NEWSLETTER MAY 2018

REACH

May 31, 2018. IS REACH OVER??

The last day of May this year was the deadline useful to register substances in compliance with Reg. 1907/2006 EC (REACH) in the tonnage band 1-100 when pre-registered in 2008 and late pre-registered by 31 may 2017. The transitional periods started 11 years ago when REACH regulation was formally published at the end of 2006. From that year (that seems now so close to us) many registrations were submitted to ECHA in terms of registration dossiers and in terms of substances. Consolidated numbers will be given shortly by ECHA and object of comments in a next Chemsafe Newsletter. On May 10, almost **22.000** new registrations were submitted for a total of **75.313** REACH registrations and **19.466** substances.
Pre-registration period lasted from June 2008 to December 2008 and resulted in around 150.000 substances pre-registered. Many of them did not reach a formal registration but also many of them were not correctly pre-registered and hence "*disappeared*" later. Late pre-registration option allowed late comers (companies that started manufacturing and/or importing chemicals later that the December 2008 pre-registration period) to include their substances in the process; mainly to have access to the related SIEF and start discussing for data sharing and/or safety classification sharing targeting their own final registrations.

Three main transitional periods were set by the Regulation:

1. December 2010 for substances with CMR properties, or environmental classification or > 1000 tons per year.
In order to comply with this deadline that emphasize hazardous properties but also huge tonnages, large consortia or task forces were build up. Such groups of company were normally leaded by big player on the market. 2010 registrations was a success and many "commodities" were correctly registered. Joint registration were mainly those submitted by Consortium Members and very few coming from simple SIEF agreement activities. Lead registrant were not so many as the process was at the beginning.

2. May 2013 for substances in the level 100-1000 tons per year
The second deadline was characterized by a different approach. Non so huge consortia and a growing number of joint registration both from consortia (due to an increase of members) and from simple SIEF agreements (due to a higher presence of Lead registrant and asking potential registrants) acted.

3. May 2018 for substances in the level 1-100 tons per year.
This last phase was completely different from the previous two for many reasons:

- Two sub-levels were included in the 2018 deadline: 1-10 tpa and 10-100 tpa. Many companies did not realize that the cost of these two levels are very different due to a huge differences among the respective experimental packages. Level 1-10 refers to REACH Annex VII that intend to study the short toxicological profile and phys-chem. characterization of the substance including technical dossier by IUCLID 6 only. Level 10-100 refers to Reach Annex VIII and includes a more challenging study package both for toxicological and environmental end-points. Furthermore, level 10-100 includes the preparation of the CSA/CSR (Chemical Safety Assessment/Chemical Safety Report), complete for hazardous substances, with exposure scenarios setting and risk assessment for each exposure scenario of use.
- Large organizations were no longer deeply involved in such deadline. Lowest tons of manufacturing or importation mainly involved Small Medium Enterprises (SME) which are those entities less trained to manage so complex regulatory work and hence more exposed to risks. Very small companies (micro) were in serious troubles due to lack of human resources and economic power to support registrations.
- Hundreds of "intermediate substances" fall in the last deadline due to tonnage (mainly in 1-10 tons level). In particular for pharmaceuticals intermediate substances there were huge problem related to confidentiality regarding identity, manufacturing and use. Such problem delayed the exchange of information between Lead Registrants and Joint Registrants during the data sharing activity. Additionally the Strict Controlled Condition

of use (SCC) definition and application was not so well understood and accepted by pharmaceutical registrants. All these issues create, on the whole, a difficult relationship environment leading to risk of not meeting the deadline. In some cases, unacceptable data sharing cost was requested to Joint registrants by a Lead Registrant (not strictly related to real data sharing cost but administrative and management costs) leading to disputes to ECHA.

- The drastic increase of experimental studies demand create an overload of testing laboratories in the last months only partially balanced by the possibility to claim for exceptional cases as granted by ECHA in special situations;
- The final huge number of registrants created an overload work to consultants who made their best to cover all requests but, for very late comers, not completely successfully.

Companies that failed and/or forgot to registered their pre-registered substances have to consider them as Non-Phase-in substances (new substances in the REACH system), stop their manufacturing or importation and register them before starting again the manufacturing and/or importation. Some exceptional cases are those substance that were registered by the deadline but fail to be in technical compliance in the technical dossier; for them ECHA is setting individual dates (communicated in Reach.it) by which to correct the information or add specific reasoning.

