GUIDELINES FOR THE GLASS INDUSTRY

Registration, Evaluation, Authorisation and Restriction of CHemicals, **REACH**

Disclaimer

This document has been drafted by Glass Alliance Europe (former CPIV) and is intended to provide guidance to its Member associations and to glass companies in order to help them comply with the REACH obligations. This document is for information purposes only and it does not constitute and/or replace specific legal advice and/or legal opinion.

1 Introduction

On the 29th of October 2003, the European Commission launched a proposal for a new European regulatory framework for chemicals, entitled REACH (*COM (2003) 644)*.

Three years later, end 2006, REACH ended up being one of the most ambitious and biggest piece of legislation ever in the European Union (EU). REACH stands for **R**egistration, **E**valuation, **A**uthorisation and Restriction of **CH**emicals and aims at completely changing the way chemicals are dealt with in Europe (you can find the final version of this European regulatory framework for chemicals (REGULATION (EC) No 1907/2006 of 18 December 2006) on the following website:
http://eur-lex.europa.eu/JOHtml.do?uri=OJ:L:2006:396:SOM:EN:HTML).

REACH entered into force on the 1st of June 2007. It replaced over 40 existing Directives and Regulations. The aims of REACH are, amongst others, to improve human health and the protection of the environment through better and earlier identification of the properties of substances. Manufacturers and importers are required to gather information on the properties of their substances, starting at 1 tonne per year and per producer/importer, which will be used, for example, in advising on safety measures. Substances will be registered in a central database at the European Chemicals Agency (ECHA). A regulation (as opposed to a Directive) is applicable in all Member States directly, without any implementation into national law.

The glass industry is concerned by REACH because:

- **It is a downstream user (DU) of chemicals, and must therefore implement the risk management measures (RMMs) identified for a specific substance by a supplier/importer and should communicate information up and down the supply chain. Glass companies should, as soon as possible, contact their suppliers in order to be certain that their use of a substance is included in the Extended Safety Data Sheet (= SDS + exposure scenario) for the substances manufactured or imported in quantities exceeding 10 tonnes per year and per producer for which a Chemical Safety Report (CSR) is required.**
- **It manufactures articles (bottles, windows, fibres, etc.) and has to communicate information about substances in articles under certain circumstances;**
- **It produces the UVCB substance glass: some actions will have to be taken.**

These guidelines do NOT constitute a summary of REACH. They aim at giving DU of the glass industry some practical information in order to help them to deal with the different REACH requirements.
Many technical guidance documents concerning the implementation of REACH have been prepared. These documents can be found on the website of the European Chemicals Agency: http://echa.europa.eu/reach/fact_sheet_en.asp

2 REACH and the Glass industry – A quick overview

As a glass manufacturer, you buy substances and mixtures (please note, that the term "preparation", used in the REACH Regulation, has been replaced by the term "mixture" in the new CLP regulation (1272/2008/EC) and will be used throughout this text):

- Sand (substance)
- Soda ash (substance)
- Calcium carbonate (substance)
- Boric acid (substance)
- Lubricants (mixture of several substances)
- Cleaning products (mixture of several substances)
- …

The general rule of REACH is that substances, if produced or imported in quantities starting from 1 tonne per year and per manufacturer/importer (on their own or in a mixture) have to be registered before they can be put on the market. A distinction is made between phase-in substances (existing substances) and non phase-in substances (new substances).

For substances produced or imported in quantities starting at 10 tonnes per year and per manufacturer/importer, the producer/importer of the substance also has to prepare a Chemical Safety Report (CSR), documenting the hazards of the substance. If the substance is dangerous, CMR, PBT, vPvB or of equivalent concern the CSR also has to look at exposure scenarios (ES) concerning human health and the environment, and this throughout the whole life-cycle of the substance (from manufacturing to disposal). You should be sure that your supplier will register your use of the substance; otherwise, you will not be allowed to use this substance for your use in the future!

If you manufacture or import substances on their own or in mixtures, you will have to register the substances.

Annex V "EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)" of REACH[1] lists substances that are exempted from registration requirements. Among the most important of these for the glass industry:

[1] Annex V and Annex IV "EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(a)) of REACH were updated on 8 October 2008 through COMMISSION REGULATION (EC) No 987/2008 of 8 October 2008 amending Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards Annexes IV and V

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- (Annex V paragraph 7) *The following substances which occur in nature, if they are not chemically modified: Minerals, ores, ore concentrates, raw and processed natural gas, crude oil, coal.*
- (Annex V paragraph 8) *Substances which occur in nature other than those listed under paragraph 7, if they are not chemically modified, unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC or unless they are persistent, bioaccumulative and toxic or very persistent and very bioaccumulative in accordance with the criteria set out in Annex XIII or unless they were identified in accordance with Article 59(1) at least two years previously as substances giving rise to an equivalent level of concern as set out in Article 57(f).*
- **(Annex V paragraph 11)** ***The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limits set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the lifecycle of the substance and those data have been ascertained to be adequate and reliable: Glass, ceramic frits.***
- (Annex V paragraph 12) *Hydrogen and oxygen.'*

This means that your suppliers do not need to register for example sand, calcium carbonate, oxygen, etc.
The above substances are only exempt from the registration requirements! The other REACH requirements, such as authorisation, are still applicable.

Other substances that do no benefit from an exemption to register (such as soda ash, boric acid, etc.) have to be registered.
Substances in mixtures (e.g. cleaning products) must be registered as well. In this case, you will receive a Safety Data Sheet (SDS) for all of the substances present in the mixture through the supplier of the mixture.

