

May 2008

GETTING READY FOR REACH: PRE-REGISTRATION

In June 2007, the European Union's Regulation (EC) No. 1907/2006 on the Registration, Evaluation, Authorization, and Restriction of Chemicals (the so-called "REACH Regulation")¹ entered into force. The REACH Regulation imposes, for the first time, sweeping requirements on all producers using substances in their goods and manufacturing processes.

This memorandum discusses the REACH pre-registration process, which will apply as of June 1, 2008, and immediate steps thereafter. In particular, the memorandum discusses (i) the difference between registration and pre-registration; (ii) the types of substances that may be pre-registered; (iii) the entities that may pre-register; (iv) legal and practical advantages and drawbacks of pre-registration; (v) the difference between so-called "only representatives" and "third party representatives"; (vi) the practicalities of pre-registration; (vii) basic concepts on data sharing among participants of the Substance Information Exchange Forum ("SIEF"); (viii) basic principles on consortia, and (ix) general rules and practicalities on counting volumes for the purpose of complying with the different REACH requirements.

1. Registration and Pre-Registration

As of June 1, 2008, all manufacturers and importers of substances on their own, in preparations and in some cases articles must register the substances they manufacture or import in quantities of one ton or more per manufacturer/importer per year, unless an exception applies. Registration will require submitting (i) a technical dossier with extensive data on the toxic and eco-toxic characteristics of the substance, which will entail substantial testing and data gathering; and (ii) a chemical safety report assessing the hazards, exposure, and risks of use during the entire life cycle for substances manufactured or imported in quantities of 10 tons or more per chemical manufacturer or importer per year. Registration will be substance and company specific. Only those chemical manufacturers and importers that register will be allowed to manufacture or import their substances or products containing them.

Importers of goods in the form of preparations are importers of substances and therefore, are subject in full to the REACH registration requirements, unless an exemption applies. Examples are importers of tobacco products, cosmetics, detergents, paints, inks, and certain types of medical devices. Importers and manufacturers of articles (*i.e.*, objects) that are intended to release substances may also

¹ A copy of the Regulation is available at:

http://eur-lex.europa.eu/LexUriServ/site/en/oj/2007/l_136/l_13620070529en00030280.pdf.

be required to register the releasing substances. Examples may include importers and manufacturers of deodorant releasing textiles, intelligent packaging, and razors with comfort strips.

On the contrary, downstream users (e.g., EU manufacturers of products using substances supplied to them by EU manufacturers or importers) will be subject to limited requirements provided that their suppliers are REACH compliant. In some cases, downstream users may try to comply with the REACH requirements themselves in order to gain control of the process.

As of June 1, 2008, manufacturers and importers of substances will not be allowed to continue to manufacture, market or import their substances until they register them. However, the Regulation provides for a phase-in period starting in December 2010 and ending in June 2018 for so-called "phase-in" substances that are pre-registered between June 1 and December 1, 2008. Non phase-in substances, in contrast, must be registered as of June 1, 2008, before their manufacture or import can continue. It is also likely that manufacturers and importers of phase-in substances that do not pre-register them by December 1, 2008 will retroactively be considered liable for registration as of June 1, 2008.

2. What Substances Can Be Pre-Registered?

Only so-called "phase-in" substances may be pre-registered, and therefore, benefit from the transitional periods for registration. Phase-in substances include:

1. Substances Listed in the European Inventory of Existing Commercial Substances ("EINECS"): There are around 100,000 substances in the European Inventory of Existing Commercial Substances list, so-called "EINECS." EINECS substances are those reported to be on the European market between 1971 and 1981.
2. So-called "No-Longer Polymers" ("NLPs"): In 1992, the European Commission created a NLPs list with around 700 substances that, even though they no longer met the EC definition for polymers, were exempted from the notification requirements of Directive 67/548/EEC, as amended. The list, however, is not exhaustive, and therefore, non-listed substances may be considered as phase-in substances if it is proven that they meet the definition of a NLP.

