principles of classification and labelling of both substances and preparations shall be applied according to the criteria in Annex VI of Directive 67/548.¹⁰ Annex VI contains both general principles of classification as well as specific criteria for each of the 15 danger categories.

In the General Introduction (1.1. of Annex VI), it is stated that the object of classification is to identify all the physico-chemical, toxicological and ecotoxicological properties of substances and preparations which may constitute a risk during normal handling or use (emphasis added).

As regards new substances, the data specified in Annex VII (so-called base set) of Directive 67/548 must be collected (Annex VI, 1.6.1 (a)). For the other substances, 1.6.1. (b) of Annex VI provides that the data required for classification and labelling may, if necessary, be obtained from a number of different sources, for example:

- the results of previous tests;
- information required by international rules on the transport of dangerous substances;
- information taken from reference works and literature, or
- information derived from practical experience.

Finally, the results of validated structure-activity relationships and expert judgment may also be taken into account where appropriate.

According to 3.1. of Annex VI, where it can be demonstrated by epidemiological studies, by scientifically valid case studies as specified in this Annex or by statistically backed experience, such as the assessment of data from poison information units or concerning occupational diseases, that toxicological effects on man differ from those suggested by the application of the methods outlined in section 1.6 (see above), then the substance shall be classified according to its effects on man. Tests on man should be discouraged, however, and should not normally be used to negate positive animal data.

2. Classification of Preparations

The rules for classification and labelling of dangerous preparations are provided in Article 4 of Directive 1999/45 according to which the general principles of classification and labelling of dangerous substances under Annex VI of Directive 67/548 (classification and labelling of dangerous substances) shall apply save where alternative criteria are provided for in Directive 1999/45 (Articles 5, 6, 7, or 10 and the relevant Annexes).

As far as the evaluation of the health hazards is concerned, Article 6 of Directive 1999/45 provides for two main methods of evaluation, the so-called 'conventional method' (calculation under Annex II), and the testing method (determination of toxicological properties by testing). The testing method cannot be used for classification as carcinogenic, mutagenic or toxic for reproduction.

¹⁰ In its version of Directive 2001/59 adapting to technical progress for the 28th time Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances; OJ L 225 of 2001.

In order to avoid animal tests, usually the conventional method has priority unless the toxicological properties of the preparation cannot correctly be determined by the conventional method or on the basis of existing text results on animals. In this case, new animal tests may also be conducted. If the toxicological properties have been determined on the basis of both the conventional and the test method, then the results from the tests shall be used for classifying the preparation, except for carcinogens where only the conventional method shall be used.

Finally, Article 6 (3) also stipulates that when a conventional assessment would under or overestimate toxicological hazards (owing to effects such as potentiation or antagonism), those effects shall be taken into account in classifying the preparation.

Also, where it can be demonstrated by epidemiological studies, by scientifically valid case studies as specified by Annex VI to Directive 67/548 or by statistically backed experience, such as the assessment of data from poison information units or concerning occupational disease that toxicological effects on man differ from those suggested by the application of the methods outlined in paragraph 1, then the preparation shall be classified according to its effects on man.¹¹ Also, where owing to effects such as potentiation, a conventional assessment would underestimate the toxicological hazard; those effects shall be taken into account in classifying the preparation. Finally, where owing to effects such as antagonism, a conventional assessment would overestimate the toxicological hazard, those effects shall be taken into account in classifying the preparation.

The European Commission [issued a position paper on the classification of preparations with extreme pH values](#).

3. Labelling of Substances and Preparations

According to Article 23 of Directive 67/548, the danger symbols and indication of the danger involved in the use of the substance must be put on the packaging. The design of the danger symbol and the wording must be those of Annex II. The standard risk and safety phrases to indicate the special risks from the danger involved in using the substances and relating to the safe use of the substances must be those indicated and assigned under Annex VI and IV. No deviations are permitted except for small or otherwise unsuitable packaging, or if the containers contain such small quantities that there is no reason to fear any danger to persons handling such substances or others¹² (if so permitted by Member States) (Article 25 (2)).

There are exemptions under 9.3 of Annex VI from labelling for alloys, preparations containing polymers, and preparations containing elastomers because they are considered to possibly not present a danger to human health by inhalation etc. in the form in which they are placed on the market. They therefore do not require a label.

For preparations, Article 12 of Directive 1999/45 allows exemptions from the mandatory labelling with danger symbol and risk and safety phrases similar to Directive 67/548 for alloys, preparations containing elastomers and polymers which in the form in which they are placed on the market, do not present any risk to health (Article 12 (2) in conjunction with Annex VII of Directive 1999/45), as well as exemptions for small containers etc. similar to those for substances (see above).

No exemptions from labelling equivalent to alloys, or preparations containing polymers are provided for other substances or preparations which do not also present any danger in the specific form in which they are put on the market. As alloys etc. are listed exhaustively, not illustratively, it will therefore not be possible to apply this exemption 'in analogy' to other substances or preparations.

