NEWSLETTER OCTOBER 2017

NEWS FROM ECHA regarding REACH and CLP

Too many companies are not updating their REACH and CLP data

ECHA reports that a study looking at companies' intentions to update their REACH registrations and CLP notifications reports that updating data on chemicals is not a priority unless requested by ECHA.

Around ***64 %*** of the dossiers submitted to ECHA since 2008 have never been updated and those were updated only after a letter from ECHA. Given that reliable data on chemicals is the basic principle of safe use and the management of risk for dangerous substances, this is putting the protection of human health and the environment in danger. Without data that reflects the reality, risk management becomes impossible. REACH becomes an empty exercise!!

Hence, improving the data is one of ECHA's priorities. With many actions already underway (e.g. screening dossiers, completeness checks), the results of the study will help ECHA and the European Commission to analyze more closely what is needed to push companies to be more proactive in updating their REACH and CLP information. The study suggests that there are four issues that affect companies' willingness and readiness to update their data:

1. Registration is considered as the end of the process.. *I have registered and so compliant with REACH!!!!*
   Many companies have the perception that receiving their registration number is the end of the REACH registration process and that no further work is needed. This perception is also worsened by the fact that the fees payable (for registering and getting access to data) are one-off payments.
2. Lack of clarity on what needs to be done, when and by whom
   The study showed that people is unclear about what needs to be updated according to Article 22 of REACH. It places an obligation on the individual to decide when an update is needed mentioning that it needs to be done based on 'new information' without 'undue delay'. As REACH is based on the 'one substance, one registration' principle, the responsibility for updates is still ambiguous (Lead registrant's task alone or responsibility of each individual registrant?
3. Limited resources
   The costs of updating can be high and the benefits perceived as non-existent. In particular, small and medium sized enterprises (SMEs) felt that REACH is just a regulatory burden. The respondents also defined "*REACH as a fatigue*" with a great deal of effort and cost already spent on the original registration.
4. Limited use of the whole set of data
   The fourth issue has to do with the practical value of the data in the dossier. People felt that the dossier as a whole contains highly technical information better suited for academics and regulators than for downstream users, who benefit more from up-to-date CLP classifications and exposure scenarios. They mentioned that the downstream users want good quality safety data sheets and that's all.

For experts who are in the REACH arena since the beginning of the story (White Paper issued on February 2001), it seems that the same problems still continue to exists. We long discussed about the SMEs problems, about the workability of the REACH system for downstream users that at the end are the real final applicators of the safety rules.

BUT…why are updates important?

Key principle: poor data means poor risk assessment and management and consequently poor quality protection of human health and the environment. Registration dossiers must be your business asset! Good quality, up-to-date information helps appropriate communication in the supply chain and makes sure that adequate safe use advice is given further down the supply chain, eventually to end users like consumers and workers.

AUTHORISATION and RESTRICTION

Regulation EU 2017/1510 (*Commisssion Regulation (EU) 2017/1510 of August 30, 2017 amending the Appendices to Annex XVII to Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) as regards CMR substances*) is aimed to update the list of SVHC substances (CMR) included in the REACH Annex XVII (Substances under Restriction). The Regulation has been published under the European Official Journal on August 30, 2017 and will be applied from September 20, 2017.

The following substances, among others, will be subjected to restriction:
tetrahydro-2-furyl-methanol, (CAS 97-99-4)
gallium arsenide (CAS n. 1303-00-0)
Tributyltin compounds, with the exception of those specified elsewhere in this Annex
1,2-benzenedicarboxylic acid, dihexyl ester, branched and linear (CAS n. 68515-50-5)
Imidazolo (CAS n. 288-32-4)
bisphenol A; 4,4'-isopropylidenediphenol (CAS n. 80-05-7)
difenacoum (ISO); 3-(3-biphenyl-4-yl-1,2,3,4-tetrahydro-1-naphthyl)-4-hydroxycoumarin (CAS n. 56073-07-5)
bromadiolone (ISO); 3-[3-(4'-bromobiphenyl-4- yl)-3-hydroxy-1-phenylpropyl]-4-hydroxy-2Hchromen-2-one (CAS n. 28772-56-7)
triflumizole (ISO); (1E)-N-[4-chloro-2-(trifluoromethyl)phenyl]- 1-(1H-imidazol-1-yl)-2-propoxyethanimine (CAS n. 68694-11-1)

We remind to all companies to carefully check their use or manufacturing of the mentioned substances in order to up to date their compliance with the new restriction rules. It has to be reminded that using a restricted substance can generate a very heavy sanction including jail for the responsible person of the company.

