PLANT PROTECTION PRODUCT AUTHORISATION

Plant protection products (pesticides to protect plant/crops) are regulated in the EU by Regulation (EC) No 1107/2009. An authorisation must be granted in each EU Member State prior to placing the product on the market. In order to obtain an authorisation in any of the 28 European Member States a regulatory dossier demonstrating that the product meets the current data requirements needs to be submitted in each MS.

Regulation (EC) No 1107/2009 provides two basic approaches to product authorisation – zonal authorisation and mutual recognition. These have specific and directly binding timelines and procedures which are elaborated in further EU Guidance.

AGREXIS offers full support all along the life-cycle of a product development, from the definition of a regulatory strategy and preparation of the regulatory dossier according to the current data requirements, to post submission support, including meeting with authorities when needed and rebuttals writing.

1. Regulatory submission strategy and Data-Gap Analysis

Under an open consultancy agreement, strictly based on actual time spent, highly experienced **AGREXIS'** regulatory and product safety experts help defining the most cost- and time-effective submission strategy (including the selection of a zonal Rapporteur Member State), make the necessary contacts with the authorities and, when applicable, prepare a notification form.

For further information please contact us
info@agrexis.com

Full review of proprietary and unprotected data is one of the key steps to a clear identification of gaps and a list of data that need to be generated to fulfil the latest data requirements. The data gap analysis also enables to better estimate the overall costs of product registration.

AGREXIS' independence from any CRO is the best assurance that the proposed list of studies to fill a gap is limited to the strictly necessary. **AGREXIS** has the know-how and the network to commission and supervise all studies necessary (except for efficacy trials) for dossier preparation on behalf of our clients, or can simply assist the client, from selection of the laboratories according to specific criteria, to the design and monitoring of a complete study programme.

2. Preparation and submission of the Product Authorisation Dossier

A draft Registration Report (dRR) is put together (with the exception of the Biological Assessment Dossier (BAD) and the efficacy section) by **AGREXIS**' regulatory and technical experts to the highest scientific quality and to the correct standards in terms of data requirements and format.

The cost of the dossier preparation varies according to the specificities of the product, the complexity of the active substance(s) it contains and the field of application.

3. Post submission work

AGREXIS offers follow-up agreements on a time-spent basis to assist the clients in any post submission work, preparing rebuttals, commenting authorities' assessments or defending existing authorisations.

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