NEWSLETTER SEPTEMBER 2018

LAST NEWS

On September 24-25, 2018 Chemsafe representatives (Lara and Antonio) attended the 2018 Chemical Watch Enforcement Summit in Bruxelles. It was, as usual, a very interesting occasion to be updated on the last developments concerning REACH, CLP in EU and Reach-Alike legislation all over the world. During the numerous speeches some important sentences were pronounced. Mainly the following with some comments:

"Registration is not the end of the process, it's just the beginning!"

What does it means?
The Regulation is still in place and ECHA/Industry as well have to manage a number of issues such as:

- Evaluate a number of dossier for each registration level (5% at least). Evaluation procedure by ECHA may lead to additional questions or the request of additional studies in order to evaluate specific safety end-points and/or evaluate the risk for specific exposure scenario during the use of the substance; so the evaluation process is self-feeding;

- Prepare/Evaluate complex Authorization and Restriction procedures for selected substances respectively listed in Annex XIV and Annex XVII and in Candidate List as well. Member States will continue to prepare Annex XV dossier for ECHA including suggestion/request to start with Authorization or Restriction process for a given substance. These process will become particularly important for industry as the involved substance are those named SVHC (Substances of Very High Concern), specifically CMR (Carcinogens, Mutagens and Toxic for Reproduction) and PBT (or vPvB), Persistent, Bioaccumulative and Toxic substances. Such substances may raised serious problems for health and the environment and, in legal terms, covered by huge sanctions in case of law breaches. Companies that intend to present an authorization dossier have to consider also the huge cost (including authorization fees) needed to support it.

- Face the article regulatory situation under Reach. This is particularly difficult and critical as many types and large quantities of articles are every day imported into Europe (millions); let's remembers as examples textile article and toys. Even though NEAs (National Enforcement Authorities) apply a lot of inspection including analytical determinations, often many these "objects" are not properly imported as contain high level of banned substances (Cadmium, Chromium, etc). It is therefore clear that EU consumers are not completely protected.

"How can we regulate the internet sales of chemical product?"

- **Internet sales** of chemicals – high levels of non-compliance found so far. This way of sales involves a broad range of REACH and CLP duties – registration, restrictions, authorisation, labelling

In most cases chemical products sold via Internet websites (detergents, cosmetics and others) do not follows Reach and CLP rules. Furthermore it's not clear who is the economic responsible operator and then eligible to be fined as for National Sanction laws. It's not clear who is responsible for CLP application.. most of labels do not report correct CLP classification or often any CLP classification. It has been reported that for a survey done at European Level, **82.4%** of product sold via Internet websites are not in compliance with the EU regulation mainly for CLP requirements (no GLP statements for hazardous products). It's clear that consumers are exposed to products not known for their hazardous properties and the main pillar of all recent EU safety legislation: information along the supply chain.. i.e. from the manufacture down to the downstream users and consumers, is not respected.
The **REF-8**, now under discussion and preparation, will be focused on Internet Sales checks and restriction process. It will be applied in 2020.

"Reach is well implemented but poorly or not well enforced"

Any law must be shall be implemented and enforced. Enforcement means "*the act of compelling observance of or compliance with a law, rule, or obligation*". This implies controls and, if needed, corrective measure, fines or sanctions. Implementation means to put the law into effect.
The enforcement of Reach regulation is particularly week, as already mentioned, at custom level. Custom agencies need to harmonize their activities with Reach, CLP, SDS requirement in the way that custom control can be quick and effective. Key points are:

- custom coding: Goods are identified at the borders by their CN code (6 digits at World level – Harmonized System - and 8 digits at EU level). REACH covers about 22 000 Substances of which only a few hundreds are identified in the CN with a specific customs tariff code. Many belong to a "basket heading" (a subdivision called "other"). There is no "matching" between REACH registered substances and CN codes. Fraud at the border is very easy!

- analytical methods: In an EU/EEA-wide project of ECHA's Enforcement Forum, inspectors found hundreds of consumer products with illegal amounts of restricted chemicals. Every fifth toy inspected contained high levels of restricted phthalates (ECHA/PR/18/04 - Helsinki, 13.02.2018). Customs controls must be quick, effective and based on modern risk management techniques Previously, Customs controls tended to focus on the fiscal aspects of customs work but in recent years there has been an increasing emphasis on the importance of customs controls for purposes such as security, safety, protection of the environment. Custom laboratories will have an increasingly important role to play in helping to ensure the correct and uniform application of Community legislation in a world where product developments occur ever more rapidly. The ECHA Forum has issued a Compendium of analytical methods to check compliance with Reach annex XVII restrictions in March 2016.

