

Newsletter No.16

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

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REACH in General

Technical Guidance Documents

New FAQ structure on ECHA website

All the many FAQs and Q&A-pairs on the ECHA website have been reorganised. The result is better searchability, easier linking to relevant web sections and better version control. This improves usability. All the existing FAQ and Q&A pairs were collected in one database without changing the wording and the content.

The new Q&A structure can be accessed here: [Q&A support](#)

Updated Navigator tool

The ECHA Navigator is an interactive tool that helps producers and importers of both chemicals and articles to identify their obligations under REACH. It works through an interactive dialogue: the user answers a series of questions and the Navigator guides him step-by-step. The Navigator also provides links to supporting documents.

The updated Navigator is consistent with current legislation and ECHA guidance. It contains more information than previously. It is available in 23 official EU languages and is complemented with new Guidance in a Nutshell on Registration.

The navigator can be accessed here: [ECHA navigator](#)

New Guidance for Down Stream Users

The revised Technical Guidance Document for Down Stream Users is expected soon. As a last step towards its publication it was recently discussed with the Member State Competent Authorities. The document is a large improvement over the 2008 version.

The latest draft of the DU-TGD can be found here: [Draft revised guidance](#)

ORO Guidance for Only Representatives

ORO, the 'Only Representative Organisation' is producing a Best Practice Guide. Publication of the first part is foreseen early 2014 at the occasion of ORO's 5th birthday. The goal is for this guide to become the 'de facto standard' for ORs

'Dissenter's Guidance for articles'

Six Member States disagree with the Commission's interpretation of the '0,1% rule' for Substances of Very High Concern in articles. Where the Commission is of the opinion that an imported car is just one article, the dissenting Member States maintain that a car consists of thousands of separate articles.

The Member States in question are: Belgium, Germany, Denmark, France, Norway and Sweden. These Member States have now published guidance for suppliers of articles.

Apart from the debatable position with regard to the 0,1% rule, it is a useful and practical document. It for example supports a 'probability based approach'. (Focus on SVHC's that may in practice occur in the material of which the article is made)

The guidance document can be found here: [Guidance document](#)

Candidate List of Substances of Very High Concern

New SVHC's expected

The Candidate List of Substances of Very High Concern counts 144 entries. For seven more the public consultations have recently been finalised. Most, if not all, of these will be added to the candidate List in the near future. This concerns:

- cadmium sulphide,
- imidazolidine-2-thione;
- disodium 3,3'-[[1,1'-biphenyl]-4,4'-diylbis(azo)]bis(4-aminonaphthalene-1-sulphonate)
- disodium 4-amino-3-[[4'-[(2,4-diaminophenyl)azo][1,1'-biphenyl]-4-yl]azo] -5-hydroxy-6-(phenylazo)naphthalene-2,7-disulphonate
- lead di(acetate)
- dihexyl phthalate
- trixylyl phosphate.)

The Candidate List of Substances of Very High Concern can be found here: [Candidate List](#)

Missing substance identifiers

Both in Annex XVII and in the Candidate List some entries have no CAS or EC numbers (for example: refractory fibres). For the automotive industry this is unworkable, since their information systems are fully based on these numbers.

When asked, ECHA was, for legalistic reasons, not willing to produce a 'translation' of these descriptive entries into a list of usable CAS or EC numbers. ACEA (automotive industry) is now making this 'translation' itself. Cooperation has been promised by several industry associations of substance producers.

SVHC Roadmap 2020

Things seem to be moving towards industry involvement in an early stage to determine the best RMO (Risk Management Option) for Substances of Very High Concern. An early choice should be made between Candidate List, Annex XVII restriction, Workers safety legislation or other regulatory possibilities. Cooperation between Member States is still necessary however. Today one Member State may evaluate a substance registration, and see no problems with the dossier or the proposed RMO's, another Member State may be preparing a dossier for the authorisation of the same substance. It would be preferable if these things happened in some logical order.

Enforcement

Report: 2nd REACH enforcement project

The project focussed on formulators of mixtures and ran from May 2011 until March 2012. It was carried out in 29 countries. In total 1181 companies were inspected, covering 6900 substances, 4500 mixtures and 4500 safety data sheets (SDSs).