Chromium trioxide (CAS n. 1333-82-0) Sunset Date expired!
From September 21, 2017 (few days ago!) the use of Chromium Trioxide has been banned from EU unless an authorization to the manufacturer or to a downstream user has been released.
Regulation EU 348/2013 *(Commission Regulation (EU) No 348/2013 of 17 April 2013 amending Annex XIV to Regulation (EC) No 1907/2006 of the European Parliament and of the Council on the Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH)*)

16.	Chromium trioxide EC No: 215-607-8 CAS No: 1333-82-0	Carcinogenic (category 1A) Mutagenic (category 1B)	21 March 2016	21 September 2017	—	—

established the "*Sunset Date*" of the mentioned substance on September 21, 2017. After this deadline the substance is not allowed to be used in the EU area unless:

- A specific authorization is granted to the manufacturer or a user before the "Sunset Date"
- An authorization dossier has been submitted by a manufacturer or a user before the Latest Application Date (LAD) of the substance which was indicated as March 21, 2016

For due information the same Regulation indicated also the following substance with Sunset Date of September 21, 2017 and related Last Application Dates (LAD) as follows:

Trichloroethylene, EC No: 201-167-4 CAS No: 79-01-6	*LAD: October 21, 2014*
Chromic acid EC No: 231-801-5 CAS No: 7738-94-5	*LAD: March 21, 2016*
Dichromic acid EC No: 236-881-5 CAS No: 13530-68-2	*LAD: March 21, 2016*
Oligomers of chromic acid and dichromic acid	
EC No: not yet assigned CAS No: not yet assigned	*LAD: March 21 2016*
Sodium dichromate EC No: 234-190-3 CAS No: 7789-12-0 10588-01-9	*LAD: March 21 2016*
Potassium dichromate EC No: 231-906-6 CAS No: 7778-50-9	*LAD: March 21 2016*
Ammonium dichromate EC No: 232-143-1 CAS No: 7789-09-5	*LAD: March 21 2016*
Potassium chromate EC No: 232-140-5 CAS No: 7789-00-6	*LAD: March 21 2016*
Sodium chromate EC No: 231-889-5 CAS No: 7775-11-3	*LAD: March 21 2016*

LEAD REGISTRANTs

ECHA has updated the list of substances for which a Lead Registrant (LR) has been declared in REACH-IT. The list now includes ***12.146 substances*** that have a joint submission and are either already registered or going to be registered for the REACH 2018 deadline. The list can be easily found in the ECHA web site and it is updated to September 25, 2017 at 9.21 time.
Lead Registrant (LR) nominations are expected to increase in the next few months due to the high number of intermediate substance expected to be registered by the last deadline of May 31, 2018. Most of these intermediate substances belongs to the pharmaceutical manufacturing processes as they are raw materials or intermediate of synthesis for APIs (Active Principle Ingredients). Despite the fact that a trend to come back to the European manufacturing of such substances is on fashion now, a huge number of these are still imported from non EU countries (India and China particularly). Importation of chemicals requires Reach registrations.

ENDOCRINE DISRUPTING CHEMICALS (EDC)

European Parliament rejects EDC criteria

On October 4, 2017, the European Parliament (EP) voted against the European Commission's proposal for criteria to identify Endocrine Disrupting Chemicals (EDCs) in biocides and pesticides asking it to come up with a new proposal "without delay".
EPs approved the objection to the draft criteria that was put forward last month by two EPs, Jytte Guteland and Bas Eickhout, by 389 votes to 235 with 70 abstentions.
EP believes that the Commission exceeded its mandate by proposing to exempt some substances, designed to attack an organism's endocrine system, from the criteria, even when they cause harm to non-target organisms of the same group of species.
This approach was considered illegal as it would change an essential element of the Plant Protection Products (PPP) Legislation which specifically calls not to approve substances that have endocrine disrupting properties on other species than the ones targeted. The European Commission will have now to draft a new version of the text taking into account EP's input.

It has to be noted that just prior to the vote, signatures from over ***315.000 Europeans*** urging MEPs to reject the Commission's proposal and to stand up for health were handed over in a massive online action by EDC-Free Europe campaign partners.
The EDC-Free Europe coalition repeatedly warned that the proposed criteria were not sufficient to protect human health and the environment not grounded in science and unlawful. The European Commission was under a legal obligation to present such criteria on account of Article 5 (3) of the Biocidal Products Regulation (528/2012), and Article 80 (7) of the Pesticides Regulation (1107/2009). However, the text proposed by the European Commission is regarded by the majority of scientific experts (including the Endocrine Society) and most civil society organizations as totally inadequate. The basic principle is that EU legislation requires that pesticides and biocides substances has no endocrine-disrupting effects on other species other than the ones targeted.

