

GUIDANCE DOCUMENT FOR IMPLEMENTING REACH IN PULP AND PAPER INDUSTRY



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1. INTRODUCTION

This guidance document for implementing REACH in the European pulp and paper industry was drafted by the CEPI REACH Issue Group. The document tries to present, in a concise way, the REACH requirements and impacts applicable for pulp and paper industry, as well as presenting tools, solutions on how to deal with them. If you have any further question on the content of this document, please contact Danny Croon, CEPI Environment & Process Manager at 0032 2 627 49 16 or d.croon@cepi.org.

REACH is the acronym for *Registration, Evaluation, Authorisation and Restriction of Chemicals*. The REACH Regulation requires manufacturers/importers of chemicals¹ to register all existing and future new substances with a new European Chemicals Agency located in Helsinki, Finland. REACH replaces over 40 existing Directives and Regulations. The aim of REACH is to improve the protection of human health and the environment through better and earlier identification of the properties of chemical substances. Manufacturers and importers will be required to gather information on the properties of their substances, which will be used in advising on safety measures, and to register the information in a central database. A regulation (as opposed to a directive) is applicable to all member states directly, without adaptation or implementation into national legislation.

Paper and Pulp industries generally do not perceive themselves as part of the Chemical community – but will have to observe the new policy in the capacity of being importers (into the EU)², manufacturers or downstream users of chemicals as well as producing articles containing chemicals, paper being such an article. Wood, pulp, recovered paper and clay are exempted from registration, but most other inputs, outputs and intermediates are affected in one way or another. The impact of REACH regarding our raw materials, purchased chemicals, internally produced chemicals, by-products and intermediates as well as our (final) products presented in this guidance represents our current best interpretation³ of the REACH Regulation. The document main focus is on thermomechanical pulp, chemothermomechanical pulp and kraft pulping. This guidance is a living document and will be updated when new important information, applicable to our industry, becomes available. Any update of this guidance will be communicated via the CEPI network.

Many EU Commission technical guidance documents for the implementation of REACH by European industries in general are being produced via the so-called REACH Implementation projects (RIPs). These documents will be found at <http://ecb.jrc.it/REACH>. The RIPs will be finalised by the end of 2007.

References within the text of this document refer to articles and annexes of the EU Regulation (EC) No. 1907/2006 of the European Parliament and of the Council from 18 December 2006 (REACH regulation).

¹ Chemicals are in REACH either called substances (on their own) or preparations. Many materials traditionally not perceived as chemicals (as cellulose, clay, gold etc.) are substances falling under the REACH Regulation.

² When the EEA countries of EFTA include REACH in the EEA agreement, Norway, Iceland, and Liechtenstein will be considered countries of origin inside EU. As for Switzerland, swiss authorities are at the present checking out how to handle the issue, avoiding new trade barriers and maintaining swiss standards.

³ CEPI takes no legal responsibility on this.



2. ROLES AND OBLIGATIONS OF PULP AND PAPER INDUSTRY IN REACH

Pulp and paper industry and converting companies have several different roles in REACH. The term “chemicals” can consist of one component (and possible solvents), called a substance, and a mixture of substances, called a preparation in REACH. Our companies can have one or more of the following roles:

1. Downstream users of “chemicals”

Downstream users of chemicals (e.g. sodium hydroxide, sodium chlorate) have to comply with the requirements of Safety Data Sheets and are advised to assist the manufacturers of chemicals in preparing exposure scenarios in certain cases. They also have to inform these manufacturers in case new properties for chemicals are revealed during the use.

2. Producers of articles

E.g. producer of different paper grades have to ensure that the articles do not contain substances of very high concern in concentrations each > 0.1 % (weight by weight).

3. Users and/or Importers of recovered paper:

following EU law, recovered paper is currently considered as waste and is outside the scope of REACH. In case recovered paper would not be any longer considered by EU law as waste, it falls under REACH. For more information on this, please see chapter 3 of this guidance (footnote on page 6).

4. Manufacturers of “chemicals”

Manufacturers of chemicals (e.g. crude tall oil, wood turpentine, bleaching chemicals) have a registration obligation. Registration is recommended to be done in consortia together with other companies to share the costs. For more information, please see chapter 3 pages 7 and 8.

5. Importers of “chemicals”

Importers of chemicals have a registration obligation, if chemicals are imported from any country outside the EU-27⁴

6. Importers of articles

Importers of articles (e.g. different paper grades) have to ensure that the articles do not contain substances of very high concern in concentrations each > 0.1 %. In case articles contain substances intended to be released (e.g. perfume, self-copying paper), such substances have to be registered.

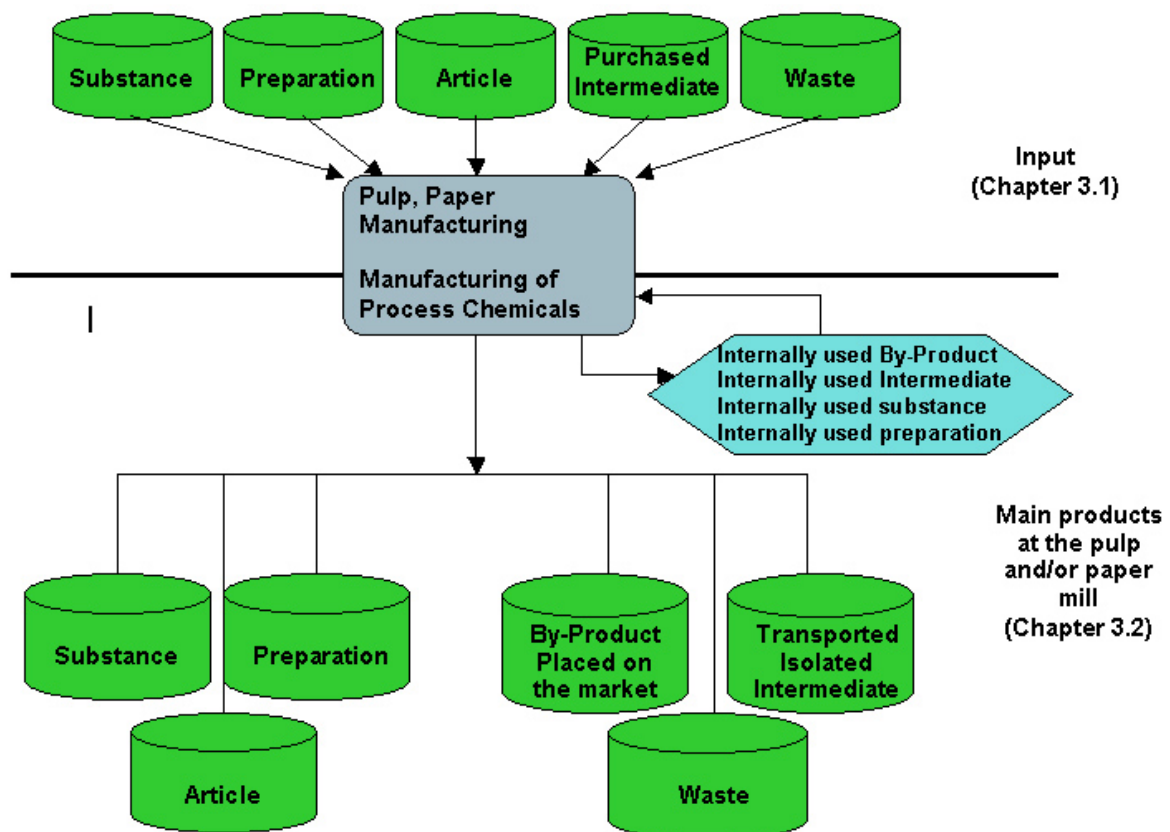
⁴ When the EEA countries of EFTA include REACH in the EEA agreement, Norway, Iceland, and Liechtenstein will be considered countries of origin inside EU. As for Switzerland, swiss authorities are at the present checking out how to handle the issue, avoiding new trade barriers and maintaining swiss standards.

