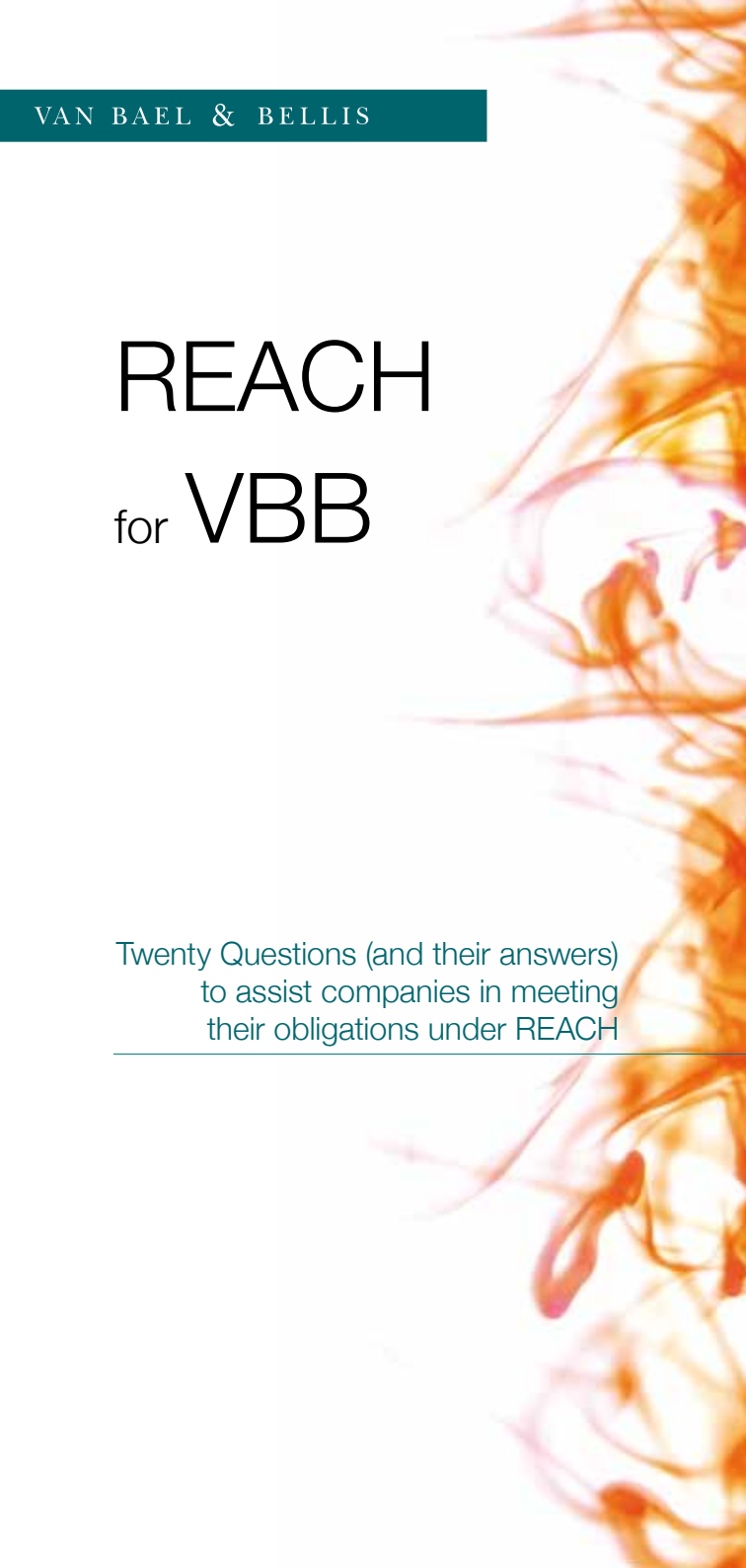
VAN BAEL & BELLIS

REACH for VBB

Twenty Questions (and their answers) to assist companies in meeting their obligations under REACH



If your business manufactures chemicals in or imports chemicals into the European Union (EU), then it will need to be aware that REACH (Regulation 1907/2006 concerning the **R**egistration, **E**valuation and **A**uthorisation of **CH**emicals) reverses the burden of proof for ensuring that chemicals are safe when they are placed on the EU market. Traditionally, such burden rested with the competent authorities, but under REACH it lies with EU manufacturers and importers. REACH also imposes obligations on EU manufacturers and importers of preparations, and certain types of articles that contain chemical substances. Thus, if your business manufactures or imports components or finished articles it could likewise be affected.