To benefit from the exemption for NLPs, manufacturers and importers must be able to provide documentary evidence that the NLP was placed on the EU market before the entry into force of the REACH Regulation. Documentary evidence is likely to include safety data sheets, order sheets, stock lists, and labels.

3. Substances Manufactured in the EU or in Acceding Member States but Not Placed on the Market after 1 June 1992. In order to benefit from this exemption, manufacturers and importers must also provide documentary evidence.

Non phase-in substances, which cannot be pre-registered, and therefore, must be registered by June 1, 2008 before their manufacture, marketing, or import can continue or be initiated, include:

1. Substances Listed in the European List of Notified Chemical Substances (“ELINCS”): The ELINCS list contains around 4500 substances that were notified in accordance with Directive 67/548/EEC, as amended. While the notifier of the substance under Directive 67/548/EEC is considered as having already registered, all other manufacturers and importers of the substance are required to register the substance as of June 1, 2008.
2. New Substances: Substances that are manufactured in, or are imported into, the EU, for the first time after June 1, 2008.
3. Substances that Are Not EINECS Listed or NLPs But Were Exempted From Notification under Directive 67/548/EEC: A special category of substances are those that were exempted from notification under Directive 67/548/EEC because they were contained in product categories that were exempted, such as cosmetic products. These substances must now be registered, unless they are also exempted under REACH, and do not benefit from a phase-in period.

3. Who Can Pre-Register?

Only potential registrants of phase-in substances may pre-register. This includes manufacturers and importers of phase-in substances in quantities above one ton per manufacturer/importer per year. As the Regulation refers to the term “potential registrants,” it is likely that the European Chemicals Agency will allow the pre-registration of any person potentially intending to import or manufacture a phase-in substance within the next 11 years.

The requirements of the REACH Regulation apply per natural or legal person established in the EU (and the European Economic Area, which also includes Iceland, Lichtenstein, and Norway). The Regulation does not define the term “legal person,” and therefore, it is likely to be interpreted in accordance with relevant principles of company law.

In the case of a corporate group, the registration and pre-registration requirements are likely to apply to each of the legal individual entities of the corporate group that are established in the EU/EEA, and not to the corporate group as a whole. Typically, corporate groups have several legal entities in the

EU, and it is perfectly possible that each of the different EU legal entities of the same corporate group may have to pre-register the same substance. On the other hand, the fact that different legal entities manufacture or import substances may result in the registration (and pre-registration) volume thresholds not being reached.

Only manufacturers and importers established in the EU can register and pre-register. REACH imposes no legal obligations on foreign suppliers of substances or goods containing them. However, in order to facilitate imports, foreign manufacturers may appoint a so-called “only representative,” who will be responsible for pre-registration and all other registration requirements. Where a foreign supplier appoints an only representative, he must inform the importers of the substance. The importers of the substance will then be considered as an EU downstream user with limited requirements.

Importers of products in the form of preparations will be subject to the REACH registration requirement for each of the substances in their products unless they benefit from an exemption and therefore should consider whether to (i) pre-register the substances themselves; and/or (ii) rely on the only representatives of their foreign suppliers. For the reasons explained below, importers should consider pre-registering themselves even if they decide to also rely on the only representatives of their foreign suppliers.

Downstream users (*i.e.*, EU entities using in their manufacturing processes substances purchased from EU suppliers) are not subject to registration, and therefore, they are not likely to be allowed to pre-register. However, a downstream user may always try to pre-register as a potential manufacturer or importer of the substance during the next 11 years.

Entities who notified substances under Directive 67/548/EEC are to be considered as already having registered, and therefore, are not likely to be subject to pre-registration. Furthermore, notified substances are, in most cases, not likely to be phase-in substances, and therefore, registration updates (for example due to increases in volume) are not likely to benefit from pre-registration and the phase-in periods.

