

# REACH – TOXICOLOGY AND RISK ASSESSMENT



The first REACH deadline passed on 30th November 2010 and ECHA received almost 25,000 registration dossiers, submitted for nearly 3,400 phase-in substances manufactured or imported at over 1000 tonnes/year. The next deadline of 2013 is for substances at over 100 tonnes/year; this will bring many small-to-medium sized enterprises (SME's) into REACH.

Because REACH will create different challenges in 2013, **toXcel** can provide assistance in a number of ways. Many SME's will have less regulatory experience and will not be familiar with working in the Substance Information Exchange Forums (SIEFs) to which all registrants are assigned. **toXcel** has the technical and regulatory support that many SME's may lack in-house and can provide management of the SIEF. For the lower tonnage bands there will be a greater reliance on read-across to other substances, QSAR models and weight of evidence arguments; these are all areas where **toXcel** can provide assistance.

**toXcel** is an experienced and reliable source of scientific support - for a single registrant or for a SIEF. Our scientists have actively been involved in industry consortia, joint registrations and full dossier compilation for 1000 tonne registrations. Examples of **toXcel's** in-house technical support capabilities include assessment of toxicology data and selection of appropriate data sets for regulatory utilization, determination of the level of reliability of studies (e.g., Klimisch scores), conducting risk assessments, development of bridging and waiver arguments, design and management of new data generation programs, and preparation of dossiers. Further, **toXcel** can provide data compensation appraisals as well as appropriate independent expertise to assist with conflict resolution regarding different interpretations of data.

#### **toXcel's** Areas of Scientific Expertise include:

- Toxicology (with emphasis on Developmental and Reproductive Toxicity, Carcinogenicity, Ocular Effects, and Neurotoxicity)
- Structure Activity Relationships (SAR), Bridging, and Development of Data Waiver Justification
- Exposure Modeling (Occupational, User, Dietary) and Risk Assessment
- Environmental Fate
- Ecotoxicity

#### **toXcel's** Regulatory Expertise includes:

- Decades of experience in regulatory affairs and preparation and submission of full dossiers on highly regulated chemicals (i.e., agricultural pesticides and biocides)
- Knowledge and contacts in all major EU countries

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