"We need to face and regulate better the relationship between REACH and OSH regulation"

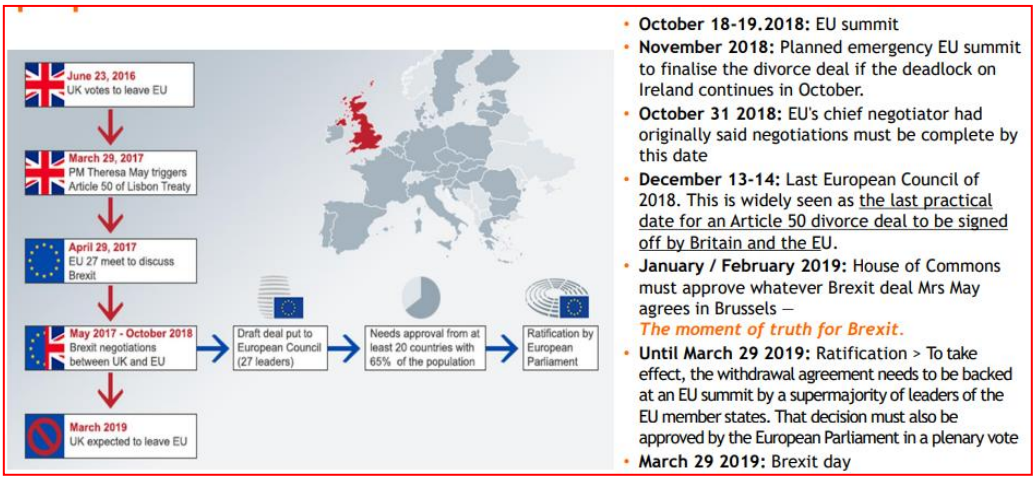
The two systems needs and can be complementary supporting each other. REACH registration produces a number of relevant safety information that are helpful to assess occupational exposure and health matters at workplace. One of the most experienced problem is the different DNEL and OEL values that can arise from registration on one site and OEL calculation (by EU-SCOEL) on the other site. Additionally there are some huge discrepancies between the application of REACH approaches when calculating safety values with National approaches (i.e. in Italy Testo Unico n. 81 for chemical risk). Another important problems is related to the awareness of the SDS content by professional users and SDS content respectively. SDS are the key tool for transmitting information along the supply chain to the users. It is therefore crucial that SDS content must be complete and able to inform correctly about hazards. On the other way, people using SDSs must be trained to understand the information included and to implement them according to PPE and containment procedures.

" SDS situation at lower supply chain is very poor"

Despite SDSs circulate in EU since the first EC directive in 1991 and despite the recent improvement requested by different EU legislation (REACH, CLP and last EU reg. 830/2015) the quality level of SDS and awareness of their role is still insufficient.
First of all quality of SDSs is still not perceived as important by many actors along the supply chain; SDSs are still considered "pieces of paper" to accompany the product; during work operation they are not collected and stored in specific spaces and therefore not easily reachable by operators. In many cases they are not updated as the CLP Regulation requires as for ATPs (Adaptation to the Technical Progress). Most of cases SDS are not translated in the user languages; many companies use to produce them in English as it is considered a sort of reference technical language.. but most of workers do not use English when working. Efforts are now ongoing by many association bodies as CEFIC and FECC in order to harmonize and standardize SDS preparation mainly on standard phrases to be used in CLP classification and exposure scenario. However, we believe that a complete standard format is not reachable at the end. The preparation of a SDS is an activity that would be done by experts and not by software .. therefore a single SDS for a give substance or product will never exist.

" What happens to your REACH registration when UK becomes a third country outside EU "

This is a BREXIT matter! The UK will leave EU on 11 PM of March 29, 2019 (6 months to go from now…..very short time!!). At the moment there is no deal regarding Reach application with EU, no deal with EU means to build up a new chemical regulation in UK a sort of "***UK REACH***". Road map for BREXIT is illustrated in the following figure:



For UK companies many actions must be done by February/early March 2019 as a "*Timed Defensive Switch*". To keep their REACH presence in EU. The next three figures summarize such actions and generally situation:

- **Lead Registrant in the UK ->Transfer/Relocate Lead Registrant in EU-27**
- **Only Representative in the UK -> Transfer/Relocate Only Representative in EU-27**
- **Manufacturer in the UK -> Set up Suspended Defensive Switch**
- **Authorisation in the UK -> Set up Suspended Defensive Switch**

Exit from REACH-insurance: A conditional agreement to transfer REACH rights in EU-27 at the appropriate time upon the UK becoming a third country outside the REACH system

- **Importer in the UK -> Negotiate transfer of LoA and re-register in EU-27**
- **Distributor in the UK -> Set up supply chain with EU-27 registered importer**
- **Downstream User in the UK -> Find alternative suppliers in EU-27**

The main critical point is referred to those EU-27 importers which are covered regarding the Reach registration of their imported substances by on OR now located in UK. Please check carefully that this OR will be transferred correctly to EU and get all necessary/mandatory documents. If not, the importer will be responsible to have its own registration under Reach or select another OR. This last is not an easy alternative as implies the selection of a new non EU manufacturer to provide your substance with the same quality and identity profile of the previous one.

