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The European Organization for Packaging and the Environment

The Impact of REACH on the Packaging Supply Chain

This publication has been produced by The European Organization for Packaging and the Environment (EUROPEN) aisbl.

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EUROPEN—The Voice of Industry for Packaging and the Environment—is an industry and trade organization open to any company with an economic interest in packaging and packaged goods. It presents the opinion of its members on issues related to packaging and the environment.

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A. Introduction

The REACH Regulation[1], which entered into force on 1 June 2007, will impact on packaging as much as any other product. Clarity, Collaboration, and Communication (3 C's) are essential to make REACH work.

Key recommendations for the packaging supply chain to comply with REACH are:

1. **The most urgent step to consider is pre-registration. Companies should begin to audit their product portfolios now and initiate dialogue with suppliers to ensure that all substances are pre-registered by the manufacturer or the importer. Indeed substances not pre-registered will not be allowed on the market after November 2008.**
2. **In order to avoid cumbersome procedures, producers of packaging should endeavour to ensure that their packaging does not contain substances of very high concern in concentrations of more than 0.1 % (weight by weight). Substances of very high concern present in articles at a concentration of more than 0.1% will have to be notified to the European Chemicals Agency (EChA). Safety information on these chemicals will have to be communicated along the supply chain and also to consumers, but only upon request (see section 1.2 - 1.4).**
3. **Companies which are downstream users of substances or preparations should inform their suppliers of how they use them, so that this identified use can be incorporated in the supplier's registration dossier and in their Safety Data Sheet (SDS). You should however wait until the corresponding guidance documents and validated electronic tools are available before seeking use and exposure information from commercial partners.**

The aim of REACH is to ensure the good functioning of the internal market while achieving a high level of protection of human health and the environment. Undoubtedly, some substances will disappear from the market. Substances used in packaging could be among them.

B. REACH and Packaging

REACH is not about packaging, but about substances. Therefore, it is important to understand how this regulation of substances impacts on packaging.

The word 'packaging' appears in the REACH Regulation many times, mainly in the context of "classification, *packaging* and labelling of dangerous substances". However, this guidance document does not dwell on packaging of dangerous substances because in practice, REACH does not introduce any changes in this area.

There are about 5 areas where packaging (in the general sense) and REACH overlap. These are provisions on: articles, food contact materials, polymers, waste, and substances occurring in nature. The provisions on articles are particularly important to note.

Please note that the impact of REACH is much greater if you import or, even more significantly, if you manufacture packaging materials in the EU. You may have obligations either as an importer of substances or as a so-called 'downstream user'.

As an importer or manufacturer of materials (meaning substances, as opposed to articles) you might be subject to registration requirements. Downstream users' obligations include the duty to transfer information along the supply chain.

REACH affects the entire packaging supply chain from suppliers of pulp and paper, plastics, metals, glass, coatings and printing inks, and adhesives, etc., to convertors and packer-fillers. REACH entails responsibilities for:

1 companies which use *articles to make another article* or are **importers** of *articles*,

2 **downstream users** who use substances and/or preparations to make *another preparation or an article*,

However, the focus of REACH is on:

3 **manufacturers and importers** of *substances as such and in preparations.*

Downstream users are defined in REACH as:

> *"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"*

Packaging is an 'article', as defined by REACH:

> *"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."*

EUROPEN has been advised that packaging will be considered an article in its own right, separate from the product it contains.

Most actors in the packaging chain are either (2) downstream users or (1) companies which use articles to make another article or import articles. These actors' obligations are limited when compared to those of (3) manufacturers or importers

1 Regulation (EC) No. 1907/2006 – available in all official languages of the European Union on http://eur-lex.europa.eu/

of substances and preparations. However it should be noted that, in some cases, those classified in categories (1) and/or (2) can also be importers of substances and/or preparations in the EU.

Below we outline the duties and requirements of the three categories of actors mentioned above.

C. Understanding the legislation

Both existing and new substances are subject to the same requirements under REACH with the only difference that a transitional regime applies to pre-registered existing substances.

