What is the procedure to follow to submit an MA application for a product containing an active substance that has still not been approved?

An existing product on the market containing one or more biocidal active substances that are not yet approved is subject to the regime of the transitional period . The active substance
(s) contained in the product must be included in the Community review programme for biocidal active substances (Regulation (
EU
) No 1062/2014 of 4 August 2014 (Annex II, Part 1). An MA application for the product under Regulation (EU) No 528/2012 must be submitted no later than the approval date of the substance(s).

What is the procedure to follow to submit an MA application for a product containing an active substance that has been approved?

When a biocidal active substance has been approved, a biocidal product containing this substance must be authorised according to Regulation (
EU
) No 528/2012. An MA application for the product should be submitted via the European
R4BP
system, no later than the approval date contained in the approval regulation for the active substance. You can find a calendar of these dates in the Regulations section.

If the approval date entered in the approval regulation for the active substance has already passed, then the product must be withdrawn from the market in accordance with Article 89.3 of the BPR .

What is the procedure to follow for submitting MA applications for products that contain an active substance listed in Annex I of Regulation (EU) No 528/2012?

To submit such MA applications, the product must meet the requirements of Article 25 of Regulation (EU) No 528/2012. The procedure to follow is also described there. The application should be submitted via the R4BP .

I have a product that contains a new active substance. Which MA application procedure do I follow for this product?

This product contains a substance that is not included in the European review programme for existing active substances (Regulation (EU) No 1062/2014). This product cannot therefore benefit from the transitional measures (Article 89 of the BPR), pending approval of the new active substance . The placing on the market of the product is therefore prohibited, while the product has not been authorised according to Regulation (EU) No 528/2012. This Regulation nevertheless provides derogation provisions to authorise a product containing a new active substance, pending approval of the latter (Article 55.2 of the BPR).