NEWSLETTER NOVEMBER 2017

SMALL MEDIUM ENTERPRISES (SME) and external consultancy support

SME are facing troubles to be in full compliance with the 2018 deadline due to many factors. Most of them do not have Regulatory Affairs Offices, or not large enough, to support the complicated actions to get registration done by the requested deadline and with good quality dossier. External consultants or consultancy companies are often crucial for SMEs and their success in managing regulatory obligations. Preparing a REACH registration is not trivial and the majority of SMEs, as said, do not have the sufficient internal know-how to be totally independent from external service providers. Furthermore, the complexity of national and EU obligations often requires the help of a professional, who has an overview of the legal parts that may be relevant for a company. When REACH regulation came into application at end of 2006 a number of new consultancy companies were suddenly established "smelling" the possible business.

There are consultants who acts very well mainly due to our long experience and history in the field of Regulatory Affairs field as established largely before 2006. They offer a clear time plan, a clear cost overview and a clear picture of what they are expected to do. However, there are also others who, for example, do not fully understand the data-sharing process or the testing requirements and, as a consequence, cause too high costs to their clients or make the cost planning a bit complicated. In principle, a good consultant does not necessarily need to be one of the big players with a lot of capacity.

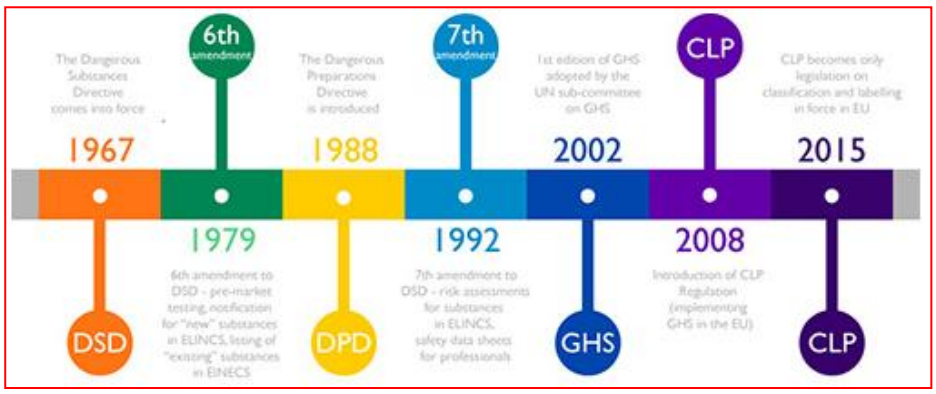
There are also small firms that really understand their job and have an excellent network for additional services they cannot themselves offer. A crucial factors is to have a multidisciplinary experience and approach to REACH solutions. Medium size consultancy company have all expertise inside; some can claim special expertise from external professionals; typical cases are those related to the legal support and SEA analysis.

On the other site, there are also good and bad clients. Some companies, for example, clearly underestimate what a REACH registration means. Sometimes they expect miracles for a very low price and in an unrealistic timeframe. A poor understanding of the regulatory requirements and impacts from the client's side are also sometimes the cause of an critical relationship with the consultant and end in unpleasant surprises about the actual workload.

Finding the right consultant will usually take time and there are some quality criteria that can support the decision. The ECHA Directors' Contact Group has prepared a checklist to hire a good consultant. The checklist can be found on ECHA's website.

In any case, SME, are suggested not to wait any longer to select their consultants…. less than 7 months from the final deadline. Time is running!!

50 YEARS of EU HAZARD CLASSIFICATION



As you all can see from the picture above, 2017 is celebrated as the fifty year anniversary of the hazard classification in EU. The Dangerous Substance Directive (EC 67/548) published in 1967 (just ten year from the Rome Treaties) is considered the "*mother*" of all the EU legislation concerning the safety on chemicals in EU. Later cornerstones are the Dangerous Preparation Directive (DSD) in 1988, the 7th amendment of DSD in 1992 which introduces the first environmental classification system and the notification system for the new substances (NONS), the GHS incoming system along with transport classification and the two implementations of the actual CLP system. All along those years the classification system has been refined and it's now considered the most complete and advance classification system in the world.

