
Dr. Iain MacKinnon

A DECADE WITHIN REACH

Dr. Knoell Consult Ltd, the UK-based affiliate of the knoell group of companies, celebrated its tenth anniversary in December 2019. In this article Dr. Iain MacKinnon, Managing Director and co-founder (with the late Dr. H.-E. Knoell) of the company, reflects on the changes seen over the past decade and some of the key challenges that knoell and its clients face as we enter a time of uncertainty for chemicals regulations in the United Kingdom.

"Hans (Knoell) and I setup the company in 2009. I had just left industry after a 20 year career which started in the lab and finished with REACH. Pre-registration of our substances felt like a great achievement but was only the end of the beginning! We foresaw that there would be a need to better support our clients with the next steps in the UK as much as in knoell's home market, Germany. We weren't wrong! Over the past decade, staff at Dr. Knoell Consult Ltd together with colleagues from knoell Germany and other affiliates in Spain, France, Netherlands and Portugal, have led and participated in countless REACH consortium meetings, written tens of thousands of end-point summaries and conducted thousands of exposure assessments for hundreds of substances. The biggest challenge faced by our clients over this time is the regulators' thirst for ever more detailed information, probably in part due to increasing public awareness and resultant pressure on authorities.

"Thus, the publication of the Read-Across Assessment Framework (RAAF) was a massive step forward. Until then, registrants … and consultants like knoell … had been trying to justify read-across in order to reduce animal testing but faced multiple rejections of dossiers. It was a little like playing a card game but only the dealer new all the rules … then the RAAF was published and the rules became clear to all!

"In terms of Project Management, the period running from pre-registration to the May 2018 deadline was (with hindsight) straightforward. There were only three deadlines: in 2010, 2013 and 2018. Data requirements at each tonnage band were more or less the same for each substance. How exactly the end-points were filled was the main challenge and where knoell scientists earned their keep. Then testing proposal decisions (for studies at Annex IX and X) started to come in and registrants were faced with 30-day commenting periods popping up and then closing, followed by a myriad of different deadlines for submitting updated dossiers. Lab slots had to be negotiated to meet these deadlines. Each dossier update taken individually was probably relatively simple but for a bundle of substances with these different timelines, the demand on resource at registering companies, regulatory consultants, and testing labs became huge.

"One new challenge facing the "regulatory community" is the recent announcements by ECHA that all dossiers will be reviewed over the next few years. Arguably a rolling programme of dossier revision should have been happening anyway but without a clear requirement to do this and faced with dossier updates caused by testing proposals, compliance checks, or substance evaluation, there was little appetite. However, the update programme supported by Cefic in response to ECHA's review is likely to require exceptional portfolio or programme management to stay on top of every dossier - virtually every end-point - as well as experienced chemists, toxicologists, and environmental scientists to see it through.

"One big unknown at the moment is "Will there/won't there be UK REACH come January 2021?". The legislation is published (albeit it may be subject to change) and, thankfully, it is a near clone of REACH: same data requirements at same tonnage band in same (IUCLID) format. However, there are some aspects which are still a cause for concern such as data sharing and compensation as well as very tight timelines (2 years to submit a registration). At knoell we are fortunate to have had many years of experience acting as Only Representative (according to REACH) for non-EEA companies. We are confident that we can combine this know-how with our understanding of the UK legislation to support companies, based in the UK, EU-27 or further afield, who will have registration obligations under UK REACH. This could easily keep us busy for the next ten years!"

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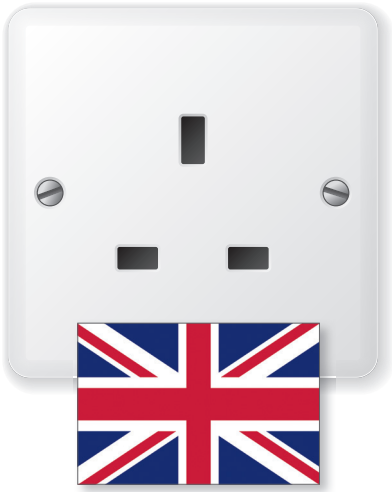

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