

Plant protection products – 12 steps to secure EU active substance approval and how Sagentia Regulatory can help

Who	You	You, EFSA	RMS (Co-RMS)	RMS (Co-RMS)	You	EFSA, RMS (Co-RMS) and You	EFSA, RMS (Co-RMS), Public and You	EFSA, RMS (Co-RMS) and You	EFSA	European Commission	You	You
	1	2	3	4	5	6	7	8	9	10	11	12
												
Action	Prior assessment (and study notification)	Pre-submission advice and dossier submission	Admissibility check (and complement if necessary)	Evaluation (12 months)	“Stop the clock”, Period 1 (6 months if necessary)	Draft Assessment Report (DAR) and peer review (45 days)	Comments (2 months)	Expert consultation and “Stop the clock”, Period 2 (6 months)	Conclusion	Decision	Authorization conditions fulfilled	Post authorization follow-up
Details	The active substance must first be approved at the European level. The first step is for the applicant to choose one (or more) representative use(s) for the active substance, then write the dossier addressing the data requirements (endpoints), then submit the dossier to a Rapporteur Member State. New studies notified to EFSA under pre-application ID. Sagentia Regulatory can help you to choose the most relevant Member State(s) for RMS, advise on generating the necessary studies to establish the endpoints and prepare the active substance and the representative product risk assessments. Sagentia Regulatory can request pre-application ID and notify specific studies on your behalf.	Pre-submission advice from EFSA may be requested. Dossier submitted to Rapporteur Member State (RMS). The dossier must be in IUCLID format. Sagentia Regulatory can support with pre-submission dialogue. We can prepare or validate your IUCLID dossier before submission.	The RMS verifies admissibility of the dossier (45 days), requesting supplementary information if necessary (3 months). In agreement with the applicant, the dossier is sanitized and published on the EFSA website, and public consultation launched. Sagentia Regulatory can assist you during this step.	The RMS shall review the applicant dossier, assessing whether the active substance can be expected to meet the approval criteria. Sagentia Regulatory can liaise with the RMS on your behalf, answering any questions they may have.	Where identified by the RMS, the applicant has to submit additional information. Sagentia Regulatory can provide any additional information requested by the RMS – risk assessment updates, new studies, argumentation and rebuttal.	The RMS submits the DAR to EFSA. EFSA shall circulate it to the other Member States and to the applicant for sanitization. Sagentia Regulatory can prepare the sanitized version of the DAR.	EFSA shall circulate the DAR to the applicant, Member States and public for consultation. Applicant can react to the comments. Sagentia Regulatory can advocate on your behalf and reply to the comments.	EFSA can request additional information (90 days) and can allow 60 days for the RMS to evaluate it. Sagentia Regulatory can respond to any additional information requested by EFSA on your behalf.	EFSA conclusion published on their website. Data gaps are specified if present. Sagentia Regulatory can scrutinize the conclusion and provide advice.	Within 6 months of EFSA's conclusion, the EC presents the draft regulation to the Standing Committee. The final decision occurs at least 3 months after this draft. Sagentia Regulatory can lobby the Commission and Member State on your behalf and provide regulatory advice.	• Risk management measures • Exposure monitoring • Alternatives development and substitution Sagentia Regulatory will help you fulfil any conditions mandated by the EC and develop the product dossier.	Sagentia Regulatory can assist you in addressing data gaps specified in the conclusion, relevant to the product authorization.



Plant protection products – 11 steps to secure EU active substance renewal and how Sagentia Regulatory can help

Who	1 2 3 4 5 6 7 8 9 10 11										
	You	You, EFSA	RMS (Co-RMS)	RMS (Co-RMS)	EFSA, RMS (Co-RMS) and You	EFSA, RMS (Co-RMS), Public and You	EFSA, RMS (Co-RMS) and You	EFSA	European Commission	You	You
Action	Prior assessment (and study notification)	Pre-submission advice, list of studies, and dossier submission	Admissibility check (and complement if necessary)	Evaluation	Renewal Assessment Report (RAR) and peer review (45 days)	Comments (2 months)	Expert consultation and “Stop the clock” (4 months)	Conclusion	Decision	Authorization conditions fulfilled	Post authorization follow-up
Details	Before submitting the dossier, the applicant should analyse all the data requirements, identify data gaps and refine the GAP where needed to support risk assessments. New studies notified via EFSA under pre-application ID. Sagentia Regulatory can advise on generating the necessary studies, choice of representative product and prepare the product and active substance risk assessments. Sagentia Regulatory can request ID and notify studies on your behalf.	EFSA Pre-submission advice may be requested. List of intended studies notified to EFSA for public consultation ahead of dossier. Dossier submitted to Rapporteur Member State (RMS) 3 years before expiry date. The dossier must be in IUCLID format. Sagentia Regulatory can support with pre-submission dialogue, list of studies and the consultation. Sagentia Regulatory can prepare or validate IUCLID dossier before submission.	The RMS verifies admissibility of the dossier (1 month), requesting additional information if necessary (14 days). In agreement with the applicant, the dossier is sanitised and published on the EFSA website, and public consultation launched. Sagentia Regulatory can advise and assist you during this step.	The RMS will review the applicant dossier, assessing whether the active substance can be expected to meet the approval criteria. Sagentia Regulatory can support you and liaise with the RMS on your behalf, answering any questions they may have.	The RMS submits the dRAR to EFSA. EFSA shall circulate it to the other Member States and to the applicant for sanitization. Sagentia Regulatory can prepare the sanitized version of the dRAR.	EFSA shall circulate the dRAR to the applicant, Member States and public for consultation. Applicant can react to the comments. Sagentia Regulatory can advocate on your behalf and reply to the comment.	EFSA can request additional information (30 days) and can allow 60 days for RMS to evaluate it. Sagentia Regulatory can respond to any additional information requested by EFSA on your behalf.	EFSA conclusion published on their website. Data gaps are specified if present. Sagentia Regulatory can scrutinize the conclusion and provide advice.	Within 6 months of EFSA's conclusion, the EC presents the draft regulation to the Standing Committee. The final decision occurs 3 months after this draft. Sagentia Regulatory can lobby the Commission and Member State on your behalf and provide regulatory advice.	• Risk management measures • Exposure monitoring • Alternatives development and substitution Sagentia Regulatory will help you fulfil any conditions mandated by the EC and develop the product renewal dossier(s).	Sagentia Regulatory can assist in addressing data gaps specified in the conclusion, relevant to product renewals.