REACH ENFORCEMENT FORUM

In the current year 2017, **REACH ENFORCEMENT n. 5** is ongoing. As known, REACH inspections, done by each Member State, are focused on Exposure Scenarios, e-SDS preparation and application, Risk Management Measures (RMM) and Operational Conditions (OC) application by downstream users.

Next two steps will consist in the following:
REF n. 6 (in 2018) is still to be defined but from public talk of ECHA people it has been understood that it will be focused on the classification system (CLP). Therefore inspection in 2018 will be 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 n. 7 (in 2019) again is still to be defined but from public talk of ECHA people it has been understood that 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!

FROM ECHA

ECHA proposes to include 107 substances in the Community rolling action plan (CoRAP) for 2018-2020 to be evaluated by the Member States.

26 substances are expected to be evaluated in 2018, **37** in 2019 and **44** in 2020. ECHA encourages registrants of the listed substances to start coordinating their actions and to contact the evaluating authorities in the Member States. Downstream users of the listed substances are invited to review the information they hold and share that with registrants.

In particular, it is important that use and exposure scenarios as well as the exposure estimations are up-to-date and clearly documented within the chemical safety reports of the registrants. For the 26 substances to be evaluated in 2018, dossier updates, where relevant, should be made before March 2018.

The draft CoRAP includes the non-confidential substance names, CAS and EC numbers, the tentative year of evaluation, contact details of the proposed evaluating Member State as well as a brief indication of the initial area of concern. This year, the groups of structurally similar substances that potentially could be evaluated together are also marked in the plan.

The list has been prepared together with the Member States, taking into account risk-based criteria to select the substances. The final plan will be adopted in March 2018.

The list will be available on ECHA web site.

Restriction proposals

A new intention has also been received to restrict the manufacturing, industrial and professional use of **N,N-dimethylformamide** (EC 200-679-5) called **DMF**. The intention has been received from Italy on 18 October 2017, and a submission is expected to be made on 5 October 2018 (last deadline).

Testing proposals

ECHA has launched **8** new public consultations on testing proposals. The deadline to comment these is 11 December 2017. In total, there are currently 23 public consultations open on testing proposals.

BIOCIDES

ENFORCEMENT

The **B**iocidal **P**roducts **R**egulation **S**ubgroup (**BPRS**) works under the umbrella of ECHA's Enforcement Forum to improve and harmonize biocides enforcement activities. Harmonization adjusts inconsistencies in different practices, schedules and procedures to make them mutually compatible. This is the target of the BPRS. The harmonization of the enforcement of the BPR will help the consistency of the interpretation at national level and, as consequence, increase legal certainty fro companies. Thanks to the subgroup activity, national enforcement authorities will now be able to rely on the help of enforcement experts, who will debate and share best practice on controlling biocidal products. Indeed, there are some critical biocidal product types such as disinfectants, preservative and pest control products. The main concern for them is related to harmful effects on both human and animal health as well as the environment. The focus will be on the used by children and pregnant women for prolonged exposure or exposure due to incidents.
REF- 6 will be the first case of collaboration between BPRS and the ECHA Forum and, as already mentioned in this Newsletters, will be focused on classification and labeling of biocidal product too. The subgroup will produce the coordinated enforcement project's manual containing a guidance document, checklist and recommendations on how to execute the project
As it is part of ECHA's Enforcement Forum, it is only natural for the subgroup and the Forum to collaborate on certain projects. One of the joint projects is **REACH-EN-FORCE-6**, which focuses on the classification and labelling of biocidal products.

COMMISSION DELEGATED REGULATION EU n. 2017/2100

The COMMISSION DELEGATED REGULATION (EU) 2017/2100 of 4 September 2017 setting out scientific criteria for the determination of endocrine-disrupting properties pursuant to Regulation (EU) No 528/2012 of the European Parliament and Council was published on the European Official Journal on November 17, 2017 (n. L301).
One of the forewords of this new regulation says that:
"The determination of endocrine-disrupting properties with respect to human health should be based on human and/or animal evidence, therefore allowing for the identification of both known and presumed endocrine disrupting substances"