3. DEFINITIONS AND IMPACT ON OUR MATERIALS

The impact of REACH regarding our raw materials, purchased chemicals, internally produced chemicals, by-products and intermediates as well as our (final) products presented below represents our best interpretation. The obligation for registration falls upon the legal entity responsible for manufacturing the substances regardless of who owns the site.

REACH does not cover the possible effects on human health of chemicals entering the diet from food contact materials and articles. Safety assessments of those chemicals by the European Food Safety Authority, specific to their use in food contact applications, will continue as before. However, the non food contact uses of those chemicals will be covered by REACH and therefore, its safety assessments and other requirements will also apply. The safety of food contact materials and the chemicals they contain is covered by EU Regulation 1935/2004⁵

To facilitate the understanding of this chapter, a flow chart of the pulp and papermaking processes has been included below; it also shows the outline of this chapter.



⁵ Of the European Parliament and of the Council of 27 October 2004 on materials and articles intended to come into contact with food

3.1. Input into the mill

3.1.1 Fibrous raw materials

- roundwood, wood chips:
No registration required because they are natural substances, not chemically modified and not classified as dangerous (*Annex V par. 8*).
- recovered paper:
According to the European Waste Directive, recovered paper is currently legally considered as waste and as such does not need to be registered⁶ (*Art. 2 par. 2*).
- Pulp:
Registration is not required for any type of pulp including recycled pulp and de-inked market pulp. These are natural substances, not chemically modified and not classified as dangerous (*cellulose pulp explicitly mentioned in Annex IV, pulps in general in Annex V par. 8*).

3.1.2 Chemicals and other ancillary materials

Most of the externally sourced chemicals require registration. This is the responsibility of the manufacturer/importer (=upstream suppliers to pulp and paper mills) of the chemicals (*Art. 6*).

The downstream user of the process chemical has also certain obligations (*Title V*); see Chapter 4 of this guidance.

- Pigments and fillers:
 - o Are mostly minerals⁷ and exempted from the registration obligation as they are natural substances, not chemically modified and not classified as dangerous (*Annex IV, Annex V par. 8*).
 - o If not exempted from registration, the manufacturer/importer is responsible for the registration (*Art. 6*).
- Polymeric paper additives (e.g. polymeric retention agents) are also exempted from registration (*Art. 2 par. 9*).
Note that polymeric paper additives are often supplied as a preparation with other constituents like stabilisers, dispersing agents, antioxidants etc. These other constituents requires registration by the manufacturer/importer in most cases.

⁶ The implementation of the European Waste Directive (EWD) might differ from Member State to Member State. In case a Member State considers what is defined as waste in the EWD as a non-waste, the legal implication of the REACH Regulation will need clarification.

⁷ Precipitated calcium carbonate (PCC): might be exempted from registration

- o as it is virtually the same substance as limestone (calcium carbonate) which is exempted from registration (listed in Annex IV);
- o as it can be regarded as a substance occurring in nature, not chemically modified and not classified as dangerous following the Dangerous Substances Directive (67/548/EEC).

The final interpretation needs to be done by the Commission.

- Biocide substances shall be regarded as being registered and the registration as completed for manufacture or import for the use in a biocidal product, if the biocide substances are covered by the Biocidal Product Directive (Directive 98/8/EC). (*Art. 15 par. 2*)
- Natural gas, liquified petroleum gas, process gases, crude oil, coke, coal are exempted from registration as these are substances that occur in nature and are not chemically modified (*Annex V par. 7*).
- Hydrogen, oxygen, noble gases and nitrogen are also exempted from registration (*Annex V par. 9*)

3.2 Main products at the pulp and/or paper mill

3.2.1 Pulp:

Registration is not required for any type of pulp including recycled pulp and de-inked market pulp. These are natural substances, not chemically modified and not classified as dangerous (*cellulose pulp explicitly mentioned in Annex IV, pulps in general in Annex V par. 8*).

3.2.2 Paper and board:

Paper and board are articles, whether it is made from fresh or recycled fibres. For the somewhat unlikely case that the concentration of any individual “substance of very high concern⁸” is present in the produced paper article above 0.1% weight by weight (i.e. 1000 parts per million) – the manufacturers will have to observe such levels and notify the substance to the European Chemicals Agency in case this threshold level is exceeded (*Art. 7 par. 2*).

Those that produce paper articles with intentional release of substances (e.g. perfume) – might have to register such substances – if not already registered for that use (*Art. 7 par. 1*).

3.2.3 Lignosulphonates:

Certain sulphite mills produces lignosulphonates, based on spent cooking liquor. The products are polymers in the form of various salts. How to handle these substances under REACH is at the present unclear. They were reported during the process of establishing ECOIN⁹, have been marketed for decades – but their provisional EINECS numbers have been delisted by the authorities - with the justification that they are “post reacted natural polymers”, and has no place on the EINECS list. The precursor for lignosulphonates is the natural polymer lignin, for which the monomer is hypothetical. Thus a registration of the monomer have little meaning. A joint solution for these substances has to be found by June 1st 2008.

⁸ These substances will be identified during the entire registration phase. The Agency shall make its first recommendation of priority substances to be included in Annex XIV (list of substances subject to authorisation) by 1 June 2009. The Agency shall make further recommendations at least every second year with a view to including further substances in Annex XIV. Basically it concerns the substances that are CMR's cat. 1 or 2, PBT, vPvB and some others (*Articles 57 and 58*).

⁹ Is the European Communities' Core Inventory; 1/3 of the EINECS database originates from ECOIN

3.2.4 Chemicals produced on-site for internal use

- Mixing of purchased chemicals
When substances and/or preparations are only mixed or diluted and no new substances are manufactured, no registration is required e.g. coating color mixture, defoamers.
- Precipitated calcium carbonate (PCC): might be exempted from registration
 - o as it is virtually the same substance as limestone (calcium carbonate) which is exempted from registration (listed in Annex IV);
 - o as it can be regarded as a substance occurring in nature, not chemically modified and not classified as dangerous following the Dangerous Substances Directive (67/548/EEC).

