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Ciba[®] Expert Services

REACH and Downstream Users



Our Knowledge – Your Advantage

REACH and Downstream Users

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1 Introduction

On 1st June 2007, a new legislation for chemicals will enter into force in the European Union. This legislation is known by its abbreviation REACH: "Regulation of the European parliament and of the council concerning the Registration, Evaluation, Authorization and Restriction of Chemicals" It proposes wide-ranging and fundamental revision of the European Union's chemical control legislation, that is, the Dangerous Substances Directive (DSD), including the notification scheme for new substances, the Dangerous Preparations Directive (DPD), the Existing Substances Regulation and the Marketing and Use Directive.

As can be concluded from its name the core piece of the bill is a scheme for the registration of commercialized substances: After the entry into force of REACH, substances will need to be registered before they are manufactured or imported in quantities of 1t/y or more. Transitional provisions apply for all substances that are currently on the market. These set different deadlines for registration, without the need to interrupt manufacture or import of these substances. Such substances are known as "phase-in substances".

For registration of phase-in substances, the following deadlines apply:

- 3.5 years: for substances produced / imported in quantities of 1000 t/a or more and all known CMR (carcinogenic, mutagenic, toxic for reproduction) class 1 or 2 substances (> 1 t/a) and substances classified as very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment (R50/53) (>100 t/a)
- 6 years: for substances produced / imported in quantities of 100 t/a or more (per manufacturer / importer),
- 11 years: for substances produced / imported in quantities of 1 t/a or more (per manufacturer / importer).

All producers and importers of chemical substances will have to register directly or have to do a pre-registration for phase-in substances. The pre-registration of phase-in substances will start 1st June 2008 and will end 6 months later. After this period the Agency will publish a list of pre-registered substances. This list is a platform for down-stream users (DU) to check whether or not the substances they use are likely to remain on the market.

One of the most important features of the proposed legislation is that it differs from the present legislation in the much stronger involvement of the professional users of chemicals. This brochure attempts to describe these specific downstream user-related aspects.

The text of the REACH regulation was published in the Official Journal of the European Union on 30 December 2006 (Regulation (EC) 1907/2006).

2 Provisions of REACH for Downstream Users

2.1 What is a Downstream User (DU)?

Downstream users¹ are companies buying chemicals and using them in their production. For example, formulators are downstream users. Companies that use substances or preparations in the course of their business, also qualify as downstream users.

Many manufacturing enterprises are downstream users as well. They purchase chemicals in order to produce, for example, cosmetics, detergents, maintenance products, coatings, aerosols, paints, adhesives, photographic materials, electronic devices, and automobiles.

2.2 What are the most important things a DU should know about REACH?

A downstream user has two main duties under REACH:

- Passing of information down the supply chain
- Assuring that his use of the substance is identified by his supplier

All actors in the supply chain will need to communicate with each other to ensure that, as far as possible, registrations of substances take account of all the uses of a substance. All uses within the supply-chain need to be identified and risk reduction measurements need to be assessed to allow safe use of a substance with regards to humans (workers) and the environment.

In order to prepare a registration for their substances, manufacturers and importers (suppliers) of substances will be seeking information from their downstream users to enable them to include their specific uses in the registration dossier. Downstream users may also on a voluntary basis provide their suppliers with information to assist in the preparation of a registration. This may have business benefits for

The aim of REACH is to provide an assessment of the risks associated with chemicals and to ensure that these are properly managed. Risk means the likelihood with which adverse effects of substances may arise in humans or in the environment. The risk depends on two factors: the hazardous properties of a substance and the level of exposure of humans and/or the environment:

•Chemicals hazards can be of physico-chemical nature (e.g. explosiveness, oxidizing properties), toxicological (e.g. harmful, carcinogenic) or ecotoxicological (e.g. toxic to fish, algae etc., persistent). The information on the hazards of a substance/preparation is communicated via the label and safety data sheet.

•Exposure on the other hand means the amount and time-period over which humans or the environment are in contact with the substance or preparation.

For most substances a "safe exposure level", expressed as a concentration or dosage per time, can be defined below which no adverse effects are expected. Under REACH these "safe exposure levels" are called "derived no effect level" (DNEL) when talking about human exposure and "predicted no effect concentration" (PNEC) concerning the environment.

Risk can be reduced by reducing the exposure, that is, by applying risk management measures. Information on substance properties is primarily to be provided by the manufacturers and importers of substances, whereas information on uses and respective exposure is to be collected by all actors along the supply chain, that is, by the downstream users.

¹ 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 (Article 3, Regulation (EC)1907/2006)

a downstream user, enhancing his chances that substances he uses will be registered for his use. However, downstream users will wish to balance the benefits of pro-active involvement against the work required and potential which to protect confidential business information.

