Technically equivalent substances

The new regulation requires that the active substances used in a biocidal product are technically equivalent to approved ones.

This is assessed by ECHA if any of these applies:

- The manufacturer is different from the one holding the original approval;
- The manufacturing process is different;
- The manufacturing location of the approved manufacturer has changed.

Sharing the costs

To ensure that the costs are equally shared, all active substance manufacturers or importers must submit a letter of access or a full dossier to ECHA for each active substance they sell or use in biocidal products. ECHA will publish and maintain a list of all companies and active substances meeting this obligation. Only the biocidal products containing the particular active substance from companies on the list are allowed to remain on the market after 1 September 2015.

Treated articles

Under the new regulation, articles can only be treated with biocidal products containing approved active substances.

Treated articles must be appropriately labelled according to the Biocidal Products Regulation and the regulation on Classification, Labelling and Packaging of substances and mixtures.

Electronic submission tools

The main tools used when applying for active substance approval or product authorisation are IUCLID and R4BP (Register for Biocidal Products).

R4BP is the central hub through which all biocides applications will be made. It will be available on ECHA's website on 1 September 2013.

IUCLID is used to collect, organise and store the data on your active substance and biocidal product. From this data, you will be able to create a dossier that is submitted to the authorities through R4BP.

IUCLID software (version 5.5 or later) can be downloaded free of charge from the IUCLID website.

echa.europa.eu

EUROPEAN CHEMICALS AGENCY
ANNANKATU 18, P.O. BOX 400,
FI - 00121 HELSINKI, FINLAND
PHONE +358-9-686180

ECHA-13-L-04-EN

ECHA
EUROPEAN CHEMICALS AGENCY

Biocidal Products Regulation

What changes on 1 September 2013?

ED-02-13-064-EN-C doi:10.2823/91374
ISBN:978-92-9217-910-6




New regulation to improve the safety of biocidal products

The new Biocidal Products Regulation aims to improve the functioning of the biocidal products market in the EU, while ensuring a high level of protection for humans and the environment.

The most hazardous active substances are assessed before approval and the biocidal products containing them are assessed before authorisation. This is to reduce the number of e.g. carcinogens, mutagens and toxic substances on the market. If the active substance is identified as a candidate for substitution, it can only be authorised in a biocidal product if no better alternatives are available.

Mandatory data sharing

One aim of the regulation is to avoid unnecessary animal testing and, as such, testing on vertebrates for the purposes of the regulation may only be carried out as a last resort.

Therefore, before carrying out any tests, you need to send an inquiry to ECHA to find out if someone has already submitted the same test or study. After this, the applicant and the data owner must make every effort to reach an agreement on the sharing of the results of the tests or studies.

New ways to authorise products

All biocidal products must get authorisation before they can be made available on the market. In addition to applying for a product authorisation in a single country, possibly followed by an application for authorisation in other relevant countries, you can now choose to apply for:

- An authorisation in one country and in other relevant countries in parallel;
- An authorisation in all EU countries in one go.

Simultaneous authorisation in several Member States

If you plan to make your product available on several EU markets, you can now start the application process in all chosen countries simultaneously. This means that an application for product authorisation, together with a list of other Member States where a national authorisation is sought, is submitted to the Member State of your choice. At the same time, you can start the application procedure for mutual recognition in parallel in the other concerned Member States.

Authorising in a number of EU countries simultaneously is faster and reduces the administrative burden.

EU-wide authorisation in one go

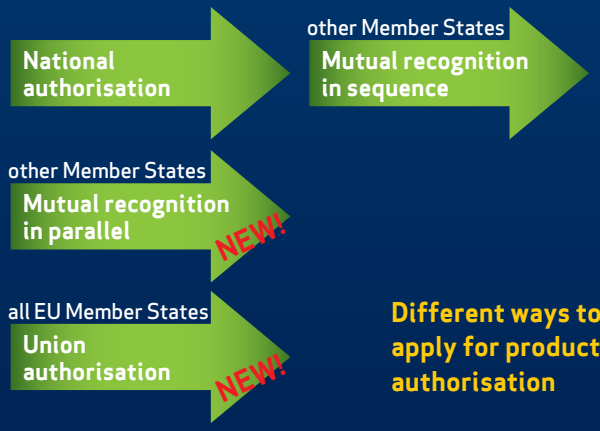
If your biocidal product will be placed on market in the whole European Union, you now have a possibility to apply for a Union authorisation.

The products seeking EU-wide authorisation need to have similar conditions of use across the Union and cannot contain active substances that fulfil the exclusion criteria. Additionally, some product types related to pest control and antifouling are excluded from Union authorisation.

Simplified authorisation

A biocidal product can be authorised through a simplified procedure if it contains only certain active substances laid down in the Biocidal Products Regulation (Annex I). To be eligible, the biocidal product cannot contain any substance of concern or any nanomaterials, it must be sufficiently effective for its purpose and the handling of the product must not require protective equipment.

The advantage of the simplified authorisation is the faster processing time of the application. The product can also be made available in all EU markets without mutual recognition.



Different ways to apply for product authorisation