The final interpretation needs to be done by the Commission.

- Bleaching chemicals
 - Dithionite, chlorine dioxide and ozone, when produced on site, are intermediates. If they are non-isolated intermediates, no registration is required. If they are isolated (e.g. storage), a limited registration (*Art. 2 par. 8; Art. 17 & 18*) is required.
- De-inking chemicals
 - e.g. fatty acid soaps, if produced on site, are substances and needs full registration.
- Retention aid, flocculation chemicals
 - e.g. aluminium sulphate if produced on site is a substance and need full registration.
- Cooking chemicals
 - e.g. white liquor and sulphite cooking liquor are substances and require full registration¹⁰.

3.2.5 By- products and isolated intermediates produced on site

- Black liquor and red liquor are both by-products and need full registration if put on the market (supplied to third party)¹¹. Since this occurs occasionally a pre-registration followed by the registration is recommended (*Annex V paragraph 5*).
- Green liquor is an isolated intermediate and needs a limited registration (*Art. 2 par. 8; Art. 17 & 18*); therefore pre-registration is needed.
- Lime mud ("mesa") might be exempted as calcium carbonate (*limestone see Annex IV*) provided same hazardous profile.

¹⁰ Note that white liquor might be mixed with other substances prior to the actual cooking; substances that might be imported (e.g. anthraquinone) or made at the mill (e.g. polysulphides). If you are the importer, manufacturer of these substances, you must register them.

¹¹ In case the black liquor is only delivered to other mills in cases of irregularities (e.g. shut downs, lack of capacity, maintenance etc.), there is the possibility that the authorities may treat that shipment as waste. Waste is outside the scope of REACH.



- Tall oil soap is a by-product and need to be registered only in case it is put on the market (*Annex V paragraph 5*); therefore pre-registration is needed.
- Crude Tall oil is a by-product and need to be registered only in case it is put on the market (*Annex V paragraph 5*); therefore pre-registration is needed.
- Wood turpentine is a by-product and need to be registered only in case it is put on the market (*Annex V paragraph 5*); therefore pre-registration is needed.

Annex IV of the REACH Regulation (list of substances exempted from the obligation to register) will be reviewed by the EU Chemicals Agency and Commission by 1st June 2008 and the outcome will be published. At that stage, CEPI will make another attempt to have the above listed by-products / intermediates included in Annex IV. Meanwhile and this to be on the safe side, pre-registration of all the above mentioned by-products / intermediates is needed.

In summary:

- By-products do not need to be registered unless they are imported or placed on the market themselves. In case you import by-products or manufacture by-products and make them available to a 3rd party, you need to do full registration (*Annex V, par. 5*).
- Isolated intermediates and transported isolated intermediates require limited registration (*Art. 2 par. 8; Art. 17 & 18*).
- As far as we know, all our by-products and intermediates are phase-in substances (definition see Chapter 6 page 16 of this guidance) so pre-registration is possible (see also Chapter 5 of this guidance pages 14, 15).

3.2.6 Process waste:

- Ash, sludge, dregs and any other material which is waste, according to the European Waste Directive, does not need to be registered¹². Waste is exempted from the entire scope of REACH.
- Saw dust and bark does not need registration since they are natural substances, not chemically modified and not classified as dangerous (*Annex V par. 8*).

A more extensive list with examples and best interpretations on process chemicals, produced on-site, supplied process chemicals and additives for pulp, paper production and auxiliary systems as well as by-products and waste will soon be released by CEPI¹³.

¹² The implementation of the European Waste Directive (EWD) might differ from Member State to Member State. In case a Member State considers what is defined as waste in the EWD as a non-waste, the legal implication of the REACH Regulation will need clarification.

¹³ You will be informed on this by your national association.

4. REQUIREMENTS FOR DOWNSTREAM USERS OF CHEMICALS

Pulp and Paper manufacturers and paper converters are in most cases not manufacturers/importers of chemicals but Downstream Users (DUs) of them.

(Note that if you are the importer of substances or preparations into the EU you have obligations under REACH as if you are the manufacturer of these substances or preparations. Note especially if you import a polymer, or a preparation containing a polymer, you may have registration obligations for some of the monomers, although the polymeric substance itself is exempted from registration)

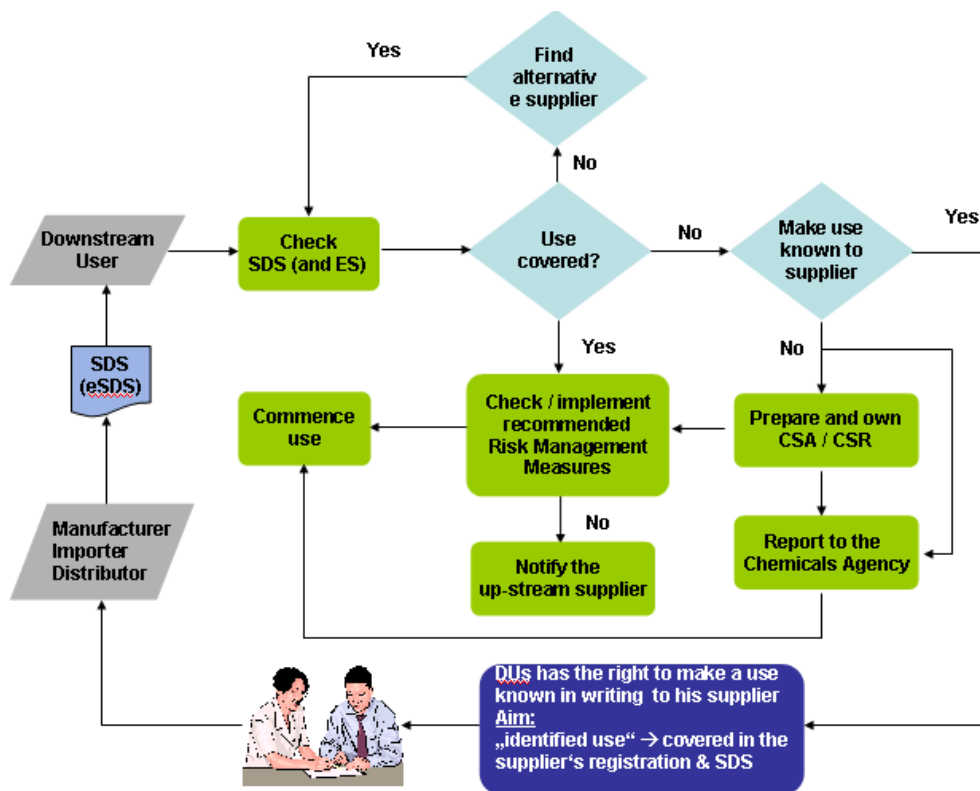


Figure 1: flowchart outlining Downstream User requirements

Mills (as DUs) should ensure that their use of chemical substances is made known as an *identified use* to his upstream suppliers and that the use is included in the manufacturers registration dossier. REACH gives DU's the right to inform manufacturers about their use in writing (*Article 3 definition of intended use + Art 37*). The manufacturer/importer is obliged to include this in the Chemical Safety Assessment (CSA) and Chemical Safety Report (CSR) or justify in writing to the informant why he has not accepted it as an identified use. If a mill (DUs) for some reason want to keep the use confidential, it needs to make the CSA and CSR itself and notify this to the EU Chemicals Agency.