REACH requires manufacturers and importers in the EU to gather comprehensive information on properties of their substances produced or imported in volumes of 1 tonne or more per year and to submit the necessary information to demonstrate their safe use in a registration dossier to the European Chemicals Agency. Failure to register will mean the substance cannot be manufactured in or imported into the EU market. As for articles containing chemical substances, the substances will have to be registered with a technical dossier where the substance present in those articles totals over 1 tonne per year, per manufacturer or importer, and if the substance is intended to be released under normal or reasonably foreseeable conditions of use.

The following questions are those which Van Bael & Bellis environmental team has found are commonly asked by manufacturers and importers of chemical substances, preparations and articles. The responses are not exhaustive, and companies doing business in Europe should seek legal advice if they feel that they may be affected by this highly complex and considerably far-ranging legislation.

01 ***When did the REACH Regulation enter into force?***

The REACH Regulation entered into force on 1 June 2007. It had, however, already been published in the Official Journal of the European Union on 30 December 2006.

02 ***We manufacture substances in, and import substances into, the European Union. Must we comply with the REACH Regulation s registration obligations from its entry into force, or does a different date apply for such obligations to begin?***

The obligations concerning EU manufacturers and importers of phase-in substances begin on 1 June 2008, when the period for pre-registration will kick-in. As this period closes on 1 December 2008, pre-registration must be carried out during this period only. Phase-in substances are, essentially, chemical substances that are already listed in the European Inventory of Existing Commercial Chemical Substances (EINECS), and number more than 100,000.

On the other hand, so-called "notified substances" (these substances, far fewer in number, are listed in the European List of Notified Chemical Substances (ELINCS)), are deemed already to have been registered. However, if you are trading a notified substance in the EU, and it reaches the next tonnage threshold as defined in Article 12 of the Regulation, an update of the registration for that substance will have to be submitted.

03 *We may find it difficult to meet all our registration requirements by the deadline for registration. Will we still be able to sell our chemical substances despite not registering them on time?*

If your substance has not been registered in accordance with the REACH Regulation, and by the deadlines provided, you will not be able to place that substance on the market. This means that you will not be able to sell the substance, or the preparations or articles containing it. EU manufacturers and importers are therefore advised to familiarise themselves with the REACH Regulation, and strictly adhere to the deadlines, or else they will lose out to their competitors.

04 *We do not wish to be responsible for the registration of our substances. Can we appoint another company to take over the full responsibility?*

Any EU manufacturer or importer may appoint a third party representative to fulfil dossier submissions or hold discussions with other manufacturers or importers on its behalf. It must, however, retain full responsibility for complying with its obligations under the REACH Regulation.

Moreover, a non-EU manufacturer may appoint a natural or legal person in the EU to fulfil, as its only representative, the obligations that an importer would have. To this end, the only representative must have a sufficient background in the practical handling of substances and the information related to them, and keep an up-to-date list of substances imported and customers sold to.

05 *We have heard a rumour that registration has to take place in each Member State that we sell our substances in. Is this correct?*

Registration (including pre-registration) can only take place with the European Chemicals Agency (ECHA), located in Helsinki. The ECHA began operations on 1 June 2007, and is set to be ready for registrants on 1 June 2008.

06 *We make chemical substances, but our scientists tell us that they are not harmful. Must we still comply with the REACH Regulation?*

Substances that are placed on the market beyond specific volumes (per manufacturer or importer, per year) must be registered once the relevant periods begin. This is the case for all substances, no matter how harmless they are believed to be, unless an exemption as specified in the REACH Regulation applies (the Regulation must be examined for all such exemptions). Exemptions include radioactive substances, substances under customs supervision, substances used in the interest of defence and covered by national exemptions, waste (unless it is recovered) and non-isolated intermediates. Additionally, substances that are used in specific products, such as medicinal products or in food or feeding stuffs (that are regulated elsewhere) are exempt from the registration obligation for those uses. Moreover, there are substances listed which are already generally known to present such low risks as not to require registration, such as water, oxygen, certain types of cellulose pulp, etc.

