

NEWSLETTER No.2

Introduction

This is the second Sitmae REACH Newsletter. With this newsletter we inform our customers about the ever-changing world of REACH. We will send you a newsletter whenever there is information which is of use to you.

The subjects in this newsletter:

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Previous Newsletters: still contain valuable information. They can be downloaded from our web site: www.sitmaereachservices.com .

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Pre-registration: the results

The pre-registration period has closed on December 1st. Result: over 2,6 million pre-registrations by more than 65.000 different companies and in total some 140.000 different items, some of which are not at all substances requiring pre-registration. The pre-registrations cover the whole EINECS list: 100.000 substances. This is far more than the expected 150.000 pre-registrations and 30.000 substances.

It is however still not sure that all the non-EU manufacturers, non-EU formulators and importers have indeed pre-registered their substances. It can be expected that once enforcement actions have taken place, there will be renewed attention for pre-registration. It is unsure whether those who have not pre-registered yet will be allowed to repair their mistake in the coming months. If not, they may perhaps go for the late pre-registration option, allowed for first time imports and manufacture

Overburdened SIEF

The cause for the enormous number of pre-registrations is the pre-registration by EU based importers of formulations and by the Only Representatives of non-EU formulators; formulators tend to use large numbers of different substances.

This happened in response to ECHA's recommendations: re-imported substances and substances that were pre-registered higher up in non EU supply lines still had to be pre-registered. Now of course, most of these pre-registrants have no intention to ever register a single substance themselves.

As a result many SIEFs ('Substance Information Exchange Forum': all the pre-registrants of a substance) now have hundreds, and sometime even thousands, of members; the majority of which will have nothing to contribute. (There are over 2.000 pre-registrations for ethanol for example). This will bring about a considerable communication problem to the companies who have offered to take the lead in the SIEFs.

Pre-registration list

Over the Christmas holiday period, ECHA will perform a check of all pre-registrations. It will for instance delete those coming from companies that are not at all entitled to pre-register under REACH.

Later in January ECHA will publish a list of all the pre-registered substances. This is done to allow down stream users to check if the substances that they use have been pre-registered by someone. This list will probably be useless, because all the 100.000 substances on the Einecs list have indeed been pre-registered by someone. But the list holds no guarantee that the substances will also be registered one day. (Two importing companies have even pre-registered all the 100.000 Einecs substances each. They could not confidently trace all the substances present in the many preparations they import.)

ECHA will also launch a new version of REACH IT. This will be on-line on January 5th 2009.

Non-EU supply lines

Importers of non-EU produced formulations and the Only Representatives of non-EU based formulators have pre-registered the substances in the imported products. This will make marketing of these products legal, until the deadline of the registration for the substances. They have thus bought time, but it is not a permanent solution.

Considering the large number of different substances used in many products, it will be far too expensive for most non-EU formulators or their importers to actually register all these substances. They will be dependent on registration by their suppliers; the non-EU based manufacturers of substances.

Where these manufacturers export, directly or indirectly, substantial amounts to the EU, these registrations can be expected to take place. But where these exports are unimportant, registration is doubtful.

Non-EU formulators are therefore faced with a substantial problem: they must either convince their suppliers of registering their substances or find alternatives. They may have to find another non-EU manufacturer who will register or they may have to use the re-importation scheme (Buy registered substances in the EU and export these back into the EU as part of the formulations). It can be seen that formulators who use a substantial number of substances, all have a major project on their hands.

First registration deadline

The first registration deadline, for phase in substances >1.000 t/a, is 30 November 2010. Manufacturers and importers cooperate in 'consortia'. They make the dossier together and save costs. For the large volume chemicals these consortia are in place and have started work. They all aim to be finished in June 2010. This means that there are 18 months left: not very long for all the work that needs to be done.

The necessary budget for a registration dossier depends on the amount of data that is available and the hazardousness of the substance. The Nickel consortium is said to need € 3 million. Several other metals and alloys need € 1 million each. Ethanol, which is a very data rich substance, still needs several hundred thousand €. The costs for the dossiers and for actually organizing the cooperation between consortia members are truly enormous.

The same deadline (30 November 2010) applies to CMR cat 1 & 2 > 1 t/a and R50/R53 >100 t/a (very toxic to aquatic organisms which may cause long-term adverse effects in the aquatic environment). Little is known of consortia for these substances.

Candidate list

A forceful lobby is going on by the NGO's to have the candidate list expanded to the originally expected 2.000 substances. Although they are not expected to win the lobby, it is certain that the present 15 substance list is not going to last long.

Work on the present list will go fast. An ECHA recommendation to the European Commission, about which substances to take up in Annex XIV (Authorisation), is expected before June 2009.

Sanctions & Enforcement

Enforcement of REACH and the sanctions for infringement are left to the EU Member States. The Member States should have notified their sanction by December 1st. Thirteen Member States have missed the deadline: Austria, Belgium, Cyprus, Estonia, France, Greece, Latvia, Luxembourg, Poland, Slovenia and Spain. Italy has notified a draft law.

So far most Member States have hooked REACH on to their existing environmental legislation and derive the penalties from that existing legislation. The highest possible jail sentences are to be had in Germany and the Netherlands (5 and 6 years respectively). The highest possible fine will probably be in Belgium; € 4 million.