It is suggested that pulp and paper mills should as early as possible inform their suppliers in writing about their use. This can be done in a fairly simple way (an example letter is included in **Annex A** of this guidance). It is also important to know whether the supplier will be able to supply the same chemicals in the future and questions related to this can also be included in the early communications with suppliers.



It is legally binding for DUs to apply the operational conditions and Risk Management Measures (RMM) recommended in the Safety Data Sheets (SDS) (*Art. 37 par. 5*). The DU should also communicate to the supplier any information that might call into question the relevance of the RMMs recommended in the SDS (*Art. 34 b*).

The DU has to inform the supplier of any new information on the hazardous properties for supplied substances that he becomes aware of (*Art. 34 a*) and must also report to the European Chemicals Agency if his classification of a substance is different from that of the supplier (if using > 1 t/y of that substance) (*Art. 38 par. 4*). DUs also have to comply with any restrictions on the use of substances and preparations.

For substances classified as dangerous (according to Directive 67/548/EEC) and produced in quantities above 10 tonnes the manufacturers are obliged to make a more extensive safety assessment involving the development of exposure scenarios and exposure assessment for all identified uses. Manufacturers will normally need to request data from DUs on their use conditions for such substances to support this assessment and DUs are obliged to provide this.

CEPI has together with the European Paper Chemicals Group (EPCG) developed a concept for the development of a generic exposure scenario for the exposure assessment of chemicals used in pulp and paper making and converting. The concept is based on a checklist with the minimum data required by manufacturers (in few cases they may need additional data to do a more specific assessment for our industry). More information on this is to be found in **Annex B** of this guidance document. The exposure assessment for classified substances will be communicated to DUs in an annex to the SDS (called extended Safety Data Sheet). The DU has an obligation to check that that his use is covered and that he complies with the use conditions described in the SDS. If not, the DU has the right to provide data on use and exposure to the manufacturer so that the exposure scenario and SDS can be updated accordingly. *Note that data on use conditions only need to be provided when suppliers specifically asks for it.*

4.1. Inventory of purchased/imported chemicals to prepare for REACH

Annex C of this guidance is a proposal for how pulp and paper mills can organise an inventory of purchased chemicals.

Note that this is an inventory for internal use only and is not something that needs to be communicated externally. Such an inventory will help the mills to get an overview of the potential implications of REACH and to support them in fulfilling their Downstream User obligations. It will also help to reveal any potential problems for purchased chemicals when REACH enters into force.

The inventory probably needs to be divided into several steps; one first step (Step 1) before REACH enters into force or in the early stages of REACH implementation. As REACH implementation is progressing the table can be extended to take care of additional information and requirements which only becomes available when registration and communication in the supply chain has started (Step 2).

Please notice that normally, your supplier (the manufacturer) will do this exercise as well. Each mill needs to check its own situation. For imported substances it can be good to be able to list the agent, the importer as well as the manufacturer.

5. REQUIREMENTS FOR MANUFACTURERS AND IMPORTERS OF CHEMICALS

5.1 Registration

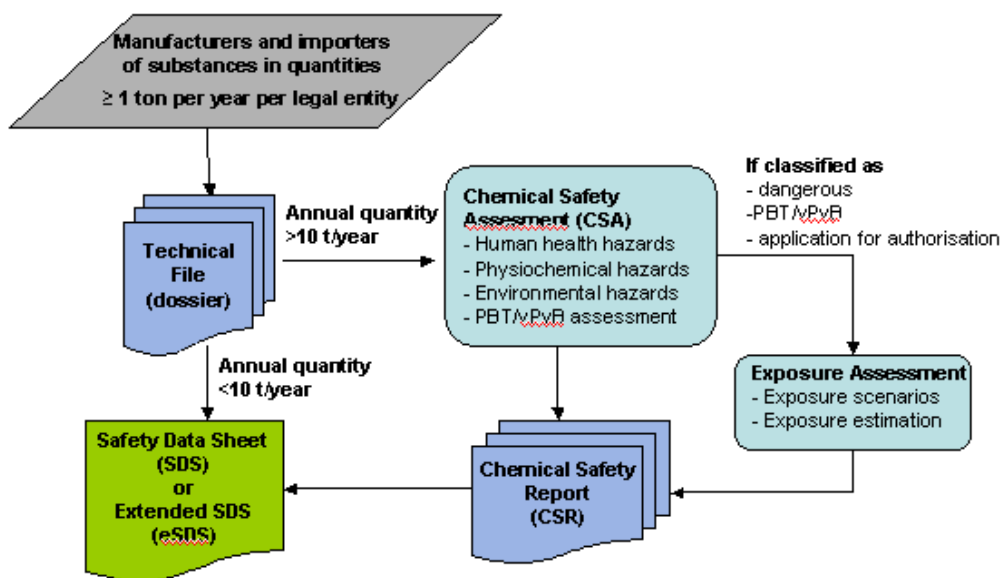


Figure 2: flowchart outlining registration

There are phase-in substances and non phase-in substances. Phase-in substances are listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). Non phase-in substances can be of two types. They are either completely new substances that have neither been used nor registered and marketed before the entry of force of the REACH Regulation or they are substances put on the EU market after 1981 and listed in the European List of Notified Chemical Substances (ELINCS). *Only completely new substances that have neither been used nor registered and marketed before the entry of force of the REACH Regulation need to be registered before they can be used in a manufacturing process.* ELINCS substances are considered as already being registered. There are different rules for phase-in and non-phase-in substances. The start of the registration of non-phase-in substances according to REACH requirements is 1st June 2008. For phase-in substances if pre-registered, there is a delay for registration of 3.5, 6 or 11 years – starting from 1st June 2008 - as indicated below in the registration timetable, depending on the hazard and annual production tonnage per legal entity.

Information for registration purposes: technical dossier and chemical safety report see **Annex D** of this guidance.

There are certain substances that are exempted from registration under REACH. These are: Annex IV and Annex V substances as well as the majority of the cases mentioned under Article 2. Annex IV and Annex V will be reviewed by the 1st June 2008.