During the glass manufacturing process, the raw materials are blended to form the batch, which is a mixture. In most cases, this batch is not put on the market, and therefore the rules of the Dangerous Preparations Directive (1999/45/EC) and the new classification and labelling regulation (Regulation 1272/2008) have only limited application.

Mineralogical transformation of this mixture (batch) takes place in the furnace leading to the material glass. Immediately after this transformation, forming and cooling in most cases transforms the material glass into an article. Articles are also covered under REACH, and in some cases (intended release, presence of substances of very high concern above a concentration of 0.1% weight by weight), you will have to either register the substances or notify them to the ECHA.

2.1 Treatment and Exemption of Glass under REACH

For glass itself, it has been decided by the Competent Authorities that "glass is the state of a substance rather than a substance as such. For legislative purposes, it can best be defined through its starting materials and production process, similar to many other UVCB substances", i.e. Substances of Unknown or Variable composition, Complex reaction products or Biological materials).[2]

Glass has been exempted from the registration requirement under REACH through Regulation 987/2008, which updated the exemptions under Annex V of the REACH Regulation and notably under Point 11. The exact wording of the exemption (as already shown above is:

> **(Annex V paragraph 11)** ***The following substances unless they meet the criteria for classification as dangerous according to Directive 67/548/EEC and provided that they do not contain constituents meeting the criteria as dangerous in accordance with Directive 67/548/EEC present in concentrations above the lowest of the applicable concentration limits set out in Directive 1999/45/EC or concentration limits set out in Annex I to Directive 67/548/EEC, unless conclusive scientific experimental data show that these constituents are not available throughout the lifecycle of the substance and those data have been ascertained to be adequate and reliable: Glass, ceramic frits.***

[2] Doc: CA/24/2008 rev.2 Follow-up to 5th Meeting of the Competent Authorities for the implementation of Regulation (EC) 1907/2006 (REACH) 25-26 September 2008

3 Specific guidelines for Downstream Users (DU)

3.1 Introduction

REACH contains a general obligation to register all existing and new substances manufactured or imported in the EU in quantities starting at 1 tonne per year and per manufacturer/importer with the European Chemicals Agency (ECHA) located in Helsinki, Finland. This obligation falls on the manufacturers or the importers of a substance, and therefore **NOT** on the Downstream User (DU). However, when a DU imports and/or manufactures himself a substance or when he does not want to communicate the substances' use to its supplier, some or all of the REACH requirements will fall on the DU.

Regarding substances, REACH distinguishes between phase-in substances and non phase-in substances:

- Phase-in (existing) substances are amongst others listed in the European Inventory of Existing Commercial Chemical Substances (EINECS) (for more information, please see definition 20 in article 3 "definitions" of REACH).
- Non phase-in (new) substances can be of two types. They can be completely new substances that have neither been used nor registered and marketed prior to the entry into force of REACH. Or they are substances that have been put on the EU market after 1981 and listed in the European List of Notified Chemical Substances (ELINCS). Only completely new substances need to be registered before they can be put on the market. ELINCS substances are considered as already registered.

Phase-in substances and non-phase-in substances have different timelines for registration under REACH.

Substances which have not previously been placed on the EU market (non phase-in substances), and phase-in substances which have not been pre-registered, must be registered before they can be placed on the market.

For phase-in substances which are manufactured or imported in quantities of 1 tonne or more per year per manufacturer/importer and which have been pre-registered, the registration provisions will apply stepwise to facilitate the transition to REACH:

- Substances manufactured or imported at or above 1000 tonnes per year and per manufacturer/importer as well as carcinogenic, mutagenic or reprotoxic substances category 1 and 2 (CMR category 1 and 2) manufactured or imported at or above 1 tonne per year per manufacturer/importer, or substances classified as dangerous for the aquatic environment with risk phrases R50/53 and manufactured or imported at or above 100 tonnes per year per manufacturer/importer will have to be registered before 1st December 2010.

- Substances manufactured or imported in the tonnage band 100-1000 tonnes per year and per manufacturer/importer will have to be registered before 1st June 2013.
- Substances manufactured or imported in the tonnage band 1-100 tonnes per year and per manufacturer/importer will have to be registered before 1st June 2018.

Pre-registration was limited to the period from 1st of June 2008 until 1st of December 2008. In January 2009, the ECHA published on their website a list of pre-registered substances.

It is very important for a DU to check whether the substances he uses have been pre-registered and will be registered, and if not, take the appropriate corrective measures (contact supplier and if necessary decide to register by himself).

3.2 Keep your chemical inventory up-to-date

As a DU of the glass industry, you should gather as much information as possible on the substances and/or the mixtures (for example batch, coatings, cleaning products, etc.) that you are using. The knowledge of substances and/or mixtures resides most likely in your Research & Development (R&D) department. Therefore, you should inform your research and development staff about REACH. They should be involved in the process as soon as possible.

The information should contain, for example, the following:

- **which substances** you are using and whether it is a phase-in substance or not;
- **in which quantities** you are using them;
- **why** you are using the substances (in REACH terms, identified use) and what their importance is for your business;
- **who** your supplier is and whether the substance is bought inside or outside the EU ;
- **if you manufacture and/or import** them by yourself;
- **if the substance is susceptible to be put on the candidate list for authorisation and/or in Annex XIV of REACH listing the substance subject to authorisation.**

This inventory can be done at the installation level or at the company level.

You should **rank** the substances and/or the mixtures that you are using, depending on how important they are to you. You should also be prepared to find substitutes if a substance is threatened to be banned (authorisation, restriction) or if your supplier intends to stop its production for economical reasons.

It is imperative to know if you are using any **substances of very high concern** (SVHC) and why you are using them, since they will be subject to authorisation and even restrictions in REACH.