SUBSTANCE EVALUATION PUBBLISHED

New substance evaluation conclusion documents are now available on ECHA's website for:

- ***4,4'-isopropylidenediphenol (Bisphenol-A)*** (EC 201-245-8; CAS 80-05-7), added to the CoRAP list in 2012 and evaluated by Germany;
- ***Cyclohexanone*** (EC 203-631-1; CAS 108-94-1), added to the CoRAP list in 2016 and evaluated by Poland;
- alcohols, C7-9-iso-, C8-rich (EC 271-231-4; CAS 68526-83-0), added to the CoRAP list in 2016 and evaluated by Italy;
- ***Reaction mass of*** (1S,1'R)-2-[1-(3',3'-dimethyl-1'-cyclohexyl)ethoxy]-2-methylpropyl propanoate, (1R,1'R)-2-[1-(3',3'-dimethyl-1'-cyclohexyl)ethoxy]-2-methylpropyl propanoate and 2-methyl-2-{[(1R,2R)-2,6,6-

trimethylcycloheptyl]oxy}propyl propanoate (EC 604-250-7; CAS 141773-73-1), added to the CoRAP list in 2016 and evaluated by Germany;
- ***dimethyl disulphide*** (EC 210-871-0; CAS 624-92-0), added to the CoRAP list in 2014 and evaluated by Germany;
- ***n-hexane*** (EC 203-777-6; CAS 110-54-3), added to the CoRAP list in 2012 and evaluated by Germany;
- ***amides, C18-unsatd., N-[3-(dimethylamine)propyl]*** (EC 800-353-8; CAS 1379524-06-7), added to the CoRAP list in 2016 and evaluated by Germany;
- ***Dapsone*** (EC 201-248-4; CAS 80-08-0), added to the CoRAP list in 2016 and evaluated by Germany;
- 6,6'-di-tert-butyl-2,2'-methylenedi-p-cresol (EC 204-327-1; CAS 119-47-1), added to the CoRAP list in 2016 and evaluated by Denmark.

BIOCIDES

The Biocidal Product Committee (BPC) met for the 22nd time on 3-4 October 2017
On October 5, 2017, the BCP has adopted opinions on applications for approval of three active substances for use in biocidal products used as disinfectants and preservatives.

The active substances are:
Chlorophene *for product-types 2 and 3*
Azoxystrobin *for product-types 7, 9 and 10*
PHMB (1415; 4.7) *for product-types 1, 2, 4, 5 and 6*

The Committee's conclusion is that PHMB (1451; 4.7) may be approved for PT2 and PT4, while it cannot be approved for PTs 1, 5 and 6.
For azoxystrobin, the Committee concluded that it may be approved for all product-types.
For chlorophene, the conclusion of the Committee is that the active substance cannot be approved for PT3. For product-type 2, (as chlorophene meets the exclusion criteria) the conclusion is that it may normally not be approved, unless one of the conditions for derogation set in Article 5(2) of the Biocidal Products Regulation (BPR) is met. This will be decided by the European Commission and the Member States.
The adopted opinions will serve as a basis for the final decision-making by the European Commission and the Member States.
The approval of an active substance is granted for a defined number of years, not exceeding 10 years.

"in situ" generated active substance

Those notified in 2016.. deadlines approaching

A substance marketed as an "***in situ***" generated active substance which is not under evaluation in the Review Program, it should have been notified to ECHA already in 2016, where possible.
If a company did that in time, it was given two years to submit a full application for an active substance approval. That application will allow such company to continue using the "*in situ*" generated active substance until the evaluation of the substance in the Review Program has been completed.
If a company have not already started to prepare its application, it is time to start now.
The deadline for submitting the active substance application was specified in the letter that confirmed the compliance of each notification. The deadline can also be found in the list of compliant notifications.

Events for September - November 2017

Committee for Risk Assessment
18-22 September

Biocides Stakeholders' Day
26-27 September

Management Board meeting
28-29 September

Biocidal Products Committee
2-6 October

Member State Committee
23-27 October (tentative)

Enforcement Forum
7-10 November

Stock-taking conference on the implementation of REACH authorisation:
13-14 November

ECHA EXECUTIVE DIRECTOR

Dr. Bjorn Hansen, Head of the Chemicals Unit at the European Commission’s Environment Directorate-General, has been appointed as ECHA's new Executive Director. Mr. Hansen told Chemical Watch that being selected as the second Executive Director of the Agency is an "honor" for him.