Pre-registration & Registration timetable for phase - in substances

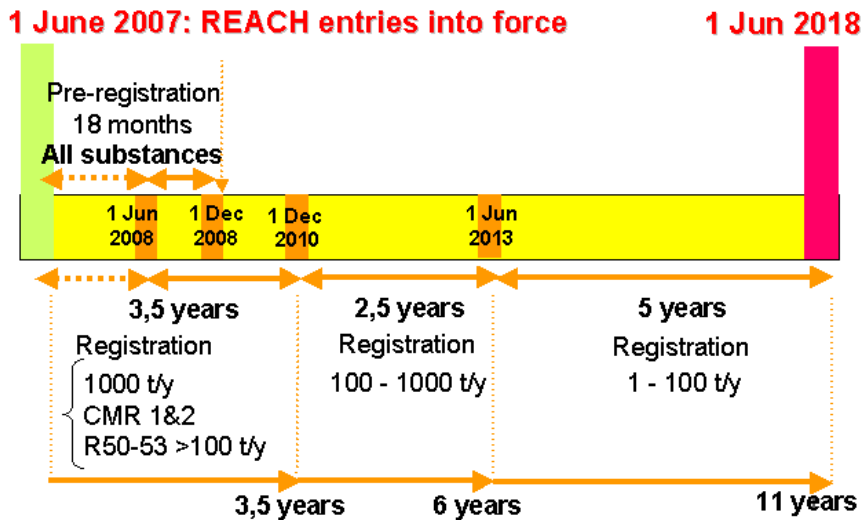


Figure 3: Registration timetable for phase-in substances

5.2 Pre-registration

The pre-registration of phase-in substances must take place between the 1st of June and the 1st of December 2008 (*Art. 28 par. 2*).

One single pre-registration should include amongst others (*Art. 28 par. 1*):

- The name of the substance (including EINECS and CAS No, if available);
- The name and address of the potential registrant (or third party);
- The envisaged deadline for registration and the tonnage band.

On the 1st of January 2009, the European Chemicals Agency will publish on their website the list of pre-registered substances (*Art. 28 par. 4*). Then, the European Chemicals Agency will establish the so-called Substance Identification Exchange Forum (**SIEF**) – containing all manufacturers and importers who have pre-registered the same substance to the European Chemicals Agency (*Art. 29 par. 1*). The aim of the SIEF is just to exchange information on the substance to minimise duplication of tests and to agree on classification and labelling (*Art. 29 par. 2*). The SIEF itself does not deal with the registration of the substance. The SIEF is operational until 1 June 2018 (*Art. 29 par. 3*).

Via the EU Chemicals Agency, downstream users and “third parties” can take part in the SIEF (*Art. 28 par. 5*) and provide information to it.

REACH requires multiple registrants for the same substance to submit their data jointly via for instance the formation of a consortium (*Art. 11 par. 1*). Some information must be submitted separately (e.g. identity, use and exposure information) to avoid sharing information in breach of EU competition rules (*Art. 25*). Companies can “opt-out” of joint registrations if they can justify either disproportionate costs, disclosure of commercial sensitive information or disagreement with lead registrant on selection of information (*Art.*



11 par. 3). Registrants can also be represented by “third party” (the identity of the registrant represented by this third party would not be known to the other registrants) (Art. 4).

5.3 The formation of consortia for registration

The consortium as such is not described in REACH. It is governed by private law and left to industry’s initiative. In many cases, it is the most suitable response to REACH single registration requirements and this because of the economic interest to share registration costs (reduce registration costs).

It was decided by the CEPI Board on 4 October 2006 to recommend the formation of consortia - which are voluntary – for joint registration and/or data sharing of our industry’s by-products and intermediates if the companies recognise a process related need and/or a financial interest to do so. Via the consortia, potential other manufacturers/importers of our industry’s by-products and intermediates will be identified. These manufacturers/importers could also join the consortia. It is also important to have a good relationship with the relevant SIEF’s and this to exchange information and agree on classification and labelling.

In a consortium, special emphasis will be put on confidentiality issues in order not to reveal any company specific information and to be fully compliant with EU competition law. It is believed that in the worst case scenario, the test data of a substance in the highest tonnage band (> 1000 tonnes per year and per legal entity) will cost 1,000,000 Euro and in the next tonnage band (100 – 1000 t/a) it will cost approximately 400,000 Euro. In a consortium, costs would be shared based on production volumes. A consortium is usually created as a “task force”. CEPI will deal with the co-ordination for the formation of consortia for the interested companies. The consortia management and registration itself will be outsourced.



6. RELEVANT DEFINITIONS IN THE REACH REGULATION

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

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

Article: means an object which during production is given a special shape, surface or design which determines its function to a greater degree than does its chemical composition;

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

Exposure scenario: means the set of conditions, including operational conditions and risk management measures, that describe how the substance is manufactured or used during its life-cycle and how the manufacturer or importer controls, or recommends downstream users to control, exposures of humans and the environment. These exposure scenarios may cover one specific process or use or several processes or uses as appropriate;

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

Import¹⁴: means the physical introduction into the customs territory of the Community;

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

Intermediate: means a substance that is manufactured for and consumed in or used for chemical processing in order to be transformed into another substance (hereinafter referred to as "synthesis"):

- (a) *Non-isolated intermediate*: means an intermediate that during synthesis is not intentionally removed (except for sampling) from the equipment in which the synthesis takes place. Such equipment includes the reaction vessel, its ancillary equipment, and any equipment through which the substance(s) pass(es) during a continuous flow or batch process as well as the pipework for transfer from one vessel to another for the purpose of the next reaction step, but it excludes tanks or other vessels in which the substance(s) are stored after the manufacture;
- (b) *on-site isolated intermediate*: means an intermediate not meeting the criteria of a non-isolated intermediate and where the manufacture of the intermediate and the synthesis of (an)other substance(s) from that intermediate take place on the same site, operated by one or more legal entities;

¹⁴ When the EEA countries of EFTA include REACH in the EEA agreement, Norway, Iceland, and Liechtenstein will be considered countries of origin inside EU. As for Switzerland, swiss authorities are at the present checking out how to handle the issue, avoiding new trade barriers and maintaining swiss standards.



(c) *transported isolated intermediate*: means an intermediate not meeting the criteria of a non-isolated intermediate and transported between or supplied to other sites;

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

Not chemically modified substance: means a substance whose chemical structure remains unchanged, even if it has undergone a chemical process or treatment, or a physical mineralogical transformation, for instance to remove impurities;

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

- (a) It is listed in the European Inventory of Existing Commercial Chemical Substances (EINECS¹⁵);
- (b) It was manufactured in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, but not placed on the market by the manufacturer or importer, at least once in the 15 years before the entry into force of this Regulation, provided the manufacturer or importer has documentary evidence of this;
- (c) It was placed on the market in the Community, or in the countries acceding to the European Union on 1 January 1995 or on 1 May 2004, before entry into force of this Regulation by the manufacturer or importer and was considered as having been notified in accordance with the first indent of Article 8(1) of Directive 67/548/EEC but does not meet the definition of a polymer as set out in this Regulation, provided the manufacturer or importer has documentary evidence of this;

Placing on the market: means supplying or making available, whether in return for payment or free of charge, to a third party. Import shall be deemed to be placing on the market;

Polymer: means a substance consisting of molecules characterised by the sequence of one or more types of monomer units. Such molecules must be distributed over a range of molecular weights wherein differences in the molecular weight are primarily attributable to differences in the number of monomer units. A polymer comprises the following:

- a) A simple weight majority of molecules containing at least three monomer units which are covalently bound to at least one other monomer unit or other reactant;
- b) Less than a simple weight majority of molecules of the same molecular weight.