In general, all substances manufactured in the EU in quantities greater than 1 tonne per year per legal entity will have to be registered, regardless of whether they are used in preparations or articles at a later stage. Substances on their own, in preparations (e.g. inks and coatings, adhesives) and those intended to be released from articles (e.g. packaging) may only be imported in quantities greater than 1 tonne per year per legal entity if they are registered. Substances may only be used in preparations or released from articles if they are registered for that specific use. Some substances may require authorisation and will be subject to certain restrictions.

In order to deal with the vast number of substances in question, those produced in large quantities with hazardous properties will be dealt with first. REACH reinforces the Safety Data Sheet (SDS) system already in place for passing information along a supply chain. In future, downstream users who deal with substances or preparations will be required to inform suppliers of how they intend to use substances. Exchange of information along the supply chain is critical, companies will not be able to meet their obligations and REACH will not function as envisaged if this doesn't happen.

D. Exemptions and exclusions

Some substances are entirely excluded from the scope of REACH, while others are exempt only from specific provisions. For the complete list of exemptions, see the REACH Regulation (Article 2, and Annexes IV and V).

Substances exempt from *registration* include cellulose pulp.

Substances in food contact materials have to be registered if they are produced in quantities above 1 tonne. The risk related to food packaging and possible transfer to food and potential negative health effects is already regulated[2] and exempt, but all other risks (e.g. environment, worker safety, etc.) have to be assessed under REACH.

Polymers are exempt from provisions on *registration* (but the Commission has a mandate to propose specific legislation for their registration). Monomers as such are included within the scope of REACH and monomers will have to be registered if manufactured in the EU or imported as such in quantities greater than 1 tonne per year per legal entity. Monomers which are part of imported polymers will also have to be registered if they fulfil the following criteria: if a polymer contains more than 2% of a certain monomer and if the total quantity per legal entity of such monomer is greater than or equal to 1 tonne per year.

Waste is excluded from the provisions of REACH and is not considered a substance, preparation or article. However, the waste stage within the normal life cycle of a substance should be taken into account to assess whether the corresponding uses of this substance are safe. Also, waste that is recycled and put back on the market as a product is covered by REACH. The plastics sector has decided that, as recyclers of plastics will not receive any data (i.e. a Safety Data Sheet) with the waste they use as their raw material, they will compile a special Safety Data Sheet-Recycling (SDS-R) using generic data. This is a voluntary decision and not a legal requirement.

Substances occurring in nature are defined as unprocessed or processed only by manual, mechanical or gravitational means, by dissolution in water, by flotation, by extraction with water, by steam distillation or by heating solely to remove water, or which is extracted from air by any means. Substances occurring in nature are exempt from Titles II (Registration), V (Downstream User) and VI (Evaluation), unless they meet the criteria in Directive 67/548/EEC for classification as dangerous.

E. Duties and requirements for the three categories of actors

1. Duties of companies which use articles to make another article or are importers of articles

1.1. Registration

Producers / importers of packaging will have to register substances that are *intended to be released* from the packaging under normal and foreseeable conditions of use *if* they are present in quantities totalling over 1 tonne per producer/importer per year. If this applies to your product(s) you should urgently consider pre-registration of the corresponding substance(s).

2 Regulation (EC) No. 1935/2004 on materials and articles intended to come into contact with food

1.2. Notification

Substances that are intended to be released from articles *or* are "substances of very high concern" (SVHC)[3] which are on the candidate list (see Section 3.2. for more details) *and* are present in packaging in quantities totalling over 1 tonne per producer/importer per year *and* above a concentration of 0.1% weight by weight (w/w) are required to be notified to the European Chemicals Agency (this procedure is less burdensome than registration). Notification is not required if the producer/importer can exclude exposure to humans or the environment during normal or reasonably foreseeable conditions of use including disposal.

The Agency can require producers or importers of articles to register a substance in an article if it is present in quantities over 1 tonne per year and it has grounds to suspect that the substance is released from the article and that this presents a health or environmental risk.

