ORIGINALLY PUBLISHED AS AN EXPERT COMMENTARY FOR LEXISNEXIS. WE KINDLY THANK THE PUBLISHER.

Thomas Gerhold and Sonja Röder on Potential Pitfalls under European Chemical Legislation and How to Avoid Them

The European Regulation on Registration, Evaluation, Authorization and Restriction of Chemicals No. 1907/2006 (REACH) entered into force on 1 June 2007. The chemicals industry and its down-stream users must comply with REACH in order to keep their products on the market. Without a registration, it is impossible to import, sell or market chemical substances in the European Union (EU) after 1 December 2008. Until 1 December 2008, substances can be registered in order to extent the deadline for registration.

Companies that operate in the EU and import materials from outside are under an obligation to register. The application of REACH is not limited to European corporations. Hence, even Chinese or US companies may face a potential ban on exports to the EU and a potentially lasting business disruption if they do not comply with REACH.

REACH will lead to the generation of large volumes of hazard data that will be disclosed for the first time during the registration process. It may lead to an increase in product liability and occupational health litigation in the medium term. Failure to address the more urgent, immediate priority to register on time may have severe consequences such as business disruption, administrative fines and criminal charges. Dr. Thomas Gerhold and Dr. Sonja Röder discuss potential pitfalls under REACH and explain how to avoid them.

Pre-Registration

As of 1 June 2008 and until 1 December 2008, chemical substances can be pre-registered. A pre-registration extends the deadline for registration (depending on the amount and characteristics of the substance) until 30 November 2010, 31 May 2013 or 31 May 2018.

Pre-registration is not time-consuming but vital for using the transitional periods of REACH. Only by submitting a pre-registration to the newly established European Chemicals Agency (ECHA) in Helsinki, a company can benefit from the delayed deadline for full registration. If registrants fail to submit this information on time, they cannot relay on these extended deadlines but must register as of 1 December 2008. In June 2008 alone, nearly 16,000 pre-registrations were submitted to the Agency.

The duration of the transitional periods varies and depends on the amount of substance produced, the characteristics and the inherent risks of the substances. It expires on 30 November 2010 for some substances of very high concern and substances imported in large amounts. However, it can last up to 11 years until 31 May 2018. Pre-registration is open for phase-in substances. These are, for example, substances listed in the European Inventory of Existing Commercial Chemical Substances (EINECS). In practice, it is necessary to create an account on the REACH Internet portal by ECHA.

The information to be provided to the Agency for pre-registration includes:

- The name of the substance including its EINECS Number or Chemical Abstracts Service Registry (CAS) Number, or, if not available, any other identity codes;

- The name and address of the registrant and the name of the contact person and, where appropriate, the name and address of the person representing him; and
- The envisaged deadline for the registration and the tonnage band.

Practice tip:

If doubts persist whether a registration is necessary, at least a pre-registration should be submitted in order to buy more time.

Scope of Registration

Registration will be necessary for substances, substances in preparations such as paints, solvents, inks and adhesives, and substances in articles if the substance is present in those articles in quantities totaling over 1 tone per producer or importer per year and the substance is intended to be released under normal or reasonably foreseeable conditions of use. ECHA has already published guidance on requirements for substances in May 2008 that should be taken into account by any practitioner.

Practice tip:

Since REACH establishes different deadlines for the registration depending on the amount of the substances imported or manufactured, a strategic advantage may be achieved by distributing imported or produced amounts between different, legally separate entities. By this, the manufactured or imported amounts per legal entity are reduced and the deadlines for registration can be delayed.

Exemptions from Requirements for Registration

REACH contains several exemptions for a wide variety of substances. For instance, waste is generally excluded from the REACH rules. However, waste can be recycled and cease to constitute waste according to national and European legislation (for example, the legislative proposal on a framework Directive on waste and the current position of the European Parliament, P6_TC2-COD(2005)0281). In this case special attention should be paid to the provisions of REACH concerning secondary recycled materials because, in contrast to waste, secondary recycled materials are subject to the REACH requirements.

An exemption only applies for substances on their own, in articles or in articles which have been registered and which are recovered in the Community. However, the following conditions must be fulfilled. First, the substance must be registered. Second, the substance that results from the recovery process must be the same as the substance that has been registered. Third, sufficient information relating to the substance must be available to the establishment undertaking the recovery.

It has been argued that companies must only register recycled products if chemical changes occur during the recycling process. However, according to the competent authority for the enforcement of REACH in Germany, (*Bundesanstalt für Arbeitsschutz und Arbeitsmedizin*) a chemical change is not necessary in order to trigger the registration requirements under REACH. The European Commission also highlights that recovery includes cases where the substance is actually the same as the one that has been registered before (European Commission, CA/24/20008, at 7).

Practice tip:

Use national helpdesks and the approach the competent national and European authorities if you have serious doubts on the extent and scope of exemptions under REACH. This, in particular, applies if the guidance issued by ECHA should remain silent on this subject or does not contain unambiguous statements.

If a company is of the opinion that it may be affected by REACH, it should start its compliance program with drawing up an inventory of substances (as such or in preparations or articles) that it uses, imports or puts on the European market. An inventory may reveal that it is necessary to re-negotiate contracts, to substitute single substances or to phase out specific products. Best practice dictates that the complete supply chain complies with REACH. Therefore, supply chain assurance should be achieved as early as possible.

Practical Guidance by ECHA

Practitioners not only should refer to the text of REACH, but should also avail themselves of guidance issued by ECHA. Guidance published by ECHA already encompasses several thousand pages. For example, a lot of companies had difficulties to find their correct substance name and were, therefore, unable to pre-register their substances correctly. The guidance for identification and naming of substances alone encompasses 115 pages but must be taken into account, since it provides valuable assistance when submitting a (pre-) registration. More guidance is yet to be published. Existing guidance is updated constantly. Hence, any practitioner should always ensure that the guidance, to which he refers, is up to date.