4. Why Should a Company Pre-Register?

Practical reasons for a company to pre-register are likely to include the following:

1. Manufacturers and importers that pre-register their substances will benefit from a phase-in registration period with the following deadlines:

- a. December 1, 2010: Registration of substances (i) manufactured or imported in volumes of 1000 tons or more per manufacturer/importer per year; (ii) Category 1 and 2 carcinogens, mutagens, and toxic-to-reproduction substances; and (iii) substances classified with the risk phrase R50/53 (*i.e.*, substances classified as very toxic to aquatic organism which may cause long term adverse effects in the aquatic environment) if they are manufactured or imported in volumes of 100 tons or more per manufacturer/importer per year.
- b. June 1, 2013: Registration of substances manufactured or imported in volumes of 100 tons or more per manufacturer/importer per year, with the exception of substances classified with the risk phrase R50/53.
- c. June 1, 2018: Registration of all substances manufactured or imported in volumes of 1 ton or more per manufacturer or importer per year.

Manufacturers and importers that have pre-registered their substances may also register their substances any time before these deadlines.

Having more time to register a substance may be useful if registration will require the gathering of data that is not currently available. Furthermore, the later an entity registers, the more likely that other entities have already registered and gathered the data for the same substance. This can be important in the case of data resulting from testing on vertebrate animals as it must be shared, although latecomers will also have to contribute to the costs.

2. Market supply. Manufacturers and importers that do not pre-register their substances are likely to be required to interrupt their manufacture or import of the substance for three weeks from the date of submission of their registration dossier during which the European Chemicals Agency may verify the completeness of the registration dossier. Hence, even if a manufacturer or importer registers a substance on June 1, 2008, it is likely that it will be required to await three weeks before it can continue to manufacture or import the substance. It is likely, however, that an entity in the EU will be able to continue to supply substances that it already has in stock in the EU.

In contrast, manufacturers or importers that pre-register their substances are likely to be able to continue to manufacture or import their substances after their registration if they submit the registration dossier no later than two months prior to their applicable phase-in registration deadline (*i.e.*, December 1, 2010; June 1, 2013; June 1, 2018).

3. Pre-registration is not likely to commit the pre-registrant to register, and a pre-registrant will always be able to decide not to register its substance later on. This, however, is also another reason for manufacturers and importers of goods to try to pre-register their substances even if their suppliers also do so. The fact that their suppliers pre-register does not ensure that they will later register the substance.
4. Where a foreign supplier changes its only representative after the end of the pre-registration period, there is the risk that the European Chemicals Agency takes the position that the new only representative may not benefit from the former's pre-registration. In that case, the importer would not be able to continue to import the substance until it is registered.
5. Pre-registration may also allow manufacturers and importers of goods to gain control of the registration process and to be able to influence the discussions on the substances that will take place in the Substance Information Exchange Forum ("SIEF") and eventually in consortia. Pre-registration may also provide additional time to the manufacturer or importer to decide whether to register the substance on its own or to choose among those suppliers that have already registered the substance.
6. Pre-registration is not likely to require revealing the identity of the pre-registrant to third parties and competitors. As explained below, a pre-registrant may appoint a so-called "third party representative" to deal with other companies when complying with REACH requirements. In these cases, while the Agency will know the identity of the pre-registrant, third parties will only be aware of the identity of the third party representative.
7. As explained below, pre-registration is likely to be rather simple and it is not subject to payment of a fee to the European Chemicals Agency.

However, there are three caveats that manufacturers and importers should consider before pre-registering. First, pre-registration obliges the pre-registrant to enter a SIEF on the substance and to share the data that it has available. This obligation is likely to apply even if the pre-registrant later decides to opt out from registration. While in practice it may be difficult for other SIEF participants to know the data that a company has available, under a strict interpretation of REACH, all pre-registrants are likely to be obliged to share the data resulting from animal testing that they have available.

Second, while in case of doubt as to whether a substance is subject to registration it is always best to pre-register, manufacturers and importers should avoid pre-registering substances that are clearly not subject to registration and that may nevertheless be problematic. Pre-registration draws attention to the substance, its manufacturers, and importers. For example, importers should carefully consider whether to pre-register substances likely to be identified as being of very high concern (*i.e.*, Category

1 and 2 carcinogens, mutagens, and toxic-to-reproduction substances; persistent, bioaccumulative and toxic substances; very persistent and very bioaccumulative substances; and substances raising an equivalent level of concern) contained in imported articles if these substances are clearly not intended to be released from the articles. This is because such pre-registration could later be problematic under the REACH restrictions, and possibly even authorization, procedures.

