

Newsletter No.15

This is the fifteenth 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

Information for Down Stream users

ECHA is in the process of revising the Technical Guidance Document for Down Stream users. This is an important document for all formulators and end-users of chemicals. The first draft looks promising: clear and much more to the point than the previous version.

Also the Questions and Answer regarding Down Stream User reports on the ECHA website has been updated.

For those who cannot wait; the draft can be downloaded: [Draft TGD Down Stream Users](#)

Find the updated Q&A's here: [Q&A DU Reports](#)

Candidate List of Substances of Very High Concern

Ten new potential SVHC's

Ten new substances are on their way to the Candidate List. The consultations have finished and the official decision is imminent.

Substance name	EC number	CAS number
Cadmium	231-152-8	7440-43-9
Cadmium oxide	215-146-2	1306-19-0
Dipentyl phthalate (DPP)	205-017-9	131-18-0
4-Nonylphenol, branched and linear, ethoxylated <i>[substances with a linear and/or branched alkyl chain with a carbon number of 9 covalently bound in position 4 to phenol, ethoxylated covering UVCB- and well-defined substances, polymers and homologues, which include any of the individual isomers and/or combinations thereof]</i>	-	-
2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol (UV-350)	253-037-1	36437-37-3
2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol (UV-328)	247-384-8	25973-55-1
2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol (UV-327)	223-383-8	3864-99-1
2-benzotriazol-2-yl-4,6-di-tert-butylphenol (UV-320)	223-346-6	3846-71-7
Ammonium pentadecafluorooctanoate (APFO)	223-320-4	3825-26-1
Pentadecafluorooctanoic acid (PFOA)	206-397-9	335-67-1

Plans for the Candidate List

ECHA published a roadmap for ‘completion’ of the Candidate List of Substances of Very High Concern. By 2020 all the relevant substances should be listed. Although there is officially no numeric goal, the document does mention that by 2020, some 440 substances will be listed on the Candidate List.

The roadmap lists the groups of substances that will be looked at in more detail. These include CMR’s, PBTs, vPvBs, endocrine disrupters and sensitizers.

An interesting point is that, before substances are taken into consideration for the Candidate List, other methods of ensuring safe use will first be regarded. Already there are substances on the Candidate List, for which an Annex XVII restriction would have been more appropriate.

The roadmap can be downloaded here: [SVHC Roadmap](#)

Other general REACH News

ECHA’s PBT assessment confirmed

ECHA identified anthracene oil, anthracene oil (low), anthracene oil (paste), and coal tar high pitch as PBT (Persistent, Bioaccumulative, Toxic) and/or vPvB (very Persistent, very Bioaccumulative) and included them in the Candidate List of SVHC. Several registrants objected and asked for a ruling of the European Court. ECHA’s decision was upheld.

In addition the Court ruled that, based on ECHA’s decision, suppliers of these substances must update their Safety Data Sheets and include the ECHA judgement.

The SIN List is back

The SIN List (‘Substitute It Now’) contains more than 600 substances that, in the opinion of NGO’s and a few producers of consumer articles, should not occur in products sold to the general public. The list was first published in 2008, and lastly updated in February 2013. It probably had political influence on the decisions about the Candidate List of SVHC.

Now ChemSec, the body responsible for the SIN List, has published the names of European producers of SIN List substances. They state that a company cannot both claim to be ‘sustainable’ and produce these substances. The top 20 includes large companies well-known like Shell, Exxon, Total, BASF and BP.

The SIN List and the producers list can be downloaded from the ChemSec website:

<http://www.chemsec.org>

ECHA on Twitter!

ECHA, being a young organisation, now has a Twitter account. ECHA will tweet information about press releases, news alerts, public consultations, events and website updates.

Interested? https://twitter.com/EU_ECHA

ECHA for the general public

The ECHA website has a section aimed at the general public: 'Chemicals in our Life'. It provides information about the hazards of chemicals, how they affect citizens and the objectives and impact of REACH.

ECHA has now launched a project to develop more content for this section. Public interest NGOs have given input for new themes in the section. The section will also have dedicated pages for workers. It will inform about the rights of citizens to demand information about chemicals in their products. The section will also address substitution; replacing dangerous chemicals with safer alternatives.

The new content will be developed in cooperation with the Agency's Accredited Stakeholder organisations. These include NGOs, industry associations, trade unions and academia. ECHA plans to launch the new content in early 2014.

Today's version of the general public section of ECHA's website: [Chemicals in our life](#)

On-line translations for REACH terminology

The terminology used in the world of REACH and related legislation is complex to say the least. The fact that the EU has 22 official languages adds to this complexity.