Some Supply Chain Implications in Case of No Deal

- **ORs:** UK based Only Representatives can no longer operate as REACH OR
  -> EEA based importers relying on their OR registration are non-compliant unless rights have been transferred prior to Brexit
- **Manufacturers:** UK substance manufacturers need to nominate an OR located within the EEA
  -> For a bigger company it may make sense to use a EU-27 based subsidiary and get the required services from a service provider
- **Group Situations:** If the UK registrant/authorisation holder (M, I OR) is a leading position
- -> the substance co-registrants/users relying on a group authorisation must agree an alternative legal entity based in the EEA well in advance and transfer the role before Brexit

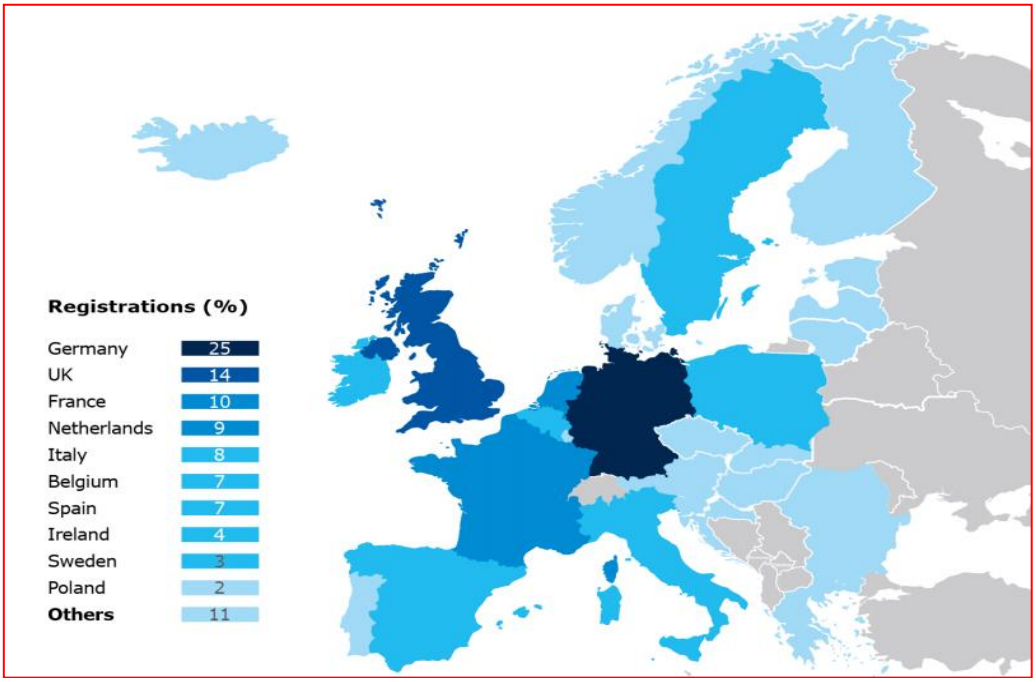
2018 REACh REGISTRATION

The next figures illustrate the results of the last deadline REACH registration.

Main outcome of the 2018 registration deadline for low volume substances (1 to 100 tons/year):

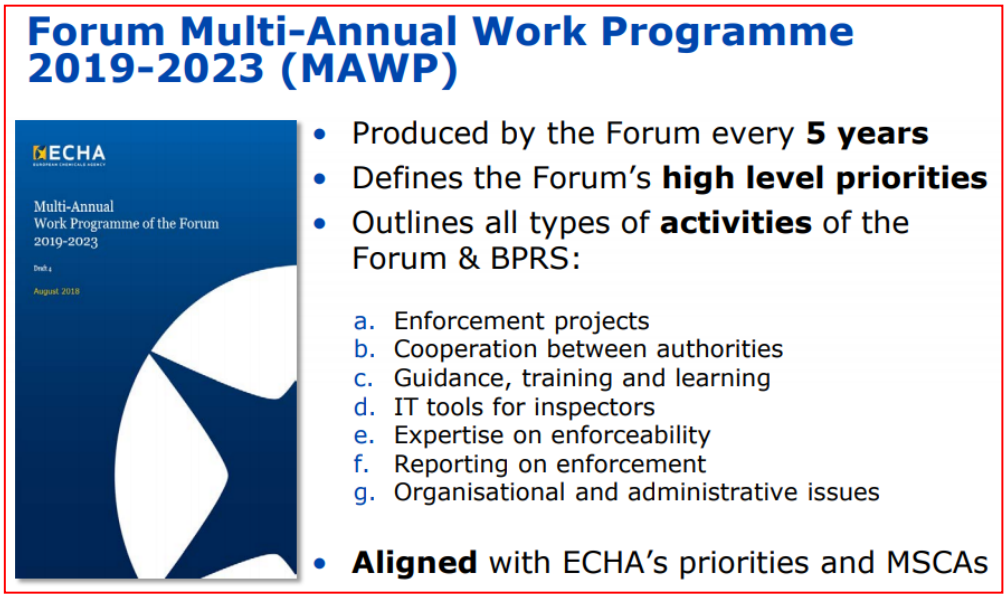
	All	Deadline 2018
Registrations	88 319	**33 363**
Substances	21 551	**11 114**

