PREPARING MY SME BUSINESS FOR THE 2018 REACH REGISTRATION DEADLINE

Complying with the EU Regulation on Registration, Evaluation, Authorisation and Restriction of Chemicals (REACH) can be a cause of much anxiety to small and medium-sized (SME) businesses. The costs of registration under REACH are often very high, despite the fact that SMEs benefit from reduced European Chemicals Agency (ECHA) registration and other fees.

According to the legislation, the main aims of REACH are to ensure a high level of protection of human health and the environment from the risks that can be posed by chemicals, the promotion of alternative non-animal test methods, the free circulation of substances on the internal market and enhancing competitiveness and innovation.

REACH makes industry responsible for assessing and managing the risks posed by chemicals and providing appropriate safety information to their users. In parallel, the European Union can take additional measures on highly dangerous substances, where there is a need for complementing action at EU level.

The final registration deadline for substances produced or imported in the EU in quantities between 1 and 100 tonnes per year (tpa) is 31 May 2018 (previous deadlines were 2010 and 2103 for higher tonnages and Substances of Very High Concern). Since the 2018 deadline concerns relatively low-volume substances, a high number of SMEs are expected to get involved in the registration process. The data requirements for substances registered in quantities below 100 tpa are reduced compared to those registered in quantities above 100 tpa, and this helps to reduce costs to SMEs. However, REACH Letter of Access (LOA)[1] and other charges also have to be taken into account and these can be significant (see Table 1).

It is important to accept that the costs of REACH need sharing across industry. Historically, larger organisations have spent considerable sums of money on substance safety assessments from which SMEs have usually benefited free-of-charge. Going forward, it is not unreasonable to expect SMEs to shoulder some of this burden in a fair manner. The problem lies with those aspects of REACH which the legislators handed over to industry to manage, where the term 'fair' will take on different meanings depending on your viewpoint. For example, did ECHA really expect 'fairness and transparency' to be the universal norm in REACH consortia[2], which largely operate as monopolies, charging essentially what they like for LOAs?

An EU Commission report into the workings of REACH (COM/2013/049), identified specific problems in relation to the powers of Lead Registrants (LRs)[3] in consortia, which role is more frequently exercised by larger companies. Remedial proposals included the imposition of flat-fees on LOAs and more specific guidance on transparency, non-discrimination and fair cost sharing in the framework of the Substance Information Exchange Forum (SIEF)[4]. It remains to be seen if these sorts of measures, designed to ease the burden of REACH on SMEs, will be effectively enacted or not.

What should SMEs do?

Costly errors are being made by inexperienced SMEs that adopt a do-it-yourself approach to REACH compliance in order to avoid consultant costs. Some SMEs have inadvertently placed themselves in the wrong substance SIEFs and subsequently undertaken incorrect registrations; it can be difficult and costly to change these. Others have failed to undertake

registrations on time and found themselves subject to enforcement action. When necessary, SMEs should be prepared to accept specialist REACH support given the considerable complexity of the legislation.

When choosing a REACH consultant, care should be exercised. There are no official standards or certifications for REACH consultants, so the quality and level of support can vary widely. SMEs should ask themselves a number of key questions when selecting their REACH consultant, to satisfy themselves that they are likely to be in good hands (see Table 2). SMEs should be especially wary of consultants that do not have the will or capability to defend their interests in the event they come up against unfair consortium practices and charges.

Most substances placed on the EU market have yet to be registered and many more SMEs will be shouldering LR responsibilities than was seen at the previous 2010 and 2013 deadlines. Invariably, they will be inexperienced and require significant specialist support. These LRs should allow plenty of time (at least one or two years, depending on their circumstances) to set themselves up in consortia with other SIEF members and fulfil all the task associated their special role (see Table 3).

Even if a SME is not a LR, it may still need to undertake a Joint Submission (JS) registration - the most common route to a REACH registration. In this case, most of the technical work on a substance is completed by the consortium members and/or their consultants and the SME buys into the substance registration via the LOA. Under REACH rules, the LOA applicant is entitled to ask for a full explanation of the basis for the LOA charges. Since these can be complex and include different types of technical and administrative costs, independent valuation of LOA charges is best left to REACH experts. Should a valuation conclude that some or all LOA charges and/or content is unjustified, it is permitted to 'opt-out' of some or all parts of the JS registration in order to reduce costs, avoid association with unnecessary animal tests etc. Should the LR / consortium refuse to negotiate about the LOA, another option is the stand-alone Individual registration. In this case, clear evidence of a refusal to negotiate must be provided to ECHA on request.

An agreement probably will need to be signed in order to become a member of a JS registration. Usually running to many pages and often containing considerable legalistic language and jargon for the unwary, the temptation for the SME is to simply sign the agreement and hope it is not disadvantaged. This can be a big risk, since there could be clauses in an agreement which compel the SME to contribute to future, as yet unknown costs, even though these may not be justified. Many LOAs are poor value for money and a lot of re-work could be required. Some consortia are known to have undertaken unjustified animal testing with which an SME may not wish to be associated e.g. when selling to the cosmetics sector. Agreements should only be signed when the SME's obligations are fully understood. Skilled REACH practitioners will be able to identify the potential traps in REACH registration agreements.

Irrespective of any requirement to register their materials under REACH, all SMEs should establish a REACH plan. This should clearly identify registration and other obligations and costs, those products which the SME believes it is likely to be to support through REACH (or not), and the 'who, what, when, how' practical steps to achieve overall REACH compliance.