What is going to happen after May 31, 2018?
REACH is not obviously over!
First of all, the Regulation is still in place and ECHA as well to manage a number of issues. Mainly:

- To 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:
- To evaluate the complex Authorization and Restriction procedure 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.

Member States and its own authorities will continue and probably increase their inspection activity for REACH (CLP and SDS) enforcement. After the last deadline and 11 years of application there are no more excuses to say "*I was not aware….. I did not have any time*"… to apply Reach. Hence.. be prepare to host inspectors!

There are at least other two more reasons, among many others, we would like to mentioned here concerning the continuation of Reach regulation in the following years:

Reach refit processes
As already mentioned on the Chemsafe April Newsletter, sixteen (16) actions has been identified by the Commission for the REACH refit in the next future. Those in blue bold are, in our opinions, the most relevant for industry:

Action n. 1: encourage updating of registration dossiers
Action n. 2: improve evaluation procedures
Action n. 3: improving the workability and quality of extended Safety Data Sheets
Action n. 4: tracking substances of concern in the supply chain
Action n. 5: promote substitution of SVHCs
Action n. 6: simplification for a more workable authorization process
Action n. 7: early socio-economic information for possible regulatory measures
Action n. 8: improve Restriction Procedure
Action n. 9: Further enhance Member State involvement in the restriction procedure

Action n. 10: Frame the application of the precautionary principle
Action n. 11: Interplay between authorisation and restriction
Action n. 12: Interface REACH and OSH (Occupational, Safety and Health) legislation
Action n. 13: Enhance enforcement
Action n. 14: Support compliance by SMEs
Action n. 15: Fees and the future of ECHA
Action n. 16: Review of registration requirements for low tonnage substances and polymers

At the end, we can expect some new requests/processes that will force companies to make additional actions of compliance to REACH Regulation.

Endocrine Disrupting Substances

The so called Endocrine Disrupting Chemicals, in brief EDC, is a wide family of substances, indeed not yet well defined, that may induce harmful effects to the organisms (human and/or animals) acting through an interference action within the hormonal system. Since mid '90s, the Scientific Community have been started the discussion on how to define and characterize the EDC activity and some Regulatory Bodies in USA as well as in Europe started to build up draft positive lists. From those years up to now such a discussion was kept alive by the debate between regulatory bodies and chemical/pharmaceutical industry; in 2006 the EDC substances have been mentioned in the REACH Regulation (EC1907/2006) within the group of the Substance of Very High Concern (SVHC). Recently the EDC category was also discussed within the regulations concerning Agrochemical and Biocides active substances and product in the frame of the cut-off criteria leading in some cases to additional special regulation publication. Regarding the pharmaceutical area, the assessment of a potential ED properties can heavily affect the ERA (Environmental Risk Assessment) of medicine when placed to the EU market firstly.
The identification of a substance as a EDC is well described in the last draft guidance published for public consultation up to end of January 2018 by joint EFSA and ECHA. In such document the analysis is focused on the so called EATS modalities (Estrogen, Androgen, Thyroid and Steroidogenic).
In addition, only for the EATS modalities there are at present standardized test guidelines for "in vivo" and "in vitro" testing available where there is broad scientific agreement on the interpretation of the effects observed on the investigated parameters. These test guidelines are compiled in the OECD Guidance Document on Standardized Test Guidelines for Evaluating Chemicals for Endocrine Disruption (OECD GD 150; (OECD 2012a), which is supported by the "OECD Conceptual Framework for Testing and Assessment of Endocrine Disrupters' providing a grouping of the studies into five levels according to the kind of information provided (OECD CF; (OECD 2012b, 2012a). OECD GD 150 including the OECD CF is currently undergoing revision and the references made in the guidance to the OECD GD 150 are based on the draft of this document of July 2017 (OECD 2017b).
From a scientific point of view there are still many concerns and doubts on how to properly define an EDC at worldwide level in a harmonized way; broad definition risks to include a wide range of possibilities and involvement of a large amount of chemicals, while, on the contrary, narrow definition may not lead to a proper assessment.
Regarding identification process, several gaps are still present in the study panel proposed as OECD is still drafting some study testing methods. On the other way the number of studies to carry out a complete ED evaluation is really huge and very expensive.
From a regulatory point of view, as seen, there is a discrepancy in EU between the application/request to evaluate ED properties between pesticide and biocide; the second already have a regulation regarding this evaluation probably under application from June 2018 while pesticides not. Therefore no harmonization is in place now in EU with consequent discriminatory behavior of regulators between these two chemical fields that may lead also to some legal discussion and actions.
All of us surely share the ethical approach to protect the human health and the environment from ED chemicals so adversely and so sneaky in their action but industry is also concern about a possible disproportionate request from regulators which may lead to test a huge number of chemicals. Expenses to do so will create and unacceptable economic burden from industry; only large organization may bear it and, again, SME will be discriminated. Last but not least, both industry and regulators have to increase their assessment capacity hiring toxicologists that will need to have a broad knowledge including health regulatory toxicology, eco-toxicology, environmental fate processes, environmental biodegradation processes, secondary dietary risk assessment, specific adverse effects and so on in a frame of a more and more multidisciplinary and integrated approach.