¹¹ Same rule as for substances, see above.

¹² This exemption does not apply to toxic substances.

4. GHS – Globally Harmonised System¹³

GHS, developed at UN level, provides a harmonised basis for uniform environmental, health and safety information on hazardous chemical substances and mixtures (preparations).

GHS will be implemented in the EU through a GHS Regulation replacing the current legislation on classification and labelling, i.e., Directive 67/548 for substances and Directive 1999/45 for preparations.

The definition of a “substance” under the draft GHS proposal is identical to the definition laid out under REACH and under Directive 67/548. “Mixtures” (replacing “preparations” under Directive 67/548) are defined as “*a mixture or solution of two or more substances which do not react.*”

- If tests must be carried out for the purposes of hazard identification and classification under the GHS Regulation, they must be carried out “*on the substance or on the mixture in the form(s) or physical state(s) in which the substance or mixture is placed on the market and in which it can be reasonably be expected to be used*” (Article 8.4 of the GHS proposal).
- The rules for the evaluation and classification of substances containing impurities are similar to those currently applicable under Directive 67/548, i.e., the limits specified in the relevant Annexes, if any, must be taken into account for the classification of the substance (Article 10 of the GHS proposal).
- Where a classification cannot be directly made on the basis of available identified information, a weight of evidence determination using expert judgment must be applied, and expert judgment may be applied in particular “*to interpret information for hazard classification of mixtures*” (Art 9.3 and part 1.1.1 of Annex I to the GHS proposal).

Differently from the current system under Directive 67/548, harmonised classification under the GHS Regulation will apply only to substances that are carcinogenic, mutagenic or toxic for reproduction, or respiratory sensitizers. The Commission may decide to add other classifications “*if justification is provided demonstrating the need for action at Community level*” (Article 38 of the draft GHS proposal).

Proposals for (harmonised) classifications at Community level may be submitted by Member States or by any supplier who demonstrates the need for action at Community level.

Further, mirroring the REACH provisions, any manufacturer or importer or group of importers placing on the market a substance that meets the criteria for classification as hazardous must notify certain information to ECHA for inclusion in the classification and labelling Inventory maintained by ECHA (Art 40a et seq of the GHS proposal). If there are different entries in the directory, the companies having notified the substance (or the registrants of the substance under REACH) must “make every effort” to come to an agreed entry for inclusion in the Inventory and shall inform ECHA accordingly (Art 42 of the GHS proposal).

If an entry in the classification and labelling Inventory has been agreed upon by one or more notifiers or registrants, the substance is considered to be *prima facie* classified accordingly and another

¹³ This Manual takes into account the draft proposal for a “Regulation of the European Parliament and of the Council on Classification and Labelling of Substances and Mixtures based on the Globally Harmonised System” (hereinafter “draft GHS proposal”), compromise version dated 27 June 2008, agreed between the European Parliament and the Council and to be adopted in the autumn of 2008.

supplier may classify the same substance differently only if he submits the reasons for doing so to ECHA when he submits his notification (Art 16 of the GHS proposal).

Substances must be classified and labelled in accordance with GHS as of 1 December 2010. Between 1 Dec 2010 and 1 June 2015, substances must be classified in accordance with both systems. The dual classification will appear on the SDS and only the GHS classification will appear on the label.

Mixtures must be classified and labelled in accordance with GHS as of 1 June 2015.

The GSH may be used for substances and mixtures as of the entry into force of the GHS Regulation until 1 June 2015 (for substances, alongside the current system between 1 December 2010 and 1 June 2015, see above). If both systems are used, the dual classification must appear on the SDS and the GHS classification must appear on the label.

Annex I to the draft GHS proposal lays out in detail the criteria applicable to the classification of substances and mixtures in different hazard categories. These differ from the current system to some extent.

For example, the supplier of a substance may derogate from the concentration limits if he follows the criteria set out in the respective chapter and future guidelines developed by ECHA, and provided that he includes justification for the different concentration limits in his notification for the C&L inventory or in his registration under REACH.

Mixtures must be classified in accordance with the data available for the complete mixture, if any, and if data on the mixture are not available, in accordance with data on the individual ingredients and similar tested mixtures.

Annex VII to the GHS proposal contains a table setting out the classification category under the GHS equivalent to the classification category under the current EU system.

However, a detailed explanation of the tests to be used for classification and interpretation of the results is provided in Annex I of the GHS. In particular, for substances/preparations with an extreme high or low pH, one can use the acid-alkali reserve (a.o. Annex I part 3.2.2.4 of the GHS proposal) and results from other tests to classify for eye and skin irritation.¹⁴

¹⁴ GHS states that there is merit considering the totality of existing information and making an overall weight of evidence determination. Primary emphasis shall be based on existing human experience and data, followed by animal experience and testing data, followed by other sources of information. Case-by-case determination is necessary.

