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

	1	2	3	4	5	6	7	8	9	10	11	12
Who	You	You	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
Action	Prior assessment (and notification)	Dossier submitted to Rapporteur Member State (RMS)	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(s) use(s) for the active substance, then write the dossier addressing the data requirements (endpoints), then submit the dossier to a Rapporteur Member State. TSG 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 dossiers.	The format of the dossier shall be to agreed EU guidance. TSG can prepare or check the dossier for you before submission.	The RMS verifies admissibility of the dossier (45 days), requesting supplementary information if necessary (3 months). In agreement with the applicant, the summary dossier is sanitized and published on the EFSA website. TSG 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. TSG 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. TSG 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. TSG 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. TSG 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. TSG can respond to any additional information requested by EFSA on your behalf.	EFSA conclusion published on their website. Data gaps are specified if present. TSG 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. TSG can lobby the Commission and Member State on your behalf and provide regulatory advice.	¬ Risk management measures ¬ Exposure monitoring ¬ Alternatives development and substitution TSG will help you fulfil any conditions mandated by the EC and develop the product dossier.	TSG can assist you in addressing data gaps specified in the conclusion, relevant to the product authorization.