NEWSLETTER FEBRUARY 2018

FROM ECHA

Helping registrants in exceptional cases in relation to the incoming 2018 deadline

May 31, 2018 deadline for phase-in substances at **1-100 TPA** level is rapidly approaching. Many companies have already realized to have problem in reaching such a deadline successfully due to many factors:

- *Difficulty in closing data sharing activities with the Lead Registrants (LRs). In particular when the LR is slow in answering or may ask a disproportionate amount of money and further discussion is needed to agree a final price;*
- *Difficulty in finding/managing experimental phases with testing laboratories. GLP EU testing laboratories are already fully booked and no possibility to commit studies, even short tests, is possible up to June/July 2018;*
- *Lack of clear company planning for the registration of a high number of chemicals. This is particularly true for companies which need to register intermediates. Some pharma-chemical companies use to offer third party manufacturing work and have a huge number of synthetic processes in their plants. Each manufacturing process involves many intermediates and therefore, at the end, the total number of intermediates/year is very high. We have customers which need to register from 30-40 up to 200 intermediates by the deadline. The intermediate registration under SCC is a smoother and quicker process but how can they succeed?*

The discussion on how to face the possible failure in reaching the deadline is on the table since months but up to the end of 2017 nothing was really decided. The **Directors' Contact Group (DCG)** was deeply involved in finding some solution to such a situation.
The DCG was set up in January 2010 in the run-up for the first registration deadline of phase-in substances. DCG provides an informal platform for the ***exchange of views*** between the European Commission, ECHA and Industry Associations. The DCG's objectives are to monitor the overall preparedness of companies and to identify and resolve the priority issues of concern in meeting obligations relevant to the registration of chemical substances. Under its initial mandate, the DCG found solutions to **28** issues of concern for industry. These solutions were shared with the Member State Competent Authorities through the CARACAL advisory body and with the EU/EEA Enforcement Authorities through the Forum for Exchange of Information on Enforcement.
In January 2014, the DCG adopted new Terms of Work for the period until 31 December 2018, with a particular focus on coordinating support to small and medium-sized enterprises (SMEs), whether registrants or downstream users.

Important information from ECHA consist in the following:
Companies facing exceptional situations that are likely to prevent them from registering on time should inform ECHA ahead of the deadline of 31 May 2018.

The Directors' Contact Group (DCG) has identified **exceptional scenarios** where registrants may, through no fault of their own, find it difficult to submit a complete registration dossier by the registration deadline.

ECHA is again ***offering help*** for companies affected by the four scenarios identified by the DCG. ECHA does so either by relying on its discretionary rights under REACH or by providing companies with a transparent means to demonstrate ***good faith***.

The **four scenarios** where exceptional circumstances could apply are:

Completeness of dossiers (Issue n. 10)
Companies that may have difficulties in providing data required in annexes VII and VIII of REACH in due time or importers of mixtures that have difficulties in getting compositional and analytical data of the substances in the mixture from their suppliers

Comment
This is the case where a registrant has already committed studies for VII and/or VIII Annex but for justifiable reasons the results of such testing are not yet available by the deadline. Of course the studies cannot be requested to testing labs in April 2018 and then claim for such justification. No good faith in this case!!

Legal entity change (Issue n. 15)
Companies that do not hold a pre-registration due to legal entity changes.

Comment
There is the need to accommodate complex unforeseen mergers/splits of enterprises (legal entities) or change in manufacturing conditions taking place within the last twelve months before the registration deadline. ECHA has in the past released a legal entity change functionality of REACH-IT which covers the standard legal entity change scenarios. Companies will be offered the opportunity to declare their situation to the Agency via the ECHA Helpdesk so that it is formally on record. This self-declaration may be taken into account by the National Enforcement Authorities in case of control

Dependency on the Lead Registrant (Issue n. 20)
If the lead registrant fails to submit a complete registration dossier on time, the member registrants may need exceptional support.

Comment
This situation can happen directly related to case n. 1 or due to negligence of the LR. Joint registrants, in this case, need to inform ECHA that their Lead Registrant is not meeting the deadline and therefore they are not able to register on time. Of course it is expected that also the LR will inform ECHA about its situation of lacking to reach the deadline; the two situations are, hence, complementary. In our consultancy activity we have a number of cases where the LR registrant is not reacting quickly to the requests of potential joint registrants. There are many reasons behind this behavior: the number of registrations that LR has to manage and the lack of resource to manage such amount of dossiers are only two of them. Last but not least, the lack of awareness of what the LR role means. Some companies and their management do not exactly still understood what LR role consist in; in some cases they register without knowing they are LR!!. By conclusion a higher level of awareness is needed: REACH regulation is into application since 2007, 11 years!!

Substance with no registration intentions (Issue n. 21)

If no registration is planned for their critical substances, downstream users may consider taking up the role of an importer and submitting a registration, or engaging another importer to do so on their behalf.