Imports to the EU - the little-known threat from REACH

There is still a widespread belief among non-EU companies with a REACH Only Representative (OR)[5] in place, that they and their EU customers have little to worry about provided they receive confirmation that their upstream non-EU suppliers have achieved REACH registrations of relevant substances. They often do not realise that an additional REACH condition relating to this indirect-supply of substances to the EU must be met if they are to avoid registration obligations themselves.

Consider the following scenario: non-EU manufacturer A sells to non-EU formulator B which then supplies its mixture to EU customer C. Company A holds a REACH registration which covers the substance tonnage it ships directly to the EU. To avoid registering itself, company B must come to a special arrangement with Company A. Company A must agree that its EU-based representative will act as OR for that portion of its tonnage that routes to EU Company C via Company B, in addition to its current registered tonnage. In practice, even some very large companies have refused to extend their REACH registration programmes to encompass their non-EU customers in this way. In that case, additional registration(s) must be made either by the OR of the non-EU customer, or ultimately the EU importer. Non-EU companies and their EU importer-customers should pay particular attention to this little-known threat to the supply of formulated products and polymers originating from outside the EU.

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[1] A Letter of Access entitles the purchaser to rights of access to a REACH registration even though he has not contributed directly to the process of generating the registration information and dossier.

[2] Businesses with a particularly high, usually commercial, interest in a substance often formally organise themselves into REACH consortia to share the registration workload.

[3] Under ECHA 'one substance – one registration' rules, one company – the Lead Registrant - is chosen to submit the Lead Registration Dossier, which is meant to fulfil the basic registration dossier requirements of other SIEF members.

[4] A SIEF is a group of companies which are automatically put together in the ECHA electronic REACH-IT system when they pre-register a specific substance. Creation of a SIEF is normally a prelude to consortium formation.

[5] A non-EU company cannot register itself under REACH, but can appoint a EU-based legal entity (Only Representative) to act on its behalf to fulfil relevant REACH tasks, including registrations.

Table 1: Example of basic 2018 REACH Joint Submission registration costs for a 10 - 100 tpa substance

Activity	Fees (Euros)	Comments
Letter of Access	4000 – 30 000	Depends on no. of registrants, costs of technical studies admin etc.
ECHA registration fee	2245	Medium-size company
Preparation and submission of Joint Submission dossier (consultant)	3000 - 6000	Assumes no data to contribute. Depends on quality of LOA package
TOTAL	**9245 – 38 245**	

Source: Stewardship Solutions

Table 2: Key questions for SMEs to put to REACH consultants

Tell me about your experiences of working with SME businesses on REACH; can you provide references & testimonials?
Are there legitimate measures I can take to reduce my REACH costs, including avoiding registration myself?
What types of REACH registrations have you undertaken (lead, joint, opt-out); how will you select the best option for my business?
Do you know how to value LOA charges, and have they you ever negotiated with lead registrants/ consortia to reduce these?
What is your experience of performing opt-out registrations according to ECHA rules, in the event that you have encountered unfair/ excessive consortium charges?
What steps will you take to keep me updated about REACH, especially if I could be directly affected in future?
Will you help to put a formal, budgeted, REACH Plan in place for my business?

Source: Stewardship Solutions

Table 3: Key tasks for Lead Registrants

PRE-SIEF Investigation and communication on whether there is an existing consortium
SIEF Agreement on substance sameness Agreement on LR identification Agreement on management and technical work & need for outsourcing (incl. compensation of LR) Agreement on operational rules including as a minimum: - data cost evaluation rules; - data sharing rules; - cost sharing rules; - management of late-comers; - pre-conditions to get the registration Token; - tasks and liabilities of the LR; - Joint Submission date; Agreement on the scope of dossier for Joint Submission: - full, intermediate Joint submission option as defined in REACH-IT: - Chemical Safety Report (CSR) incl. Exposure Scenario (ES) if applicable; - review by third-party; - Guidance on Safe Use; Survey on data availability, selection of key studies, summarize studies for IUCLID 5 Define data gaps and assess possibility to fill-in data gaps with read-across data Agreement on need for further studies and who will do that Agreement on testing proposals Regular information on SIEF progress Proposal and agreement on Classification & Labelling. Prepare a Classification & Labelling Notification Creation of JS in REACH-IT and communication of name and token Identification of of uses supported by SIEF (if CSR part of the Joint submission), description of ES and Risk Managent Measures and clustering them Preparation and agreement on the content of Joint submission dossier Run completeness check Submission of the JS (LR dossier including the information submitted jointly) Payment of registration fee Communication of confirmation of sucessful submission (registration number has been received) Submission of the individual dossier (dossier of each individual member of the JS) Payment of registration fee by individual members Management of late-comers: re-invoicing, new tokens, etc.

Source: CEFIC

Want to know more?
Preparing your SME business for the 2018 REACH registration deadline can be a daunting prospect, and we hope our suggestions are helpful to you. Please contact us if you would like to know more. We look forward to hearing from you.

About Stewardship Solutions
Dr. Chris Eacott is a chemicals management expert with over 30 years' experience gained in the chemical industry. He founded Stewardship Solutions in 2003 and supports the REACH/CLP compliance needs of EU and non-EU companies in a wide range of industry sectors. Stewardship Solutions is a REACHReady-approved service provider.

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