In conclusion, be aware.. REACH is not finished.. we are only at the beginning!!

BIOCIDES

UK study questions use of chlorine in food washes

A UK study has suggested that food washes containing chlorine may be less effective at preventing the spread of food-borne pathogens than previously thought. The paper, published in the American Society of Microbiology's *mBio* journal, says that chlorine can make bacteria undetectable. Researchers from the University of Southampton incubated pathogen populations – *listeria monocytogenes and salmonella enterica* - on spinach leaves. These were then washed in solutions with chlorine. Rather than killing the pathogens completely, it seems that the washes made them enter a dormant state. This viable but non culturable (VBNC) state is how some bacteria respond to environmental stresses. By keeping a very low metabolic activity, they stay alive and have the ability to become culturable once resuscitated. Studies have reported that many food-borne pathogens can be induced to enter the VBNC state by being exposed to extreme temperatures, drying, irradiation or by adding preservatives and disinfectants. Once in such a state the bacteria are no longer detected by the standard laboratory techniques, used to test for food contaminants, according to the researchers. The study shows that VBNC pathogens "*can both be generated and avoid detection by industrial practices, while potentially retaining their ability to cause disease*," says the author. He adds that the findings could have implications for the biocide claim that products containing chlorine are allowed to make. The researchers collaborated with Vitacress Salads on the study. The company recently became the first in the UK to obtain supermarket approval to sell fresh produce washed in spring water without chlorine.

Latest events

AFI Symposium for Pharmaceutical and Medical Device industry
6-8 June 2018. Palexpo Rimini Italy, ***Two Chemsafe Workshops***

Chemical Watch Expo 2018: Global Chemical Regulations
12-13 June 2018, Chemical Watch, Courtyard Brussels

Biocidal Product Regulation - Introduction & Biocidal Product Authorisation Applications
13 June 2018, Yordas, Lancaster, UK

OECD QSAR Toolbox V 4.2 training: Basic (June 11-12) and Advanced Practical (June 13-15)
11-15 June 2018, Reach Monitor SL and LMC OASIS, World Trade Center, Barcelona, Spain

Practical Risk Assessment Training
20-21 June 2018, Chemical Watch, London

Chemspec Europe 2018
20-21 June 2018, Mack Brooks Exhibitions , Cologne, Germany

TSGE Prague Biocide Conference 2018, Prague
Focus on SMEs - Keeping up with the progress on active substance approvals
Date: 21 - 22 June 2018, ***Two Chemsafe Lectures***

Risk Assessment for Biocides
4-5 September 2018, Chemical Watch, Le Chatelain

CHCS Training “Essentials of Regulatory Chemistry - Substances, Mixtures and Polymers” (Module 22)
3 October 2018 * Chemical Hazards Communication Society (CHCS) * London, United Kingdom

CHCS Training “EU CLP (GHS) Classification for Supply - Substances” (Module 17)
30 October 2018 * Chemical Hazards Communication Society (CHCS) * London, United Kingdom

