

Newsletter No.13

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

We have increased the frequency of our newsletters from approximately three to ten per year. This makes for shorter documents that hopefully are easier to read. We appreciate your comments.

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

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REACH in General

Candidate List & Authorisation

54 new potentials for the Candidate List

Two years ago, two European Commissioners committed themselves in front of the European Parliament to a Candidate List of 136 substances by the end of 2012. The Member States, who have to make the relevant dossiers, were however not productive enough. A legal loophole has been used in a desperate attempt to fill the gap.

Presently there are 54 substances 'under consultation'. For 37 of these the dossier is lacking: but they are all known Carcinogenic, Mutagenic or Toxic to reproduction (CMR); and this is theoretically enough. The consultation ends on October 18th. This will leave just enough time to expand the Candidate List before the end of the new year.

Since there are 84 substances on the Candidate List today, there is a 'spare' of only two substances. As a result the consultation process will probably not change much to the intentions.

- Today's Candidate List of 84 substances can be found here: [Candidate List](#)
- The list of 54 substances under consultation can be found here: [Consultations for the Candidate List](#)

REACH & Chemicals

Registration & Pre-registration

ECHA Statistics

ECHA has published new registration statistics. The dedicated webpage will be renewed monthly.

By June 1st there had been 27.321 registrations covering 4.632 different substances. Half of these substances are registered as intermediates (used for chemical reactions to produce other substances). Only Representatives have done 5.545 registration for 1.423 different substances.

In addition some 5.000 substances are regarded as already registered, because of their notification as new substances under previous legislation.

The ECHA statistics can be found here: [ECHA registration statistics](#)

Improved compliance checks for registrations

At the moment of their submission, ECHA checked all the registration dossiers for completeness. This was however limited to see whether all the appropriate boxes had been ticked and if sufficient documents were attached in the right places. The actual content of the dossiers was however not studied. It was later found however that a considerable number of dossiers was probably noncompliant.

ECHA has now developed a new compliance check. This check will be focussed on specific parts of large numbers of dossiers. Areas of concern have been identified. There will be 'IT assisted targeting'. Main points of interest are the endpoints that matter to human health and the environment. Emphasis will be given to substances that are Persistent, Bioaccumulative and Toxic (PBT); Carcinogenic, Mutagenic or Toxic to reproduction (CMR) and substances that have sensitising (S) properties.

ECHA states that the chances of non-compliant dossiers being identified has now considerably been increased.

Intermediate registrations checked

The registration of 'intermediates' is simple and cheap. The drawback is that substances thus registered may only be used under 'strictly controlled conditions'.

Of the 5.500 registration dossiers for intermediates however, almost half included uses that are incompatible with these 'strictly controlled conditions'. A large number of registrants has been asked to 'carefully review' their submissions. After three month ECHA will screen the dossiers again and identify those that 'require regulatory action'.

At the same time ECHA has published a guidance documents specifying what can and cannot be regarded as 'strictly controlled conditions'.

The guidance can be found here: [Guidance on 'Strictly Controlled Conditions'](#)

Next registration deadline

ECHA continues to try to find lead registrants for the next registration deadline in 2013. Registrations for almost 3.000 additional substances are expected. For most of these the work seems to be in progress, but for some 700 no lead registrant has yet been identified.

Authorisation

No Cobalt under authorisation

A number of Cobalt compounds featuring on the Candidate List were prioritised by ECHA for authorisation (cobalt (II) sulphate, dinitrate, diacetate, carbonate and cobalt dichloride). The European Commission seems to have decided however that it prefers an Annex XVII restriction over authorisation for these substances. The restriction would address 'surface treatment' as being the particular use where risk to human health are sometimes not adequately controlled. The substances will remain on the Candidate List.

Other REACH & Chemicals news

C&L database updated

ECHA has updated the database with all the notifications of Classification and Labelling. It now also contains the substances for which notifiers have indicated that a classification is not necessary. More than 5 million notifications for 120.000 substances are on record.

ECHA is also developing a web based discussion platform. This will help industry to reach agreement on the classification for each substance, as required under the CLP regulation. To come to some sort of industry agreement is necessary. At present the database contains a great number of nonsensical classifications.

The public C&L inventory can be found here: [The public C&L inventory](#)

REACH & Articles

Annex XVII Restrictions

New restrictions in REACH Annex XVII

Four new sets of restrictions have been added to REACH Annex XVII. These restrictions affect mixtures or articles for certain uses, containing certain substances. These products may not be made or sold in the European Union.

Cadmium

The use of Cadmium was already restricted in paints. Now a long list of plastic materials is added. Mixtures and articles made from these plastics may not be sold in the EU if they contain cadmium.

The legal text can be found here: [Cadmium in Annex XVII](#)

Lead

A new entry (No.63) covers lead in jewellery and parts of jewellery. The limit is 0,05% by weight. A number of exemptions apply; such as crystal glass, internal components of watches and some precious stones. The application starts in October 2013 and jewellery produced before 1961 is excluded.

The legal text can be found here: [Lead in Annex XVII](#)

Mercury

The use of mercury was already restricted in barometers and some other measuring devices. The list has become longer and more detailed.

The legal text can be found here: [Mercury in Annex XVII](#)

NGOs are pleased with the expanded restrictions. They now also wish to get rid of the mercury in existing measuring devices. In the meantime, stopping the use of mercury in dental fillings is subject to international negotiations.

Phenylmercury

A new entry (No.62) covers five different substances; all compounds of Phenylmercury. After 10 October 2017 these substances may no longer be marketed in the EU; either as substances on their own or in mixtures. The same will be the case for articles containing more than 0,01% of these substances.

The legal text can be found here: [Phenylmercury in Annex XVII](#)

Other changes to Annex XVII

A number of clarifications and smaller changes to Annex XVII is also in the pipeline. They have passed the 'comitology committee' where Member States 'assist' the European Commission in the execution of its powers. They will become law in a few months' time.

For those interested in the details: [Planned changes to Annex XVII](#)

Other REACH & Articles news

Danish phthalates ban

The Danish proposal to ban four phthalates (DEHP, DBP, DIBP and BBP) from certain consumer products was not accepted by EU scientific committees. In spite of this Denmark intends to proceed on its own. This national ban will be limited to products intended for indoor use and other products which may come into contact with skin or mucous membranes. It will exclude certain products such as cosmetics and toys which already fall under other legislation.

If the ban becomes effective, no doubt the European Commission will try to find a way to have it repealed. Such a distortion of the internal market and lack of confidence in the European decision making procedures is not accepted lightly.

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