07 *We also make preparations and goods containing substances. We have heard these also need to be registered. Is this true?*

It is important to keep in mind that only substances (meeting the tonnage thresholds laid down in the Regulation) need to be registered. This means that registration will have to be carried out for substances if they are placed on the market on their own, but also if they are contained in certain articles or in preparations. An example from the European Commission of the substance in an article that would need to be registered, is ink from printer cartridges.

08 *We have heard that our substances need to be pre-registered; does this mean that we have to register our substances twice?*

In order to benefit from the transitional periods under REACH for registration, each potential registrant of a phase-in substance in quantities of 1 tonne or more per year, must submit pre-registration information to the ECHA. This includes basic information, such as the EINECS number and name of the substance, the registrant s contact details, and the envisaged deadline for the registration and tonnage band. Such information must be submitted between 1 June 2008 and 1 December 2008. (For non-phase-in substances, instead of pre-registration, an inquiry process applies, in which an inquiry must be submitted, to see whether a registration has already been submitted for the same substance).

Once full-fledged registration becomes necessary, this must be accompanied by a technical dossier containing a variety of data on the substances, and possibly a chemical safety report.

09 *Is there only one deadline for registration of our substances, following the pre-registration stage?*

Once a substance is pre-registered, the registrant will benefit from transitional periods before registration begins. The first registration period begins on 1 December 2010, i.e., for phase-in substances (either on their own, in preparations or in articles) manufactured or imported in quantities greater than 1000 tonnes per year, per manufacturer or importer, or which meet hazardous criteria and which reach 1 tonne (or 100 tonnes in the case of risks to the aquatic environment) or more per year per manufacturer or importer. The second registration period begins on 1 June 2013, while the third begins on 1 June 2018. For both these, the registration requirement is triggered based on volume/tonnage bands.

10 *Is it not wasteful from a cost point of view that traders selling exactly the same substances have to carry out their own tests, leading to a massive duplication of tests?*

Each manufacturer or importer is obliged to submit a registration for each of its substances. However, where the same substance is manufactured or imported by more than one entity, they must submit certain information together (joint submission of data), i.e., on hazardous properties, classification and labelling, a testing proposal (if any), and, if they agree, the chemical safety report and guidance on safe use. In this way, it is hoped that registrants will reduce costs, through cooperation. Opt-out possibilities exist, but only under certain circumstances.

It is important to note that data must be shared for the same substance involving tests on vertebrate animals. For other tests, the data must be shared if requested by a potential registrant of the same substance. It is foreseen that the sharing of data will take place in exchange for payment, so as to prevent free-riding.

11 *Is it true that the REACH Regulation totally bans animal testing on substances?*

While animal testing is not banned, the Regulation aims to avoid unnecessary animal testing as far as possible. Thus, duplicate animal testing has to be avoided, and testing on vertebrate animals shall only be undertaken as a last resort.

12 *When we register, do we have to provide only the information which we already have?*

Manufacturers and importers have to collect all available existing information on the intrinsic properties of a substance (regardless of the tonnage band in which it falls), as well as on its manufacture and uses. This information has to be compared with the standard information requirements, which depend on the tonnage band (quantity of the given substance per manufacturer or importer, per year). The Regulation s annexes VII to X specify the standard information requirements according to four tonnage bands from 1 tonne per year to more than 1000 tonnes per year. There are instances in which the standard requirements may be adapted, when justified. However, there are also likely to be instances where new data will have to be generated.

13 *We acknowledge that traders of the same substance need to cooperate, but how are we to do this, and how do we find those that are scattered all over the EU?*

For manufacturers, importers and only representatives of non-EU manufacturers, the main communication mechanism per phase-in substance will be the Substance Information Exchange Forum (SIEF), following pre-registration (for non-phase-in substances, the mechanism is the inquiry process). As each potential registrant of a phase-in substance would normally wish to benefit from the transitional periods before registering, their details, including identity, will be submitted as part of the pre-registration process. Pre-registration, and the establishment of SIEFs, is thus intended to facilitate cooperation and the data sharing process.