If you have measurements concerning human exposure and/or environmental exposure of substances and/or of mixtures, particularly relating to the SVHC, collect them and document them. Your supplier could be interested in receiving this information for the registration process of the substance that you are using. They could also be very useful in the future, for example, if these substances fall under the authorisation regime.

Moreover, Article 34 of REACH imposes on the DU the obligation to communicate information up the supply chain in the following cases:

a) **new information is available on hazardous properties, regardless of the uses concerned;**
b) **any other information is available that might call into question the appropriateness of the risk management measures identified in a safety data sheet**

You should also look for **substitutes** for the substances and/or the mixtures that you are using, especially for the SVHC, since they could be subject to authorisation in the future and/or be no longer available on the market.

It is also important to identify the uses of the substances that you want to keep confidential in the future, because you will have to register your use by yourself (and perform the CSR if > 10 tonnes/year per manufacturer/importer). You may refer to the registration of your supplier.

You will find in the annexes an example sheet developed by CPIV for collecting information concerning a substance. It can be used to keep your chemicals inventory up-to-date.

3.3 Communicate with your suppliers

Once the inventory described in the previous section is done, you should contact your supplier(s) in order to find out whether or not these substances have been pre-registered and will be subject to registration, authorisation and if the supplier(s) intend(s) to register them or not for your use (in REACH terms: identified use).

It is important to stay in close contact with your suppliers since they have to register the substances that you use. They may also hold important information concerning the substances and/or the mixtures, for example, if a substance and/or a mixture) is going to disappear from the market in the near future.

You can also provide information to your supplier in order to assist him in the preparation of a registration dossier. Manufactures and importers are obliged to cover uses communicated to them in their registration dossier provided that the DU has delivered the appropriate information that enable the manufacturers and importers to develop an Exposure Scenario (ES). However, in the following situations the manufacturers and importers are not obliged to develop an ES:

- if they choose not to sell to the DU for this use
- if it is not possible to develop an ES for a given use because the risk cannot be adequately controlled. In this case these uses could be included in the SDS (under *heading 16 – recommended restrictions on use*).

If the manufacturer/importer does not want to register a substance for your use, but you still want to use the substance, you will have to perform the CSR by yourself and send it to the ECHA. In this case, you must not register the substance completely, but the use that you do not want to communicate to your supplier, including the CSR for substances produced above 10 tonnes per year. You can refer to the registration of your supplier.

As mentioned before, as a DU, you are also obliged to communicate information to the next actors up and down the supply chain.

3.4 Collect Safety Data Sheets (SDS) and check their completeness

The person responsible for placing a substance or a mixture on the market is required to prepare a SDS if the substance or mixture meets one of the following criteria:

1) For substances:
   a) the substance is classified as dangerous in accordance with Directive 67/548/EEC[3] or Regulation 1272/2008,
   b) the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioaccumulative (vPvB),
   c) any substance listed on the candidate list for authorisation (SVHC).

2) For mixtures:
   a) the mixture is classified as dangerous in accordance with Directive 1999/45/EC[4] or Regulation 1272/2008;
   b) On request by the recipients, if the mixture does not meet the criteria for classification as dangerous according to Directive 1999/45/EC or Regulation 1272/2008, but contains:
      i) at least one substance posing human health or environmental hazards in a concentration ≥ 1 % by weight for non-gaseous mixtures and ≥ 0.2 % by volume for gaseous mixtures;
      ii) at least one substance that is persistent, bioaccumulative and toxic or very persistent and very bioaccumulative and non-gaseous in a concentration ≥ 0.1% by weight;
      iii) a substance for which there are Community workplace exposure limits.
      iv) a substance listed in the candidate list for authorisation (=SVHC) is present in the mixture in a concentration ≥ 0.1% (w/w) for non gaseous preparations and at least 0.2% by volume for gaseous preparations.

SDSs are required regardless of the volume imported and/or produced in the EU. SDSs are a well known and widely used communication tools for conveying relevant information from the manufacturer or importer down the supply chain. Existing SDS will not change dramatically under REACH. The following points will be subject to modifications:

1) the SDS will contain relevant information for the DU from the CSR (all of the information on all the identified uses of the recipient must be provided, e.g. DNEL[5], PNEC[6], summary of the Risk Management Measures, Waste Management Measures, etc.). A SDS containing information on ES is called an extended SDS (E-SDS);
2) sections 2 and 3 are switched due to GHS[7] requirements,

[3] Council Directive 67/548/EEC of 27 June 1967 on the approximation of laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances
[4] Directive 1999/45/EC of the European Parliament and of the Council of 31 May 1999 concerning the approximation of the laws, regulations and administrative provisions of the Member States relating to the classification, packaging and labelling of dangerous preparations
[5] DNEL = Derived No Effect Level (for human beings)
[6] PNEC = Predicted No Effect Concentration (for the environment)
[7] GHS= Globally Harmonised System of Classification and Labelling of Chemicals (will repeal the currently existing EU Directives on classification and labelling, i.e. Directive 67/548/EEC and 1999/45/EC, after a transitional period) - http://www.unece.org/trans/danger/publi/ghs/ghs_rev01/01files_e.html

3) the e-mail address of the person responsible for the SDS must be provided in Annex 1.

Manufacturers and importers have to register the substances and their use(s) in mixtures under REACH. This means that you, as a DU of the European glass industry, only have to collect the SDS, check whether a CSR is necessary and if your use of the substance has been included and to respect their provisions. **You must also respect the Risks Management Measures contained in the SDS!**

You should prepare your own SDS if you are producing and/or importing a substance and/or a mixture that meets the criteria for a SDS.