The producer or importer of the packaging containing the substance requiring notification as outlined above will inform the European Chemicals Agency of:

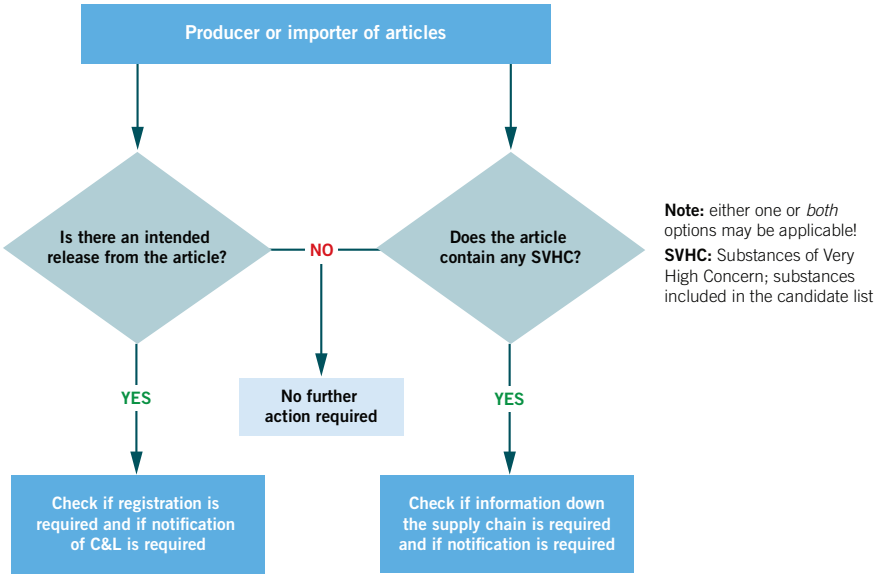
- his identity and contact details;
- the registration number(s), if available (i.e. if the substance is being registered for a particular use);
- the identity of the substance (i.e. information enabling the substance to be identified);
- the classification of the substance(s);
- a brief description of the use(s) of the substance(s) in the article and the uses of the article(s);
- the tonnage range of the substance(s)

Notification is not currently as urgent as pre-registration of substances released from articles which has a deadline of 30 November 2008.

1.3 Communication on Substances of Very High Concern (SVHC) present in the article throughout the supply chain

Suppliers of articles containing substances of very high concern in quantities greater than 0.1% (w/w) must also provide sufficient information to their customers to allow safe use of the article including, as a minimum, the name of the substance. If the recipient is a consumer and requests this information, it must be provided to him free of charge within 45 days of his or her request.

Figure 1: Requirements for Substances in Articles



Source: European Photo and Imaging Association, REACH Guidance Document III

3 CMRs (Carcinogenic category 1 or 2, mutagenic category 1 or 2, toxic to reproduction category 1or 2), PBTs (persistent, bioaccumulative and toxic), vPvBs (very persistent and very bioaccumulative), substances which give rise to an equivalent level of concern to those listed here based on scientific evidence.

1.4 Additional obligations

- Comply with any restrictions on the use of a substance indicated in Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles)
- If using substances subject to authorisation, ensure that this specific use is authorised and report this use.

2. Duties of downstream users

2.1. Communicate use to their supplier or to the Chemical Agency

It is vital that all actors in the supply chain communicate with each other to ensure that, as far as possible, registrations of substances take account of all their uses. Just because a substance is registered does not mean that you can continue using it, it has to be registered for your specific use.

This will have to be done by the downstream user, if the following criteria are met:

- the substance is manufactured or imported in quantities greater than 10 tonnes per year per legal entity, and
- the downstream user buys it in quantities greater than 1 tonne per year per legal entitiy, and
- the substance is classified as dangerous.

Downstream users have the right to:

a make their use of a substance known to suppliers in order to have it included in their supplier's registration dossier and Safety Data Sheets (SDS) (in addition, downstream users will also have to provide some exposure data to their suppliers to allow the latter to perform an exposure scenario) or,

b if they do not wish suppliers to know their use, downstream users must complete themselves a risk assessment and, for substances over 1 tonne, a Chemical Safety Report and notify the Agency of their use if this is not covered in the SDS received from their supplier. For dangerous substances, they will have to make an exposure scenario.

Suppliers of substances will be required to inform their downstream users or distributors of hazards and measures needed to adequately control risks. Downstream users will have to implement the risk management measures (RMM) indicated in their exposure scenario and possibly comment back to the supplier on their appropriateness if the downstream user does not agree with them. Information on new hazards and any challenges to received data will need to be sent back up the supply chain.