14 *Does REACH provide express provisions on the setting up of consortia for data sharing?*

There are no provisions in the REACH Regulation on the setting up of consortia. Nonetheless, it is generally acknowledged that there are benefits to be gained by companies forming consortia, such as a reasonable allocation of time, money and the sharing of the load for dossier preparation between companies. Nonetheless, collaboration between multiple registrants by means of a consortium requires negotiations and the careful drawing up of the consortium agreement.

15 ***Is there not a risk that, where consortia are formed, EU competition law will be breached and members of the consortia may be charged with participating in cartel-like behaviour?***

It is crucial that in the forming of consortia, companies agree to cooperate only with regard to the preparation of the registration and technical dossiers, including chemical safety reports if required. Thus, they can agree to share existing test and study data, and generate new data if necessary. However, any collaboration must be restricted to such activity, and companies must never exchange information concerning their market behaviour, in particular as regards production capacities, production or sales volumes, import volumes, market shares, etc.

16 *Do we have to provide a safety data sheet (SDS) to our downstream suppliers?*

When supplying a substance or preparation to another party, the supplier must provide a safety data sheet to all the downstream users and distributors it supplies, as soon as the substance on its own or in the preparation falls within one of a list of categories (e.g., it meets criteria for classification as dangerous). In addition, an SDS must be supplied on request by a customer for preparations which meet other applicable criteria. The obligations concerning the SDS already began on 1 June 2007.

17 *We have heard that classification and labelling rules also apply. What are these?*

If the substance is one which has to be registered or is within the scope of Article 1 of Directive 67/548/EEC, meets the criteria for classification as dangerous and is placed on the market above the concentration limits specified in Directive 1999/45/EC, the registrant must notify the ECHA electronically of the information related to its classification and labelling, if the registrant puts the substance on the market, and if he has not already submitted a registration. This has to be done before 1 December 2010 for substances already on the market at that date or as soon as it is put on the market for substances not on the market yet on 1 December 2010. If the substance is registered before 1 December 2010, the classification and labelling will have to be contained in the technical dossier (in which case a separate notification is not necessary).

18 *Do we have to communicate any information down the supply chain for our articles?*

The REACH Regulation places an information obligation on the supplier of an article which contains more than 0.1% of a substance that meets hazardous criteria and has been identified as such under a committee procedure which will be established from 1 June 2008. The supplier must provide the recipient (although not consumer) of the article with sufficient information, available to the supplier, to allow safe use of the article including, as a minimum, the name of the substance.

Additionally, consumers are entitled to request, and thereupon receive, information on articles from suppliers, if they contain more than 0.1% of a substance that meet hazardous criteria and has been identified as such, to allow safe use of the article including, as a minimum, the name of the substance.

19 *Can you provide us with a list of all the substances which are going to be subject to registration under REACH?*

The European Commission has estimated that about 30,000 substances (excluding intermediates) will be subject to registration. It is not possible to provide a list of all the substances that will be registered. However, the Commission has indicated that substances listed in the HPV-LPV database included in the European Chemical Substances Information System (ESIS) might be a good indication of existing substances marketed in volumes at or above 10 tonnes per year, that will need to be registered. Further information on the database can be accessed via the following link: http://ecb.jrc.it/esis/

20 *Where is the line to be drawn between substance registration, evaluation and authorisation?*

Registration includes a completeness check by the ECHA. In itself this is an automated check of the availability of all the required information, without judging quality. Dossier evaluation enables a quality check, and will be carried out on at least 5% of the dossiers registered in each tonnage band. The ECHA will develop criteria for prioritising substances for evaluation. Such criteria are to be risk-based.

The REACH Regulation identifies the different groups of substances that may be subject to authorisation. For CMR (carcinogenic, mutagenic or toxic for reproduction) category 1 and 2 substances the criteria are already established in current EU legislation. For PBT (persistent, bioaccumulative and toxic) and vPvB (very persistent and very bioaccumulative) substances the criteria are included in Annex XIII of the Regulation. For any other substances scientific evidence must exist of probable serious effects to humans or the environment which give rise to equivalent concerns as CMR category 1 and 2, PBT or vPvB substances.

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For more information on the REACH Regulation, and the various ways in which it could affect your business operations in the European Union, please contact Reshad Forbes:

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