XII. SAFETY DATA SHEETS



CEMBUREAU has set up Guidelines on establishing safety data sheets for Portland cement clinker and Portland cement, which take into account REACH requirements. These guidelines include recommended templates for harmonised SDS. [These guidelines](#) are set out in the Annex hereto.

Set out below is an outline of a safety data sheet as well as a comparison chart of existing safety data sheet requirements versus safety data sheet requirements under REACH (Art 31).

Any manufacturer or importer of a substance placed on the market either on its own or in preparation shall provide the recipient of the substance with a safety data sheet compiled in accordance with Annex II of the REACH Regulation if one of the following conditions is met:

- The substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548 or 1999/45;
- The substance is a PBT or vPvB in accordance with the criteria set out in Annex XIII of REACH;
- The substance is on the candidate list for authorisation for other reasons than above.

The supplier of a preparation shall provide the recipient at his/her request with a safety data sheet where the preparation does not meet the criteria for classification as dangerous under Directive 1999/45 but contains:

- in an individual concentration of > 1% by weight for non-gaseous preparations and > 0.2% by volume for gaseous preparations at least one substance posing human health or environmental hazards;
- in an individual concentration of > 0.1% by weight for non-gaseous preparations at least one substance that is PBT or vPvB in accordance with the criteria set out in Annex XIII; or has been included for other reasons than under the first indent into the candidate list;
- a substance for which there are Community workplace exposure limits.

For substances subject to registration and above 10 tonnes, a so-called eSDS (extended safety data sheet) shall be provided. An eSDS is a SDS that contains the relevant exposure scenarios (including use and exposure categories where appropriate) in an annex to the safety data sheet covering identified uses and including specific conditions resulting from the application of section 3 of Annex XI (risk management measures).

With regards to SDS for preparations, the exposure scenarios for the substances in the preparation have to be added to the SDS if applicable unless a chemical safety report with an exposure scenario has been developed for the preparation itself.¹⁵

All safety data sheets shall be provided free of charge on paper or electronically in the official languages of the country in which the substances are marketed at first delivery. Safety data sheets must be re-sent once they have been updated. They must be updated once new information becomes available affecting risk management measures or new information on hazards, or once restrictions have been imposed.

¹⁵ This is evident from Article 31 (7) in conjunction with Article 31 (2) second sentence REACH stating that in cases a chemical safety report was developed for a preparation, it is "sufficient" that the information in the SDS is consistent with the chemical safety report for the preparation.

Safety Data Sheets under REACH

1. Identification of the substance/preparation and of the company/undertaking
 - 1.1 Identification of the substance or preparation
 - 1.2 Use of the substance/preparation
 - 1.3 Company/undertaking identification
 - 1.4 Emergency telephone
2. Hazards Identification
3. Composition/Information or Ingredients (= all hazard information)
4. First Aid Measures
5. Fire Fighting measures
6. Accidental Release Measures
7. Handling and Storage
 - 7.1 Handling
 - 7.2 Storage
 - 7.3 Specific Uses
8. Exposure Controls/personal Protection
 - 8.1 Exposure limit values
 - 8.2 Exposure controls
9. Physical and chemical properties
 - 9.1 General information
 - 9.2 Important health, safety and environmental information
 - 9.3 Other information
10. Stability and Reactivity
 - 10.1 Conditions to avoid
 - 10.2 Materials to avoid
 - 10.3 Hazardous decomposition products
11. Toxicological information
12. Ecological information
 - 12.1 Ecotoxicity
 - 12.2 Mobility
 - 12.3 Persistence and degradability
 - 12.4 Bioaccumulative potential
 - 12.5 Results of PBT assessment
 - 12.6 Other adverse effects
13. Disposal Considerations
14. Transport information
15. Regulatory information
16. Other information (e.g. key data, training, recommendations on use restrictions)

ANNEX (NEW!):

Exposure scenarios (based on chemical safety report, i.e. above 10 tonnes and subject to registration and dangerous/PBT/vPvB)



XIII. AUTHORISATION

Under REACH,

- substances that meet the criteria for classification as carcinogenic, mutagenic or reprotoxic cat. 1 or 2 ('CMRs', Article 57 (a)-(c) REACH)
- substances that are PBTs (persistent, bioaccumulative, and toxic, see criteria in Annex XIII)
- substances that are very persistent and very bioaccumulative ('vPvB', see criteria in Annex XIII REACH) or
- substances that are of equivalent concern (e.g. endocrine disruptors) for which there is scientific evidence of probable serious effects to human health or the environment and which are identified on a case-by-case basis in accordance with the procedure set out in Article 59 REACH (Article 57 (f) REACH)

qualify for entry into Annex XIV of REACH, the list of substances subject to authorisation. This is the so-called "candidate list". A first list of substances proposed to go on the candidate list can be found [here](#).

Once substances are entered into Annex XIV, manufacturers, importers or downstream users cannot place them on the market for a use or use them themselves unless the specific use of the substance on its own or in a preparation or incorporation of the substance into an article has been authorised in accordance with Articles 60 to 64 REACH (unless the concentration in preparations is below a concentration limit of 0.1% weight by weight) (Article 56 (6) (a) REACH).