If a substance and/or a mixture does not meet the above mentioned criteria, you are unlikely to receive a SDS from your supplier, but he will need to communicate different pieces of information to you (see Article 32 "*Duty to communicate information down the supply chain for substances on their own or in mixtures for which a safety data sheet is not required*"):

- the registration number(s), if available (for substances covered by the following points);
- if the substance is subject to authorisation and details of any authorisation granted or denied;
- details of any restriction imposed;
- any other available and relevant information about the substance that is necessary to enable appropriate risk management measures to be identified and applied including specific conditions.

You should receive this information in writing at the latest at the time of the first delivery of a substance following the entry into force of REACH (1st June 2007). Suppliers should update this information and communicate it to you without delay in the following situations:

- as soon as new data which may be necessary to enable appropriate risk management measures to be identified and applied become available;
- once the substance has been registered;
- once an authorisation has been granted or refused;
- once a restriction has been imposed.

The new information should be provided free of charge to all recipients to whom the supplier has delivered the substance or mixture within the preceding 12 months.

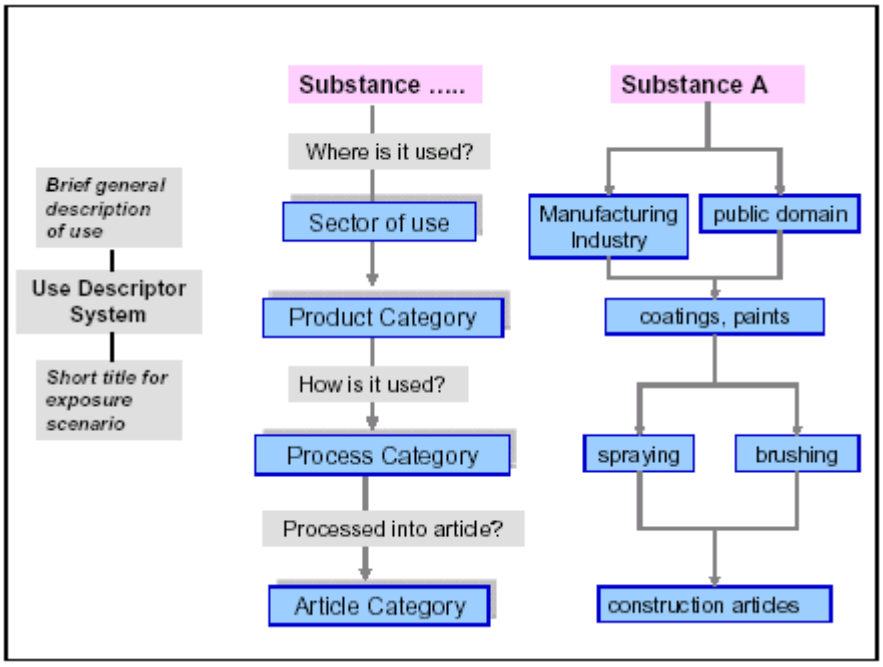
3.5 Check whether your use is included in the Chemical Safety Report

For those substances manufactured or imported in quantities over 10 tonnes per year and per manufacturer/importer, a CSR has to be prepared. If the substance is dangerous, this CSR must include an ES including use and exposure categories.

An ES defines the conditions under which a substance as such, in mixtures or in articles can be used safely. The ES must cover the whole life-cycle of the substance, from production to disposal (even if waste is excluded from the scope of REACH, safe disposal measures must be documented in the ES).

Annex VI N°6 of REACH gives some indications on how to interpret the terms "use categories" (industrial, professional, consumer use), and how to interpret the terms "exposure routes".

The use (category) is further described in a generic way according to the use descriptor system described in chapter R12 of the "Guidance on Information Requirements and Chemicals Safety Assessment"[8]. This use description is based on four elements: sector of use (SU), chemical product category (PC), process category (PROC) and article category (AC).



8 http://guidance.echa.europa.eu/docs/guidance_document/information_requirements_r12_en.pdf?vers=20_08_08

Each user of a substance or mixture for which an ES is supplied, must ensure that his use conditions are covered by the ES. This means that he has to compare the operational conditions and the Risk Management Measures (RMMs) described in the ES in order to find out whether the measures in the ES are implemented.

To analyse for each substance the relevant exposure routes, the "Guidance for downstream users"[9] proposes the following approach, described in Table 24:

Table 24 List of data for each dangerous substance, for each use and life-cycle stage

Substance name:		**Concentration range:**	
Use: (e.g. Professional, Scientific And Technical Activities (NACE M-74), Washing and Cleaning Product, Air dispersive techniques)			
Life cycle stage: (e.g. Application of product)			
Possible exposure route[67]	**Exposure route of relevance**	**DNELs, DMELs, PNECs,**	**Risk management measure**
Human: Oral			
Human: Dermal			
Human: Eyes			
Human: Inhalation			
Environment: Water			
Environment: STP			
Environment: Sediment			
Environment: Air			
Environment: Soil			

The table below, taken from the earlier RIP 3.5-2, gives three examples illustrating how the ES, as described in the CSR provided by a manufacturer/importer, can differ from the actual utilisation at the downstream user level.