The regulation therefore is aiming to give the scientific criteria to determine the possible endocrine (ED) properties of the active substances used in the biocidal product.
In the Annex n. 1 of the regulation, such properties are divided in two groups:
Section A : Endocrine-disrupting properties with respect to humans
Section B : Endocrine-disrupting properties with respect to non-target organisms

In brief, for both groups the evaluation is based on three general principles:

a) the substance shows an adverse effect in an intact organism or its progeny, which is a change in the morphology, physiology, growth, development, reproduction or life span of an organism, system or (sub)population that results in an impairment of functional capacity, an impairment of the capacity to compensate for additional stress or an increase in susceptibility to other influences;

b) the substance has an endocrine mode of action, i.e. it alters the function(s) of the endocrine system;

c) the adverse effect of the substance is a consequence of the endocrine mode of action.

The Regulation will be adopted on December 7, 2017 and it will be into application by **June 7, 2018** unless different opinion by the Biocidal Committee by this date.

Some difficulties has been underlined by the Industry in relation to the application of this regulation; in particular when referring to the Agrochemical parallel Regulation that failed to pass the EU vote (see Chemsafe Newletters October 2017). Hence, when ED criteria for Biocides will be applied from June 7, 2018 those for agrochemicals are still pending.

Updated Biocides Guidance Volume IV Environment - Assessment and Evaluation (Parts B + C) published

ECHA has published an update to its Guidance on the Biocidal Products Regulations (BPR): Volume IV Environment, Part B Risk assessment (active substances).

The scope of the update covers the revised text on risk assessment of active substances and biocidal products. The update also includes the Transitional guidance on mixture toxicity and a new Annex on Substances of Concern (SoC). In addition, the updated document incorporates in its structure Part C, which deals with the evaluation of active substances and biocidal products.

This guidance will be useful for the Biocidal Product Committee and its working groups for their opinion-making process as well as for companies (in particular SMEs) to facilitate their implementation of BPR

ECHA Events for November 2017 – February 2018

Exchange Network on Exposure Scenarios
23-24 November

Committee for Socio-Economic Analysis
27-30 November

Committee for Risk Assessment
27 November - 1 December

Committee for Risk Assessment
4-5 December

Member State Committee
11-15 December

Biocidal Products Committee
11-15 December

Management Board meeting
14-15 December

REACH 2018 Stakeholders' Day
29-31 January 2018

Member State Committee
5-9 February 2018

WORLWIDE

South Korea's Environment Ministry announced significantly reduced registration data requirements for substances currently classed as "non-hazardous" under the UN globally Harmonized System (GHS) classification from June 2018.

The decision comes as a response to appeals from industry to decrease the burden of registration. The government has accepted the industry case that requiring the same test data indiscriminately, regardless of a substance's currently understood hazardousness, does not make sense.
Reduced data requirements for a number of substances – or what the government calls "dualizing" the data submission based on hazardousness – will come into effect from June 2018. Lower requirements in the form of a simplified dossier will apply for substances which are not classified as hazardous under the GHS classification and labeling standards. Under the proposals, the number of tests results required to support data submission for these substances will be reduced from 47 to 15.

CHEMSAFE NEWS

By the end of November this year Chemsafe will launch a Task Force for the authorization of biocidal product based on ***Sodium Hypochlorite*** (CAS n. 7681-52-9, EINECS n. 231-668-3). A dedicated team of Chemsafe experts (technical/scientici, legal and commercial) has been targeted to build up such a Task Force: Ipo TF is aimed to help SME (in particular small companies) to authorize their products. The criteria of the task force follow the BPR family approach and the way to joint are inspired by REACH data sharing criteria. Each member of the Task Force will participate to share a basic common testing package and a father dossier preparation. Each of them will then submit its own dossier avoiding to pay for a same biocidal product dossier (clone). We believe this way will allow company to save a good amount of money, have a high level of confidentiality and possess its own dossier other than a simple clone.
Further news on December Chemsafe newsletter.

PARTICIPATION TO EVENTS

Our Managing Director, Antonio Conto attended the ***Chemical Watch Enforcement Summit EUROPE 2017*** hold on November 13-14 in Bruxelles (Belgium). He introduced a speech on "***REACH Inspections in Italy and the Chemsafe case***" on November 14, afternoon session.