Uses or categories of uses may be exempt from the authorisation requirements provided that, on the basis of the existing specific Community legislation imposing minimum requirements relating to the protection of human health or the environment for the use of the substance, the risk is properly controlled.

Legally, the inclusion in the "candidate list" does not have any binding consequences within the authorisation process (the only formal effect of the "candidate list" is in the context of notification of substances in articles and in relation to the provision of safety data sheets). However, it is expected that the market could react to such inclusion immediately by de-selecting substances identified as "candidate".

The decision on inclusion of "priority" substances into Annex XIV is taken by the European Commission acting together with the Member States and the European Parliament. The Annex XIV inclusion will refer to the exempted uses (see above) and the "sunset date", as of which manufacture, import or use will be prohibited unless use and user-specific authorisations are obtained. Companies (manufacturers/importers/downstream users) who applied for an authorisation 18 months before the sunset date, but who have not yet received the authorisation, may continue to place on the market or use the substance pending final decision on their application.

The authorisations are granted by the European Commission according to the following rules:

- Authorisations will be granted if the applicant can demonstrate that the use is "adequately controlled", by reference to point 6.4 of Annex I of REACH. REACH establishes that adequate control cannot be demonstrated for CMRs, endocrine disruptors or substances of "equivalent concern", for which there is no threshold below which there are no effects and for PBTs and vPvBs;
- If "adequate control" cannot be demonstrated, authorisation may be granted if it can be demonstrated that there are no suitable alternative substances or technologies and that the socio-economic benefits outweigh the risks to human health or the environment.

According to Art 66, downstream users who use a substance subject to authorisation in accordance with the conditions set out in the authorisation, must notify ECHA of that use within three months of first supply of that substance.

In Summary:

The manufacture, placing on the market and use of CMRs cat. 1 or 2, PBTs, vPvBs and substances of “equivalent concern” (such as endocrine disruptors) may be subject to a “use-specific” authorisation under REACH.

In addition, certain substances that can be identified as such may be included in a “candidate list” and may thereafter be de-selected as a result of market forces.

Downstream users who use substances subject to authorisation must notify ECHA within 3 months of first supply.



CEMBUREAU may assist the European cement industry in defending substances against inclusion in the “candidate” or “priority” lists or in Annex XIV, or in exempting specific uses from authorisation. This will help cement companies in their filing of authorisation dossiers, if applicable. The applications for authorisation are company specific and CEMBUREAU can therefore not file for authorisation on behalf of individual companies.

PETCOKE

Uses of substances such as petcoke as fuel in mobile or fixed combustion plants of mineral oil products and uses of substances as fuels in closed system are exempt from authorisation (Art 56.4(d)). Petcoke (provided it is not considered as waste) and other mineral oil products used by cement kilns are not liable to authorisation under Articles 55 et seq. REACH even if they would fulfil the respective danger categories (e.g. carcinogens 1 and 2) and their uses for other purposes would be included into Annex XIV REACH (list of substances subject to authorisation), because Article 56.4(d) REACH exempts "uses as fuel in mobile or fixed combustion plants of mineral oil products and use as fuels in closed systems". Cement kilns are generally considered as fixed combustion plants.

In Summary:

Uses of substances such as petcoke as fuel in mobile or fixed combustion plants of mineral oil products and uses of substances as fuels in closed systems are exempt from authorisation (Art 56.4(d)).

Coal producers assume that coal is exempt from authorisation because it does not present any of the properties which would make it subject to authorisation.

XIV. FEES

[The fees Regulation](#)¹⁶ sets out the fees and charges that companies (legal entities) have to pay to ECHA for: registration, authorisation applications, notification of classification and labelling, notification of use of substances subject to authorisation, notification of research and development exemptions, modifications to dossiers, appeals against decisions of ECHA, etc.

Registration fees are lower for joint registrations than for individual registrations and the fee height depends on the size of the company. Table 2 below gives an overview for the registration fees for substances produced in volumes > 1000t/y

Size of company	Individual registration	Joint registration
Large company	€ 31,000	€ 23,250
Medium (<250 workers and turnover < 50 M€)	€ 21,700	€ 16,275
Small (<50 workers and turnover < 10 M€)	€ 12,400	€ 9,300

Table 2: Registration fees per legal entity and for substances produced in volumes over 1000 t/y.

¹⁶ Commission Regulation (EC) No 340/2008 of 16 April 2008 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)

XV. MARKETING & USE RESTRICTIONS

REACH allows the introduction of restrictions concerning the manufacture, placing on the market or use of certain substances if these substances are found to pose an un-acceptable risk that must be addressed at the Community level. The restrictions Annex (Annex XVII of REACH) takes over the current marketing & use restrictions included in Directive 76/769. This includes restrictions for chromium VI content of cement (see below in box):

Directive 76/769:

“(1) Cement and cement-containing preparations may not be used or placed on the market, if they contain, when hydrated, more than 0.0002 % soluble chromium VI of the total dry weight of the cement.