[9] http://guidance.echa.europa.eu/docs/guidance_document/du_en.pdf?vers=29_01_08

Parameter	Description in ES	Implementation at DU	Difference	Reason
Physical state of substance	Liquid	Powder	Qualitative	The substance behaves differently in liquid and solid particle form. This leads to different relevance of exposure routes for the powder form, which are not part of the ES received
Process / type of application	Brushing	Spray painting	Qualitative	Spraying leads to the formation of aerosols, which are usually not created during brushing. The exposure to aerosols needs to be assessed differently, since exposure to 'drops' is a different exposure route (inhalation) and risk management measures to protect the skin are different (gloves vs. overall)
Risk Management Measures (RMM)	Local ventilation extracts 70% of workplace emissions	Encapsulation of process releasing 5% to workplace	Quantitative	The RMM differs from the ES but the effect (workplace receives < 30%) is more efficient and does not change the exposure of other targets. The structure and algorithm of the ES communicated can be used.

If you purchase the same substance from different suppliers you may receive different ES. You should select the ES with the most stringent conditions of use (lowest use amounts, lowest frequency and duration of use, most efficient RMMs etc.).

3.6 Anticipate Authorisations and Restrictions

Watch out for chemicals that might be banned

Under REACH, **SVHC** could fall under the authorisation procedure. It is expected that about 1500 chemicals will be subject to authorisation in the future. Substances subject to authorisation will be listed in Annex XIV "LIST OF SUBSTANCES SUBJECT TO AUTHORISATION" of REACH. Prior to being listed in Annex XIV, they will be included on a Candidate List. These lists are today (June 2007) empty and will be filled in according to recommendations by Member States and the European Commission. The first candidate list[10] was published by the ECHA on 28 October 2008 and contained 15 substances. Further substances will be added to this list. The list for substances subject to authorisation (Annex XIV) is today (February 2009) still empty.

If a substance requires authorisation, an application must be made for each use of that substance. This process is completely independent of the registration process, meaning that a substance exempted from registration could be subjected to authorisation.

You or your supplier can apply for authorisation of your use of the substance. If the application for authorisation is not successful, your use of the substance must be phased out by a specified date (the 'sunset date').

The authorisation will be automatically granted if the risks are adequately controlled, which means that the risk management measures ensure an exposure level lower than the DNEL or the PNEC.

If the risks are not adequately controlled, or if the substance is a CMR without a threshold, a PBT or a vPvB, the authorisation can only be granted if there is no alternative (substitution) AND if the socio-economic benefits outweigh the risks.

REACH also contains restriction provisions for the manufacture, placing on the market or use of certain substances if these substances are found to pose an unacceptable risk that must be addressed at EU level. The Annex on Restrictions (Annex XVII "RESTRICTIONS ON THE MANUFACTURE, PLACING ON THE MARKET AND USE OF CERTAIN DANGEROUS SUBSTANCES, PREPARATIONS AND ARTICLES" of REACH) takes over the current marketing and use restrictions included in Directive 76/769/EEC. The restriction is designed as a "safety net" to manage risks that are not addressed by the other REACH processes. Proposals for restrictions will be prepared by Member States or by the ECHA upon request by the European Commission in the form of an Annex XV dossier.

[10] http://echa.europa.eu/chem_data/candidate_list_en.asp

Suppliers could as well, for economical reasons, decide to stop manufacturing a substance and/or a mixture, which implies that you will have to find substitutes for these substances and/or mixtures.

You should determine the substances and/or the mixtures that are critical to you and at risk, and for which you have substitutes. You should then start looking at the costs for implementing these substitutes.

3.7 Register substances that you import and/or manufacture

If you import substances on their own or in mixtures from outside the EU in quantities from 1 tonne per year, you will have to register these substances with the ECHA. The same applies if you manufacture a substance and/or a mixture.

Depending on the tonnage of the substance that you import and/or manufacture, different types of information concerning the substance are needed from you. For more information about the different information requirements, please refer to Annexes VII to XI of REACH.

3.8 Conduct the CSR yourself if you want to keep your use(s) confidential

If you do not want to make your use of a substance known to your supplier (for example for confidentiality reasons), you have the possibility to conduct the CSR for the substance for that specific use yourself. You need to conduct your own CSR if:

- your supplier is required to conduct a CSR (i.e. manufacturer/importer is above 10 tonnes/year);
- you use the substance differently from the uses communicated to you by your supplier;
- the substance requires a SDS.

The CSR will need to cover uses identified by the DU, including the use of the substance in the production of articles and consumer use of these articles. For the identified uses the CSR also has to cover waste management measures that the manufacturer or importer of the substance recommends to be implemented by the DU or consumer.

3.9 Participate in Substance Information Exchange Forum (SIEF)

In January 2009, the ECHA published on its website the list of names of the substances that have been pre-registered, together with the envisaged registration dates. All potential registrants of a same substance who have pre-registered will be part of a (SIEF) Substance

Exchange Forum, to share data for the purpose of registration. DU may participate in the SIEF. This can help them to ensure that their uses of a substance are covered in any ES being prepared for the purposes of registration. If a substance is very important for you, or if you fear that your use would not be registered, participating in the SIEF can be a good idea.

3.10 Distinguish between waste, raw materials and by-products

Article 2 (2) of REACH states 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** (waste is of course subject to strict rules under waste legislation).

However, if, through recovery operations, this waste is chemically modified, and a new substance, mixture or article is obtained, the provisions of the REACH regulation apply to this new substance, mixture or article. This is the case, for example, if plastic waste is submitted to a cracking process and new substances are generated for certain uses. This does not include purely mechanical recycling processes such as glass recycling, as the cullet is not chemically modified and no new substance is manufactured (grinding glass is not regarded as preparing a new substance). Accordingly, CPIV understands that internal glass recycling does not fall under the scope of REACH.

The situation for external glass recycling (recovered glass) will be clarified by the new EU Waste Framework Directive (WFD - Directive 2008/98/EC on waste and repealing certain directives). An EU Comitology committee has the task to clarify the criteria that need to be developed to determine when waste ceases to be waste. The Comitology procedure – Technical Adaptation Committee (TAC) – was mandated to start work from 12 December 2008 on the implementation of the Directive.