In the context of this definition a “monomer unit” means the reacted form of a monomer substance in a polymer;

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

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

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

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

¹⁵ EINECS substances are phase-in substances. ELINCS substances are substances to which the REACH Regulation directly applies and are as such non phase-in substances.



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

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

6.1. Definitions from other REACH related documents

The definitions below are relevant for this guidance and are either provided by CEFIC or either made by the CEPI REACH Implementation Issue Group

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

Chemicals: substances on their own or in preparations. *(Definition provided by REACH Implementation Issue Group).*

Evaluation: there are 2 types of evaluation

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

Legal entity: could be one or more mills. Seek legal advice if needed. *(Definition provided by REACH Implementation Issue Group).*

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

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

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



7. ABBREVIATIONS USED

CAS: Chemical Abstract Service number

CEFIC: European Chemical Industry Council

CEPI: Confederation of European Paper Industries

CMR: Carcinogenic, Mutagenic or toxic to Reproduction, category 1 and 2

CSA: Chemical Safety Assessment

CSR: Chemical Safety Report

DU: Downstream User

DSD: Dangerous Substances Directive

ECB: European Chemicals Bureau

ECOIN: European Communities' Core Inventory

EEA: European Economic Area

EFTA: European Free Trade Area

EINECS: European Inventory of Existing Commercial Chemical Substances

ELINCS: European List of Notified Chemical Substances

EPCG: European Paper Chemicals Group

ES: Exposure Scenario

i.m.: indirect measurements

IUPAC: International Union of Pure and Applied Chemistry

n.a.: not available

PBT: Persistent, Bioaccumulative, Toxic

p.p.m.: parts per million

(Q)SAR: Quantitative Structure Activity Relationship

REACH: Registration, Evaluation, Authorisation and Restriction of Chemicals

RMM: Risk Management Measures (e.g. personal protective equipment)

SIEF: Substance Identification Exchange Forum



(e)SDS: (extended) Safety Data Sheet

s.s.d.: specific substance data

UEM: Use and Exposure Matrix

VCI: German Chemical Industry

vPvB: very Persistent and very Bio-accumulative

w/w: weight by weight



ANNEX A

Example letter to upstream suppliers on intended use¹⁶ and other relevant questions

To whom it may concern

REACH, the Registration, Evaluation, Authorisation and Restriction of Chemicals Regulation is due to enter into force on 1st of June 2007. As the Regulation presents an important challenge to supply chain management, companies are now preparing for compliance.

Use information

“Company name” is a purchaser of chemical substances and/or preparations from you. According to REACH it is apparent that downstream users have the right to notify their suppliers (in writing) of the use of the purchased products.

“Company name” would like to confirm that all products supplied by you are used in Industrial Processes namely the manufacturing of pulp, paper and paper products.

In the papermaking process only products referred to as functional or process chemicals are consumed directly in the production of paper and paper products.

Your products are ... (choose one alternative in table 1, see next page)

The expected exposure to individuals working on site is primarily via skin contact or inhalation. Ingestion of the products is always possibility, but we view that as an incident; this will not occur during normal use.

Questions to our suppliers

We are sure that you are aware of REACH and its potential implications. As REACH requires a substance-by-substance approach to implementation, we would also like to ask if you could provide us with answers to the following questions:

Q1. *Are there any substances within the products supplied to us considered of “high concern” according to the REACH definition and that may be subject to Authorisation? If so, which products would this affect?*

We need this information to help us plan ahead and to anticipate any problems as REACH comes into force.

Q2. *Are you able to reassure us that each of the substances that you supply to us (individually, as part of a preparation or to be intentionally released from an article), are going to be registered by yourself or another company further up the supply chain?*

Is there a reason to believe that our use of the substances you supply will not be incorporated in the registration dossier? We request you to notify us in due time if this would be the case

We need this information to see if we need to make specific use notifications under REACH

¹⁶ Reflects our interpretation on how detailed a mill shall describe its use to his supplier.



Q3. For which of the substances/preparations supplied to us do you anticipate needing our input to develop Exposure Scenarios and when will this process begin?

We need this information so that we can start any necessary investigations.

Q4. Are you able to reassure us that as a result of REACH, the products that you supply to us are not at risk of reformulation or withdrawal from the market?

We need this information so that we can plan any necessary formulation changes to maintain production.

We realise you may not be able to answer these questions directly and might need to refer in turn to your suppliers, especially if you yourself are not responsible for a substance's registration. If this is the case please let us know when you expect a response to be provided

Yours sincerely

Table 1 - Alternatives for different uses

Alt 1	.. used as functional products, used directly in the pulp and papermaking process resulting in inclusion into the pulp and paper matrix. As such there is expected to be losses to the environment in the normal use of these products due to a proportion staying in the waste water and passing through our effluent treatment plant. Solid waste from this plant is sent to landfill/combusted. The majority of the product is expected to be retained in the paper article and is not expected to be released during normal use of that article.
Alt 2	.. used as maintenance products. As such there are no losses to the water environment in the normal use of these products.
Alt 3	.. used as cleaning products in ancillary applications e.g. As such there is expected to be losses to the environment in the normal use of these products due to being washed into the municipal water treatment plant or due to the product evaporating during normal use if solvents are included.
Alt 4	.. used as lubrication, surface treatment of machines or gluing products in ancillary applications and around the process. As such there is expected to be losses to the environment in the normal use of these products due to the product evaporating during normal use if solvents are in the formulation. Lubrications could incur minor losses through the effluent plant to the river/lake/sea. The effluent treatment plant discharges water directly to the river/lake/sea after treatment and solid mass is sent to landfill/combusted.
Alt 5	.. used as process enhancing products used in the papermaking process. As such there is expected to be losses to the environment in the normal use of these products due to a proportion of unreacted chemical staying in the waste water and passing through our effluent treatment plant. Solid waste from this plant is sent to landfill/combusted. The majority of the product is expected to be reacted during the process, which in turn will be diluted and pass out through the effluent plant.
Alt.6	.. aerosols used throughout the site. As such there is expected to be losses to the environment in the normal use of these products due to the product escaping to atmosphere during normal use.