(2) If reducing agents are used, then without prejudice to the application of other Community provisions on the classification, packaging and labelling of dangerous substances and preparations, the packaging of cement or cement-containing preparations shall be legibly and indelibly marked with information on the packing date, as well as on the storage conditions and the storage period appropriate to maintaining the activity of the reducing agent and to keeping the content of soluble chromium VI below the limit indicated in paragraph 1.

(3) By way of derogation, paragraphs 1 and 2 shall not apply to the placing on the market for, and use in, controlled closed and totally automated processes in which cement and cement-containing preparations are handled solely by machines and in which there is no possibility of contact with the skin.”

Annex XVII will initially incorporate the current marketing and use restrictions of Directive 76/769, including those for cement (see above).¹⁷ Directive 76/769 will then be repealed as of 1 June 2009 and accordingly all national legislation based on Directive 76/769 (possibly using a different approach for chromium VI) will have to be repealed too and will be considered replaced by the directly applicable REACH restrictions.

However, according to Article 67 (3) REACH, Member States may maintain any existing and more stringent restrictions in relation to Annex XVII until 1 June 2013 provided these have been notified to the European Commission. The European Commission must publish an inventory of such national restrictions by 1 June 2009.

Marketing and use restrictions can be proposed by Member States or by ECHA at the request of the European Commission. The proposal is reviewed by ECHA's Risk Assessment and Socio-Economic Committees, which transmit their opinions to the European Commission. The final restrictions are adopted by the European Commission acting together with the Member States and the European Parliament.

Substances that are carcinogenic, mutagenic or reprotoxic cat. 1 or 2 ('CMRs') will be restricted for consumer uses (as such or in preparations) through a fast-track process. Substances manufactured, placed on the market or used in scientific research and development are exempt from the imposition of marketing & use restrictions.

In summary:

Substances may be included in the restrictions Annex XVII of REACH by the European Commission and companies will have to comply with those restrictions as far as manufacture, placing on the market or use of the specific substance is concerned.

¹⁷ See Recital 84 of REACH.

XVI. REACH COMPLIANCE STEPS FOR CEMENT COMPANIES

Set out below is a draft programme for cement companies to prepare for the entry into effect of REACH on 1 June 2007, and which would enable cement companies to assess the implications of REACH for their operations.



CEMBUREAU made an inventory of the most commonly used substances in cement manufacturing and the REACH requirements which apply to these materials. See the next section for the substance identity cards.

If companies have to disclose information when complying with REACH requirements, it is recommended to identify confidential business information and to ensure that appropriate steps are taken to protect this confidential information.

First Step: Fact Finding

- Set up an inventory of all substances as such and in preparations / mixtures imported, manufactured or used in the EU (including process chemicals not present in final products), per site and per legal entity, and who supplies them from where;
- Set up an inventory of all products marketed by your company (substances, preparations, 'articles');
- Establish tonnages of substances per site and entity;
- Identify applications/uses;
- Identify suppliers and customers;
- Collect updated applicable safety data sheets;
- Collect data on substances already in possession / ownership of your company.

Second Step: Assessment of Substances Individually

- Within scope of REACH;
- Applicability of exemptions;
- Which REACH requirements and dates apply;
- Subject to authorisation, restrictions;
- Existing restrictions;
- Availability of data; which data is required; which data is missing;
- Use and exposure categories;
- Review SDS, labelling, packaging;
- Action required (collection of data, upgrade SDS, registration, authorisation, substitution, etc.);
- Identify legal entity which will need to act for the substances

Third Step: Assessment of Articles

- Does your company purchase / use / market any articles with substances subject to notification (CMR, PBT, vPvB) at relevant concentrations.

Fourth Step: Suppliers and Customers

- Review supply and customer contracts for duration, liabilities, information requirements, insurance;
- Check whether suppliers will continue to deliver once REACH comes into effect;
- Check that the supplier will apply the relevant REACH requirements to the products (eg register for use in cement value chain, appointment of only representative in case of outside EU producers);
- Assess whether your company will want to continue the customer relationship
- Prepare information which will have to be passed on to customers.

Fifth Step: Various

- Formation of task forces and consortia under REACH necessary or desirable; identify and set up such; Data protection action needed;
- Set up formalised REACH record keeping and documentation management system;
- Set up REACH compliance review procedure and team;
- Review insurance contracts for REACH compliance coverage;
- Streamline supply structure;
- Streamline manufacturing;
- Identify and set up REACH compliance budget.

XVII. CONTRACT AND INSURANCE IMPLICATIONS OF REACH

1. Insurance

CEMBUREAU recommends that companies review whether their REACH compliance or failure to comply is covered by insurance coverage (i.e. product liability insurance, manager insurance, general liability insurance, environmental insurance).

