

Newsletter No.17

This is the seventeenth Sitmae REACH Newsletter. With this newsletter we inform our customers about the ever-changing world of REACH.

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REACH in General

ECHA Guidance

Safety Data Sheets

The ECHA Guidance on Safety Data Sheets has been updated and translated into 22 EU languages. It now also contains information on the 'extended' Safety Data Sheet with Exposure Scenarios. There is also an 'in a nutshell' version.

Link to all [ECHA Guidance](#)

Downstream users

Also the ECHA Guidance for Down Stream Users was updated and translated into 22 EU languages. An 'in a nutshell' version is also available

Link to all [ECHA Guidance](#)

Helpdesks

Every EU Member State has a REACH Helpdesk. They provide answers to almost every question on REACH. They coordinate their answers to complicated questions and publish useful factsheets.

The link to the [factsheets](#)

Substances of Very High Concern

Candidate List expanded again

The Candidate List of Substances of Very High Concern now features 151 substances. Of these, 22 substances are also listed in annex XIV 'authorisation' and 21 are 'prioritised'; meaning that they will be next in line for an upgrade to Annex XIV.

The latest additions to the candidate list are:

- Cadmium sulphide (ec 215-147-8, cas 1306-23-6)
- C.I. Direct Red 28 (ec 209-358-4, cas 573-58-0)
- C.I. Direct Black 38 (ec 217-710-3, cas 1937-37-7)
- Dihexyl phthalate (ec 201-559-5, cas 84-75-3)
- Imidazolidine-2-thione (2-imidazoline-2-thiol) (ec 202-506-9, cas 96-45-7)
- Lead di(acetate) (ec 206-104-4, cas 301-04-2)
- Trixylyl phosphate (ec 246-677-8, cas 25155-23-1)

The [latest version of the Candidate List](#) can found on the ECHA web site.

Expected additions to the Candidate List

ECHA has recently closed the consultations for four new substances earmarked for the Candidate List. These are the probable next additions:

- 1,2-benzenedicarboxylic acid - branched and linear
- cadmium chloride
- sodium perborate
- sodium peroxometaborate.

Further details: [table of previous consultations](#) on the ECHA website.

It is expected that in August two more substances will be proposed for inclusion: cadmium fluoride and cadmium sulphate. There will first be a public consultation.

The intentions with regard to future expansion can be found in the table of [SVHC intentions](#).

Enforcement

EU Industry wants ‘free registration riders’ policed

Registration dossiers are often very expensive. Hundreds of thousands of Euros per substance is no exception. In a joint submission these costs are shared between all registrants. Still, the use of such a dossier may cost tens of thousands of Euro’s per registrant. For quite a few substances, second ‘joint registrations’ are opened by companies that do not share in these costs. They copy public information from the first registration and submit a dossier without financial contribution. These registrations are illegal because the registrants are not in possession of the studies that were used for the original dossier.

A number of European industry associations, each heavily involved in producing registration dossiers, have now asked ECHA and Member State authorities to go after these free riders. The call for action necessary, because Member States are often reluctant to address the problem, even if they are told exactly what has been going on. Also ECHA IT does not filter out these fraudulent registrations.

ECHA compliance checks

By the end of 2013 ECHA had concluded 1.130 compliance checks of registration dossiers; 5.7% of the 2010 registrations. Some 69% were found non-compliant. Most frequent shortcomings: the identification and composition of the substance, insufficient justification for waiving certain studies and missing information in the chemical safety report.

ECHA has recently however slightly changed the rules on how UVCB substances (such as refinery streams), should be identified in the dossiers. As a result all the older dossiers are now found to be non-compliant and will have to be updated. Sitmae customers with such registrations will be asked for additional information. We will update the dossiers and will charge a small fee for this work.

The dossiers to be checked were selected because of their potential non-compliance. The percentage of non-compliance is therefore no indication for the quality of all the dossiers in general.

REACH & Chemicals

Registration & Pre-registration

Toll manufacturers

Toll manufacturers are companies that manufacture chemicals for other companies. Under REACH, these companies are regarded as ‘manufacturer’ and ‘supplier’ of the chemical and have all the corresponding obligations. This may give rise to complications and disagreements.

ECHA has published a fact sheet explaining the concept, the obligations and some advice on how to prevent disagreements. The fact sheet can be found here: [Fact sheet – toll manufacturer under REACH](#)

Registered substances database

The functionality of the ECHA registered substances database has been improved. It is now possible to search by product category, sector of use, process category and environmental release categories. It is now also possible to filter the registered substances by publication date. The database contains almost 11.000 unique substances.

The database can be found here: [Registered substances](#)

Intermediates

Intermediates are substances that are only used to produce other substances. Their registration is relatively simple and cheap. No surprise that some intermediate registrations are submitted for substances with a somewhat wider application than intended. ECHA has screened some 2400 dossiers, checking for non-intermediate uses. Some 2.000 of these dossiers have now been improved, of which 100 were upgraded to full registrations. More than 100 dossiers have been ‘identified for regulatory action’.

Substance identity

In the case of a joint registrations a Lead Registrant (LR) submits the registration dossier and ‘co-registrants’ hook on to this dossier. Of course all the co-registrants’ registrations must concern the same substance as registered by the LR. In the case of UVCB’s (Substance of Unknown or Variable composition, Complex reaction products or Biological materials) this is not always self-evident. The LR’s description of the substance must be such that it adequately covers all the other registrations. But the description may not be too ‘wide’, otherwise the toxicological conclusions do not apply across the board.

ECHA is now checking the substance identities of LRs of UVCB’s. Where the substance identity must be narrowed down, this not only affects the Lead’s registration, but also co-registrations that are no longer within the new narrower scope. Expensive registration updates and sometimes second registrations may become necessary. It is not surprising that refinery substances are particularly affected.