Third, pre-registration and participation in the SIEF is likely to involve a significant amount of work and discussions with other SIEF members. Even if a pre-registrant remains inactive within the SIEF, it may be involved in SIEF discussions and dragged into eventual disputes among SIEF members.

5. Only Representatives Versus Third Party Representatives

As explained above, foreign suppliers may facilitate the REACH compliance of their EU importers by appointing an only representative in the EU. In that case, the only representative will be liable for the pre-registration and registration of the substance and the importers will be considered as downstream users.

The Regulation provides that a foreign person “who manufactures a substance on its own, in preparations or in articles, formulates a preparation, or produces an article that is imported into the Community” may appoint an only representative. This has led the European Chemicals Agency to currently exclude foreign distributors from appointing an only representative in the EU. This interpretation may *de facto* prevent parallel imports and, if applied strictly, could also pose a challenge to foreign companies using contract manufacturers. The concept of “only representative” suggests that a foreign manufacturer (or formulator) can only appoint one only representative per supplied substance.

The Regulation requires that only representatives meet two conditions: (i) they must have sufficient background in the practical handling of substances and the information related to them; and (ii) they must be established in the EU. Only representatives must also keep available and up to date information on the quantities imported and the customers and information on the supply of the latest safety data sheet. Only representatives are not likely to be required to disclose the identity of their represented foreign manufacturers to other participants in the SIEF.

In the case of corporate groups, it is likely that one of the corporate group’s legal entities established in the EU may act as the only representative of all other foreign legal entities of the group. The pre-registration of this only representative legal entity would then cover the imports of all other EU legal entities of the same group.

It is likely that the only representative that pre-registers a substance will become liable for the pre-registration and registration and all other REACH requirements, such as those resulting from authorization. The European Chemicals Agency's and European Commission's current position is also that the only representative can represent several foreign manufacturers of the same substance. However, that interpretation also suggests that where an only representative represents several foreign suppliers of the same substance, that only representative must submit a registration for each of the foreign suppliers it represents even if they all supply the same substance. This would also mean that, in the case of data sharing, the only representative would have to buy the data for each of the foreign suppliers of the same substance that it represents.

Foreign suppliers and importers should be particularly careful when appointing an only representative. The Regulation provides that it is the only representative who is liable for registration and pre-registration. However, where the only representative is unable to face its liability, there is the risk that enforcement authorities may also hold importers liable. Furthermore, where an only representative represents the imports of a substance of more than one foreign manufacturer this may pose confidentiality issues and may also be problematic from the point of view of European competition rules.

Thus, importers of goods relying on the only representatives of their foreign suppliers may wish to ensure that the only representative meets certain technical and quality standards and has good financial standing.

"Third party representatives" are different to only representatives. EU manufacturers, importers, and downstream users of substances can appoint a third party representative in order to ensure that their identity is not disclosed to third parties, including their competitors.

A third party representative can be used for purposes of participation in a SIEF, data sharing, joint submission of registrations, evaluation discussions, and presumably also in consortia. Where a third party representative is appointed, the liability for pre-registration, registration and data sharing and all other REACH requirements is likely to fall on the manufacturer or importer pre-registering, and not on the third party representative.

6. How Will Pre-Registration Work?

The pre-registration period will start on June 1, 2008 and will end on December 1, 2008, but REACH also provides specific rules for latecomers wishing to pre-register.

Pre-registration will require the submission of the following limited information:

1. Basic identification of the substance. Pre-registration will only require the name of the substance, the International Union of Pure Chemistry Nomenclature (“IUPAC”) name or other chemical names, and the EINECS and/or CAS numbers if available or other codes that are available. Significant more detailed information is required for purposes of registration.
2. The name and contact details of the pre-registrant. Where the substance is being pre-registered through an only representative in the EU, the pre-registration must include a letter from the foreign manufacturer authorizing this person to act as a legal representative. Where the pre-registrant wishes to appoint a “third party representative,” the pre-registration must also specify this and the name and contact details of this representative.
3. The envisaged tonnage and registration deadline.
4. The name and identity of substances for which available information might be relevant, where the pre-registrant intends to use “read across data” (data on other substances that will be relied upon by extrapolation) in his registration.
5. Whether the pre-registrant is wishing to act as a facilitator in the SIEF.