2. Contracts

It will be necessary to assess

- Whether suppliers/customers will continue their supplies/purchases once REACH enters into effect;
- Who will bear which contractual obligations (supply and sales contracts) in relation to REACH;
- Whether the contract partners will provide warranties or indemnities for inaccurate or incomplete information (information in the supply chain) that must be provided under REACH;
- Whether contracts will provide the necessary flexibility/stability in relation to product price increases due to REACH;
- Data ownership/use rights for new/existing data developed under REACH.

Legal departments of companies or other legal advisors should be made aware of REACH implications.

XVIII. REACH COMPANY CHEMICAL INVENTORY



REACH Chemical
Inventory.XLS

XIX. SUBSTANCE IDENTITY CARDS

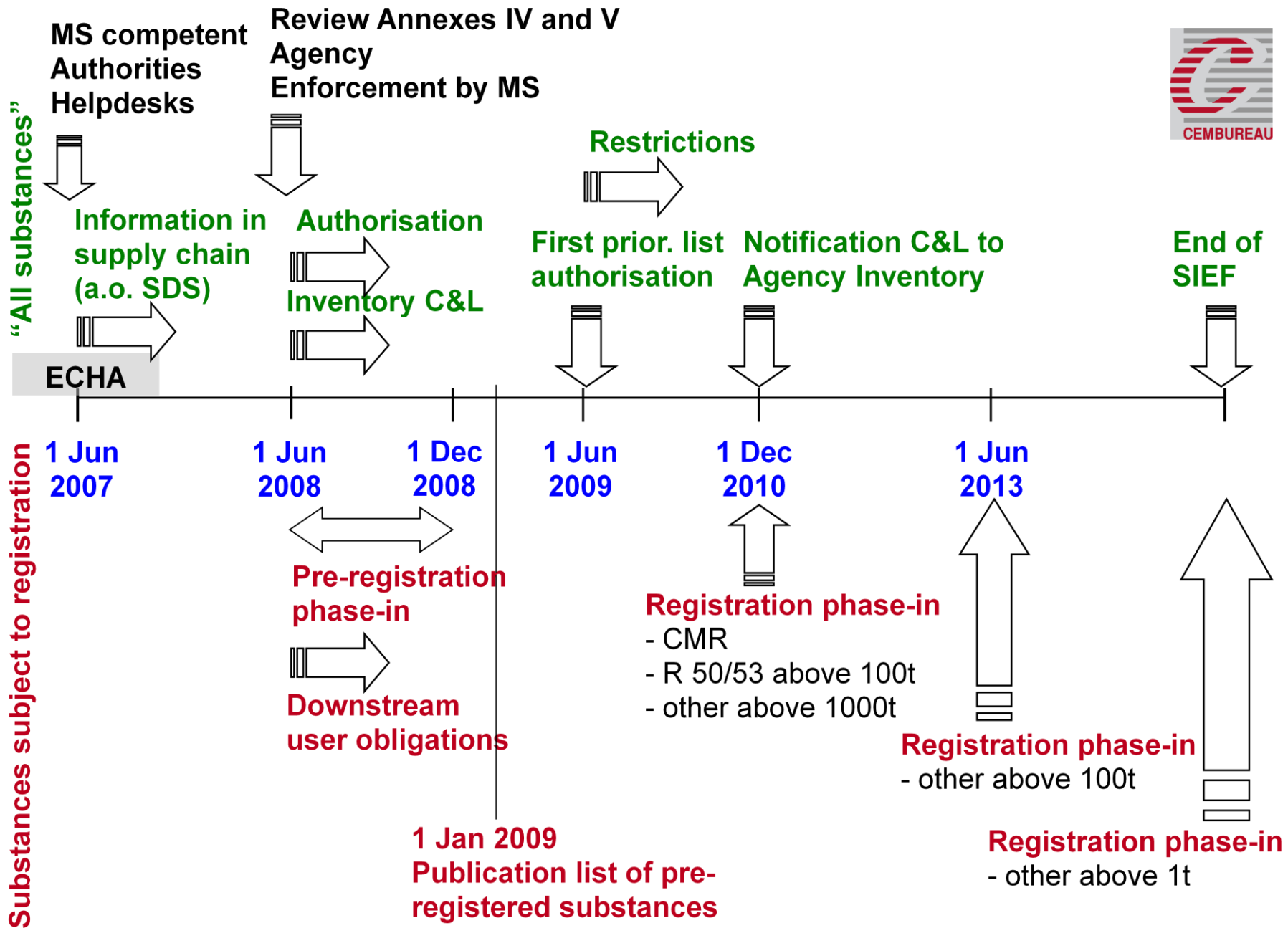
In order for manufacturers and importers to classify and label their substances correctly, they must first correctly determine the chemical composition of their substances and preparations, including their purities, impurities and so on. Annex VI. 2. of REACH sets out the headings for this substance identification.



CEMBUREAU will be working with its Members to set up [substance identity cards](#) for the most commonly used and produced products.