Alt. 7	<p>.. gases used throughout the site, of which some are burned and some are used to evacuate enclosed areas.</p> <p>As such there is expected to be losses to the environment in the normal use of these products due to the product, or its bi-products escaping to atmosphere during normal use.</p>
Alt 8	<p>.. used as part of articles with the intention to be released.</p> <p>As such there will be losses to the environment during the normal use of the product a due to the product escaping to atmosphere during normal use.</p> <p>Users of the article may experience exposure from inhalation or through skin contact.</p>



ANNEX B

Checklist for exposure scenario model for substances used¹⁷ in pulp and paper production and converting

Tick the appropriate box unless otherwise specified

= guidance on this question available

**All data should be given
for one production unit,
i.e. a mill or plant,**

**Identity of production
unit:**

Contact person:

Date:

¹⁷ Reflects our interpretation on how detailed a mill shall describe its use to his supplier.



1. Commercial name of traded chemical product:

Supplier:

Use (e.g. functional additive):

2. Field of application?

-	Industrial	-	<input type="text"/>
-	Professional		<input type="text"/>
-	Consumer		<input type="text"/>

3. Annual quantity used per year

Tonnes /
Year

4. Is the chemical product intended to be part of the final paper product/final product?

Yes No

5. Production of paper, containing the chemical product considered

(if the answer in question 3 is "no" this question does not need to be answered)

Tonnes /
Year



6. Substance retention to the fiber/paper/final paper product

Name of substance(s)	Calculated / Measured %	Estimated %	Unknown

7. Number of days in operation per year, using this chemical product?

8. What are the possible exposure routes during normal operation?

If there is a possibility of exposure what is the estimated frequency / duration of the exposure?



- Human exposure

	oral	dermal (skin contact)	inhalative
None			
Short-term			
Long-term		-	

- Environmental exposure

	water	air	soil
None			
Short-term			
Long-term			

Comments:



9. Are the Risk Management Measures mentioned in the Safety Data Sheet implemented?

Yes No

List any deviations from the Risk Management Measures given in the Safety Data Sheet?

(i.e any additional measures implemented or reduced level of implemented measures as well as justify these deviations listed).

10. Are there any monitoring methods and data available ?

	Yes		Result (Conc.)	Method	No
	ssd	im			
Human					
Water					
Air					
Soil					

ssd: specific substance data / im: indirect measurements (e.g. COD)

11. Effluent data

a) Flow output from waste water treatment plant (wwtp)

Calculated	[m ³ /h]	Estimated	[m ³ /h]
------------	---------------------	-----------	---------------------

b) Flow rate of receiving water

Calculated	[m ³ /h]	Estimated	[m ³ /h]
------------	---------------------	-----------	---------------------

12. How is sludge from waste water treatment plant treated?

Incineration
 Sludge to land
 Landfill
 Other industries (bricks,...)

	Type of sludge

13. Disposal of waste that includes the chemical product?

Land filling
 Incineration
 Recovery

Yes	Specify the source	No



De-inking sludge
Land construction
Other

14. Treatment of exhausted gases from incineration?

Yes No

15. Treatment of exhausted gases from drying section of machines?

Yes No

16. Any additional comments (if any):

Guidance for completing ANNEX B

For the questions highlighted in yellow in the checklist, clarification is given here below.

A checklist has been developed with questions regarding a chemical product that you use. The chemical product may contain one or more chemical substances (in case of a preparation).

The checklist can be filled in for a single substance (if the necessary information is available) or for a complex chemical product i.e. a preparation.

It is important that you describe the use, exposure and Risk Reduction Measures as they are at your site. For example, do not copy personal protective equipment listed in the safety data sheet, but instead, describe what people really use at your site. Information from real life is invaluable in order to secure the availability of safety data sheets that really fit our purposes.

Question 1: always complete the commercial name of the traded chemical product, supplier and use (e.g. functional additive). The use is very helpful for assessing the exposure.

Note that since data will be asked for by the supplier, the supplier should normally give the name of the chemical product (substance or preparation) for which he needs information.

Question 4: include your own assessment of whether the chemical will end up in the paper or not. Typical examples of products designed to be retained in the paper are sizing agents, wet strength resins, dry strength resins, adhesives and printing inks. Typical examples of products used but NOT retained in the paper are defoamers and biocides.

Question 6: retention defines how much of a substance that ends up in the paper (% of dosage). A distinction is made between calculated/measured and estimated retention to the fiber/paper. Please complete as appropriate. Use best estimate if no data are available. The column “name substance(s)” needs to be completed by the supplier if he wants information for specific substances in a preparation otherwise data should be given for the preparation itself. In case the retention to the fiber/paper is unknown, tick the column unknown.

Question 8: indicate (tick) the exposure routes that are possible (as if no risk management measures are in place e.g. personal protective equipment). Note that both possible human and environmental exposure should be given. Comments can be added: e.g. the exposure is only applicable during maintenance activities.



What is to be understood under:

A. Human exposure

Short-term:

Industrial Inhalative exposure (is in case of aerosol, dust formation or volatile substances)

- a) 7 x ½ hour per week (1/2 hour per day, e.g. sample taking) or
- b) 1 x 4 hours per week (e.g. in maintenance activities) (does not apply for substances with log pow higher than 3)

Industrial Dermal (skin contact) exposure

- a) 7 x ½ hour per week, or
- b) 1 x 4 hours per week

Industrial Oral exposure

Due to industrial hygiene measures, not foreseeable in normal use.

Long-term: Duration/frequency > short-term (according to above definition). In the given context, long-term industrial oral exposure does not need to be examined because it is not relevant.

B. Environmental exposure

Short-term: 1/28 d

Long-term/Repeated: > 1/28d

Question 9: this question is to verify whether the Risk Management Measures (amongst others personal protective equipment) recommended in the safety data sheet are in place. “Deviation” means either additional Risk Management Measures or that not all Risk Management Measures are applied. If that is the case, please describe the “deviation”.

Question 10: Write down in case of specific substance data (s.s.d.) the name of the substance and in case of indirect measurement (i.m.), which i.m. (e.g. COD). In case there are data available, please also write down the monitoring method. If no monitoring data are available tick the “No” box



Question 11: For each subquestion, a distinction is made between calculated (= measured) and estimated. Please complete as appropriate. Use best estimate if no data are available.

The receiving water is a body of water. Flow rate of receiving water can only be given for streams and rivers, not for lakes neither for oceans where flow rate is zero.

Question 12: Type of sludge: can be for instance biological, chemical. So when you have ticked the box how the sludge from waste water treatment plant is treated, please also specify the type of sludge.

Question 13: tick either the box yes or no for the different ways (e.g. land filling) the waste is treated. In case of yes, please also specify the source/type of the waste e.g. reject from filters, broke, used chemical containers, used dosing equipment, pulping/bleaching fractions etc. Note that you only have to include waste that could possibly contain the actual chemical product.

Question 16: this is for writing down any additional comments (if any) to the information provided.