Most of the inspected companies were small or medium-sized. More than half were not only active as 'downstream users' but were also active as manufacturers, importers, distributors or only representatives.

Of all the inspected companies, 67% were non-compliant. Most common were: no registration or pre-registration (8%), missing CLP notifications (15%), failure to keep information (20%) and deficient risk management measures (12%).

Almost all companies had SDSs on site, but 52% of the inspected documents showed deficiencies. There was however an improvement in the formats used and availability of SDSs in comparison to earlier inspections.

ECHA's SME checks

Small and Medium Sized companies pay substantially lower ECHA fees. There are strict rules that determine whether a company is entitled to this fee reduction. ECHA checks every single SME claim. Companies must provide proof with complete annual accounts and several other official documents.

In 2011 some 80% were not able to demonstrate adequately that they were an SME, and most of these (76%) were not SMEs at all. In 2012, these figures were 62% and 56%. In the meantime several companies are seriously challenging ECHA's competence in this area.

Dutch annual inspection report (chemicals)

The Dutch authorities inspected mainly producers, importers and traders. The companies made or marketed chemicals, cosmetics, paints, adhesives, sealants, washing/cleaning products, and consumer products. All the companies were in compliance with registration and pre-registration obligations, but many were not in compliance with other REACH obligations.

Compared to previous year a substantial increase of violations regarding classification and labelling of chemicals was found (only 60% in compliance versus more than 75% in previous years). This increase is probably caused by the fact that more Small and Medium Sized companies were inspected and that the content of Safety Data Sheets was checked more thoroughly. Small companies lack sufficient knowledge and experience to classify and label hazardous substances correctly.

Outdated Safety Data Sheets were also a problem. Of almost 300 inspected end-users, 44% did not have up-to-date Safety Data Sheets.

Other general REACH News

Impatient Parliament

Several Members of the European Parliament are concerned about what they consider the slow progress of the implementation of REACH. They criticise the Commission's plan to have the 'Candidate List of Substances of Very High Concern complete in 2020 and the fact that so far only three new restrictions to marketing and use have appeared.

US EPA wants REACH data

The US Environmental Protection Agency has its eye on the data that was collected and generated for the REACH registration dossiers. Discussions between ECHA and EPA are taking place. An important problem is that much of the data is confidential and all is owned by the registrants; and not by ECHA. Also, more often than not, the registrants are contractually bound to use the data only for REACH purposes and not to disclose them to anybody else than ECHA.

The EPA in the meantime, is considering to use its considerable legal power. The EPA can force US based companies to disclose new risk information on chemicals. Many US based companies own registrations under REACH and they may be forced to cooperate.

Paperless Safety Data Sheets for the car industry

European, Japanese and Korean car producers, together with their suppliers are pushing a standardised data-exchange system for Safety Data Sheets through their entire supply chain. The system called SDSComXML is open source, although it will require some adaptations to the current IT systems in the companies that will use it. It contains standard phrases in 30 languages, including Japanese, Korean and Chinese. Large chemical producers, who of course already have their own systems, are not always keen to follow.

REACH & Chemicals

Registration & Pre-registration

Second registration deadline passed

The second registration deadline, for quantities > 100 t/a, has passed. The total number of different substances registered is now almost 6600. More than 9000 registrations were submitted by almost 3200 companies. Some 1700 registrations were submitted by SME's (Small and Medium sized companies), almost 2100 were submitted by Only Representatives.

Registrations came from 29 EU countries, with the highest percentages coming from Germany (31 %), the United Kingdom (12%), Italy, France and the Netherlands (each 8%).

The numbers were expected by ECHA. As a result, the ECHA IT system again worked without problem. Some 800 substances that, based upon their pre-registration tonnage bands, were expected to be registered, were not. There are however not yet any signs of these substances disappearing from the European market.

The registration statistics may be accessed here: [registration statistics](#)

Petroleum substances

ECHA has published the results of a study into the methodologies used by industry for the environmental risk assessment of petroleum substances. The main conclusion is that one of the important models used requires improvement in a number of areas. The report also recommends additional safety factor to address uncertainties.