The [Technical Guidance Document on substance identity will assist](#) companies in identifying and defining substances. This is particularly useful for minerals and other composite substances. We recommend that companies use this Technical Guidance Document in case they require assistance in substance identification.

XX. REACH TIMELINES



XXI. REACH GLOSSARY AND ABBREVIATIONS USED

An extensive REACH glossary can be downloaded [here](#).

The below abbreviations were used in this manual:

CAS	Chemical Abstracts Service maintains the most comprehensive list of chemical substances. Each substance registered in the CAS Registry is assigned a CAS Registry Number. The CAS Registry Number (commonly referred to as CAS number) is widely used as a unique identifier of chemical substances.
C&L	Classification & labelling of substances and preparations.
CMR	Carconogen, mutagen and reprotoxic
CSA	Chemical Safety Assessment
CSR	Chemical Safety report
ECHA	European Chemicals Agency based in Helsinki, Finland. In charge of, among others, registration; C&L Inventory; public access to information; recommendations for inclusion of substances in Annex XIV (authorisation).
EEA	European Economic Area. Unites the 27 EU Member States and the three EEA-EFTA States (Iceland, Liechtenstein, and Norway) into an Internal Market governed by the same basic rules. These rules aim to enable goods, services, capital, and persons to move freely about the EEA in an open and competitive environment, a concept referred to as the four freedoms.
EFTA	European Free Trade Association. An intergovernmental organisation set up for the promotion of free trade and economic integration to the benefit of its four Member States: Iceland, Liechtenstein, Norway and Switzerland
EINECS	European Inventory of Existing Commercial Chemical Substances
ELINCS	Community list of “new” chemicals substance, i.e. those marketed as of 18 September 1981 and registered (notified) under Directive 67/548.
EU	European Union
FGD gypsum	Flue gas desulphurisation gypsum
GHS	Globally Harmonised System. This Manual takes into account the draft proposal for a “Regulation of the European Parliament and of the Council on Classification and Labelling of Substances and Mixtures based on the Globally Harmonised System” (hereinafter “draft GHS proposal”), compromise version dated 27 June 2008, agreed between the European Parliament and the Council and to be adopted in the autumn of 2008. GHS was developed at UN level. GHS will be implemented in the EU through a GHS Regulation replacing the current legislation or classification and labelling, i.e., Directive 67/548 for substances and Directive 1999/45 for preparations.
IUCLID	IUCLID (International Uniform Chemical Information Database) is a database including a tool for data collection on chemical substances. In particular IUCLID5 enables to prepare a registration dossier as well as to prepare other types of REACH dossiers (PPORD dossiers, C&L notifications, notifications of substances in articles, DU reports and Annex XV dossiers) as well as dossiers for other EU and international jurisdictions. REACH requires that registration dossiers are submitted to the Agency following IUCLID format. IUCLID5 is built using internationally harmonized formats for reporting data on intrinsic properties of chemicals that were prepared and accepted by many national and international regulatory authorities within the OECD.
LPG	Liquified petroleum Gas
PBT	Persistent, Bio-accumulative and Toxic.
vPvB	Very Persistent, Very Bio-accumulative.
PPORD	Product and Process Oriented Research and Development. Includes pilot plant, or production trials, or field of application tests.

R50/53	Very toxic to aquatic organisms, may cause long-term adverse effects in the aquatic environment
QSAR	Quantitative Structure Activity Relationship.
REACH	Registration, Evaluation, Authorisation and Restriction of Chemicals
SDS	Safety Data Sheet. Information on substance identity, handling and use, classification, warnings to be provided simultaneously with first delivery of substance and to be updated regularly.
SIEF	Substance Information Exchange Forum under REACH. All manufacturers and importers that have submitted information for the same phase-in substance (see Articles 28 and 29) become participants in SIEF automatically. SIEF participants are subject to data sharing/data generation obligations under Article 30 <i>et seq.</i> REACH.
SVHCs	Substances of Very High Concern.
UN	United Nations.

XXII. FOR FURTHER REFERENCE

European chemicals Agency:

<http://echa.europa.eu/>

About REACH – Short ECHA guidance

http://reach.jrc.it/about_reach_en.htm

ECHA fact sheets:

http://echa.europa.eu/reach/fact_sheet_en.asp

REACH Technical Guidance Documents

http://reach.jrc.it/guidance_en.htm

REACH navigator to help determine REACH obligations:

http://reach.jrc.it/navigator_en.htm

REACH FAQ ECHA:

http://echa.europa.eu/reach/faq_en.asp

REACH in brief:

http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

f

REACH national helpdesks

http://echa.europa.eu/reach/helpdesk/nationalhelp_contact_en.asp

Fees and charges

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

REACH-IT

http://echa.europa.eu/reachit_en.asp

IUCLID5:

<http://ecbwbui5.jrc.it/>

The European Chemicals Bureau EINECS and ELINCS information system with search functions for substance names, EINECS or ELINCS number and CAS number <http://ecb.jrc.it/esis/index.php?PGM=ein>. It also allows searches for harmonised classification and labelling under Annex I of Directive 67/548, IUCLID data and so on.