Whatever the decision of the committee, recycled glass will be exempted from registration for two reasons. Firstly, glass cullet is exempted under Article 2(7b) of the REACH Regulation as it is broken glass and glass is basically exempted under Annex V(11) of the REACH Regulation. Secondly, glass cullet is exempted under Article 2(7d) of REACH, which exempts substances that have undergone a recycling process and fulfill further conditions.

Annex V "*EXEMPTIONS FROM THE OBLIGATION TO REGISTER IN ACCORDANCE WITH ARTICLE 2(7)(b)*", point 5 states that: *"By-products are exempted from the obligation to register, unless they are imported or placed on the market"*. However, no definition of by-products is given in REACH. According to the "*common sense*" definition of by-products (residues), the glass industry buys or sells different by-products, for example filter dust, sludge from wastewater treatment, acids derived from surface treatment and slag from the steel industry.

The treatment of those materials may currently differ from Member State to Member State. For instance, some Member States consider blast furnace slag as a by-product. However, due to the WFD, which has to be implemented into national laws by 12 December 2010, these differences should disappear in the future. Article 5 (1) WFD defines that by-products result from a production process without being its primary aim. Further conditions are that further use has to be certain, the substance or object can be used directly without any further processing other than normal industrial practice, the substance or object is produced as an integral part of a production process and further use is lawful. This may not be the case for furnace slag because it will be granulated before being used, and may have certain additives added to make it usable and to have a positive economic value for other industries. The European Commission published a communication on waste and by-product[11].

[11] COM(2007) 59 final - COMMUNICATION FROM THE COMMISSION TO THE COUNCIL AND THE EUROPEAN PARLIAMENT on the Interpretative Communication on waste and by-products

4 Specific guidelines for producers of articles

4.1 Article 7 - Notify or register if necessary the substances in your articles

In some cases, substances present in articles must be registered or notified to the ECHA. This is covered by Article 7 "Registration and notification of substances in articles". The glass industry will generally not be concerned by registration, but may in some limited cases be concerned by notification.

1) You have to register any substance contained in the articles, if the substance is not yet registered for that use and if both of the following conditions are met:
   a) the substance is present in the articles in quantities over 1 tonne per producer or importer per year;
   b) the substance is intended to be released under normal or reasonably foreseeable conditions of use.
2) You have to notify the ECHA, if the substance is not yet registered for that use and if your article contains a SVHC and if all of the following conditions are met:
   a) the substance is present in those articles in quantities totalling over 1 tonne per producer or importer per year;
   b) the substance is present in those articles above a concentration of 0.1% weight by weight (w/w);
   c) you cannot exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal.

The provisions of Article 7 apply also to imported articles.

The concept of intended release has been clarified in the "Guidance on requirements for substances in articles"[12]. Generally, articles made of glass do not intentionally release substances.

[12] A release of substances from articles is intended when

- the release is essential for the end use function of the article (examples: release of ink from felt tip pens (function = writing, requires the release of the ink from the pen), release of detergents from cleaning wipes for glasses (function = cleaning, the release of detergents contributes to the cleaning function of the wipes)
- or the release contributes to a quality or minor function of the article (example: release of perfume from a perfumed eraser (function = to erase, added value / function for convenience = quality to smell good)

Notification will also be required only rarely for the glass industry, since glass itself is considered as a substance and this substance is not generally hazardous. Notification is much easier than registration. Only some basic information on the substance needs to be notified (identity, contact details of the producer or importer, identity and classification of the substance, and a brief description of the use(s) of the substance(s) in the articles, etc.).

After notification, the ECHA may decide to require producers or importers of articles to submit a registration, if the substance is released from the articles, and the release of the substance from the articles presents a risk to human health or the environment.

Moreover, when an article contains a SVHC at a concentration exceeding 0.1% (w/w) it is obligatory to inform the recipients of the article as a minimum about the chemical name of this substance and how the article can be safely used (Article 33 of REACH, see below).

4.2 How to measure the concentration of 0.1% weight by weight (w/w) of your article?

(This part is still under discussion and could be subject to modification. The main discussion point is to know whether the concentration of the SVHC is to be calculated compared to the whole weight of the article or compared to the weight of homogeneous parts. Some EU Member States have divergent views on this.).

Below, you will find an example taken from the ECHA "*Guidance on requirements for substances in articles*"[13] of May 2008 on how a concentration could be calculated. The basic idea is to compute the concentration of the substance w/w in the whole article (and not in the homogeneous parts as it is the case for the RoHS or the ELV directives). Generally, packaging is regarded as a separate article.

Formula:

$$\text{Conc. of SVHC}\,[\%] = \frac{\text{Amount of SVHC}\,[\text{g}]\cdot 100}{\text{Weight of the whole article}\,[\text{g}]}$$

Example 11 Calculation of a concentration

Example of calculating a concentration:

A chair consists of a wooden part and a plastic detail. The weight of the chair is 2.001 kg.

The wooden part of a chair contains 10 mg of a SVHC. The weight of the wooden part is 2 kg.

A plastic detail of the chair contains 1 mg of the same SVHC and the weight of the plastic detail is 1 g.

The SVHC concentration in the chair: $\frac{(10\cdot 10^{-3} + 1\cdot 10^{-3})\text{g}\cdot 100}{(2001)\text{g}}\% = 0.0005\%\,(\text{w/w})$, which is $< 0.1\%$.

Conclusion: The producer/importer has neither to communicate information down the supply chain according to Art. 33 nor to notify according to Article 7(2).