Croatian registrations due

Last year Croatia became a member of the European Union. Croatian manufacturers and importers of chemicals must now submit their REACH registrations. Substances produced in amounts more than 100 tonnes per year, or that are carcinogenic, mutagenic or toxic to reproduction (CMR, categories 1a and 1b), must be registered by 1 July 2014.

Authorisation

Application process under way

For the first batch of substances subject to authorisation, the applications are being processed. The authorisations will be granted only for specific uses, if at all. The official ECHA Committees for Risk Assessment (RAC) and Socio-economic analysis (SEAC) are adopting their first opinions. The first authorisation will probably go to Rolls Royce; for the use of DEHP in the manufacture of aero-engines.

The committee opinions can be found here: [The opinions by RAC and SEAC](#)

The applications for authorisation can be found here: [Applications for Authorisation](#)

Aviation Safety and authorisation

In the aeronautical industry, safety requirements and REACH are sometimes at odds. Safety requires the use of substances that are under REACH subject to authorisation. ECHA, the European Aviation Safety Agency (EASA) and other relevant stakeholders of the aerospace industry have published a report on best practice in the authorisation process. The report may also benefit other industries. A link to the report is provided below.

[An elaboration of key aspects of the authorisation processing the context of aviation industry](#)

Consultations on alternatives

An essential part of the authorisation process is the search for alternative chemicals. When good alternatives are available, authorisation will not be granted. ECHA is actively seeking contributions from the public.

For those interested: [Public consultations on alternatives](#)

Safety Data Sheets

Standard phrases for Exposure Scenario's

European Safety Data Sheets consist of standard phrases. The same standard phrases exist in all EU languages. This makes automatic translation into all these languages possible. For the new 'Exposure Scenario's', large documents that must today accompany the SDS of registered substances, standard phrases are still being developed. Cefic, the European trade association for the chemical industry has published an updated version of the ESCom Phrase catalogue. The Catalogue is still in English only. Translations will no doubt follow later.

The catalogue can be downloaded as an Excel file: [ESCom 1.4](#)

Please note: Sitmae can already today produce Exposure Scenario's in all EU languages. We are licensed to use translations that were made for a large multinational company.

Poison Centres

Safety Data Sheets must provide an emergency telephone number. National poison centres often provide the emergency service. The way in which these centres wish get their information differs from country to country. A harmonised method of notification is expected in 2018. Major issues need to be solved, such as confidentiality, exemptions for R&D and cost.

Other REACH & Chemicals news

Cosmetics: Newly restricted substances

Five Parabens have been added to the list of prohibited substances in cosmetics: isopropylparaben, isobutylparaben, phenylparaben, benzylparaben and pentylparaben.

In addition new maximum concentrations have been adopted for triclosan, hydroxybenzoic acid and its salts and esters. All product will have to comply from July 30th.

Link to the amendment of the [relevant annexes](#).

REACH & Articles

Annex XVII Restrictions

New restriction

A new restriction (No.64) has been added to Annex XVII. It concerns 1,4-dichlorobenzene (cas 106-46-7, ec 203-400-5). The substance may no longer be used in air fresheners or deodorisers in toilets, homes, offices or other indoor public areas in a concentration > 1%.

Other REACH & Articles news

World Cup Football (Soccer)

As always before such a huge tournament, Greenpeace also seeks publicity. Adidas, Nike and Puma, large producers of sportswear and shoes, are accused of using hazardous substances in their products. Tests show perfluorinated chemicals (PFCs), nonylphenol ethoxylates (NPEs), phthalates and dimethylformamide (DMF). All three companies state that they comply with European legislation and that their products are safe to wear. By Greenpeace this is called 'Greenwash rethoric'.

Lead and Nickel in children's jewellery

The Austrian authorities have recently tested children's jewellery sold by large multinational retail chains. In three (of the nine) tested products the concentrations of lead and nickel were higher than the REACH limits. In one case more than ten times.

How to avoid phthalates of concern

Danish industry and authorities have together published guidance on how to limit phthalates of concern in articles. It addresses both phthalates subject to restrictions in REACH and those additionally subject to Danish legislation. The document is in English.

Download: [Business guidance on phthalates](#)

Biocides

Biocidal Products Regulation (BPR)

Mid 2013 the new Biocidal Products regulation came into effect. The system of separate authorisation by each EU Member State is replaced by one of authorisation for the whole European Union. ECHA, the European Chemicals Agency, well known from REACH, is the coordinating body.

Link to the legislation: [Biocidal Products Regulation](#)

BPR and articles

Only authorised biocides may be used. This also applies to 'Treated Articles' that are imported. There was considerable confusion and panic amongst importers of articles. The definition of a 'Treated Article' is very wide. It looked as if even biocides that were used during the non-EU production process (for example in water-based paints and inks), needed to conform to the new legislation.

The European Commission has now proposed a clarification of the scope of the legislation. For an article to be a 'Treated Article' it should: a) contain a 'biocidal product' and b) the treatment must have a 'beneficial and desired effect on the final item'. This excludes cases where the article simply contains remainders of preservatives that were only used at some stage in the manufacturing process.

A decision is expected in September.

BPR Guidance & database

A considerable amount of guidance has been published regarding the Biocidal Products Regulation. Recent EU wide biocidal product authorisations are taken up in a public database. (This database is not yet comprehensive. Additional information can be obtained from the ESIS database under 'PBT').

Some useful links:

[BPR Guidance](#)

[BPR Frequently asked questions](#)

[ECHA database biocidal products](#)

[ESIS database](#)

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