How and where do I submit an application for the approval of an active substance to be listed in Annex I to Regulation (EU) No 528/2012?

Regulation (EU) No 88/2014 specifies the procedure for amending Annex I to the BPR . All applications are to be submitted via the
R4BP
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My product contains several active substances belonging to the same product types, what is the procedure for submitting my application?

A marketing authorisation application must be submitted before the deadline indicated on the approval regulation for the active substance with the latest approval date. For example, your product contains substance X and substance Y, which both belong to PT12. If the Approval Regulation for substance X states a deadline of 01/05/2018 and that for substance Y a deadline of 01/11/2018, then your application must be submitted no later than 01/11/2018.

If I have a product that contains several substances that do not all belong to the same product types, what is the procedure for submitting my application?

A marketing authorisation application must be submitted before the deadline indicated on the approval regulation for the active substance with the latest approval date. For example, your product contains substance X belonging to PT8 and substance Y belonging to PT18. If the approval regulation for substance X states a deadline of 01/05/2018 and that for substance Y a deadline of 01/11/2018, then your application must be submitted no later than 01/11/2018.

Are the active substances in Annex I to Regulation (EU) No 528/2012 approved for a particular purpose?

The active substances in Annex I to the BPR are not approved for any specific product type (PT). They may therefore be the subject of a marketing authorisation application for one or more of the 22 biocide product types.

Can I submit a first authorisation application for a new formulation created from a product that is currently on the French market and that I would like to stop marketing?

You can submit a first MA application (or mutual recognition application) directly for the product with the new composition. As soon as the MA has been obtained, the product with the old formulation must be withdrawn from the market.