Pre-registration is likely to be possible through (i) the REACH IT website of the European Chemicals Agency; or (ii) the submission of a bulk pre-registration covering several substances and prepared separately on a specified computer file prepared by the Agency. It is likely that pre-registrants will be allowed to amend their pre-registrations by just submitting another pre-registration before the end of the pre-registration period. However, it is also likely that after the end of the pre-registration deadline, only some refinements of the pre-registration (including refinements in the substance identification) will be possible.

It is expected that upon pre-registration, pre-registrants will be directed to a website created for all substances with the same EINECS or other identifiers. The website is expected to display the corresponding entry in the EINECS, or CAS number or other identification codes, the details of all pre-registrants (or third party representatives), the tonnage band of the different pre-registrants and whether they are willing to act as “facilitators” in the SIEF. This website is expected to be accessible

only to those entities that have pre-registered, and therefore, required to join the SIEF, and to those third parties holding data who wish to join SIEF.

The identity of pre-registrants will not be disclosed to persons other than those who pre-register and other third parties who join the SIEF. In particular, in January 2009, once the pre-registration period has concluded, the European Chemicals Agency must publish the list of pre-registered substances. This list will not include the name of the pre-registrants, but only the name of the substances, their EINECS and CAS numbers if available or other identity codes, and the first envisaged registration deadline (for all pre-registrants of the same substance).

Thus, downstream users and those importers of goods relying on their suppliers will not be able to check whether their suppliers have pre-registered (unless their suppliers give them copy of their pre-registrations). Instead, non pre-registrants will only be able to see whether their substances have been pre-registered.

The Regulation also establishes special rules for the pre-registration of latecomers. It applies only to those manufacturers or importers of substances that manufacture or import a phase-in substance in quantities of one ton or more for the first time after the pre-registration deadline. These manufacturers or importers may submit a pre-registration after December 1, 2008 if they do so (i) within six months of their first manufacturing or importation of the substance in quantities above one ton per year; and (ii) at least 12 months prior to the registration deadline that it is applicable to them.

REACH also foresees a procedure for the case where a downstream user finds out that its substance has not been pre-registered. In these cases, the downstream user may notify the European Chemicals Agency of its interest in a substance. This will require disclosing its identity and also that of its supplier. The Agency will then publish the name of the substance on its website and, upon request, provide the contact details of the downstream user to a potential registrant. In practice, this mechanism is only likely to be effective for suppliers of substances that are also latecomers (and not suppliers that failed to pre-register in time). Furthermore, this mechanism is not likely to guarantee that downstream users will be able to find a pre-registrant after the pre-registration deadline.

7. SIEFs and Data Sharing

As already explained, all pre-registrants will automatically join a SIEF for each substance they pre-register. The purpose of the forum is to facilitate the sharing of data for the purposes of registration and to agree on the classification and labeling of a substance when there is disagreement between potential registrants. The forum will be operational until June 1, 2018.

REACH also foresees that third parties who are not potential registrants may also join the forum for a particular substance. These third parties include the so-called “data holders”: (i) manufacturers or importers of the substances in volumes below one ton; (ii) downstream users; and (iii) any third party. These parties may join the forum if they have data.

Downstream users, NGOs and public institutes may wish to join the forum to share (and sell) their data and also to try to influence the information on the substance that is finally submitted. Joining the forum could also be a way to monitor and control the information that is available on the substance. NGOs, institutes and other entities, are not likely to be able to use a third party representative; instead, they must disclose their identity when they participate in a SIEF.

Pre-registrants of a substance with the same identification codes will have to agree on the “sameness” of the substance. This is because some EINECS numbers include different substances, and it is also known that some of them are erroneous entries. Thus, it is possible that a significant number of SIEFs will be split into different *fora* with different substances.