The 'Forum for Exchange of Information on Enforcement' is the place where Member States coordinate their enforcement policies. The Forum has adopted a project manual for the first coordinated REACH enforcement project in 2009. This project will focus on pre-registration and Safety Data Sheets for phase-in substances. It will be carried out in more than 20 EU Member States and Norway and Iceland; sometime in 2009.

Registry of intentions

This Registry provides information on the intentions of the Member States to submit proposals for harmonised Classification and Labelling of substances, proposals for identification of Substances of Very High Concern, and proposals for restrictions.

The list can be found at the ECHA web-site (Click: 'ECHA CHEM' and 'Registry of intentions'). At present it contains twenty-one entries for harmonized Classification and Labelling and seven entries for Substances of Very High Concern.

Substances <1.000 t/a

For substances <1.000 t/a there is little activity as yet. All efforts seem to be concentrated on the high volume substances for the moment. The deadlines for the other substances are still years away

Below an interesting part of a presentation by Chris Braun from Akzo Nobel at the 6th Annual REACH Conference in Brussels on November 27 and 28:

*"The SIEF has to agree on classification and labeling, and submit that to the Agency by December 1, 2010. That means that **all** SIEFS have to go to work now, even if all members produce less than 100 tpa and the substance will only be registered by 2018. By the way, even if one produces less than a ton, but the substance is hazardous according to Directive 67/548, a classification must be given to the Agency. It's relatively easy if there are Tier 1 registrants (PV: producing > 1.000 t/a), they'll have to do a dossier anyway so they will come up with C&L before that date anyway. But for substances for which all registrants are in Tier 2 or 3, there is no such activity. And it's quite likely that everybody is going to postpone this to the last moment, but Q3 2010 is the time when all available experts will be fully occupied with Tier 1 dossier approvals, so the recommendation is: even if your substance is a Tier 2 or 3, better start with the C&L as early as possible, don't wait until November 2010."*

Chris Braun refers to Title XI of REACH (Art. 112 – 116). The deadline given in Article 116: 1 December 2010.

Risk Management Measures

The future 'Extended Safety Data Sheets' will have to contain 'Risk Management Measures'. (RMM's) These are safety instructions for the users of the chemicals. Under REACH, the users will have to abide by these instructions. They can no longer use alternative safety measures of their own design. It is therefore important that the RMM's will be practical, and that none of the existing good practices is forgotten.

It is also important that the RMM's will be expressed in standard phrases that can automatically be translated in all the many EU languages. The BDI (German Industry Federation) has drafted a complete set of these standard phrases. It is intended that these will also be adopted by the industry federations in the other EU Member States. The BDI version is available in German and English. It can be downloaded from: <http://reach.bdi.info/378.htm>

Guidance to Annex V

The Commission has prepared guidance on the revised Annex V (exemptions to REACH.) The formal publication is expected soon on the ECHA web site. The latest draft can be found at: http://ec.europa.eu/enterprise/reach/docs/reach/com_rev_anx_V_guidance_081010_en.pdf

Toll manufacturing

In some industries it is usual to job out the production of substances to others; the so called 'toll manufacturers'. The question arises, who should register the manufactured substance: the owner of the substance or the toll manufacturer. According to the European Commission this is in general the toll manufacturer. However, it is allowed for the principal and the toll manufacturer 'to make practical arrangements to reduce the burden for the toll manufacturer'. These arrangements are to be judged on a case by case basis. It is not specified what kind of 'practical arrangements' could be applied.

Recovered substances

Substances that are recovered in the EU do need not be registered again; provided that they have already been registered by someone else and the necessary information (i.e. the Extended Safety Data Sheet) is available.

The Legal Services of the European Commission, in their infinite wisdom, have decided that this exemption does not apply to pre-registration! Recovered substances therefore must be pre-registered, until the substance in question has been a registered and an adequate extended SDS is available. This means for instance that solvents that are recovered from the waste gasses of coating machines must be pre-registered.

Please note that the exemption (no need to register) only applies to recovery in the EU. Recovered substances that are imported from outside the EU will need to be registered as if they were virgin material.

Pending issues

0,1% rule

The obligations for Candidate list substances in articles kick in when the article contains more than 0,1%. The question arises 'what is an article'? Is it the whole Korean car or every separate nut and bolt on that car? The Commission legal services have decided that it is the whole car! Several Member States, amongst which Sweden, do not agree. Sweden intends to force a court case for clarity. Some other disagreeing Member States intend to use the first review of the regulation in 2012 to clarify the issue (= nut and bolt level)

Data cost

Many consortia assume that once a study has been published, the use of the information is paid for when the article is paid. Authors and original owners of the data are however heard to disagree. They want substantial payment as a contribution towards the actual cost of the underlying research. If the authors and data-owners win, the budgets for 'data rich' substances will have to be augmented substantially.

No OR for non EU distributors

Non-EU based distributors are not allowed to appoint Only Representatives. This is clearly an omission in REACH, but there are no signs of any attempt to repair this mistake. It leads to strange and costly situations where for instance large Swiss based trading companies have to completely rearrange their logistics. They have to establish one single EU based importer who is allowed to pre-register and register the substances.

We at Sitmae REACH Services hope that this information is of use to you. If it raises any questions, please do not hesitate to contact us. Other comments are also welcome.

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December 2008