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G&CO EU Update: Pre-Registration Controversy Alert – The Precautionary Principle Turned on its Head?

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The REACH Pre-Registration process has been in full swing since it began earlier in the summer and it now only has two months to run, ending on 1 December 2008. Businesses eligible to Pre-Register and who have not yet done so are of course strongly advised to pull out all the stops to complete this, otherwise their substances and finished articles containing a substance ("articles") will not be able to remain on the EU market until full Registration of such items has taken place.

The European Chemicals Agency ("the ECHA") in Helsinki, Finland, the regulator which has the operational task of managing Pre-Registration and Registration, has in fact just released some interesting but controversial news about Pre-Registration.

The ECHA has stated that, as at mid-September, some 352,641 Pre-Registrations had taken place with the greatest majority of those coming from Germany followed by the UK who both lead the pack by a very long way, after which come applications from Holland, Italy and France. Whilst it might be thought that the ECHA would be pleased at such a large take-up in that this would demonstrate a measure of regulatory success, the organisation has in fact sounded a warning cry as it claims that "a number of these pre-registrations may not be valid."

Although the precise details as to why this may be the case are not clear, two main basic reasons for such an alleged problem are cited by the ECHA.

First, according to the ECHA, certain substances do not apparently qualify as so-called "phase-in" substances (one of the main Pre-Registration conditions).

By way of brief reminder, phase-in substances must meet one of three criteria: either, they are listed in the so-called European Inventory of Existing Commercial Chemical Substances ("EINECS"); or, they are manufactured in the EU (including the recent EU accession countries) but they have not been placed on the EU market after 1 June 1992; or, they are so-called "no-longer polymers." All substances that do not fulfil such criteria are considered as so-called "non phase-in substances" and do not benefit from the extended Registration periods (and in fact their Registration should have been undertaken as from 1 June 2008 before they could continue to be manufactured in or imported into the EU market).

Second, there also apparently seem to be problems with certain so-called "Only Representatives," allegedly it seems as concerns their appointment. By way of brief reminder, a non-EU manufacturer, i.e a natural or legal person that is manufacturing a substance or an article that is then imported into the EU and who wishes to continue to place its substance or article on the EU market, must appoint an "Only Representative" in order to fulfil Registration (and other REACH obligations of importers) on its behalf. In order to qualify as an "Only Representative" such an entity must be a legal or natural person established within the EU, who "must have a sufficient background in the 'practical handling of substances', and, the information related to them", and, who "must keep 'available and up-to-date information on quantities imported and customers sold to'", as well as keep information "on the supply of the latest update of the safety data sheet." Where an "Only Representative" is appointed (in conformity with the above-mentioned criteria) the non-EU manufacturer then has to inform the importer(s) within the same supply chain of this appointment who are then considered as so-called "downstream users" (not to be confused with distributors) for the purposes of various REACH obligations.

The ECHA has stated clearly that, in its view, some Pre-Registrations are in breach of the above-mentioned REACH regulation rules concerning "phase-in" substances and "Only Representatives" and "may therefore be subject to enforcement actions by the authorities of the relevant Member States."

Further, the ECHA has also attacked Pre-Registrations made by two separate companies (supposedly one from Germany and one from the UK) which each apparently cover the entire above-mentioned EINECS inventory (made up of some 100,000 substances). ECHA claims that these Pre-Registrations are a kind of abuse of process as they make data-sharing and participation in the so-called "Substance Exchange Fora" ("SIEFs") "umanageable", and, this also puts at a disadvantage those "downstream users" who may wish to later

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notify the ECHA of their interest in a substance that has not been Pre-Registered in order to facilitate a later (also time-limited) Pre-Registration (under certain specified REACH conditions).

By way of a policy statement ECHA is therefore requesting "companies to pre-register only the substances they intend to register."

Further, the ECHA also claims that in certain Pre-Registrations the name of some substances does not refer to a chemical name that could be used within the context of a SIEF, i.e by implication again rendering the workings of the SIEF problematic.

The ECHA says that in those cases where it has doubts about the validity of a Pre-Registration it is contacting the companies concerned for clarification purposes, and, that those companies who now wish to delete their Pre-Registrations may make such a request of the ECHA.

Both the above-mentioned two "mass" Pre-Registering companies and those Pre-registrations which are deleted will apparently also not appear in the intermediate list of Pre-Registrations that the ECHA intends to publish in October.

Further, the ECHA has now placed a maximum limit of 10,000 substances that can be Pre-Registered in bulk - companies seeking to go beyond this limit must first seek prior approval to do so from the ECHA.

Given the complexities and significant regulatory demands of REACH on industry it has been received wisdom by many on both sides of the fence that "if in doubt Pre-Register." Therefore, it is no surprise that some in industry are now crying foul about the ECHA's latest pronouncement, especially as regards the policy statement that only substances intended to be Registered must be Pre-Registered. The commercial reality faced by some businesses is that they are at risk if they sit and wait and rely on all of their suppliers to Pre-Register all their (i.e the suppliers') substances. In addition, some suppliers are understood to be insisting on guarantees of Pre-Registration from their customers before agreeing to future supplies. Therefore, it should not come as a surprise that there has been such a heavy take-up of Pre-Registration as many will be doing so by way of precaution. As regards the legal basis of the ECHA's policy declaration to apply such a brake on the Pre-Registration process it can be commented that this is not so clear and it may therefore be open to challenge.

In any event, whether the ECHA is right or not in its approach, businesses involved in Pre-Registration should pause for thought and take stock of this latest development when planning the way forward, especially as the Pre-Registration time-frame is closing fast.

Footnotes:

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