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 ($\underline{\sf EU}$) No 88/2014 specifies the procedure for amending Annex I to the $\underline{\sf BPR}$. All applications are to be submitted via the $\underline{\sf R4BP}$

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 <u>active substance</u> 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 <u>active substance</u> 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 <u>BPR</u> are not approved for any specific <u>product type</u> (
<u>PT</u>

). 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 <u>mutual recognition</u> 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 As soon as the MA has been obtained, the product with the old formulation must be withdrawn from the market.