It may be expected that as a result the dossiers will have to be updated. Quite a task for Concawe (EU refineries trade association), who prepared over 400 dossiers for refinery products.

The report can be found here: [RIVM Report](#)

Substance Identification

The European Commission is commissioning a study into the difficulties in the identification of complex substances (Mainly UVCB's: Substances of unknown or variable composition or of a biological origin). The contractor will have quite a job. He will have to make a list of all the complex substances, take a representative sample and analyse and assess their 'Substance Identity Definition' as provided by the Lead Registrants, and extract and assess the elements and strategies used to define the SID. The preliminary results will be discussed in a workshop with stakeholders.

Authorisation

DEHP & DBO consultations

ECHA has received seven applications for authorisation DEHP and DBP. Interested parties are invited to submit relevant information on alternatives to these requested uses. The public consultation closes on 8 January 2014.

Other REACH & Chemicals news

Corrosive cleaning products in Denmark

The Danish Environment Ministry inspected over 160 cleaning products sold in DIY stores. On almost half of the inspected products, the labels did not tell consumers how corrosive the products were. Following this action 73 of these products were banned.

REACH costs in the Aluminium industry

The European Aluminium industry has studied the overall cost resulting from of EU legislation. The REACH component in these costs were approximately € 45 million; a considerable amount, but only a small part of the total. (The costs related to energy legislation were far larger.) The registration costs alone were almost € 20 million for the 46 plants studied. Human recourse accounted for almost € 10 million.

Supply chain disruption

The European aeronautical and automotive industries are worried about disruptions in the supply chain due to non-registration of substances for products purchased outside the EU. So far it has been difficult to find examples for individual substances. The Commission is not unwilling to look into the matter, but wishes to have 'live examples' first.

Although it is still probable that in 2018 substances will disappear from the market, another and more urgent problem seems to occur. Essential mixtures, produced outside the EU, disappear from the market. Already some US based producers of products like adhesives, sealants no longer wish export to the EU because of REACH. Although these decisions may be questionable at this point in time (there are no registration obligations < 100 t/a yet), it is an indication of what may be awaiting EU industry in a few years' time.

REACH & Articles

Annex XVII Restrictions

No new restriction for DINP and DIDP

ECHA has reviewed the risks posed by articles containing the phthalates DINP and DIDP. Today these phthalates may not be used in toys and childcare articles which can be placed in the mouth by children. ECHA concludes that indeed a risk from the mouthing of toys and childcare articles with DINP and DIDP cannot be excluded. However, no additional further risks were identified. ECHA concludes that there is no need to re-examine the existing restriction.

Cadmium

Sweden proposes to add a restriction to Annex XVII regarding cadmium and cadmium compounds in artist paints and pigments (enamel, ceramics etc). Cadmium may end up in waste water treatment sludge through cleaning activities. The sludge is spread on agricultural land and thus cadmium may end up in food.

Other REACH & Articles news

Hazardous substances in Swedish toys

Kemi, the Swedish Chemicals Agency, inspected plastic and electronic toys. They found banned phthalates and lead in 53 out of the 211 tested toys. More than 40 companies producing, importing or just selling toys were checked. Several of these companies did not know about the legislation affecting their products.

Swedish skin-tight clothes

Kemi also examined some 110 'skin-tight' clothes such as swimwear, underwear, T-shirts and sweaters. Almost half of these contained nonylphenol ethoxylate (NPE), some in very high concentrations. Under REACH the use of NPE is not allowed in clothes because it is toxic to aquatic organisms. Some scarves and a T-shirt were found to contain azo dyes; also forbidden. All the non-compliant products were withdrawn from the market.

Dutch annual inspection report (articles)

The Dutch authorities inspected mainly companies that made or marketed consumer products. Excessive levels of cadmium were found in about 8% of 336 inspected products. Banned plasticisers were found in 27% of the inspected toys. Phthalates featuring on the candidate list were found in 44% of the 470 tested products (>0,1%). Imported articles were most to blame. The Dutch authorities state that much more attention should be given to SVHCs in imported articles.



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