Introducing Eurofins Regulatory AG...

Eurofins is shaping its regulatory offering to meet these new challenges by offering complete support to the agrochemical industry.

We have the expertise to provide a tailored strategy for the successful worldwide registration of agrochemicals, biopesticides, biocides and pharmaceuticals (ERA).

The Group comprises the largest regulatory risk assessment and modelling team in the CRO sector. With extensive Study Monitoring experience, the team have worked under a range of partnership models over many years of active operation.

Meeting the challenges of the regulatory environment

The new regulation, implemented in June 2011, to replace the 91/414 directive, brings new elements into play. Namely, that it provides the possibility to reject active substances on the basis of their intrinsic properties; a concept commonly known as ‘hazard-based cut-off criteria’. This ‘hazard based approach’ is not just limited to conducting and reporting the required studies. It is more to define the right criteria irrespective of exposure or risk and whether safe uses can be identified, e.g. to model certain situations such as run-off, spray drift and other scenarios in surface water, to have the right approach with regards to non-target arthropods such as bees and small mammals, or to define the studies necessary to address any toxicological effect.

Here at Eurofins, we understand these complexities and can offer a level of expert management that may not be available ‘in house’ for many companies engaging in product registration.

With the development of new greener formulations on the increase, making molecules more environmentally friendly, regulatory expertise with its new challenges is often not a core competency. Also, due to the current economic climate and on-going changes within the industry (i.e. acquisitions and re-structuring) the level of outsourcing for regulatory expertise is on the increase.

Our expertise

At Eurofins, we have technical experts in all disciplines who constantly keep their knowledge up to date on all the evolving technical requirements and guidance documents. Maintaining and developing this expertise is our priority, enabling us to identify and address specific technical problems. We will offer strategic advice to our clients on the best way to proceed by identifying studies or assessments best suited to the clients regulatory objectives through to support with life-cycle-management.

Be confident in our knowledge of recent developments and changes to the current regulation – this allows us to update Eurofins Study Directors on new developments directly in-house.

The experts at Eurofins Regulatory AG are well placed to provide up to date advice on new guidance initiatives, new study designs and new tactical approaches can be implemented quickly and efficiently.

We are mindful of all developments within these areas and are able to advise on implications of evolving data requirements. We have expertise in identifying any additional studies and risk assessments required to upgrade existing dossiers to meet current regulatory requirements. Regulatory support does not necessarily stop at the dossier submission. It can continue with a life-cycle-management of the active and/or formulation – we are ready to offer the full program of support.

Eurofins Regulatory AG can liaise with regulators to help answer any questions that may arise during the evaluation of your dossier. The team are closely linked to the major markets and can ensure all regulatory requirements are met with local and national requirements taken into consideration. In summary, we provide:

- Data gap analysis
- Proactively engaging with Regulatory Authorities at an early stage of project definition
- Proposing appropriate countries for initial submissions
- Scoping out the studies required and likely timelines to submission and market
- Project management from outset to completion
- Problem solving
- Compilation (including CADDY format) and submission of the completed Dossier
- Post-evaluation Dossier stewardship

There is no doubt that the current regulatory environment and future challenges of evolving legislation will remain a constant battle. Our aim? To guide our clients efficiently through the demanding registration process.

If you need more advice or need help, please don’t hesitate to ask.
Contact Andreas Wais; MD Eurofins Regulatory AG at andreaswais@eurofins.com