Exposure scenarios are sets of conditions describing how substances are manufactured or used during their life-cycle as well as the suppliers' recommendations for exposure control. The exposure scenarios must include appropriate risk management measures which, when properly implemented, ensure that the risks of use of the substances are adequately controlled. Manufacturers and importers must develop exposure scenarios to cover all "identified uses" which are the manufacturers' or importers' own uses, and those made known to the manufacturer or importer by his downstream users. Relevant exposure scenarios will be annexed to the Safety Data Sheets supplied to downstream users and distributors.

Although there is little chance of exposure to substances from packaging, downstream users may be asked by their suppliers to provide information on what they do with the substances, so that the supplier can fulfil his obligation to perform a Chemical Safety Assessment and include the use of the substance in packaging in the registration dossier. Further guidance on this will be available in early 2008 when the Commission is expected to publish the relevant technical guidance documents. Once these are available, EUROPEN will consider whether it would be useful to carry out a generic exposure scenario (or scenarios) for packaging which packer/fillers could send to their suppliers if requested.

Supply chain information duties in summary

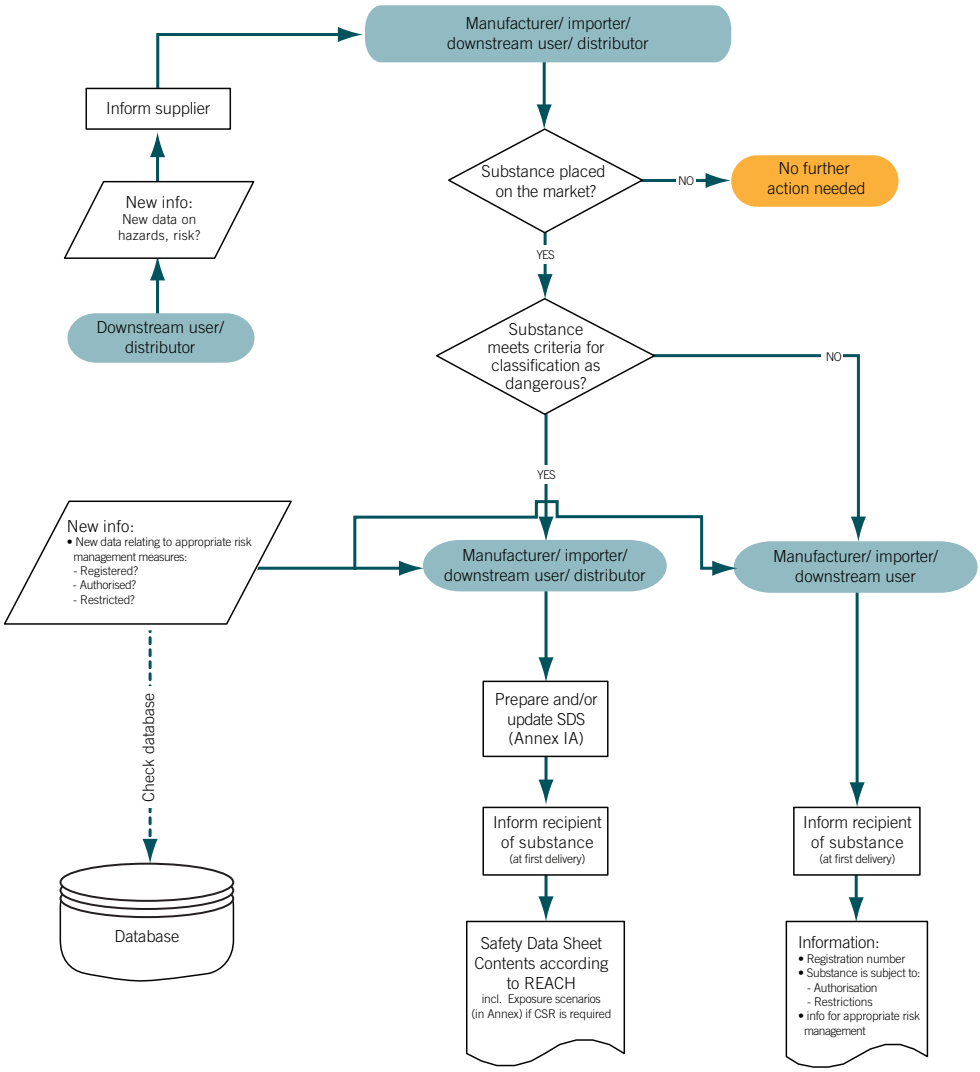
Producer / Importer

- Required to identify specific downstream uses of a substance
- Prepare chemical safety assessments and recommend risk reduction measures
- Deliver SDS to the Downstream user
- Usually has the best knowledge of the chemical's intrinsic properties
- Usually posses good knowledge of the safety of the chemical and applicable risk reduction measures

