Newsletter No.14

This is the fourteenth 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.

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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

Technical Guidance Documents

New moratorium in place

For a period of six months before the next registration deadline (31 May 2013) ECHA will not publish any new or updated guidance and it will not update its IT tool.

In the six months before the last deadline, a similar moratorium was kept at the request of industry. In those days, frequent updates of guidance documents made the preparation of registration dossiers into something like shooting at a moving target.

Candidate List of SVHC

Candidate List: now 138 substances

ECHA succeeded to satisfy the Commission and the European parliament. Still in 2012 the Candidate List was expanded to 138 entries. ECHA even slightly 'surpassed' the political goal of 136 entries. Environmentalists point out however that in their opinion there are still 1.500 substances fulfilling the SVHC criteria. And all of these should feature on the list. (ECHA disagrees: see next item)

Amongst the new entries are five PBT or vPvB substances (PBT: Persistent, Bioaccumulative and Toxic, vPvB: very Persistent and very Bioaccumulative) and several 'substances of equivalent concern'; three respiratory sensitisers and two endocrine disruptors. The other 44 additions are CMRs. (Carcinogenic, Mutagenic, Toxic to Reproduction)

The candidate list can found here: http://echa.europa.eu/candidate-list-table. From the same page, the list can be also be downloaded.

Expectations for the Candidate List

It is the intention to have the Candidate List 'finished' by 2020. A roadmap to that end is being discussed between ECHA and the Member States. More than before, alternatives such as Annex XVII restrictions and Harmonised Classification and Labelling are also being looked at.

The new entries will mainly be PBT, vPvB or substances of 'equivalent concern'. There are not many CMRs left that could be included. Of the 400 CMRs that have been registered, 250 are from petroleum streams and 150 for another use. Nearly all of these have already been screened. There are currently 13 SVHC-intentions, meaning that for 13 substances Member State are preparing a special SVHC dossier.

Other general REACH News

REACH Review

The European Commission has finally published its long awaited 'REACH Review Communication'. The plan was to publish it in June 2012. It was however postponed several times. It must have been difficult to get consensus between the 'Environment' and 'Enterprise' Directorates General.

The Communication reveals the Commission's conclusion from a number of different studies. The official Commission Communication counts 15 pages. But there is also a ten times larger Staff document. Since the devil is always in the detail, the staff document will also have to be studied very carefully by all stakeholders. A public consultation can be expected.

As could be expected, there is nothing fundamentally wrong with REACH. A very important Commission conclusion is that it is not necessary to change anything in the REACH legislation itself. Some improvements are necessary, but these can be obtained through ECHA Technical Guidance Documents, clarifications, changes to the REACH annexes etc.

It was already known that the Commission was very reluctant to change the core of the legislation. It would be opening a can of worms. Every Member State, every NGO and every Industry Association would ask for changes.

A particular worry to the European Commission are the SMEs (Small and Medium sized Enterprises). The Commission worries about their REACH compliance and also about the associated cost

The Commission Communication and the Staff document can be downloaded here: http://ec.europa.eu/enterprise/sectors/chemicals/documents/reach/review2012/index_en.htm

REACH & Chemicals

Registration & Pre-registration

Next registration deadline coming up!

The next REACH registration deadline is 31 May 2013: less than three months to go! All substances that are manufactured or imported in a quantity of over 100 t/a must be registered by that date. ECHA expects the submission of some 15.000 registration dossiers.

Not only will ECHA be very busy, but the same goes for consortia, consultants, service providers and Only Representatives. In normal times the lead-time of a joint submission registration (i.e. one based upon a 'Lead Registrant' dossier) will often be more than six weeks. This lead-time will certainly increase when the deadline gets closer.

Our advice is obvious and simple: do not wait any longer!

Registrations database

The ECHA database of registered substances now also shows the names of all the registrants. It also shows which registration numbers have been issued. The two, names and numbers, are however not linked.

The database is not up-to-date and not reliable. The present version should list most registrations made before November 2012. A next up dated version is programmed to appear in February 2013. The web-page does however not state that recent registrations may be missing.

Some older registrations also seem to be missing however. And where Only Representatives have registered substances, there is no logic as to whether the OR's name or the name of their principal is given.