There is a translation tool on the ECHA website. It provides on-line translations and definitions for more than 1.000 terms related to REACH, CLP and biocides. It includes the CLP precautionary and hazard statements, and pictograms. There are filters and the results may be downloaded.

The tool already existed but so far required user registration. The registration requirement has been lifted. The tool is now accessible to anyone.

The link: [ECHA Term](#)

REACH & Chemicals

Registration & Pre-registration

Good progress for the 2013 registration deadline

ECHA regularly publishes updates on the progress with the 2013 registrations. The situation in the beginning of May was:

Phase-in substances intended to be registered for 2013 deadline	
Number of substances for which someone has declared the intention to register the substance	3991
<ul style="list-style-type: none"> • Of which already registered by the 2010 deadline 	872
<ul style="list-style-type: none"> • Of which no longer intended to be registered for 2013 	27
Result: 'new' substances to be registered for 2013 deadline	3094
<ul style="list-style-type: none"> • Of which a lead registrant is known to ECHA 	2491
<ul style="list-style-type: none"> • Already registered by a lead registrant 	1217
Substances for which ECHA has neither a lead registrant nor a registration	536

In theory the substances without lead registrant may become 'orphaned': no longer available on the European market after the registration deadline. This situation however resembles that of the last month before the 2010 registration deadline. After that deadline users of substances did not report anything 'missing due to non-registration'.

The latest statistics and a lot more detail can be viewed at: <http://echa.europa.eu/reach-2013/overview>

Results of ECHA's Intermediate dossiers checks

Late 2012, ECHA checked some 5.500 dossiers for intermediate registrations. Intermediates are substances that are only used to manufacture other substances. Their registration is simple and cheap, but 'Intermediates' may only be used under 'Strictly Controlled Conditions'.

Some 2.400 of these dossiers, for 760 different substances, included uses that were not 'Intermediate' or did not answer to the required 'Strictly Controlled Conditions'. The registrants were informally asked to review their registration. As a result some 1850 dossiers were updated, of which 40 to a 'full' registration. Some 100 registrants have indicated that they are working on their update. The remainder received a final reminder and the threat of ECHA action.

Evaluation

The first Evaluation results

The E in REACH stands for Evaluation. The dossiers for at least 5% of all the registered substances will be 'Evaluated'. This is done by EU Member State authorities. The first 36 substances have now undergone the process.

For 32 of these substances, the Member State authorities have requested more information from the registrants. Only four dossiers were found complete and correct. The four substances were: Ethylene oxide, Tributyl phosphate, M-Tolylidene diisocyanate, and Toluene. If the world were a fair, this should for ever put an end to the allegations that Toluene is a very dangerous carcinogen.

More evaluations

CoRAP has been updated. This Community Rolling Action Plan lists the substances that will be evaluated in the coming years. It lists 115 substances; 62 of these are new, 53 were already on the 'old' list. It is hoped that the Member State Authorities will be able to evaluate 50 substances per year.

The latest version of CORAP can be found here: [CoRAP](#)

Authorisation

Eight new substances 'subject to Authorisation'

Eight Candidate List substances have been 'promoted' to Annex XIV: 'Substances subject to Authorisation'. After the sunset date, these substances may not be used in the EU without a permit. Applications for a permit must reach ECHA before the 'Latest Application' date.

Substance Name	EC Number	CAS Number	Latest application	Sunset date
Trichloroethylene	201-167-4	79-01-6	21-10-14	21-04-16
Chromium trioxide	215-607-8	1333-82-0	21-03-16	21-09-17
Acids generated from chromium trioxide and their oligomers. Group containing: Chromic acid, Dichromic acid, Dichromic acid, Oligomers of chromic acid and dichromic acid	231-801-5, 236-881-5	7738-94-5, 13530-68-2	21-03-16	21-09-17
Sodium chromate	231-889-5	7775-11-3	21-03-16	21-09-17
Potassium dichromate	231-906-6	7778-50-9	21-03-16	21-09-17
Potassium chromate	232-140-5	7789-00-6	21-03-16	21-09-17
Ammonium dichromate	232-143-1	7789-09-5	21-03-16	21-09-17
Sodium dichromate	234-190-3	7789-12-0, 10588-01-9	21-03-16	21-09-17

Five Cobalt salts (cobalt sulphate, cobalt dichloride, cobalt dinitrate, cobalt carbonate and cobalt diacetate) were also on their way to Annex XIV, but in the end they were not included. These substances will probably be subject to a new Restriction to Marketing and Use (REACH Annex XVII). A study towards that end has started.