REACH provides for complicated rules on the sharing of data. The main principle is that all data resulting from testing on vertebrate animals must not be repeated and, if available, must be shared. This sharing of data must be in return of the costs, which must be determined in “a fair, transparent, and non-discriminatory way,” and it is likely that the interpretation of this standard will in many cases result in disputes among SIEF members.

Data owners who fail to share their data will be penalized through the imposition of fines or preventing the owner from registering its substance. In the case of pre-registered substances it is possible that owners of data who do not need to pre-register until the later phase-in deadlines (for example 2018) will have to share their data with those registering first. However, in practice, it is more likely that those that register first will have to share their data with those registering at a later time. This is because it is upon registration that other parties will know that the registrant has the data.

REACH protects the data owner for 12 years from the date of registration. Thus, where data was submitted under the Dangerous Substances Directive notification requirements, it may be possible that new registrants will have access to the data for free if the notification was done at least 12 years ago. Furthermore REACH is not likely to prevent registrants from using data that was submitted in third countries under these countries regulatory regimes and that has later become publicly available.

8. Consortia

Trade associations and other groups are currently discussing the possibility of creating different forms of cooperation among companies in order to comply with the different REACH requirements, including registration. These different forms of cooperation are so called “consortia.”

The REACH Regulation, however, does not require nor regulate consortia. In particular, there is no equivalence between SIEF and consortia. For example, among the manufacturers and importers participating in a SIEF there may be different consortia to deal with different classification issues, volumes, etc. Consortia may also cover more than one substance, while REACH requires the creation of one SIEF per substance. Consortia may also start before the SIEF and can even last longer.

In some cases, of course, consortia are likely to be useful. For example, it is likely that after the pre-registration deadlines many SIEFs will be created and these will include many different types of participants. Thus, it might be best to have consortia clearly regulating how the costs of generating the data will be shared. Consortia may also be useful to ensure a proper communication and REACH compliance between suppliers and customers manufacturing goods outside the EU. Consortia can also be used to defend together a particular substance during the entire REACH processes. For example consortia can also deal with authorization issues.

Consortia are likely to be subject to basic principles of contract law and, most importantly, EC competition rules. A consortium agreement is likely to regulate (i) the purpose and scope of the consortium; (ii) membership criteria; (iii) bodies of the consortium; (iv) ownership of the data; (v) data compensation issues; (vi) rules on protection of confidential information; (vii) financing aspects; (viii) liability; (viii) governing law; and (ix) dispute resolution issues.

Companies should always bear in mind that a consortium is an association among competitors. Thus, EU and national competition rules will apply to consortia. In general, this requires taking into account two main principles:

1. The consortium must establish transparent and non-discriminatory criteria for membership. This in practice means, among other things, that membership cannot be exclusively based on size or turnover or limited to only members of a trade association.
2. The exchange of information must be limited to that required by REACH. The consortium should not exchange information on prices, production capacities, cost of production, sales volumes, future plans regarding investment.

Thus, pre-registrants should ensure that their company representatives participating in consortia get appropriate training on EU competition rules and that such participation is also always monitored by a lawyer. Companies are also recommended to appoint a third party trustee responsible for dealing with the exchange of information among consortium members. All meetings and discussions in the consortium should also be well documented. Companies should also ensure a coordinated strategy if they participate in different consortia. Only representatives representing more than one foreign manufacturer of the same substance are likely to be particularly at risk with respect to competition rules.

9. Methods for Calculating Volumes

Counting correctly the volume of a substance that an entity manufactures, imports or uses is essential for a correct compliance with the REACH Regulation's requirements. Most importantly, the volumes of the substance determine whether an entity must register a substance, and therefore, whether it should consider pre-registering it. The registration requirement applies only to manufacturers or importers of substances, on their own, in preparation, or in articles (if they are intended to be released) in quantities of one ton or more per manufacturer/importer per year.