2.3 Key elements concerning Downstream Users:

- Main REACH requirements, e.g. registration apply typically to suppliers. However, their registrations must be use specific. That is, the DU must inform his supplier on how he uses the substance to be registered (identified use).
- Downstream users do not fall under the registration requirements under REACH. However, if they import chemicals on their own, DU will have to register these substances which they directly import.
- Typically, downstream users will be able to rely on suppliers to define and take responsibility for the risk management measures required for each substance. It is important, however, that suppliers are aware on typical use and hygiene conditions.
- Certain products may no longer be available due to their potential unprofitability as a result of registration and testing costs for suppliers.
- Niche specialty products may be vanishing from market.
- Articles are typically exempt. However, in case you import them from outside the EU, you should check whether these specific articles fulfill the criteria for exemption (see our REACH Overview brochure)
- Labelling of products will change. Some classifications might be more severe than today.

2.4 New obligations for Downstream Users:

Most of the current legal requirements related to the placing on the market and use of substances and preparations will remain unchanged. Under REACH, however, additional obligations will be implemented - also for downstream users of substances and preparations.

- Downstream users placing dangerous substances or preparations on the market have to provide a safety data sheet (existing requirement). Under certain conditions, these Safety Data Sheets have to have an Annex with an exposure scenario, describing how the customers and further downstream users have to use the substance or preparation safely. It is the duty of a downstream user to develop and provide such an exposure scenario for his customers.
- Downstream users of dangerous substances and preparations will receive safety data sheets (SDS) which will look like those provided today. In addition, under certain conditions², these SDSs will have an Annex which is called exposure scenario. This exposure scenario is a description of how the substance or preparation is to be used safely. If a downstream user receives such an exposure scenario, it is his obligation to ensure that the way he uses the substance or preparation does not pose a higher risk than prescribed by the exposure scenario of his supplier.
- A downstream user has the right to make his use known in writing to his supplier, to ensure that the use becomes an identified use and that the Exposure Scenarios he later receives are appropriate for him.

² That is, if the substance itself or at least one of the substances in a preparation is classified dangerous, it is produced/imported in amounts exceeding 1 t/a per producer or importer, it is registered by the producer or importer and, if part of a preparation, is contained in concentrations exceeding the limits defined in the dangerous substances or dangerous preparations directive or those specified in the REACH regulation.

- Due to the need to know more about the actual uses of a substance, communication along the supply chain is expected to increase significantly. A downstream user is part of the supply chain and thus also the information chain. Under REACH, he is required to pass on information he holds, or which is communicated to him, up and down the supply chain.
- REACH contains mechanisms to ensure that substances of very high concern³ are not used in applications which do not adequately control their risks. These are the authorization procedure, where the use of a substance must to be authorized in advance, and the restrictions procedure, which is similar to the current procedures for marketing and use restrictions under Directive 76/769/EC. Downstream users will have to comply with any marketing and use restrictions and have to seek authorization for their use of these particularly hazardous substances.

2.5 Classification and labeling and GHS

After December 1st 2010, the Agency has to be notified on the classification and labeling of substances subject to registration under REACH and of substances that are at present on Annex I of the dangerous substances and preparations directive. Although this requirement is part of the REACH regulation, the situation is likely to be more complicated by the fact that the European Commission has stated that the GHS implementing legislation will be adopted at the same time as the REACH.

The United Nations Globally Harmonized System of Classification and Labeling of Chemicals (GHS) will provide harmonized health and safety information for chemical substances and mixtures. GHS will replace, after a transitional period, the currently existing provisions on classification and labeling of chemicals, as set out in Council Directive 67/548/EEC and Directive 1999/45/EC as amended.

The introduction of GHS may well present a challenge equivalent to the implementation of REACH, in terms of administrative efforts. All actors in the supply chain will be required to update their SDS according to GHS.

3 Business implications

Downstream users typically invest a significant amount of time, money and resource to develop products that they believe to be equal or superior to competitive products in order to stay in business, ensure a reasonable profit, and remain competitive.

Each of the fundamental REACH processes, including pre-registration, registration, evaluation, authorisation, Classification & Labelling database, and safety data sheets, require different information to be disclosed. Although complete formulation details are not disclosed in any document or database, under REACH, competitors might be able to harvest this information from multiple publicly available sources.

Note that the intensified flux of information can negatively influence your commerce as certain information which is important for your business might become available to suppliers, competitors, and customers. A pro-active approach towards REACH might make the decisive difference for the success of your company.

³ Carcinogenic, mutagenic, or toxic to reproduction (CMRs) categories 1&2, persistent organic pollutants (POPs), persistent, bio-accumulative and toxic pollutants (PBTs), very persistent and very bio-accumulative substances (vPvBs), and on a case-by-case basis endocrine disruptors and substances of an equivalent level of concern

Further important aspects are:

- The danger of information overload and bottlenecks of data processing, especially if the company has a broad range of products.
- The sensitivity for a discontinuity of supply (Your raw material could be phased out, discontinued at all, or not registered for your specific use pattern)
- Demands from retailers in terms of consumer-sensitive issues and prices.
- Pressure from suppliers passing REACH-related costs to their customers.

Testing in animals required by REACH and commissioned by your suppliers might be a problem for your customers.

