

THE REGISTRATION, EVALUATION, AUTHORISATION AND RESTRICTION OF CHEMICALS (REACH): ARE YOU READY FOR 2018 REGISTRATION?

The final REACH deadline for the tonnage bands 1 - 10 and 10 - 100 tonnes/year will be here soon. This will impact many small-to-medium sized enterprises (SME's), many of whom will not be familiar with the registration process or data requirements.

One of the lessons from the previous deadlines was the need to start working together as early as possible. Pre-registrants of the same substance have been grouped together in the Substance Information Exchange Forum (SIEF). From this group a lead registrant must be agreed who will submit the joint dossier.

The dossier will contain all of the basic information on physical chemistry, environmental effects, and human health. If your registration is for greater than 10 tonnes then a Chemical Safety Report (CSR) may also be required. Even if you are a joint registrant you will be required to submit your own data on substance identification and you must ensure that the generic exposure scenarios cover all of the uses required by your downstream users.

toXcel has an office in the UK and we have been actively involved in the registration process. We offer the following services:

- Only-representative for non-EU manufacturer (there is no ECHA fee for changing only-representative prior to registration)
- Late pre-registration (only applicable if you have not previously manufactured or imported over 1 tonne into the EU) and enquiry dossiers
- SIEF or consortium representation
- Data compensation validation and negotiation
- Data gap analysis (the data requirements vary according to tonnage)
- Literature searches to fill data gaps
- Guidance on the requirements for substance sameness—review of data for acceptability
- Entry of data into IUCLID 5, including summaries and risk assessment
- Generation of Exposure Scenarios
- CSR compilation
- Support for joint registrants—completing IUCLID 1-3 (and other sections as required) and actual submission to ECHA via REACH-IT
- Registration after care. Responding to questions from ECHA, placement and management of toxicology studies, dossier updates

toXcel is a group of dedicated professionals with experience in chemistry, toxicology, and ecotoxicology. We offer you complete registration support, or you can use us to supplement your own in-house capabilities. If you would like more information please contact us.

toXcel, LLC

7140 Heritage Village Plaza
Gainesville, Virginia 20155
USA

Phone: 703-754-0248 x111
Email: Alan.Katz@toxcel.com

toXcel International Ltd.

P.O. Box 93
Ledbury, HR8 9JE
United Kingdom

Phone: +44 (0) 1531 638999
E-mail: Christine.McAlinden@toxcel.co.uk

www.toxcel.com