Comment

In our opinion, this is the case that will create future lack of correct registrations. The reason is multiple. Many downstream users still think that the Reach application is something for manufactures and importers; not under their responsibility!!. They have still difficulties in understanding when they become importers and hence subjected to REACH Title II (Registration). In particular, downstream users/importers of mixtures, in many cases, are not able to determine the exact mixture composition and not able to calculate the exact amount of importation of each component. Non EU providers do not help in understanding the exact composition for confidentiality reasons. Engaging another importer, again, is frequently a not easy task. Commercial reasons and competition factors influence this choice.

The conditions under which the solutions apply are described on the DCG section of ECHA's website. It also describes how an affected registrant should contact ECHA.

Every affected company will need to contact ECHA as far ahead of the deadline as possible and by **24 May 2018** at the latest. The registrant needs to provide detailed justification of its situation and an explanation of the measures that it has taken to comply with its obligations under REACH. When ECHA receives this information, ***it will give instructions on how to submit a registration by the deadline***.

By conclusion, it is absolutely important to review all registration plans and evaluate critically each registration procedure. Companies must be ready to justify their delay and submit real justifications by May 24, 2018 in order to claim for exceptional cases.

We have all to realize that the application of these exceptional cases is not to be considered as a derogation to the May 31, 2018 deadline; this is finally set by the law! So no change in the deadline date. ECHA will evaluate each request and decide how to process it.

For more detailed explanation see also "*Compilation of the four DCG Solutions to be re-activated for the 2018 REACH registration deadline*" by Director's Contact Group (DCG3/Support document/1/2017, 15 December 2017

New strategy promotes substitution to safer chemicals in the EU

ECHA's substitution strategy targets to encourage the replacement of harmful chemicals by boosting the availability and adoption of **safer alternatives and technologies**. It highlights networking, capacity building, and improving access to data, funding and technical support as key areas for action.

The strategy outlines four main areas of action for coordinated, EU-wide support of substitution:

Capacity building along the supply chain

Initiating dialogue about the opportunities and challenges of substitution and building collaboration that advances research, evaluation and the adoption of safer alternatives to substances of concern.

Funding and technical support for substitution initiatives

Improving awareness by mapping the available funding and technical support relevant for substitution-related projects and making the information more accessible to companies.

Using ECHA's chemicals data more efficiently

ECHA's databases on chemicals are a valuable tool in supporting sustainable substitution through a proper understanding of the hazards and risks associated with the substances to be substituted. The strategy proposes several projects that could be developed to further facilitate the use of this data for substitution.

Developing coordination and collaboration networks

In addition to developing existing networks, the strategy proposes to establish a multi-stakeholder network comprising the European Commission and Member State competent authorities, industry organizations, individual companies, NGOs, research organizations and consumer associations interested in substitution.

The strategy draws on feedback from stakeholders, Member States and the European Commission. Its implementation will form part of ECHA's annual work plan and learning from supply chain collaboration workshops will help to further develop the strategy from 2019 onwards. Progress on the strategy's implementation will be reported annually.
The strategy is linked to the EU priorities of a more circular and bio-based economy, the sustainable manufacture and use of chemicals and a non-toxic environment.

Comment
The ECHA strategy to promote substitution to safer chemical use is strongly and correctly based on REACH pillar principle to avoid the use of most hazardous chemicals (SVHC) and assure the higher level of protection for human health and environment. This principle is surely shared between all stakeholders (citizens and consumers included). The REACH, CLP and Biocidal Products regulations have been designed to put pressure on and provide incentives for industry to try to replace hazardous substances with less hazardous ones. By ensuring that these regulations are implemented successfully, ECHA supports substitution both directly and indirectly.
The problem is still workability of such strategy! The problem is still SMEs and their survival in a very competitive global economy. Do SMEs act successful in supporting such strategy? Or again, this is an exercise to help large organization? "Ai posteri l'ardua sentenza" A. Manzoni (posterity will judge!).

ECHA proposes seven substances for authorisation

Seven substances of very high concern (SVHCs) are recommended to be added to the Authorization List. They have been prioritized from the Candidate List because of their intrinsic properties in combination with high volume and widespread uses, which may pose a threat to human health or the environment. Some of these substances are currently not used in the EU but ***could replace*** other substances recommended for or already on the Authorization List. They are recommended to avoid ***regrettable substitution***.

ECHA's eighth recommendation to the European Commission to prioritize substances of very high concern for authorization includes seven substances. Two of these substances are toxic for reproduction. The other five have persistent, bio-accumulative and toxic (PBT) and/or very persistent and very bio-accumulative (vPvB) properties.

ECHA organized a public consultation on the draft recommendation between March and June 2017. The Member State Committee (MSC) considered the comments received and adopted its opinion on 11 December 2017.

ECHA proposes seven substances for authorisation

The recommended substances, including examples of their uses in the scope of authorisation, are presented in the table below.

