

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



Who	1	2	3	4	5	6	7	8	9	10	11
	You	You	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 notification)	Dossier submitted to Rapporteur Member State (RMS) 30 months before expiry date	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	<p>3 years before the expiry date, the applicant must apply for renewal. They must analyze all the data requirements, identify data gaps and refine the GAP where needed.</p> <p>TSG can manage the application, advise on generating the necessary studies and prepare the product and active substance dossier.</p>	<p>The format of the dossier must be to current EU guidance.</p> <p>TSG can prepare and check the dossier before submission.</p>	<p>The RMS verifies admissibility of the dossier (1 month), requesting additional information if necessary (14 days).</p> <p>TSG can advise and assist you during this step.</p>	<p>The RMS will review the applicant dossier, assessing whether the active substance can be expected to meet the approval criteria.</p> <p>TSG can support you and liaise with the RMS on your behalf, answering any questions they may have.</p>	<p>The RMS submits the dRAR to EFSA. EFSA shall circulate it to the other Member States and to the applicant for sanitization.</p> <p>TSG can prepare the sanitized version of the dRAR.</p>	<p>EFSA shall circulate the dRAR to the applicant, Member States and public for consultation. Applicant can react to the comments.</p> <p>TSG can advocate on your behalf and reply to the comment</p>	<p>EFSA can request additional information (30 days) and can allow 60 days for RMS to evaluate it.</p> <p>TSG can respond to any additional information requested by EFSA on your behalf.</p>	<p>EFSA conclusion published on their website. Data gaps are specified if present.</p> <p>TSG can scrutinize the conclusion and provide advice.</p>	<p>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.</p> <p>TSG can lobby the Commission and Member State on your behalf and provide regulatory advice.</p>	<ul style="list-style-type: none"> ▮ Risk management measures ▮ Exposure monitoring ▮ Alternatives development and substitution <p>TSG will help you fulfil any conditions mandated by the EC and develop the product renewal dossier(s).</p>	<p>TSG can assist in addressing data gaps specified in the conclusion, relevant to product renewals.</p>