Conclusion: in this case, the producer/importer neither has to communicate information down the supply chain according to Article 33 "*Duty to communicate information on substances in articles* "(see below) nor to notify ECHA according to Article 7(2)

If you are above the threshold, you will need to notify the ECHA. If you are below the threshold, you do not need to do anything.

[13] http://guidance.echa.europa.eu/docs/guidance_document/articles_en.htm

4.3 *Article 33 "Duty to communicate information on substances in articles"*

Article 33 concerns the obligation to communicate information on the presence in articles of a SVHC exceeding a concentration of 0.1% w/w. Contrary to Article 7, this obligation is independent of the annual tonnage of the SVHC placed on the market.

- Part 1 of Article 33 of REACH requires suppliers of articles containing any SVHC exceeding a concentration of 0.1% w/w to provide their professional and industrial customers (not the public!) with sufficient information to allow safe use of the article. The minimum information to be provided is the name of the substance.

- Part 2 of Article 33 of REACH requires suppliers of articles containing any SVHC exceeding a concentration of 0.1% w/w, upon request by a consumer, to provide him with sufficient information in order to allow safe use of the article. The minimum information to provide is the name of the substance. The relevant information shall be provided, free of charge, within 45 days of receipt of the request.

As explained above, glass is regarded as a substance under REACH. The articles made by the glass industry consist of the substance glass, which is not on the "candidate list" and can be assumed never to be on it. Thus, there is no duty under Article 33 to communicate information on substances in articles for articles made entirely of glass.

5 Where to find more information?

GLASS ALLIANCE EUROPE is at your disposal for any questions you may have concerning REACH: info@glassallianceeurope.eu (+32 2 538 44 46)

The European Chemicals Agency (ECHA), DG Enterprise and Industry and DG Environment have their own websites on REACH:

http://echa.europa.eu/reach_en.asp
http://ec.europa.eu/enterprise/reach/index_en.htm
http://ec.europa.eu/environment/chemicals/reach/reach_intro.htm

REACH imposes on each Member State to create a National Helpdesk where industry can ask questions. To find the addresses and other contact details for all the national helpdesks, please look at the following ECHA webpage:

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

6 Annexes

6.1 Example of a data sheet for substances to keep inventories up to date

Substance sheet inventory

Substance name					
CAS Number					
EINECS/ELINCS number					
Other identification code					
Is the substance a Phase-in substance ?	**YES**	**NO**	***Important for registration deadline***		
Do you import by yourself this substance from outside Europe ?	**YES**	**NO**	***If yes, you have to register by yourself***		
Quantity used on site (in tonnes per year)					
Supplier (name of the company, contact person,…)					
Is the substance a dangerous substance ? (e.g. explosive, oxidising, flammable, toxic, corrosive, irritant,CMR, PBT,…)	**YES**	**NO**	***If yes, a SDS is needed. And if produced tonnage > 10 tonnes per year, a Chemical Safety Report is needed***		
Is my use of the substance adequately described in the CSR attached to the SDS ? (if tonnage produced is > 10 tonnes per year)	**YES**	**NO**	***If no, take urgently contact with your supplier***		
Has my supplier pre-registered?	**YES**	**NO**	***If no, take urgently contact with your supplier*** ***If yes, note pre-registration number***		
Has my supplier registered?	**YES**	**NO**	***If no, take urgently contact with your supplier*** ***If yes, note registration number***		
Is the SDS available ?	**YES**	**NO**	***If no, take urgently contact with your supplier***		
Are the Risk Management Measures described in the SDS in place ?	**YES**	**NO**	***If no, implement them immediately***		
Is the substance a substance of very high concern (CMR, PBT, vPvB, endocrine disrupting properties, or equivalent ?	**YES**	**NO**	***If yes, authorisation could be needed.***		
If yes, which?:	**CMR**	**PBT**	**vPvB**	**ENDOCRINE DISRUPTING PROPERTIES**	
Is the substance already listed on the Candidate list ?	**YES**	**NO**	***If yes, anticipate authorisation***		
Is the substance already listed on Annex XIV of REACH ?	**YES**	**NO**	***If yes, use of the substance is not allowed without autorisation***		
What is the Importance of the substance for your business ?	**Important**	**Not Important**			
Are there possible non-SVHC substitutes ?	**YES**	**NO**			
If yes, which ?					
Remarks					

6.2 Definitions and concepts used in the guidelines

6.2.1 Article

Article means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition. (Article 3 "*Definitions*").

To test whether your product is an article, ask yourself the question: If I provided my product to the customer in a different form, e.g. if I crushed the glass instead of selling it as a beaker, thin sheet or lens, would he be able to use it? If the answer is "no", you are selling an article.

6.2.2 Candidate List

The EU Member States may propose substances of high concern to be put on the so-called candidate list for potential integration on the list of substances requiring authorisation (Annex XIV). Listing of a substance on the candidate list does not mean that it will automatically be transferred to Annex XIV and hence subject to restrictions or requiring authorisation. However, listing on the candidate list means that a producer of any article containing this substance above 0.1% has to inform his industrial customer about the presence and inform consumers upon request (see Article 33).