Downstream User

- Receives the SDS to verify/inform of the safe use of the chemical
- Requested to inform the specific use of the chemical to the chemical suppliers
- Usually possesses the best knowledge of how the chemical is used and the current risk management measures in place
- Requires pro-active communication towards the supplier
- Records the SDS for easy access

Figure 2: Information through the Supply Chain



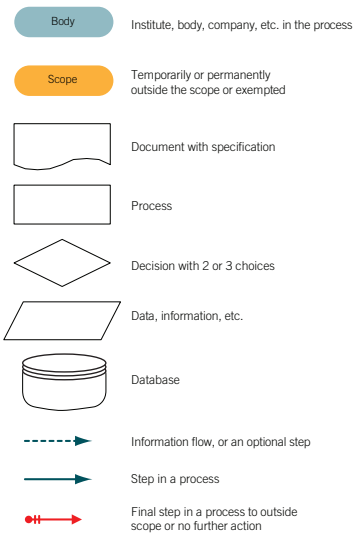
Source: European Commission, Flowcharts on the new EU chemicals legislation, 4 April 2004[4]

2.2 Prepare Safety Data Sheets on preparations

REACH takes over and builds on the existing requirement for manufacturers, importers, downstream users and distributors to compile and supply a Safety Data Sheet (SDS) for substances and preparations classified as dangerous, or persistent, bioaccumulative and toxic to reproduction (PBTs), or very persistent and very bioaccumulative (vPvBs). If a preparation itself is not classified as such, an SDS is still required if the preparation contains classified substances.

The provisions of the former Safety Data Sheets Directive (91/155/EEC) were carried over to REACH and expanded so that some additional information is now required (e.g. exposure scenario covering downstream user's uses should be provided in the annex). Unless requested by retailers or consumers, Safety Data Sheets do not need to be supplied where dangerous substances or preparations offered or sold to the general public come with sufficient information to enable their safe use and protection of health and the environment.

Chart Keys for Figures 2 and 3



2.3 Communicate information on substances that do not require a Safety Data Sheet

Even if a substance does not require a Safety Data Sheet, certain information must be communicated down the supply