#	Substance name	SVHC property	Examples of uses in the scope of authorisation
1	5-sec-butyl-2-(2,4-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [1], 5-sec-butyl-2-(4,6-dimethylcyclohex-3-en-1-yl)-5-methyl-1,3-dioxane [2] [covering any of the individual stereoisomers of [1] and [2] or any combination thereof]	vPvB	Fragrance in soaps and detergents
2	2-(2H-benzotriazol-2-yl)-4,6-ditertpentylphenol	PBT, vPvB	UV stabiliser, e.g. in plastic products, rubber, coatings
3	2,4-di-tert-butyl-6-(5-chlorobenzotriazol-2-yl)phenol	vPvB	1)
4	2-(2H-benzotriazol-2-yl)-4-(tert-butyl)-6-(sec-butyl)phenol	vPvB	1)
5	2-benzotriazol-2-yl-4,6-di-tert-butylphenol	PBT, vPvB	1)
6	1,2-benzenedicarboxylic acid, di-C6-10-alkyl esters; 1,2-benzenedicarboxylic acid, mixed decyl and hexyl and octyl diesters with ≥ 0.3% of dihexyl phthalate (EC 201-559-5)	Toxic for reproduction	Plasticiser in PVC compounds, adhesive
7	1-methyl-2-pyrrolidone	Toxic for reproduction	Widely used solvent, e.g. in coatings, cleaning agents, functional fluids, etc.

BREXIT- Industry concern continues

The lack of progress on any ***final Brexit deal*** continues to worry the UK chemicals sector.
Announcing this week broadly positive economic results from its latest survey of 31 chemical and pharmaceutical companies, the UK Chemical Industries Association (CIA) claims almost half of the firms reported Brexit uncertainty as a concern.
A UK government cross-departmental briefing, leaked last week, will have done nothing to alleviate such fears. The briefing stated that whatever option the government chooses, the UK will be left relatively worse off, with chemicals among the sectors worst hit.
The analysis suggests that a 'no-deal' scenario, under which Britain reverts to WTO rules, would ***cut UK economic growth of eight percentage points over the next 15 years*** compared with current projections. Under a free trade agreement with the EU, growth would drop by ***five percentage points***.
A Norway-style option of remaining in the single market – which has been ruled out by the Prime Minister – would see a two percentage point fall.
In response, Downing Street said the analysis did not cover its preferred option – an undefined "deep and special" relationship with the EU.
A workshop held by Chemical Watch, at a recent meeting of the UK Environment Ministry's chemical stakeholders forum, took the temperature of UK companies' preparedness for Brexit. It found an expectation that some will consider ***moving production to the EU*** rather than bear the costs of operations remaining in the UK. Not surprisingly, participants raised a number of questions, including:

- whether remaining part of the REACH framework in some way, will be agreed as part of a future UK-EU free trade agreement;

- how the regime will look if UK regulations after the transition period diverge from REACH.

In contrast, delegates reported hearing little evidence of any specific supply-chain preparations because companies lack the information to make plans. Instead, most attention is focused on meeting this year's final REACH registration deadline.

Further information can be found under ***ECHA BREXIT Q&A webpages***. They have recently been revised. For example, a new Q&A can be found explaining how a UK-based manufacturer can transfer a registration or authorization to an OR within the EU-27 prior to the UK's withdrawal from the EU without it becoming void.

CHEMSAFE NEWS

We are continuously focused in the activity related to Biocides Products Task Force building up. There are at the moment at least two (2) Task Forces in progresses. We expect they will be finalized by the members formal signature by mid/end of March 2018 at the latest. Our Business Unit Agro/Biocides, headed by Francesca Fasano with the help of Alice Basilio, is strongly involved and hardly working on such projects. As already said, our model is inspired by the ***data sharing principles*** and will allow each task force member to have their own dossier property. This is the only way to assure to each task force member complete freedom to manage their biocidal product, to add mutual recognitions when they want, to change their formulation in future to improve the efficacy of the product, to decide to spend their money with an investment mind. All these features will not be covered and allowed by other task force models, i.e. those which imply the access to "same biocidal authorization" dossier (clones). In such cases the cost "may" be lower but companies are not free to manage its dossier as totally linked with the "father" dossier authorized by the Lead company within the Task Force. At the end they give money mostly to authorized the "father" dossier and not for their clones. We believe they are at risk in the future due to common saying "*spend less to spend more*".

PARTICIPATION TO EVENTS

2018 will be an important year for Chemsafe! We are successfully entering in different Regulatory Affairs fields. The acquisition of Paolo Rossi as BDM of the chemical area has already brought some positive results in terms of client visits, future event participations and new networking. More than 10 active participations are already planned and budgeted for 2018. Some of these events are strictly scientific in both field of chemicals and pharmaceuticals. The Chemsafe presence in terms of scientific/regulatory publication at international level is growing constantly. On the other site, the participation as exhibitor and/or attendance to global conferences is growing too.

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; your are all welcome!!