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PUBLISHED 1Q 2021

Biocides GB: The Challenge Lies Ahead

Preparing for the new Great Britain biocides regime

MARCH 11, 2021

At 11PM on 31 December 2020, the EU-UK withdrawal agreement finally expired and was replaced by the EU-UK Trade and Cooperation Agreement. Leaving the EU allows the UK to develop its own regulatory policy for the management of biocides and other chemicals. However, on leaving the EU, the UK became a "third country" unable to participate in EU decision-making processes, with no access to the European Chemicals Agency (ECHA) databases. The UK was instrumental in the development of the original biocides directive in the 1990s and for many years carried out the majority of product assessments. The remaining member states must now absorb some of the UK's workload and proceed without their former partner, and industry must navigate compliance with the new UK regulatory system as well as the EU Biocidal Products Regulation (BPR), which continues unimpeded.

The withdrawal of the UK from the EU creates special challenges for the UK, the EU, and their regulated industries. On leaving the EU, the UK "lifted and shifted" the existing EU biocides framework into UK law so that the new system currently mirrors the EU's system but with changes to facilitate its operation in the UK. For example, dispute and decision-making processes move from ECHA and the European Commission to the Health and Safety Executive (HSE) and UK Government Ministers. The new "Great Britain" system—the EU BPR continues to apply in Northern Ireland—also introduces company residence requirements whereby holders of authorisations, approvals, and listings may, depending on current status, need to have a legal presence in GB, and the loss of access to EU databases and IT systems means that applicants may have to resubmit data and applications to HSE within a short time frame.

Staying on the Market in GB – the Need to Act Now

Since the UK has no access to ECHA databases and systems, to remain on the market in GB, information on active substances and products that had been submitted to ECHA and other EU member states must now be resubmitted to HSE within specified deadlines or risk the loss of active substances and product approvals. Depending on the circumstances, the deadlines range from 31 March 2021 to 31 December 2022. The HSE has identified at least 14 different scenarios that may apply depending on the category of information submitted to them.

HSE have indicated that there is no charge for the resubmission of data to HSE but that there will be a fee for its evaluation. These fees are significant: for an active substance currently under the review programme, HSE's estimated evaluation fee is 160,000 GBP for one product type and 50,000 GBP for an active substance renewal. Fees for product applications are lower but still significant (25k GBP). These fees are in the same range as under the ECHA system but offer much smaller market access. A GB approval gives no EU market access and vice versa. Effectively the UK and EU are duplicating each other's efforts.

Companies based in GB who formally used an HSE evaluation and the mutual recognition procedure to establish authorisations in the EU must now find an EU member state to evaluate their product and act as the evaluating Competent Authority. Early indications are that many companies are finding this difficult, with member states unwilling to take on additional work as they are already at capacity. Since a GB company cannot hold an EU authorisation, or an article 95 active substance listing, companies have been transferring regulatory assets to EU affiliates or distributors.

All existing substance and UK product authorisations currently remain valid in GB, but the HSE will have its own procedures for approving and renewing active substances. Likewise, HSE will have its own list of active substance suppliers—the GB Article 95 list.

Future Uncertainty

In addition to considering costs for separate evaluations in GB, companies need to check their supplier arrangements to confirm that any data access agreements are applicable in GB or risk losing access to data and loss of approvals. Inevitably over time, the GB system will diverge from the EU system, potentially leading to different approval decisions and conditions of approval. For example, it is unclear whether GB will adopt the latest revisions to Annexes II and III of the BPR concerning active substance and product data requirements. Companies will need to consider the risk that a GB evaluation will reach a different conclusion and whether this is worth the commercial risk and expense.

How Exponent Can Help

Exponent's team of experts in biocide regulation, chemistry, risk assessment, efficacy, environmental fate, and toxicology have decades of experience at UK regulatory authorities, contract research organisations, and industry. We provide techno-regulatory solutions to techno-regulatory problems, offering accuracy, simplicity, and speed to market.

James Pemberton, M.Sc.
Chemical Regulation & Food Safety
Senior Managing Scientist
+44 (0) 1423 853207
jpemberton@exponent.com