SME free access to REACH data

ECHA proposes "free" SME access to REACH registration data

ECHA proposes to grant small and medium sized companies conditional free access to REACH data and joint submissions to reduce the burden of data sharing negotiations for the 2018 registration deadline.

In a recent paper, the Agency calls for the REACH Directors' Contact Group (DCG), an informal group of directors from the European Commission, ECHA and Industry Associations, to endorse the proposal at its meeting later this month. Following the DCG endorsement all parties should then "*promote this voluntary approach and spread existing information on negotiations and dispute procedure among existing or future registrants that may be interacting or about to interact with SMEs in the context of their SIEFs*".

The Agency says industry could make a "major contribution" if the letter of access for the data and the token to join would be made available for SMEs for free "in certain cases".

This could be done when a registration already exists and data is submitted to ECHA, the paper says. This approach would avoid any negotiation between parties and save costs. Free access would "reduce *uncertainty on the decision to register for SMEs*".

It does, however, say the following conditions could be imposed:

- the new registrant presents a self-declaration that it complies with the definition of an SME;
- the SME agrees with the classification in the lead dossier and the safety data sheet, and hence to implement and communicate the corresponding risk management measures;
- the SME would need to agree to waive its right to request a detailed cost itemisation and a reimbursement scheme;
- it should be in a position to confirm that it has the same substance and that it does not possess any additional information relevant for the registration dossier;
- the access to free data only applies to existing data for the 2018 deadline, and is without prejudice to sharing costs for new data, for example after substance evaluation.

The paper adds that it is important to ensure SMEs have "easy access" to all available support material and, if necessary, to the dispute mechanism. "*In order to achieve that, all parties should engage in as many channels as possible to disseminate information on data and cost sharing*." Existing registrants and their consortia or associations could play a role in informing the SME wanting access on the available information, it says.

It is well known that, in many cases, the long disputes/discussion between Lead Registrants and Joint Registrants about Data Sharing process and costs are leading to waste a huge amount of time; as closed as we are to the 2018 deadline such behavior is becoming very dangerous and risky for the success of some registrations. Nevertheless, the free access to data by some kind of companies (SME) appears to be difficult to manage as all actors must act in the same way.. and this is unrealistic!!. Additionally it may appear as discriminatory in front of companies that have paid the entire cost of the data sharing despite they are large companies or SMEs.

WORLWIDE

ITALY

The Istituto Superiore di Sanità (ISS) informed that a new fee has been established by companies which make data entry in the National Inventory of dangerous mixtures (Archivio dei preparati pericolosi presso ISS). Such fee consist in 50,00 € per legal entity which notified mixtures. After payment it is necessary to update its own profile by entering in the section "*profilo pagamento*" to be allowed to continue the use of the system.

CHEMSAFE NEWS

On October 9, 2017, we celebrate all together the 10th anniversary of *Loredana Savin* as our colleague. This is the second time: Elena Meriano was already celebrated in 2014 as first company employee.
Loredana, owning a degree in Biological Science, joint Chemsafe in October 2007 and after a training time of several months she started taking care of SDS preparation/revision as well as safety classifications. At that time CLP regulation was not yet under application; Loredana moved her first steps with older classification systems and SDS layouts and had the possibility to follow the updates of the regulation in such field all along these years.
She is now responsible of the CLP/SDS Subunit of the main Business Units CHEMICAL headed by Lara De Luca. She has prepared thousands of SDS and prepared/reviewed hundreds of classification acting as Project Leader for important Italian and foreign customers.
We really thank Loredana for her contribution to the success of our company and for her utmost professionalism.

On October 16, 2017 *Paolo Rossi* will start his activity in Chemsafe as Business Development Manager for the Chemical Area. Paolo will focus his BD activity on Italian and EU customers mainly cooperating with the Chemsafe CHEMICAL and AGRO/BIOCIDE Units. Paolo has a 10 years experience as BD having worked in international CROs and selling experimental studies for chemical companies; the contribution of Paolo will be a key factor for the successful development and consolidation of Chemsafe in the chemical business as Regulatory Affairs company. Our best wishes to Paolo for his new challange!

From beginning of 2018 *Antonio Conto*, Chemsafe Managing Director will focus his Business Development Activity in the pharma sector; the target is to consolidate and increase the presence of Chemsafe activity in the Pharma and Medical devices fields as well as in the Food area.

PARTICIPATION TO EVENTS

Antonio Conto will take part of the ***Chemical Watch Enforcement Summit EUROPE 2017*** that will be held on November 13-14 in Bruxelles (Belgium). He will introduce a speech on "***REACH Inspections in Italy and the Chemsafe case***" on November 14, afternoon session.