The volumes of the substance manufactured, imported or used, however, also determine whether that entity must comply, and how, with many other REACH requirements. For example, the volumes will determine: (i) the timing of registration in the case of phase-in pre-registered substances; (ii) the amount and type of data to be submitted upon registration; (iii) whether a registration must be updated; (iv) whether a chemical safety report must be included in the registration (10 tons); (v) whether a downstream user must draft a chemical safety report (1 ton); and (vi) whether the substance may benefit from a R&D authorization or restrictions exemption (1 ton).

For the purpose of registration (and pre-registration) the volume of one ton or higher must be reached at least once after June 2007. The counting of volumes, however, is different depending on whether the substance is a phase-in substance or not. In the case of non phase-in substances, the volume must be established on the basis of the calendar year of registration. In contrast, in the case of phase-in substances that have been manufactured or imported for at least the last three consecutive years, the volume must be established on the basis of the average of the quantities manufactured or imported during the three preceding calendar years.

The volume of the substance must be established on the basis of that manufactured or used by an EU manufacturer or downstream user and that imported by an EU importer; it does not refer to the volumes manufactured or supplied by the foreign supplier. Where the foreign manufacturer appoints an only representative in the EU, it is likely that the relevant volumes will be those of the foreign manufacturer that are actually imported into EU. As explained above, the European Chemicals

Agency's current position is that an only representative may represent various foreign manufacturers of the same substance and that, in such case, their exported volumes must be cumulated.

The volume must be established on the basis of each legal entity that manufactures, imports or uses a substance. In the case of a corporate group, the volume must be established on the basis of each and every one of the different legal entities established in the EU that manufactures, imports, or uses the substance. However, for each legal entity, the volume must be established by looking at the same substance in all products across the board manufactured or imported by the same legal entity.

The volumes of a substance in an imported good in the form of a preparation and those of the substance imported in bulk must be cumulated. There is, however, no cumulation of imported volumes and those purchased from EU suppliers. There is also no cumulation of the volumes of imported substances, on their own, or in preparations, and those of imported or manufactured articles.

In the case of manufacture or import of articles intended to release substances, the relevant volume of the released substance is that contained in the article and not only that which is released. Similarly, for the purpose of notification of substances of very high concern that are contained in articles, the volume must be established on the basis of the substance contained in the article. The volumes are likely to be established on the basis of all the articles of the entity that release substances (or contain substances of very high concern) and not per brand or model.

The volumes of exempted uses must not be taken into account. Similarly, the volumes of intermediates must not be cumulated with those of other uses of the substance.

There are also special rules for counting the volumes of constituents where the constituents and not the multi-constituent substance are registered or pre-registered. In that case, it is likely that the volume relevant to establish whether registration of the constituent is required, its timing and data, must be based on the total volume of the substance and not that of the individual constituent. Where the entity uses the constituent in different multi-constituent substances that it manufactures or imports, it must take the highest threshold (that of any of the multi-constituent substances, or the volume of the constituent when used in the different substances).

A corporation may envisage reorganizing the importation or manufacture of substances (on their own, in preparations or in articles) in order to reduce its registration requirements (spreading the volumes among different legal entities), or by concentrating the volumes in order to centralize compliance with the REACH requirements (this, however, may result in higher data requirements, earlier registration in the case of phase-in substances, and a higher registration fee). However, any reorganization of the import and manufacture of substances should take careful consideration of strategic issues, such as fiscal considerations.

* * *

The REACH Regulation is technical in nature and many of its provisions are open to different interpretations. It is important to monitor how the rules are being implemented in more detailed provisions and guidelines.

The information in this memorandum is not intended as legal advice, which may often turn on specific facts. Readers should seek specific legal advice before acting with regard to the subjects mentioned herein.

For further information, please contact:

Peter Bogaert	+32.2.549.5243	pbogaert@cov.com
Cándido García Molyneux	+32.2.549.5261	cgarciamolyneux@cov.com

Covington & Burling LLP is one of the world's preeminent law firms known for handling sensitive and important client matters. This alert is intended to bring breaking developments to our clients and other interested colleagues in areas of interest to them. Please send an email to unsubscribe@cov.com if you do not wish to receive future alerts.

© 2008 Covington & Burling LLP. All rights reserved.