TGD - Technical Guidance Document on risk assessment <http://ecb.jrc.it/tgd/>

Manual of Decisions. Contains guidance on interpretation issues in relation to the existing EU chemicals legislation http://ecb.jrc.it/DOCUMENTS/New-Chemicals/Manual_of_decisions.pdf

EUSES - ECB step by step tool for company decisions on risk assessment of chemicals

<http://ecb.jrc.it/euses/>

ANNEX: GUIDELINES FOR THE SAFETY DATA SHEET FOR CEMENT AND CLINKER



GUIDELINES FOR THE SAFETY DATA SHEET FOR CEMENT

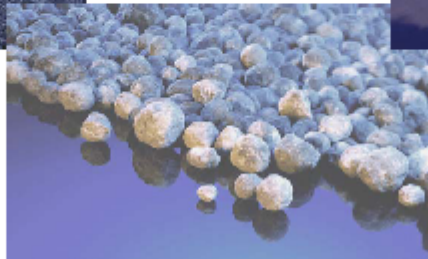
1. Safety Data Sheets under REACH

The REACH regulation (Regulation EC n° 1907/2006) considers the safety data sheet (SDS) as the key element in the hazard and risk management communication from chemical substance suppliers and formulators to Downstream Users (DU): from manufacturers to their professional customers.

When a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC, *the person responsible for placing that substance or preparation on the market, whether the manufacturer, importer, downstream user (DU) or distributor, shall supply the recipient, who is a downstream user or distributor of the substance or preparation, with a SDS.* Unless requested by the DU or distributor, a SDS will not have to be supplied for substances or preparations sold to the general public if sufficient information is provided to enable users to take the necessary measures with regard to the protection of the environment and human health.

The SDS shall be supplied in the official languages of the Member States in which the substance or preparation is placed on the market (unless the Member State provides otherwise). The SDS shall be supplied on paper or electronically at the latest at the time of first delivery of a substance following entry into force of the REACH Regulation (1 June 2007). Suppliers shall update it without delay as soon as new information, which may affect the risk management measures, or new information on hazards becomes available. The same applies if an authorisation is granted or refused or a restriction has been imposed. The new dated version of the information identified as "Revision: (date)" shall be provided free of charge to all former recipients who have been supplied with the substance in the preceding 12 months (Article 31 REACH Regulation). Workers or their representatives shall be granted access by their employers to the SDS of the substances or preparations they use or might be exposed to in the course of their work.





GUIDELINES FOR THE SAFETY DATA SHEET FOR PORTLAND CEMENT CLINKER

<p>1. Safety Data Sheets under REACH</p>	<p>The REACH regulation (Regulation EC n° 1907/2006) considers the safety data sheet (SDS) as the key element in the hazard and risk management communication from chemical substance suppliers and formulators to downstream users (DU): from manufacturers to their professional customers.</p> <p>When a substance or preparation meets the criteria for classification as dangerous in accordance with Directives 67/548/EEC or 1999/45/EC*, the person responsible for placing that substance or preparation on the market, whether the manufacturer, importer, downstream user (DU) or distributor, shall supply the recipient, who is a downstream user or distributor of the substance or preparation, with a SDS. Unless requested by the DU or distributor, a SDS will not have to be supplied for substances or preparations sold to the general public if sufficient information is provided to enable users to take the necessary measures with regard to the protection of the environment and human health.</p> <p>* To be updated once the GHS Regulation enters into force</p>	<p>The SDS shall be supplied in the official languages of the Member States in which the substance or preparation is placed on the market (unless the Member State provides otherwise).</p> <p>The SDS shall be supplied on paper or electronically at the latest at the time of first delivery of a substance. Suppliers shall update it without delay as soon as new information, which may affect the risk management measures, or new information on hazards becomes available. The same applies if an authorisation is granted or refused or a restriction has been imposed. The new dated version of the information identified as "Revision: (date)" shall be provided free of charge to all former recipients who have been supplied with the substance in the preceding 12 months (Article 31 REACH Regulation).</p> <p>Workers or their representatives shall be granted access by their employers to the SDS of the substances or preparations they use or might be exposed to in the course of their work.</p>
<p>2. Scope of SDS - Record keeping - Chemical Safety Report (CSR)</p>	<ul style="list-style-type: none"> The SDS is meant for professional users and should provide them with useful health and safety (H&S) information. However, a SDS may be used as a basis for internal H&S protocols for the clinker production plant work force. Provided that the required personal protection equipment is correctly used in the production plant, 	<p>then the health impacts for workers are considered as adequately controlled by what is explained in this SDS.</p> <ul style="list-style-type: none"> The SDS has to be kept on file for 10 years after the last manufacture, import, supply or use of the substance/preparation (Article 36 REACH) (including information used for its compilation).