6.2.3 Supplier of an article

Supplier of an article means any producer or importer of an article, distributor or other actor in the supply chain placing an article on the market. (Article 3 "*Definitions*")

6.2.4 Recipient of a substance or a mixture

Recipient of a substance or a mixture means a downstream user or a distributor being supplied with a substance or a mixture. (Article 3 "*Definitions*")

6.2.5 Recipient of an article

Recipient of an article means an industrial or professional user, or a distributor, being supplied with an article but does not include consumers. (Article 3 "*Definitions*")

6.2.6 Producer of an article

Producer of an article means any natural or legal person who makes or assembles an article within the Community. (Article 3 "*Definitions*")

6.2.7 Chemical Safety Reports (CSR)

The chemical safety report (CSR) for substances manufactured or imported in quantities starting at 10 tonnes documents the hazard classification of a substance and the assessment as to whether the substance is persistent, bioaccumulative and toxic (PBT) or very persistent and very bioacccumulative (vPvB). The CSR also describes exposure scenarios for specific uses of substances classified as dangerous and for PBT and vPvB substances.

6.2.8 Downstream user (DU)

Downstream user means any natural or legal person established within the Community, other than the manufacturer or the importer, who uses a substance, either on its own or in a mixture, in the course of his industrial or professional activities. A distributor or a consumer is not a downstream user. A re-importer exempted pursuant to Article 2(7)(c) shall be regarded as a downstream user. (Article 3 "*Definitions*")

6.2.9 Exposure scenarios (ES)

Exposure scenarios are sets of conditions that describe how substances are manufactured or used during their lifecycle and how the manufacturer or importer controls, or recommends to control exposures of humans and the environment. The exposure scenarios must include the appropriate risk management measures that, when properly implemented, ensure that the risks from the uses of the substance are adequately controlled. Exposure scenarios need to be developed to cover all "identified uses" which are the manufacturers' or importers' own uses, and uses which are made known to the manufacturer or importer by his downstream users and which the manufacturer or importer includes in his assessment. Relevant exposure scenarios will need to be annexed to the safety data sheets that will be supplied to downstream users and distributors. Substantial information on how to prepare exposure scenarios is given in the ECHA "Guidance for Downstream users"[14].

[14] http://guidance.echa.europa.eu/docs/guidance_document/du_en.htm

6.2.10 Identified use

Identified use means a use of a substance on its own or in a mixture, or a use of a mixture, that is intended by an actor in the supply chain or that is made known to him in writing by an immediate downstream user. (Article 3 "*Definitions*")

6.2.11 Placing on the market

Placing on the market means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market. (Article 3 "*Definitions*")

6.2.12 Preparation/Mixture

Preparation means a mixture or solution composed of two or more substances. (Article 3 "*Definitions*").

According to Article 57, the word preparation in the REACH Regulation will be changed to the word mixture in the new GHS-regulation. Regulation (EC) No. 1272/2008/EC (on classification, labelling and packaging of substances and mixtures, amending and repealing Directives 67/548/EEC and 1999/45/EC, and amending Regulation (EC) No 1907/2006) representing the EU implementation of the Globally Harmonised System (GHS) replaces the term "preparation" by the term "mixture" as of 20 January 2009.

To take this change into account, we have used the word "mixture" throughout this document.

6.2.13 Safety Data Sheets (SDS)

SDSs are 16-section summaries of information on the properties of hazardous substances and their safe use. They are a long-established instrument for transmitting safety information down the supply chain. Information on how to prepare a SDS can be found in *ANNEX II GUIDE TO THE COMPILATION OF SAFETY DATA SHEETS* of the REACH Regulation.

6.2.14 SIEF (Substance Information Exchange Forum)

All manufacturers and importers that have submitted information for the same phase-in substance become automatically participants in a SIEF. SIEF participants are subject to data sharing/data generation obligations under Article 30 et seq., and should submit a joint registration dossier regarding hazardous properties, classification and labelling and testing proposal(s). REACH. DU may participate in SIEFs.

6.2.15 Substance

Substance means a chemical element and its compounds in the natural state or obtained by any manufacturing process, including any additive necessary to preserve its stability and any impurity deriving from the process used, but excluding any solvent which may be separated without affecting the stability of the substance or changing its composition (Article 3 "*Definitions*").

6.2.16 Substances of very high concern (SVHC)

Substances of very high concern are substances meeting the following criteria:

a) **C**arcinogenic category 1 and 2;
b) **M**utagenic category 1 and 2; = CMR cat 1 and 2
c) Toxic for **r**eproduction category 1 and 2;
d) PBT: persistent, bioaccumulative and toxic;
e) vPvB: very persistent, very bioaccumulative;
f) Having endocrine disrupting properties or those having persistent, bioaccumulative and toxic properties or very persistent and very bioaccumulative properties, which do not fulfil the criteria of points (d) and (e) and which are identified as causing serious and irreversible effects on humans and the environment equivalent to the other categories above.

Substances that are included on the so-called Candidate List have been identified as Substances of Very High Concern (SVHC).
See http://echa.europa.eu/chem_data/candidate_list_table_en.asp for the current candidate list.

6.2.17 Use

Use means any processing, formulation, consumption, storage, keeping, treatment, filling into containers, transfer from one container to another, mixing, production of an article or any other utilisation. (Article 3 "*Definitions*")

6.2.18 The Registration Process

Manufacturers and importers of substances have a general obligation to submit a registration to the ECHA for each substance manufactured or imported in quantities of 1 tonne or more per year and per manufacturer/importer (legal entity). This applies to both hazardous and non-hazardous substances.

This obligation applies to substances as such and to substances in mixtures. Special registration obligations apply for substances in articles (e.g. manufactured goods such as cars, textiles, electronic chips). However, certain substances are exempted from registration under REACH (see scope of REACH).

Failure to register means that the substance cannot be manufactured, imported or put on the market in amounts of 1 ton/year or more.

6.2.19 Risk Management Measures

Risk Management Measures means measures designed to reduce or avoid direct and indirect exposure of humans (including workers and consumers) and the different environmental compartments to the substance during use and waste disposal and/or recycling.

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