ANNEX C

Inventory of purchased chemicals

Step 1

Product	SDS	Substance/ Preparation	Composition <i>Known / Unknown</i>	CAS	EINECS/ ELINCS	Use	Confidential	Alternative	Critical	Annual tonnage ¹⁸	Supplier	Country of origin	Subject to auth.	Comment

Step 2

New SDS	Use covered	RMMs implemented	Deviations form RMMs	Compliance with Exposure scenario	Comment

Example of a completed inventory table

Product	SDS	Substance/ preparation	Composition	CAS	EINECS ELINCS	Use	Conf.	Alt.	Crit ical	Annual Tonnage ¹⁹	Suppl. i.	Country of origin	Auth.	Comment
XXX	No	Substance	Known			Industrial Biocide	No	Yes Substance	Yes	< 1 tonne	A	Spain	No	
YYY	Yes	Preparation	Unkown	n.a.	n.a.	Industrial	Yes	Yes, Supplier	No	1-10	A	Belgium	No	
ZZZ	Yes	Preparation	Known	n.a.	n.a.	Industrial Bleaching	Yes	Yes, Process	No	10-100	B	Norway	Yes	
UUU	Yes	Substance	Known			Industrial	No	No	Yes	100-1000	C	Switzerla nd	No	

n.a = not available

¹⁸ Only relevant when you are manufacturer/importer and have registration responsibilities

¹⁹ Only relevant when you are manufacturer/importer and have registration responsibilities

Guidance for completing Annex C - Inventory of purchased chemicals

Product:

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

SDS:

Is SDS available, yes or no?

Substance or Preparation

Is the purchased product a substance or a preparation (see definitions in chapter 6 of this guidance). Check with the supplier.

Composition:

In case of preparation, is the chemical composition known?

If yes, list substances and CAS/EINECS/ELINCS number in the appropriate columns.

This will be especially important if you import preparations from outside EU since you need to check that all components of the preparation are registered.

For EU manufactured preparations it is the obligation of the manufacturer to ensure that all components are registered and in these cases the DU has no obligations.

CAS number

Chemical Abstracts number i.e. a single number allocated to a specific substance.

Only applicable if the purchased product is a substance or in case of preparations with known compositions.

EINECS/ELINCS

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

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

Identified use

Define the use of the substance (e.g. industrial, professional, and consumer).

For the paper and board manufacturers industrial use is applicable in most cases. It could be good to indicate a more specific use like bleaching, maintenance, water treatment etc.

Confidentiality

Do you want to keep your use confidential yes or no?

Be aware of the fact that if you keep your use confidential you need to do the chemical safety assessment yourself compile a chemical safety report and notify the Chemicals Agency.

Alternative

Are there any alternatives on the market for the actual chemical product yes or no?

Such alternatives can be:

- Another substance/preparation which gives the same functionality
- Another supplier of the same substance/preparation



- *Another process where the substance/preparation is no longer needed*

Lack of alternatives may cause problems in case of disappearance from the market or subject to large price increases

Critical

Is this a key chemical i.e. crucial to the production either from an economical perspective or for technical reasons? If there are no alternatives, which are accepted for use at your mill, the product is probably critical. This information is valuable to be able to evaluate the consequences of restrictions of disappearance from the market.

Annual tonnage

Annual quantities used of the chemical product (per legal entity)?

Suppliers

Who is the supplier?

Country of origin²⁰

Do you buy the product within EU-27 or outside (or both)?

Note that if a non EU manufacturer has not appointed an EU representative for registrations you are considered as the importer and must take care of the registration yourself.

Subject to Authorisation

Are any of the substances (on their own or as part of a preparation) subject to authorisation yes or no?

These substances are the ones that have the highest potential to disappear from the EU market or to be severely restricted to just a few uses. If you use substances subject to authorisation you need to notify the European Chemicals Agency.

To date, Annex XIV is empty. The European Chemicals Agency shall make its first recommendation of substances included in Annex XIV by 1st June 2009.

New SDS

Is a new SDS available which includes all information required according to REACH? New data sheets will not appear before 2009.

Use covered

Is your use covered in the registration by your upstream suppliers? This should be communicated to you in the SDS. If not you have the right to inform your supplier of your use and he is obliged to include this and update the SDS accordingly.

RMMs implemented

Are all the recommended Risk Management Measures communicated to you in the SDS implemented, yes or no?

Deviation from RMMs

If the answer on the previous question is no, please list the deviations. Note that you need to notify the Chemicals Agency about any deviations from the recommended RMMs with a justification.

²⁰ When the EEA countries of EFTA include REACH in the EEA agreement, Norway, Iceland, and Liechtenstein will be considered countries of origin inside EU. As for Switzerland, swiss authorities are at the present checking out how to handle the issue, avoiding new trade barriers and maintaining swiss standards.



Compliance with Exposure Scenarios

Do you comply with the use conditions described in the extended SDS?

For substances classified as dangerous (according to 67/548/EEC), PBT or vPvB substance and substances subject to authorisation, the manufacturer is obliged to do an extended safety assessment including exposure scenarios and exposure estimations. The result of this will be communicated to DUs in an annex to the SDS. DUs need to ensure that they comply with the operational conditions described in the extended SDS.



ANNEX D

Information for registration purposes: technical dossier and chemical safety report

Common information for all registrations: sections 1 to 5 of Annex VI as well as all relevant and available test data (incl. a literature search).

Substances in quantities between 1 and 10 tonnes/year (per legal entity): section 6 of Annex VI (info on exposure)

- **Phase-in substances:** **prioritisation according to Annex III**
If prioritised: Annex VII
If not prioritised: only information on phys-chem properties
- **Non phase-in substances:** Annex VII

Prioritisation according to Annex III if the substance is likely to be CMR category 1 or 2 or PBT or vPvB (according to criteria in Annex XIII) on basis of QSAR or other evidence; or the substance has dispersive or diffuse use(s), particularly in consumer preparations or consumer articles; and if the substance is likely to be hazardous (DSD) on basis of QSAR or other evidence.

Substances in quantities above 10 tonnes/year (per legal entity)

Is the same for phase-in and non phase-in substances.

- > 10 tonnes/year (per legal entity): Annex VII + Annex VIII
- > 100 tonnes/year (per legal entity): Annex VII + Annex VIII + Annex IX + testing proposals for Annex IX
- > 1000 tonnes/year (per legal entity): Annex VII + Annex VIII + Annexes IX and X + testing proposals for Annexes IX and X

Adaptations to these testing regimes are described in Annex XI

Chemical Safety Report (CSR) / Chemical Safety Assessment (CSA) are required for substances manufactured/imported > 10 tonnes per year (per legal entity). This CSA needs to include an exposure scenario when:

- a manufacturer or importer wishes to register a substance classified as dangerous (following DSD); or
- a substance having PBT (persistent, bioaccumulative, toxic) or vPvB (very persistent, very bioaccumulative) properties; or
- when an actor applies for an authorisation for use of substances on Annex XIV (list of substances subject to authorisation).