A busy anniversary

As REACH turns ten, a number of deadlines call for action

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This is a very important year for industry and authorities under REACH. It is when manufacturers, importers and downstream users of chemicals have to make sure they do not miss several critical deadlines. This article sheds light on key dates, actions and time needs relevant to the chemicals industry and its clients.

Last call for registration 2018

The most important deadline for industry in 2017 is 31 May 2018. And no, I have not mistyped. The critical checks and steps needed to meet the final registration for existing ('phase-in') substances, manufactured in the European Economic Area (EEA), or imported, in volumes of 1-100 per year, should be completed as soon as possible this year. It could be too late for 2018 otherwise.

The most critical check is to ascertain whether each substance important to a company's business – provided that it is properly identified – has been validly pre-registered in the supply chain and a joint registration already exists, or a nominated lead registrant has this well under way (see Echa list of substances with lead registrants). If this is not the case, urgent action is recommended to ensure business continuity.

Late pre-registration closes on 31 May 2017

Most chemicals manufacturers and importers, operating in the EEA today, will have pre-registered their existing substances already, allowing them to benefit from the transition period until registration is complete. For new market entrants – first-time manufacturers and importers – the possibility of late pre-registration will only be available until 31 May. First-time non-EEA manufacturers need to allow additional time to appoint an only representative. From 1 June, the duty to submit an inquiry to Echa, prior to registration under REACH Article 26, fully applies. This process may be very time consuming, especially for UVCB substances. It may also give an outcome that conflicts with previously agreed Sief sameness criteria.

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Negotiations are set to begin soon, but a 'hard' Brexit could have significant impacts on numerous existing REACH industry agreements with UK legal entities

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Nominating a competent lead registrant

The key challenge of nominating without delay a competent lead registrant for successful 2018 registration cannot be over emphasised. Many large manufacturers and consultants have a good level of know-how from previous deadlines, but that is not the case for SMEs which currently need this expertise. Therefore, help from experienced consultants in planning and executing lead registrant work and its multi-disciplinary aspects is essential. This is especially so, since the 2016 entry into force of the data-sharing Regulation. Selecting a consultant, deciding who is to take up the lead registrant role – with the corresponding pre-funding commitments of registration expenses – and obtaining the agreement from co-registrants (Sief) to start the work can be a lengthy process.

Testing needs and lead dossier development

With data gaps tending to be greater than for high-volume substances, the reduction of information requirements, due to the lower tonnage band, is often outweighed by increased testing needs. This, in turn, puts additional pressure on the capacities of testing laboratories and adds to the time required for data collection. And, the contracting of laboratories demands that the lead registrant has completed the analysis of data gaps, alternative non-testing methods (such as read-across and Qsar) and waiving possibilities. Thus the

time window for registration is further shortened. Once the study reports are available, enough time must be allowed to draw up robust summaries and to compile the joint registration dossier. These should be ready for submission two months prior to the deadline, preferably before April 2018 – as Echa recommends – to enable subsequent member registrations.

Substance-specific 'time sinks'

For some categories of substance, there are further considerations which can increase deadline pressure. These are:

» for UVCB substances, the correct substance identification and Sief formation may be very difficult. There is a greater likelihood of being the only registrant – with no possibility of cost sharing;

» for uncommon speciality chemicals, use of read-across is likely to be limited; and

» substances in the annual tonnage band of 10-100 require a chemical safety report (CSR). If the substance is classified as hazardous, this should also contain an exposure assessment.

Use identification requests until 31 May 2017

Few downstream users are aware of their right under REACH, to make their use of a substance known to the chemical supplier in order to 'cover it' for continued use in the registration. For phase-in substances to be registered by the 2018 deadline, downstream users have to request this by 31 May 2017. Only then can they enforce supplier compliance (REACH Article 37(2) and (3)). However, in practice, supply chain complexity makes this very difficult to implement. Use maps, provided by sector associations for registration purposes, can help.

Authorisation deadlines

An important 'sunset date' will be 21 September. From then, the placing on the market and the use of key chromium VI substances, such as chromium trioxide, will be prohibited unless an authorisation has been granted by the European Commission, or a decision on an application received by 21 March 2016 is still pending. A high number of downstream users in various sectors (such as automotive, aerospace and defence) are expected to rely on the upstream application for authorisation by the CTACSub Consortium, comprised of seven chromium trioxide suppliers, for continued use. These downstream users will have to notify Echa after the authorisation is granted, within three months of the first supply of the substance (REACH Article 66(1)). The opinions of Echa's Risk Assessment and Socio-economic Analysis Committees adopted in September 2016 on this application, and now being evaluated by the European Commission, suggest strict authorisation conditions and timescales.

For the first time since 2014, the Commission is expected to add a number of substances to the REACH authorisation list (Annex XIV) this year.

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Enforcement

A joint EU-wide enforcement project on extended safety data sheet (eSDS) quality and compliance (REF-5) began this January. Suppliers of hazardous substances and mixtures are advised to review their eSDSs (including the annexed exposure scenarios) to ensure compliance with REACH and registered CSRs. At downstream user level, workers' adherence to risk management advice in the sheets will be checked.

Second REACH Review

A key action for the European Commission this year is its publication of a five-year general report on the operation of REACH. The public consultation of stakeholders closed on 28 January. The report will provide useful insights for industry on the possible evolution of the Regulation beyond 2018.

Consequences of Brexit vote

Last but not least, the future of REACH in the UK following the Brexit vote is likely to remain a key topic for UK-based industries, as well as their suppliers, customers and co-registrants. The UK government's intention to leave the EU single market and the jurisdiction of the European Court of Justice, which has in previous years ruled on several important aspects of REACH, could result in rather fundamental changes in relation to REACH and the UK. Such a 'hard' Brexit could also have significant impact on the numerous existing REACH industry agreements with UK legal entities, for example, only representative appointments and joint registrations. The way forward should become clearer after next month, when negotiations are expected to begin. In the meantime, company decisions on REACH should already be taking the issues around Brexit into account.

The views expressed in contributed articles are those of the expert authors and are not necessarily shared by Chemical Watch.

Overview of key REACH dates in 2017

Deadline	Action/event	Main relevance for industry
Without delay	Lead registrant nomination and testing for registration by 31 May 2018	Risk of missing the 2018 deadline, if testing cannot be done in time
31 May	Late pre-registration for registration by 31 May 2018	New EEA market entrants. After 31 May only inquiry route before registration
31 May	Downstream user right to make use known for registration by 31 May 2018	Risk of use not covered in registration dossier and need for own DU CSR
1 June	Commission REACH Review Report	Informatory, planning beyond 2018
21 September	Authorisation sunset date for critical Cr(VI) substances, for example chromium trioxide for surface treatment uses	Non-applicant DUs have to be covered by an upstream authorisation and need to notify Echa (REACH Article 66(1))
All year	Joint EU enforcement project on (e)SDS quality and compliance (REF-5)	Concerns all supply chain actors and workers handling hazardous chemicals