Annex XIV now contains 22 substances. The list of authorised substances can be downloaded here: [Annex XIV](#)

Authorised substances in recycled plastic

European plastic recycling companies are worried about substances subject to authorisation in their products. These are mainly phthalates. The companies intended to apply for authorisation; an expensive and complex procedure.

In the opinion of the European Commission however, this is not necessary. The raw material is waste, and therefore exempted from REACH. The waste ceases to be waste only once a plastic article has been produced. And by that time, there is no longer any need for authorisation.

The recyclers have withdrawn their application.

Other REACH & Chemicals news

New ECHA fees

The European Commission has published a new version of the ECHA fee regulation. The registration fees for large companies have increased, the fees for SME's (Small and Medium Sized Enterprises) have been reduced. The highest fee (large company, > 1.000 t/a) went from € 23.250 to € 24.901. The lowest fee (micro enterprise, 1-10 t/a) went from € 120 to € 64.

The new ECHA fees regulation also provides some much needed clarification. Where a non-European company claims to be SME (Small or Medium Sized Enterprise), the proof has to be provided in an official EU language and preferably in English.

ECHA checks SME claims

ECHA is in the process of checking all the SME claims for a lower registration fee. If an SME claim is found to be incorrect, the registrant must of course pay to ECHA the missing part of the fee. In addition ECHA may send out an invoice for 'administrative charges'. These charges depend on the size of the company and vary between € 8.000 and € 20.000.

Under the new fees regulation, registrants are very much encouraged to voluntarily 'upgrade' their registration if necessary. If this is done before ECHA asks for documents proving the SME status, these administrative charges are waived completely. If the upgrade is done voluntarily after the ECHA letter was received, the charges are halved. If however the registrant does not react at all, or if his documents are found not to be in order, ECHA invoices the full administrative charge.

Classification and Labelling Inventory

ECHA's Classification and Labelling Inventory lists millions of different classifications for over a hundred thousand different substances. These were all submitted by manufacturers and

importers. No coordination took place and as a result the database is a mess and absolutely useless. For every substance there are many different suggested classifications.

The Inventory needs a clean-up and legally this is an industry responsibility. Now ECHA has launched a tool to facilitate the process: the C&L Platform. This is a kind of ‘chat room’ for each substance where discussions between the ‘notifiers’ can take place.

The C&L platform can be entered here: [C&L Platform](#)

Test your knowledge of the new pictograms

With GHS (Global Harmonised System) coming into force, the labels on the packaging of dangerous chemicals will be changing. There is a quiz on the ECHA web site which allows you to check your knowledge of the new symbols.

The quiz can be found at: <http://echa.europa.eu/clp-quiz>

REACH & Articles

Annex XVII Restrictions

Systematic approach to restrictions

So far Annex XVII (Restrictions to Marketing and Use) tends to be adapted in a haphazard way. The European Commission is now taking a more systematic approach. It has identified 44 CMR substances (Carcinogen, Mutagen, Reprotoxic) that are often used in articles. From these, the substances that occur in consumer articles will be selected for a future restriction

SVHC in Articles

Notifications of SVHC in articles

When a group of articles contains more than 1 tonne and > 0,1% of a Candidate List substance, this must be notified to ECHA. By March 2013 only 228 notifications were received. This is much less than ECHA expected. Especially importers of articles seem to do few notifications.

Notification is not necessary, when the substance has been registered 'for that use'. Generic use descriptions of a substance can be found in the excerpts of the registration dossiers as published on the ECHA website. ECHA states however that this information is not detailed enough to be used for this derogation.

Remark Sitmae: This ECHA point of view is debatable. This is best illustrated with an example. Where the dossier on the ECHA website gives as a use 'in metal articles', this is indeed not very specific; it may mean cars, tables, chairs or airplanes. But when there are also no 'uses advised against', one may conclude that this means all metal articles, and thus also applies to ventilators and central heating. There is no need for much more detail.

Other REACH & Articles news

France bans BPA in baby food packaging

EFSA (the European Food Safety Authority) has repeatedly studied BPA (Bisphenol A) and concluded that, at the concentrations in which BPA is used in plastics, it represents no danger to the public. In spite of this, France has decided to ban the substance from food packaging for young children and pregnant women. Other food packaging containing BPA will have to be labelled. The legislation will enter into force on October 1st 2013. (Unless of course the European Commission takes France to court for obstruction of the common market.)

Nasty metals in Swedish toys

Excessive Cadmium, Nickel and Lead and banned Phthalates were found in toys and jewellery on the Swedish market. One third of the researched jewellery and a quarter of the toys were non-compliant.

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