ECHA's database can be found here: http://echa.europa.eu/information-on-chemicals/registered-substances

Statistics

ECHA has published comprehensive statistics of the registrations until October 2012. The data are available in various breakdowns.

The data includes:

- The overall number of registrations and registered substances for both existing and new substances. (Almost 5.000 substances and more than 28.000 registrations)
- The number of registrations presented by:
    - Registration type: full registrations (3000 substances) or intermediate registrations (6.600)
    - Joint submissions (26.000) versus individual submissions (2.200)
    - Company size of the registrants (Large: 24.500, SME 3.860)
    - Registrant's role in the supply chain (Only Representatives 5.800)

  - From which EU/EEA countries the registrations originate. (Germany 7052, Liechtenstein 8)

- The most frequently registered substances (Calcium Hydroxide: 325)
- The registered substances by total tonnage band.

The statistics can be found here: http://echa.europa.eu/information-on-chemicals/registration-statistics

Small & Medium Sized Enterprises (SMEs)

SMEs pay lower ECHA registration fees. ECHA however does not trust many of these SME claims. Registrants claiming SME status are now asked to submit proof of their status. If an Only Representative registers a substance, the size of the non-EU producer counts. (ORs are generally small companies, but their customers may be huge multinationals).

Where audited accounts in English or in another official EU language are available, it is generally no great problem to provide the required information. But non-EU companies may have to provide translations of these official documents. Also in many countries, the accounts of the smaller companies are not audited.

If an SME claim is found to be unjustified, the 'missing part' of the registration fee must to be paid and an 'administrative charge' applies. This 'administrative charge' is really a sizeable fine. It almost doubles the total ECHA charges. This fine may get reduced by 50%, if company declares an unjustified SME claim immediately after receiving ECHA's letter with nasty questions.

ECHA plans to do at least 300 SME checks in 2013.

Evaluation

Update to CORAP

The 'Community Rolling Action Plan' is the list of REACH registered substances, of which the dossiers will be evaluated by one of the Member States. A draft for an updated version of CORAP has been published by ECHA. The proposal now lists 116 substances to be evaluated in the period 2013-2015. Of these, 63 are new on the list.

The new CORAP proposal can be found here:
http://echa.europa.eu/documents/10162/13628/draft_corap_2013-2015_en.pdf

Authorisation

New proposals for Annex XIV

Soon eight more substances will be subject to Authorisation: Trichloroethylene, Chromium trioxide, Acids generated from Chromiumtrioxide and their oligomers (Group containing: Chromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid), Sodium dichromate and Potassium dichromate.

After the publication of the expanded Annex XIV, Trichloroethylene will be given 21 months for the application for authorisation and the sunset date will be after 36 months. For the other substances these periods will be 35 months and 53 months respectively.

Remarkably, the Commission did not follow the ECHA proposal to include a number of Cobalt salts. For these substances, ECHA is asked to prepare a dossier with a view to draft an Annex XVII Restriction to Marketing and Use. This applies to the following substances: Cobalt (II) sulphate, Cobalt dichloride, Cobalt (II) nitrate, Cobalt (II) carbonate and Cobalt (II) diacetate. The Cobalt industry very much welcomes this turn of events and will cooperate with ECHA.

Ten new substances prioritised

ECHA has prioritised ten more substances that already feature on the Candidate List. Prioritisation is the second step on the road to Annex XIV of substances subject to authorisation.

The ten new priorities are:

- Formaldehyde, oligomeric reaction products with aniline (technical MDA)
- Arsenic acid
- Dichromium tris(chromate)
- Strontium chromate
- Potassium hydroxyoctaoxodi-zincate dichromate
- Pentazinc chromate octahydroxide
- Bis(2-methoxyethyl) ether (Diglyme)
- N,N-dimethylacetamide (DMAC)
- 1,2-dichloroethane (EDC)
- 2,2'-dichloro-4,4'-methylenedianiline (MOCA)

It is yet unknown when these substances will be included in Annex XIV. Before their 'promotion' to Annex XIV, there will first be a public consultation.