However, it has to be borne in mind that the guidance is not legally binding. In particular, the courts are not bound by any guidance published by ECHA. Yet, the factual influence of this guidance in the day-to-day practice of European and national authorities must not be underestimated. If a company deviates from these guidelines, it will have to put forward convincing arguments and must be prepared to defend its position before the European Court of Justice (ECJ) or, if competent, courts of Member States.

Only Representative and Third Party Representative

If a non-European producer of substances as such or in preparations or articles wants to import these into the EU, it cannot act as a registrant itself. However, it can appoint an Only Representative who will act on his behalf. By this, a non-European company can protect its business secrets because it does not have to share any confidential business information with his customers who may be considered importers under REACH. If a non-European manufacturer appoints an Only Representative, importers of his product will be considered down-stream users under REACH. In contrast to importers, down-stream users generally do not have to submit a registration and have only limited obligations.

Practice tip:

Agreements for appointments of Only Representatives must address complex issues such as confidentiality and the respective liability of the Only Representative. It is the Only Representative who is liable for compliance with REACH *vis-à-vis* the Agency. The potential liability for non-compliance due to insufficient or incomplete data provided by the non-European manufacturer must be reflected when drafting an agreement for an Only Representative.

If a registrant wants to remain anonymous *vis-à-vis* other parties in the registration process, he can appoint a representative (Third Party Representative) according to Article 4, Sentence 1 of REACH. He will, however, have to reveal his identity for the Agency and remain responsible for compliance with REACH. This Third Party Representative must clearly be distinguished from an Only Representative who can only be appointed by a non-European manufacturer.

Substance Information Exchange Forum

The practitioner must also be cautioned that REACH to some extent demands a mandatory sharing of data, in particular studies involving tests with vertebrate animals in order to minimize testing on vertebrate animals. Producers or manufacturers of the same phase-in substances are automatically participants of a Substance Information Exchange Forum (SIEF). All SIEF participants must provide each other with existing studies and arrange for further necessary studies collectively.

Refusal to provide studies to other participants in the SIEF can result in a refusal of a registration and fines. Since REACH does not contain any detailed rules for potential agreements to form a SIEF, legal advice is mandatory for agreements. The Agency has also issued guidance on data sharing in September 2007 which needs to be taken into account and can be used as a starting point.

Consortia Formation

Even apart from mandatory cooperation in a SIEF, companies can form consortia for the preparation and compliance with REACH if they manufacture or import the same substances. However, when the decision is taken to form or participate in a consortium, several aspects must be kept in mind. In particular, a practitioner must take into account the protection of trade secrets and intellectual property on the one hand and European competition law on the other hand.

The exclusion of a company without objective reasons from a consortium may interfere with European competition law. Therefore, consortium agreements must contain special provisions on the exclusion of third companies. At least, it must be possible for a third party to obtain a letter of access to data held by a consortium. A letter of access can grant the right to refer to the full study report when submitting a registration (European Chemicals Agency, Guidance on pre-registration and data-sharing (September 2007), at 54 *et seq*.) Otherwise, the consortium agreement runs the risk of being invalid or the parties subject to measures against anticompetitive behavior. Furthermore, the obligation for compulsory cooperation is most likely to become problematic as soon as it requires the sharing of business data. An example is the mandatory sharing of customer data that may be necessary for describing the exposure scenario of the chemical safety assessment. Such an exchange of sensitive information between competitors may well interfere with competition law. An agreement must achieve a balance between giving sufficient information to satisfy the REACH requirements and limiting disclosures to the necessary data in order to protect business secrets and avoid infringements of European competition law. A possible solution is to appoint a trustee.

Enforcement

Companies should not be tempted to speculate on a sloppy enforcement of REACH by Member States authorities. In Germany, a respective law for the enforcement of REACH has

already been enacted. The Law "On the Implementation of Regulation Number 1907/2006" (*REACH-Anpassungsgesetz*) has entered into force on 1 June 2008. It amends the Law "On Chemicals" (*Chemikaliengesetz*) and lays down the competences of the German authorities. According to the amended Law "On Chemicals", non-compliance with REACH can constitute an administrative offence that can be fined with up to EUR 200,000.00. Moreover, non-compliance with REACH can amount to a criminal offence and may lead to an imprisonment of up to 5 years or a legal penalty.

Legal Review of Measures

The practitioner must be cautioned that legal review under REACH must take into account its specific features.

National Legal Review

National authorities remain competent for the evaluation of a substance. Moreover, it is left to Member States to maintain a system of official controls. If German authorities impose administrative fines or legal penalties, these national measures will be subject to a legal review under German law.

European Legal Review

National authorities do not implement all measures under REACH. Instead, the Agency and the Commission will take several decisions under REACH. Attention must be paid to a special procedure of administrative review by an independent Board of Appeal. An appeal is for example required if the Agency rejects a registration because it claims that the registration is incomplete or if the Agency gives permission to another registrant to refer to information provided in a dossier by a previous registrant. This administrative review is a necessary prerequisite for a subsequent legal review by the ECJ.

Decisions of the Board of Appeal and decisions by the Agency itself that cannot be brought before the Board of Appeal can be challenged in front of the ECJ. Examples are decisions of the Commission to grant or deny an authorization. Future litigation will depend on the striking of a proper balance between the precautionary principle, the principle of proportionality, possibly diverging rights of consumer protection, environmental rights, rights of companies to protect business secrets and rights to property.

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