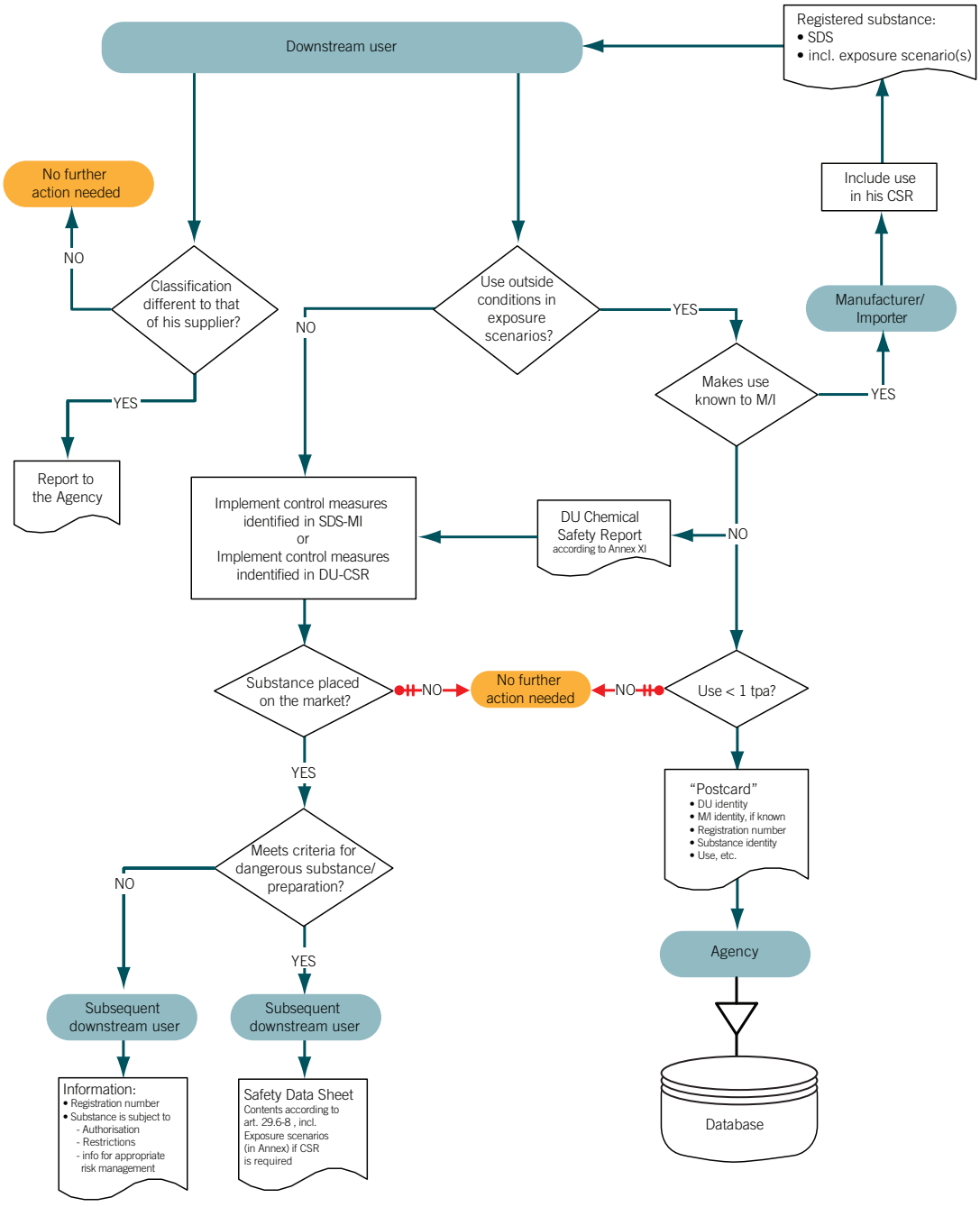
4 Available to download at http://ecb.jrc.it/documents/REACH/REACH_PROPOSAL/COM_PROPOSAL_2003/Visio-REACH_final_proposal_flowcharts_04-04-2004.pdf

chain. Manufacturers, importers and downstream users must state whether the substance is subject to authorisation, or if its use is restricted; information relevant for risk management; registration number; and sufficient information to allow safe use of articles containing substances of very high concern and requiring notification.

2.4 Additional obligations

- Comply with any restrictions on the use of a substance indicated in Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles)
- Request for authorisation to use a substance of very high concern (see Section 3.2.), if this has not already been done by the supplier
- If using substances subject to authorisation, ensure that this specific use is authorised and report this use to the supplier or to the European Chemicals Agency.

Figure 3: Downstream User Requirements in Case of a Substance Registered (starting at 10 tonnes)



Source: European Commission, Flowcharts on the new EU chemicals legislation, 4 April 2004—see footnote 4

3. Duties of manufacturers and importers of substances or preparations

3.1. Registration and Pre-Registration (2008)[5]

Registration essentially means submitting data to the European Chemicals Agency on the properties, uses and classification of a substance. This requirement applies to every substance manufactured or imported in quantities greater than 1 tonne per year per legal entity. A Chemical Safety Report is required for substances manufactured or imported in quantities of 10 tonnes or more per year. If these substances are classified as dangerous the Chemical Safety Report must include an exposure assessment. Built into the REACH system are provisions for avoiding unnecessary animal testing and for data sharing among registrants. Where new animal testing is needed to support registration (for substances manufactured in volumes above 100 tonnes per year), the registrant must first submit a testing proposal to the regulatory authorities. Many substances used to make packaging, such as inks, coatings, adhesives, and substances in the packaging itself will need to be registered.

