PLANT PROTECTION: ACTIVE SUBSTANCE APPROVAL

Active substances (*AS*) can only be included in plant protection products (*PPP*) and put on the EU market if they have been included in the List of Approved *AS*.

This inclusion requires the submission of a complete dossier on both the *AS* and at least one formulated *PPP*. The dossiers cover a wide range of matters including the identity of the *AS* and a *PPP*, their physical and chemical properties, the effects on target pests and the risks to operators, workers, consumers, the environment and non-target plants and animals.

To ensure that risk assessments are kept up to date and that *PPPs* can continue to be used safely, approval of an *AS* is given under current Regulation (EC No 1107/2009) for a limited period of time, with a maximum of 15 years. A new review of the inherent qualities of the *AS* must be completed before the authorization expires.

Whether a registration dossier is submitted to gain first approval for an *AS* or to renew an existing one, the dossier is assessed by a *Rapporteur* Member State (RMS). The *Rapporteur*'s Draft Assessment Report (DAR) is peer reviewed by the European Food Safety Authority (EFSA), which provides its conclusion to the Commission and may also suggest options for risk management. In light of this conclusion, a proposal for approval/renewal or non approval/non-renewal is made by the Commission which is subject to a vote by all Member States.

Development of a complete data package for registration of a new *AS* is long and expensive with costs depending on the molecule. Current estimates range from 6 to 8 years for development and registration, with costs up to 100 Mo €[1].

Any applicant can file an application for the re-approval of an *AS* if he can demonstrate access to a full data package (*AS* + *PPP*), either by owning the original data package or because data protection has elapsed. As a common early activity for approval (first or subsequent), applicants evaluate their data base for potential data gaps and make sure all required safety studies are available in time for submission.

AGREXIS offers full support in the preparation of an *AS* regulatory dossier when first approval or renewal of an approval (for example AIR 3 compounds) is sought.

The highly experienced **AGREXIS'** team help defining the most cost- and time-effective strategy to create a dossier in support of an *AS*, make the necessary contacts with the authorities, participate in pre-submission meetings, project management and study monitoring

AGREXIS offers in particular

- Complete analysis of publicly available data
- Literature search and evaluation
- Data protection evaluation
- Data gap analysis in light of new data requirements
- Preparation of the Updating Statement
- Compilation of an Annex II dossier

For further information please contact us
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1 Source: ECPA

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