- All registrations submitted by 31 May - **processed** by ECHA
- 16% of registrations from **SMEs**
- Registrations from **outside of EU/EEA**: 48% from importers and 28% from only representatives



NEXT REFs EXPECTED

The REF projects are planned by the FORUM every year based on a planning schedule as for the next figure.



REF 5 ongoing
REF 6 ongoing, it is focused on the classification system (CLP). 2018 inspections are directed to CLP issues both on substances and mixtures including biocidal products. As said, it is expected a more severe approach to apply sanctions due to low quality of registration dossier but mainly related to the poor quality of safety data which do not assure a correct and sufficient knowledge of the substance/mixture safety profile.

REF 7 (2019), it will be focused on registration obligation including substances registered as intermediates. EU National Enforcement Authorities (NEA) Inspectors will be requested to check whether companies that need to register substances on their own or in mixture after the last registration deadline (i.e. May 31, 2018) have a valid registration (Art. 6 and 7 of REACH Regulation). The target will be the last tonnage band (1-100 tpa) but is not excluded that inspector can go back to check old tonnage bands (100-1000, > 1000 tpa), hence assessing registration from higher tonnage bands that have been submitted before. Inspectors will check the correctness of registration as substance or as intermediate depending on the use of such substances and the condition applied. In particular, regarding the intermediate substances registration as for REACH Art. 17 or 18 (light registration procedure), they will check that a substance is only manufactured or imported and used under Strict Controlled Conditions (SCC) according to the mentioned articles and, possible, to the related ECHA guidance of edited in 2010. This will be a crucial factor for many companies as the registration of an intermediate substance is much less expensive than for a full substance registration. We will see the outcome of such inspections later!

REF 8 (2020) on internet sales and restrictions

Public consultation on 18 substances proposed for authorization under REACH

ECHA invites comments on its proposal to include 18 new substances in the REACH Authorization List. Comments can be given until 5 December 2018. (list of ECHA web site)

ECHA is considering recommending the Commission to include 18 substances in the Authorization List (Annex XIV to REACH). ECHA invites comments and further information on the uses of the substances and possible exemptions from the authorization requirement as well as information on the structure and complexity of the supply chains.
In parallel to ECHA's public consultation, the European Commission is calling for information on the possible socio-economic consequences of including these 18 substances in the Authorization List. The information received will be passed on directly to the Commission and will not be considered by ECHA.

If a substance is included in the Authorization List, it can only be placed on the market or used after a given date if an authorization is granted for a specific use. Companies that are using, manufacturing or importing these substances can apply for authorization.
ECHA regularly recommends substances from the Candidate List for inclusion in the Authorisation List to the Commission. The draft recommendation is based on an assessment of the data in REACH registration dossiers and other available information, and an initial consultation with the Member State Committee. Registrations will be checked for any updates at the end of the public consultation.

Next steps

The Member State Committee will prepare an opinion on ECHA's draft recommendation taking into account the comments received during the public consultation. Based on the opinion of the Committee and the public consultation, ECHA will provide its final recommendation to the European Commission. This will be ECHA's ninth recommendation. The Commission will decide on which of the substances to include in the Authorization List and on the respective conditions applicable for each substance.

Latest events

CHCS Training "EU CLP (GHS) Classification for Supply - Mixtures" (Module 18)
31 October 2018, Chemical Hazards Communication Society (CHCS), London, United Kingdom

CHCS Training "EU CLP (GHS) Labeling for Supply" (Module 19)
1 November 2018, Chemical Hazards Communication Society (CHCS), London, United Kingdom

CHCS Training "Advanced Preparation of Safety Data Sheets" (Module 15)
6 November 2018, Chemical Hazards Communication Society (CHCS), London, United Kingdom

CHCS Training "Risk Characterisation and the Chemical Safety Report" (Module 53)
12 December 2018, Chemical Hazards Communication Society (CHCS), Manchester, United Kingdom

CHCS Training "The Extended SDS - Understanding Exposure Scenarios" (Module 20)
13 December 2018, Chemical Hazards Communication Society (CHCS), Manchester, United Kingdom

End of the Newsletter