Registration of substances that have already been on the market will be phased in according to tonnage (and, in some cases, according to their properties). These are referred to as "phase-in substances" and potential registrants will have a duty to pre-register a substance between 1 June 2008 and 1 December 2008 in order to benefit from the transitional provisions of "phase-in". If you do not pre-register your substance, it will lose its "phase-in" status and will either have to be registered immediately, or taken off the market by December 2008. If you do pre-register the substance, there is no penalty for not completing the registration later, so it is in everyone's interest that all substances be pre-registered. Pre-registration dossiers can be completed very easily and is free (no fees required). Possible decisions to delist certain substances (i.e. take them off the market) need not be taken until the final registration deadline.

The pre-registration period runs from 1 June to 30 November 2008. The following information will have to be sent to the Agency (the first three points below are obligatory; the last one is voluntary):

- name and address of the producer of the substance (or third party if anonymity required)
- substance name and EINECs and/or CAS number (if available)
- the envisaged deadline for the registration/tonnage band (set in the Regulation, see below)
- names of substances for which read-across[6] of data is proposed

On 1 January 2009, the Agency will publish the list of pre-registered substances, following which "Substance Information Exchange Fora" (SIEFs) will be established. Pre-registration is designed to enable manufacturers and importers of the same substance to find partners for consortia formation and data sharing. All manufacturers and importers who have pre-registered the same substance will participate in a SIEF which will aim to minimise duplicate tests and, where there is a difference, to agree on the substance's classification and labelling.

In general, the registration obligation falls on manufacturers and importers, but downstream users will also need to ensure that their specific uses are registered (see above for more details). The amount of information and data needed for registration will depend on the quantities or tonnage of the chemicals with more data needed at higher tonnage levels. Higher tonnage substances require the most data, and have to be registered first; lower tonnage substances require less data and can be registered later:

- 1 December 2010: substances manufactured/imported in quantities of 1,000 tonnes or more per year; CMRs (categories 1 and 2) manufactured/imported in quantities of 1 tonne or more per year; substances toxic to the aquatic environment (R50/53) manufactured/imported in quantities of 100 tonnes or more per year;
- 1 June 2013: substances manufactured/imported in quantities of 100 tonnes or more per year;
- 1 June 2018: substances manufactured/imported in quantities of 1 tonne or more per year.

Registration in practice: forming a consortium

In general, manufacturers/importers who produce/import the same substances will be required to submit certain information jointly—the so-called "one substance one registration" approach—through the SIEF. The SIEF's objectives are two-fold: to share data (to avoid duplication of tests on animals) and to agree on classification and labelling of substances. The desire to reduce costs and testing by sharing data will have to be carefully balanced to ensure respect of EU competition rules.

3.2. Authorisation and Restriction

'Authorisation' in the context of REACH really means 'ban'. Substances of very high concern (see footnote 3 above) will be banned, regardless of the volumes put on the market. A temporary exception may be made only where a substitute is not immediately available and the producer can prove that the risks of using the substance can be adequately controlled or that the socio-economic benefit of its use outweighs the risk. Such substances will be authorised for a limited period and only for certain uses or subject to specific restrictions.

5 Sources: *"REACH is coming—are you ready?"* by Keller and Heckman Services and *"REACH-Overview"* by Ciba Expert Services

6 It can be assumed that chemicals with similar structures (or similar structural elements) will in general share (eco)toxicity features. Therefore, the clustering of chemicals with similar structures into groups will permit "read-across" of toxicological properties within the groups, thus reducing the extent of testing required for chemicals within the group.

Candidate List

Substances identified as meeting the criteria requiring authorisation will be included on a candidate list for eventual inclusion in the authorisation procedure. This list will be published on the Agency's website and will effectively constitute a continuously evolving black list of substances which can still legally be used, but which are likely to disappear from the market because of their status as pending for ban.

