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# G&CO Client REACH Alert January 2008

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You have no doubt heard of the EU's new chemical regulatory regime commonly referred to by its acronym "REACH".

But are you aware of just how crucial REACH is this year 2008 and the significant impact it might have on your business ?

**By way of a brief reminder REACH stands for the following:**

- **R = "Registration" -** this is the key regulatory obligation that companies will have to deal with. Where quantities of 1 ton or more of a chemical are placed on the EU market companies must register information about this chemical with the European Chemicals Agency. This requirement becomes particularly significant above 10 tonnes as the submission of a technical dossier containing a "Chemical Safety Report", which will document a "Chemical Safety Assessment", will be required - risk management recommendations will also need to form part of the dossier. The information requirements for Registration increase depending on tonnage and/or the hazardous nature of a chemical. Every company entity must register, but a company group "Pre-registration" is possible (see below). Manufacturers outside the EU must also ensure proper Registration, either through an importer or an "only representative". Failure to comply with Registration will mean that a chemical will be excluded from the EU market (now consisting of 27 EU Member States);

- **E = Evaluation -** there are two types of Evaluation: first, a straightforward check that the information submitted under Registration is complete, and, second, where there may be concerns about a chemical regarding dangers for human health or the environment, a more substantive analysis of the data will be conducted. In this latter case either an Authorisation procedure or a Restriction procedure may follow (see below);

- **A = Authorisation -** the riskiest category of chemicals, namely those of "substances of very high concern" must follow an additional process in addition to Registration in that they must be authorised in order to be on the market. Authorisation will focus on a chemical's use. In some cases, to obtain authorisation, it will have to be shown that the use risks can be adequately controlled or that the socio-economic benefits outweigh such risks and that there are no suitable alternatives. In any case, an analysis of potential alternatives must form part of the process. Authorisation will be time-limited and reviewable and possibly subject to conditions. An initial list is already being prepared by regulators of those chemicals that will need to undergo Authorisation;

- **CH = Chemicals -** although chemical substances and their mixtures are the prime regulatory target, finished products are also covered, referred to as "articles". A separate REACH regime applies to chemicals in articles whereby all substances intended to be released from articles during normal and reasonably foreseeable conditions of use are subject to Registration (which includes Pre-registration) where those substances are present in the article above 1 tonne per producer or importer (being the entire amount contained in the article). Further, Registration may be required in certain prescribed cases where there is an unintentional chemical release;

- **R "plus" =** There is another letter, omitted from the acronym, namely another "R" which stands for Restriction. Separate to Authorisation, due to possible dangers presented to human health and the environment, chemicals may also be subject to certain restrictions - in some cases this will in effect amount to a ban. A specific Restriction procedure will have to be undertaken to determine whether restrictions will be applied - REACH already contains a list of existing restrictions (carried over from previous EU legislation).

What must be highlighted for companies is the "Pre-registration" process. In order for Registration to be conducted in an orderly manner, because of the expected significant number of chemicals and articles that will be submitted to Registration, a system of transitional time periods will operate, primarily depending upon the tonnages of the chemicals on the market. In order to be able to benefit from these time periods, so-called "phase-in" chemicals can be "Pre-registered" - a "phase-in" chemical is essentially a chemical that is currently listed in the "European



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Inventory of Existing Commercial Chemical Substances" (more commonly known under its acronym, "EINECS"). The information required to be submitted for "Pre-registration" (which will be done through a specific IT system) is straightforward in itself but the actual preparation for "Pre-registration" will be resource- and time-intensive and will necessitate cooperation with other producers, importers etc of the same chemical (see below). Pre-registration itself will take place in a very limited time period, namely:

**1 JUNE - 1 DECEMBER 2008**

It cannot be emphasised just how important this deadline is - missing it will in effect mean that companies will be prohibited from putting their (phase-in) chemicals on the market until full Registration is complete, with just a limited exception of a 6-month extension and only with respect to downstream users for certain prescribed types of cases. Even if at a later date, for whatever reason, a company decides to not fully register, pre-registration is strongly advisable in order to maintain being able to take advantage of the transitional time periods.

It must also be highlighted that, in order to both lighten the administrative burden and cost and to minimise testing (especially on animals), through Pre-registration, companies are legally obliged to work together in a so-called "Substance Information Exchange Forum" ("SIEF"). This means that a number of issues concerning data-sharing will need to be addressed - commercially this may also present opportunities as compensation will have to be paid for reliance by companies on other companies' data. Needless to say, in undertaking such activities, companies will also have to conduct themselves in a manner that does not infringe either EU or national competition laws as market sensitive data must not be exchanged or discussed.

It must also be emphasized that REACH does not solely affect chemical manufacturers. Downstream users also have particular obligations to comply with, especially as they must provide information concerning so-called "exposure scenarios" (in effect, how the chemical is used). Importers and distributors are also affected by REACH, especially importers as they may carry the burden of Registration if there is no EU manufacturer of the chemical or article in question.

It should also be stressed that failure to comply with REACH may not only mean that a chemical or article has to be withdrawn from the market, but, in addition sanctions may be imposed - in some EU Member States such penalties will be criminal.

In addition to coming to grips with specific issues, for example, scoping whether a product is an article or not for the purposes of REACH, companies may also need to address the following areas:

- **Consortia -** although a SIEF is not a consortium as such, because SIEF membership is obligatory under REACH, the best vehicle to operate a SIEF may be to set up a consortium, for which legal agreements will need to be drawn up (with special attention paid to data-sharing arrangements). Many consortia are in fact already up and running and so negotiations will need to entered into to join these. Alternatives to consortia also exist, such as licensing arrangements;

- **Long-Term Supply and Purchase Agreements -** clauses in such agreements are likely to need to be revised, especially as regards areas such as concerning liability;

- **Intellectual Property -** these rights may be affected, notably concerning confidentiality;

- **Customs -** customs clearance issues may arise as regards REACH compliance, especially in the context of "rogue" REACH-compliance claims;

- **Access to Information -** you may not always get the information you are seeking under a given REACH process and so you may need recourse to particular specific official legal access to information channels to find out certain information (and your company may also indirectly be on the receiving end of such an inquiry);

- **Compliance strategy -** this should be carefully thought-through, especially in the light of the possibility of sanctions and liability;

- **Insurance -** it is likely that insurance policies will require revision; and,

- **Avenues of redress -** in addition to the possibility of judicial review before the European Court, REACH appeals before a Judicial Board of Appeal are provided for in certain prescribed areas.

As you will have surmised, the burden of complying with REACH squarely lies with industry. Grayston & Company's regulatory team can help you deal with this challenge. We can also partner with other organisations where the tasks necessitate this, notably as regards the technical scientific aspects of REACH.

Don't get caught out and don't forget to pre-register !

***Footnotes:***

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