TARN-PURE

PRODUCT AUTHORISATION EXPLAINED

There are two regulatory steps to be taken before your biocidal products may be lawfully sold and used in the UK and/or the Territory of the BPR.

1. Active Substance Approval

2. Product Authorisation

> Although not within our specific regulatory framework, as the poison is actually characterised as a pesticide, not a biocide, it is possible to think of the difference between an active substance and a product by considering a can of fly spray. The tiny drop of poison in the aerosol is the “active substance”. The aerosol can, the pressurised gas in the can in which the poison is mixed and the valve that releases the spray into the atmosphere is the Biocidal Product.

Under EU and UK regulations it is necessary to first manufacture or formulate your Product using an approved Active Substance.

You must then also apply for Authorisation for the Product itself, within which the active substance has been manufactured or formulated.

Timing of Product Authorisation Applications

To secure Product Authorisation it is necessary to prepare and submit a Dossier for review by your Member State Competent Authority (“MSCA”).

However - it is only possible to apply for Product Authorisation AFTER THE ACTIVE SUBSTANCE YOU WISH TO USE IN YOUR PRODUCT HAS BEEN APPROVED AND IS LISTED IN ANNEX 1 OF THE BPR OR UK EQUIVALENT.

At the date of publication of this page, in December 2020, neither Copper nor Silver have been approved as Active Substances. Silver is permitted to remain on the market until it is approved as it is defined as an “Existing Active Substance”. Due to an administrative oversight Copper was excluded from use as a biocide in 2013. After representations were made by individual Member States the EU commission permitted copper to remain on the market in any State that applied for a derogation from the non-inclusion decision on grounds

of Essential Use. 19 Member States were granted this derogation which remains in force until Copper is finally approved as a biocide, now expected in mid 2022.

In order to place biocidal products on the market after Annex 1 approval is granted for the copper and/or silver that you might with to use you would be expected to apply to your own MSCA. In the UK this is the HSE.

If you are trading in the EU and you wish to sell into a plurality of member states in the EU you may ask your MSCA to notify the other States into which you may wish to sell using a process called “Mutual Recognition”. Alternatively you may also apply directly to ECHA for Product Authorisation and ask that the authorisation be granted for any or all of the Member States that comprise the Territory of the BPR using a process called “Union Recognition”.

As the pursuit of these authorisations is entirely dependent upon the complexity of the active substance and the product, it is completely impossible to even hazard a guess at the length of time that each application will take, or the cost. In order to understand better the details of this process we recommend that you refer to the ECHA web site pages that deal explicitly with Product Authorisation; and a good starting point will be the page that you can reach through this link:

http://echa.europa.eu/regulations/biocidal-products-regulation/authorisation-of-biocidal-products

The structure for biocides registrations is governed by another EU regulation (EU/564/2013) and full details of the fees may be found in the three Annexes to this regulation which appear in pages 22 - 25 inclusive:

https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=CELEX%3A32013R0564

The costs of this process are high. If you do not have adequate resources within your own organisation, the cost of employing consultants to prepare a product authorisation dossier could easily reach €200,000 (estimate made in June 2020). The cost to register a product with ECHA may vary between €40k and €150k with discounts for small and micro-cap companies. The dossier preparation budget does not include the cost of any studies that your product may need to evidence that it is safe to use and is effective. These costs also do not include the cost of securing access to the “active substance” dossier, which must be secured either by joining the relevant Task Force or buying a Letter of Access from, and entering into a long term supply agreement with, a duly authorised Active Substance supplier.

For further details please also read:

BPR Explained

Letter of Access Explained