Chromates consortium

A group of companies in the Chromates business have formed a consortium. They will prepare the application for authorisation. The group will begin with Ammonium dichromate, Potassium dichromate, Sodium dichromate and Sodium chromate.

In a later stage other substances that at this moment only recommended for authorisation (i.e. prioritised) will follow: Dichromium tris (chromate), Strontium chromate, Pentazinc chromate octahydroxide and Potassium hydroxyloctaoxodizincate dichromate.

The uses that will be addressed include surface treatment of metals and the use in products like paints, lacquers, sealants and coatings.

Other REACH & Chemicals news

ECHA Nanomaterials working group

ECHA has established a nanomaterials working group. It is an informal advisory group consisting of experts from Member States, the European Commission, ECHA itself and accredited stakeholders organisations. The group will give informal advice on scientific and technical issues regarding REACH and CLP. Industry will contribute its recently gained experience in documenting intrinsic properties of the nano-forms of substances.

There will be cooperation with another group already working on nanomaterials: the 'Group Assessing Already Registered Nanomaterials' (GAARN). The purpose of this group, which

was established by the European Commission itself, is to build consensus on best practices for assessing and managing the safety of nanomaterials under the REACH. Its aim is to increase the confidence and mutual understanding among stakeholders.

National nanomaterials registers

Several EU Member States plan to establish a national nanomaterials register. Companies will be asked to report their use of nanomaterials. France has taken the initiative. The Netherlands, Belgium and Denmark will do something similar. Sweden is in the contemplation phase.

The developments are worrying to industry. The worry is not that there will be a register, but that one day there may be twenty seven different registers. In the meantime the European Commission states that it is not yet convinced that an EU wide system is justifiable.

REACH & Articles

Annex XVII Restrictions

Chromium VI in leather articles

A new Annex XVII restriction for chromium VI in leather articles is in the making. The public consultation process is almost over. The limit will be 3 mg/kg. The exact phrasing of the expected restriction is still unknown. Whether it will be just 'articles' or also 'parts of articles', or whether will it be 'in contact with the skin' or in 'prolonged contact with the skin' is still unclear.

Cadmium in plastics

Today, the use of Cadmium and Cadmium compounds is restricted in articles that are made of sixteen different plastics. ECHA is investigating an expansion of this restriction to all plastics. It is presently collecting information.

PAHs in articles

The occurrence of Polycyclic Aromatic Hydrocarbons (PAH) in articles will soon be restricted. The restriction will apply to articles coming into direct and prolonged contact with the human skin or the oral cavity.

The substances concerned are: Benzo[a]pyrene, Benzo[e]pyrene, Benzo[a]anthracene, Chrysene, Benzo[b]fluoranthene, Benzo[j]fluoranthene, Benzo[k]fluoranthene and Dibenzo[a,h]anthracene.

Adoption of the legislation is expected in the second half of 2013.

Busy Sweden

This time it is Sweden rather than Denmark that advocates additional restrictions to marketing and use. It is holding consultations on a restriction for Lead in articles for consumer us. Sweden has also called for more restrictions for hazardous chemicals in textiles and the Swedish Chemicals Agency has found high levels of phthalates, lead and cadmium in plastic shoes.

The Fins on the other hand have found a lot of cadmium in imported jewellery; most of which came from China.

As always, the Rapex weekly updates make interesting reading. This lists with consumer products that infringe all kinds of safety legislation, can be viewed and downloaded at: http://ec.europa.eu/consumers/dyna/rapex/rapex_archives_en.cfm

Other REACH & Articles news

SVHC Notification web-form

When articles contain more than 0,1% of a candidate List substance (SVHC), a notification to ECHA may be required. Exemptions exist. Notification is, for example, not necessary if the use of the substance in such an article is addressed in the registration dossier.

Notification always was very difficult. The use of the utterly complicated IUCLID software was necessary. This possibly explains why the number of notification was never very high (by end of November 2012: 219 notifications, almost half for the use of DEHP).

Things have been simplified now. A special web form is available for those who have to do but few notifications.

The webform can be found here: http://echa.europa.eu/web/guest/support/dossier-submission-tools/reach-it/notifying-substances-in-articles

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