4 Technical Guidance Document for Downstream users

A special Technical Guidance document for downstream users is being prepared by the European Commission. The aim of this Technical Guidance document is to enable the professional users of chemicals to identify what is required from him under REACH and to give the necessary guidance on meeting those requirements (<http://ecb.jrc.it/reach/> documents RIP final reports 3.5-1).

Even with this Guidance, many downstream user companies might find it difficult to comply with REACH, because they have sometimes limited experience or very limited internal resources. In such a case, these companies might wish to look for professional assistance from their trade associations and experienced consultancy companies.

5 Actions to be taken now

Downstream users of chemicals can be very diverse, as for instance, a company of 40 employees manufacturing a low volume niche product used by professionals on one hand and a corporation producing high volume consumer products on the other. Hence two different exemplary action lists are shown below. The first applies to a small downstream user and the second to a larger downstream user. Obviously, between these two situations, many other scenarios are imaginable and which case certain items in each list might be applicable to your specific situation.

5.1. Action list for small downstream users

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.

If appropriate, request your supplier to include your use in the registration.

Pay attention to the fact that, in the case, you purchase raw material from outside the EU, you could be obliged to register the substance (See our brochure on import).

Contact your national or European trade association to ask which support it can give to you while preparing for REACH. If no support for your specific crucial issues is tangible from the association, consider to involve a consultant.

If possible, line up with other members of your sector in order to prepare a common and if necessary anonymized (to protect confidential business information) response on data requests. For instance, sector-wide frame formulation can be a solution, if you and your competitors do not want to reveal the recipes of preparations. Associations and/or consultants might be able to help.

5.2. Action list for larger downstream users

Prepare a REACH Masterplan (with the definition of short- and long-term resources) taking into account the following points:

- Create a company inventory of individual chemical substances and preparations. Identify the CAS numbers of substances and, if possible, the EINECS or ELINCS numbers.
- Identify for each substance or preparation the status from the perspective of REACH and your situation in the supply chain.
A company can be a Manufacturer or a Downstream user or both (the latter is the case if the company manufactures a substance or imports a substance/preparation and purchases additional quantities from a supplier within the EU).
- Determine whether individual substances and preparations fall into the following categories:
 - ⇒ Imported by your company into the EU (You are an importer according to the definition of REACH and may fall under the registration obligation. See our brochure for importers)
 - ⇒ Purchased by your company from a supplier established within the EU (you are a downstream user under REACH).
 - ⇒ Confirm for substances and preparations their annual volumes.
 - ⇒ Identify confidential business information. Figure out how to protect it!
 - ⇒ Initiate collaboration with suppliers where possible.

6 Actions to be taken soon

- Identify and list your suppliers (per substance, that is, per CAS No. and/or preparation).
- Communicate with your suppliers about a potential cooperation with the latter, if such cooperation is appropriate for your situation.
- Decide whether to identify uses to supplier or not.
- Assess risk of portfolio with respect to the risk for loss of substances and need for substitutions.
- Assemble readily available information on uses and conditions of uses for the substance or preparation, i.e. exposure of the environment, your own workforce, at your customers' workplaces and eventually in final uses, at least by broad use categories:
 - ⇒ industrial use
 - ⇒ professional use
 - ⇒ consumer use.

- confirm with suppliers support of substances under REACH
- confirm uses being considered

7 Further perspectives

Review your classification and labeling and evaluate changes brought by the Globally Harmonized System of Classification and Labeling of Chemicals (GHS). Compare and adjust in agreement with other.

- In some cases your classification might not be the same as your competitors.
- In some cases this will be easily rectified across producers.
- In other cases this may be difficult, especially where variations are due to impurities (marketing edge due to concept of safer product).
- The GHS requirements will change some classifications.

8 Conclusion

After the introduction of REACH, all existing substances manufactured within the European Union or imported into the EU (which are not exempt) with a volume above 1 ton per annum must be registered according a tonnage-triggered schedule.

The related procedure is complex and has significant business implications. It is thus important to have thorough regulatory guidance in devising the appropriate strategy and in handling individual critical issues.

Ciba® Expert Services is the right partner for you to meet these challenges.

9 *Services for REACH by Ciba® Expert Services*

- ***Training and education***
We will organize seminars on the forthcoming changes in legislation and their implications.
- ***Portfolio examination***
We can review product and development portfolios to increase insight into the properties of your substances and to identify problematic substances in advance.
- ***Issue management***
We assist to handle critical issues on the base of longstanding experience.
- ***Defense of specific uses of substances***
We help on a case by case base ensuring that specific uses are compliant with legislation.
- ***Collecting relevant data***
We are able to find relevant data on your substance or close chemical analogues from the many available sources of information.
- ***Reviewing and revising classification and labeling***
We have wide experience in applying criteria for Classification and Labeling and preparing EU-format Safety Data Sheets. Our services are readily available for your products.
- ***Preparing/updating Chemical Safety Reports***
We prepare EU-format risk assessments on a regular basis and always ensure that possible future implications of risk assessment conclusions are addressed.
- ***Support beyond the introduction of REACH***
We permanently maintain your product portfolio in terms of compliance with European substance safety related legislation.

10 Ciba® Expert Services

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