The constant updating of this list will present practical difficulties for many operators. Substances on this list present in packaging in quantities totalling over 1 tonne per producer/importer per year *and* above a concentration of 0.1% weight by weight (w/w) will have to be notified to the Agency (see Section 1.2)

3.3. Additional obligations

- Comply with any restrictions on the use of a substance indicated in Annex XVII (Restrictions on the manufacture, placing on the market and use of certain dangerous substances, preparations and articles)
- Prepare 'extended' Safety Data Sheets on substances or preparations. Although the provisions on Safety Data Sheets are already in force, the extended Safety Data Sheet can only be prepared when the Chemical Safety Report has been issued, that is at the actual time of registration of substances imported or manufactured in quantities greater than 10 tonnes per year per legal entity and classified as dangerous.

F. Suggested REACH implementation steps for industry

Short list - essentials

- First of all, acquaint yourself with the provisions in the REACH Regulation on "articles", that is, Articles 3.3, 7, and 33.
- Have a look at the guidance document on articles, which was created within the framework of the REACH Implementation Project 3.8. This document is available on the web site of the European Chemicals Agency[7]. Understand its structure and acquaint yourself with the terms "intended release" and "unintended release".
- Determine which legal role(s) (importer – manufacturer – downstream user) applies to your company
- Have a look at Annex IV of the REACH Regulation which lists exempted substances.
- Have a look at Annex V of the REACH Regulation which names exempted categories of substances.
- Acquaint yourself with the definition of a "substance of very high concern". Check whether your products contain relevant amounts and concentrations of such substances.
- Do not miss pre-registration (1 June – 1 December 2008) if you identify any substance in your product portfolio which requires registration.

Long list

- Create a company inventory of individual chemical substances and preparations. Identify the (EC-) EINECS and ELINCS numbers of substances and, if possible, the CAS number.
- Identify for each substance or preparation the status from the perspective of REACH and your situation in the supply chain. For imported preparations, find out the composition. Determine which substances are exempt or excluded from certain provisions.
- A company can be a manufacturer or a downstream user, or both. Determine whether individual substances and preparations fall into the following categories:
  - Imported by you into the EU (if so, you are an importer according to REACH and you may fall under the registration obligation)
  - Purchased by you from a supplier established within the EU (if so you are a downstream user according to the definition of REACH)
- Regarding imports of articles/preparations, know the role of each actor in the chain and the first and final "physical" recipient in the EU. Such information is necessary, for example, to distinguish between the responsibilities of your (local) factory and the trading company or entity that might import articles or preparations on your behalf. It will be the legal importer, i.e. the one who pays the customs duty, who will be responsible and who will bear the costs triggered by REACH.
- Confirm for substances as such, in preparations or to be released from articles the annual volume produced or imported (per legal entity)
- Secure your supply chain. Start a dialogue with suppliers in order to secure availability of raw material. When talking to a representative of your supplier, ask him whether the introduction of REACH will have any influence on the supplies necessary for your business. If so, prepare for the changes, or map out alternative suppliers.
- Identify critical substances and how they can be substituted

7 Guidance on requirements for substances in articles, RIP 3.8, http://ecb.jrc.it/reach/rip/

- Request your suppliers to pre-register all of the substances you use (deadline 1 June – 1 December 2008).
- If appropriate, request your supplier to include your use in the registration (the timing of this step will depend on the registration deadline: 2010 – 2013 – 2018).
  - Inform supplier of identified uses you wish to have covered in the CSR (chemical safety report). Downstream users must provide sufficient information to allow suppliers to develop exposure scenario (ES)
  - Or perform own chemical safety assessment for "non-identified uses". The downstream user must separately report these to the European Chemicals Agency
- Assess situation with suppliers (EU – non-EU). Pay attention to the fact that if you purchase raw material from outside the EU, you could be obliged to pre-register and register the substances in the raw material. Identify chemicals that are directly imported into EU
- Communicate your case to suppliers for inclusion in their exposure scenarios using generally accepted standardised tools (at the time of writing these tools are not yet available and are expected in early 2008)
- Communicate REACH impact (potential delays, changes in substance formulations, etc.) within your company
- Contact your national or European trade association to ask what support they can provide
- Collect additional information as appropriate: intrinsic properties of substances, vertebrate animal studies owned by company, costs of studies and/or payments for shared/joint studies, information on classification & labelling of substances, Safety Data Sheets
- Compile readily available information on uses and conditions of use: industrial / professional / consumer use, human and environmental exposure, frequency of exposure (accident / infrequent non-controlled release)

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