

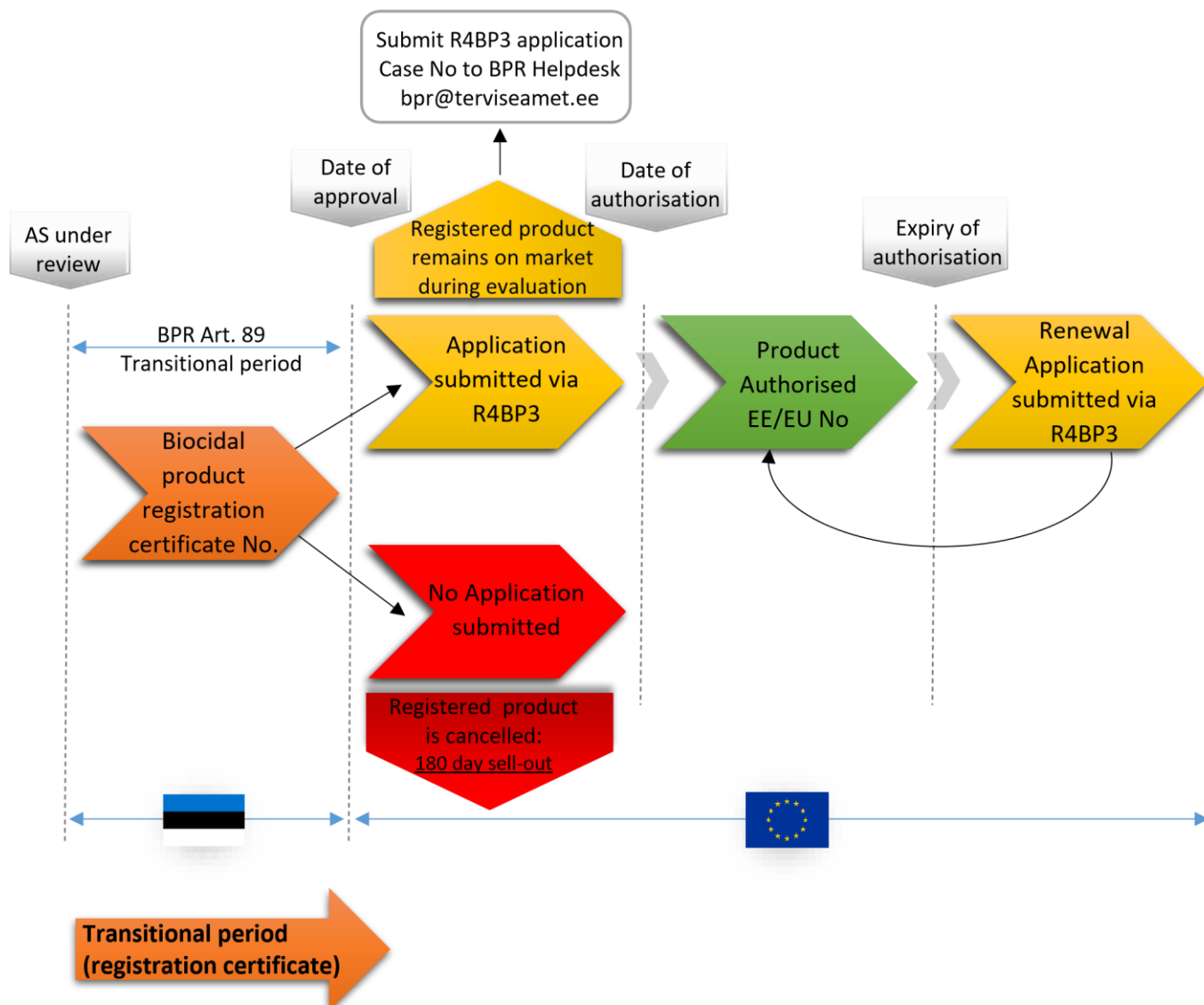
Important Information PLEASE READ

Biocidal products shall not be made available on the market or used unless authorised in accordance with the Biocidal Product Regulation No 528/12 (BPR) or registered on transitional period in accordance with the Estonian Biocides Act.

Before placing a biocidal product on the Estonian market for a particular type of product you will need to ensure that the active substance is either approved or under review in that Product Type. The status of the active substance can be checked from the ECHA webpage:

(<https://echa.europa.eu/web/guest/information-on-chemicals/biocidal-active-substances>).

Figure 1: Biocidal product approval Life Cycle

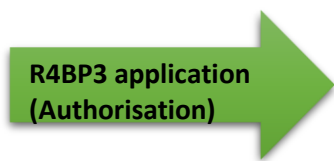


In case the active substance is still under the [BPR review program](#) the national requirements on transitional period apply to the biocidal product and the biocide needs to be registered or the change requested.

The registration certificate issued during the transitional period is valid until the approval of the active substance(s) or **until the 31 of December 2024 (BPR Art. 89(1))**.

For the biocidal product added to the list of the registered biocidal products, the producer is responsible for controlling and ensuring the efficacy of the product and for labelling the product according to the BPR requirements. Listing the product shows that the required information have been submitted to Health Board and that the product can be made available and used in Estonia.

Please be aware that registration certificate is only a transitional measure until the active substance(s) in biocidal product are approved at EU level. You should follow your active substance status in the review programme on the [ECHA Website](#) so you know when to submit an application for National or Union authorisation



Applications for authorisation shall be submitted no later than the date of approval of the last active substance for that product type.

- An application for National or Union authorisation of this product must be submitted to ECHA via R4BP3 on or before the "Date of Approval" of the final AS in your product. Further information in the table below.
- It is important to select an evaluating Member State and contact them well in advance of the date of approval of the last active substance in your product.
- It is important to contact the evaluating Member State early to ensure that they have the resources to evaluate your product.
- It is essential to meet your evaluating Member State early to receive advice prior to generating studies.
- You must make contact with testing laboratories early to ensure your studies (particularly storage stability and efficacy) are completed before the submission deadline (date of approval).

APPLICATION FOR NATIONAL OR UNION AUTHORISATION SUBMITTED VIA R4BP3	NO APPLICATION FOR NATIONAL OR UNION AUTHORISATION SUBMITTED
<p>When the application via R4BP3 has been submitted, then we ask you to send the Case No to BPR Helpdesk: bpr@terviseamet.ee. Until the application is in progress, the registration certificate is valid and product information can be seen on the Health Board webpage under the "List of the registered biocidal products".</p>	<p>If by the time that all of the active substances of the product have been approved no application for national or union authorisation has been submitted, then the biocidal product registration certificate will be cancelled and deleted from the list on our webpage.</p>
<p>Registration certificate is valid and biocidal product can remain on the market for up to 3 years or by the date of authorisation decision (whichever comes first).</p>	<p>Registration certificate is cancelled and product needs to be removed from the market, 180 days to sell out existing stock from date of approval of last AS.</p>
<p>Newly authorised biocidal product will receive an EE or EU Number to replace the Registration certificate number. The 180 day sell out for existing stock from the date of authorisation applies.</p>	

For further information on authorisations please contact us at bpr@terviseamet.ee .

Health Board
Department of Chemical Safety
Email: bpr@terviseamet.ee