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

Biocides Europe
27-28 November 2018, Chemical Watch, Vienna

ITALY

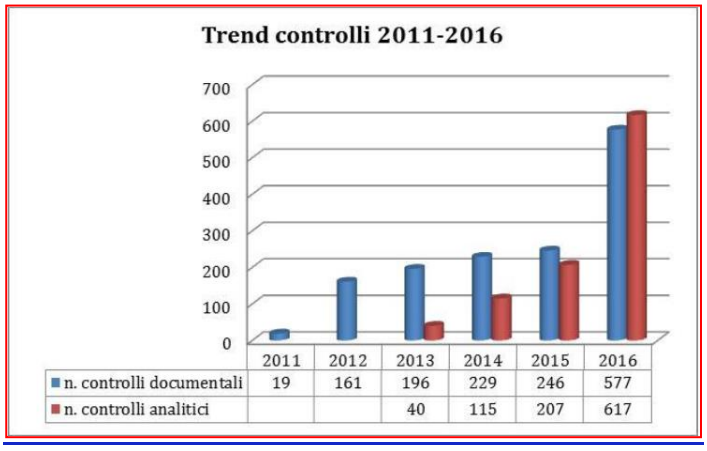
The Italian Ministry of Health published the document "Reporting of inspection activities and applied sanctions for 2016" related to REACH (SDS) and CLP enforcement as for the Italian National Enforcement 2016 Plan. The two following table refers respectively to control check and given sanctions (in Italian). The last table reports the trend of inspection activities from the beginning (2011) to 2016.

Tabella 1 - Riepilogo risultati dei controlli effettuati PNC 2016	
n. controlli documentali	577
n. controlli analitici	585
n. controlli totali	1162
Alcuni elementi in dettaglio:	
n. controlli documentali reattivi	25
n. imprese controllate*	393
n. controlli condotti in collaborazione tra diverse autorità	20
n. sostanze e miscele controllate	885
n. SDS controllate	833
n. articoli controllati*	85
n. violazioni	124

Tabella 2: numero violazioni accertate

Decreto	**n. violazioni accertate**
D.Lgs. 133/2009	50
D.Lgs. 186/2011	20
Totale	**70**

Legenda: D.Lgs. 133/2009 refers to violation to REACH (SDS) Regulation), D.Lgs. 186/2011 refers to violations to CLP Regulation



CHEMSAFE: PARTICIPATION TO EVENTS

In the frame of our pharmaceutical/medical health activity, we are now engaged in organizing two workshop during the Italian ***AFI*** (Associazione Farmaceutici Industria) Symposium in Rimini on 6-8 June 2018.
The first workshop will be focused on ***Medical Devices*** and the second one on ***ERA*** (Environmental Risk Assessment) of medicines. 8 Chemsafe experts will be directly involved as speakers; we expect also to have external guests from companies. Both workshop will be held on Wednesday June 6, 29018 in the morning session. The participation is free; you are all welcome!!

Chemsafe will sponsor and participate as speaker at the **TSGE Prague Biocide Conference 2018**: *Focus on SMEs - Keeping up with the progress on active substance approvals*
Date: 21 - 22 June 2018
Venue: Hotel Occidental Praha (formerly known as Barceló Praha Hotel), Prague
TSGE Forum's annual biocide conference will be returning to the Occidental Praga Hotel, Prague for the fourth consecutive year. Suitable for those involved in the biocides industry, the conference is ideal for meeting a wide range of EU regulators, experts and industry participants from across Europe. The 2018 program will focus on the experience and challenges of SMEs in respect to Mutual Recognition procedures and further progress made in active substance approvals. In addition latest developments in data protection issues, BPR enforcement, borderline cases with other EU legislations and EU guidances will be discussed.
As with previous conferences, the event will offer plenty of networking opportunities, including a drinks reception.

Confirmed speakers include:
Dr Mandy Osterloh - Dow Microbial Control

Product Authorization: Industry Experience with Union Authorization
Thomas Raas - Redebel Regulatory Affairs

Dr. Antonio Conto - Chemsafe Srl
BPR Dossier Project Management, regulatory and management challenges

Dr. Francesca Fasano - Chemsafe Srl
Risk Assessment of Disinfection By-Products

Tatjana Röder - Aquagroup AG

End of the Newsletter