Simplified Authorisation

Introduction

In order to encourage the use of biocidal products which are less harmful for the environment, human and animal health, a simplified authorisation procedure has been introduced by the Biocidal Products Regulation. Compared to the processes of National and Union authorisation, this procedure allows for a biocidal product authorisation to be obtained: more quickly; with the provision of less data; and at a cheaper cost. It also removes the requirement for the granting of mutual recognition in other Member States where the product is subsequently placed on the market.

Qualifying products

In order to be eligible for the simplified authorisation procedure, a biocidal product must comply with all of the following conditions:

- All the active substances in the biocidal product must be listed in Annex I to the BPR and comply with any specific restrictions given therein;
- None of the co-formulants within the biocidal product are substances of concern*;
- Sufficient effectiveness against target organisms is demonstrated; and
- Handling and use of the biocidal product does not require the use of personal protective equipment (PPE).

*Substances of concern are substances classified as hazardous under the CLP Regulation, and present at concentrations which lead to the classification of the product as hazardous; or substances meeting the criteria for being persistent organic pollutants (POP), persistent, bio-accumulative and toxic (PBT), or very persistent and very bio-accumulative (vPvB).

Procedure

1. Although the data requirements are reduced from those of a National authorisation, applicants must still create an IUCLID file containing: a draft summary of biocidal product characteristics (SPC); relevant efficacy data; and any other relevant information demonstrating that the product meets the conditions, given above, for simplified authorisation. IUCLID is a software programme which can be downloaded from the website of the European Chemicals Agency (ECHA).
2. The IUCLID file is submitted to ECHA using the web-based software R4BP3, which is the programme through which all communications with ECHA and the Member State

Competent Authorities is undertaken. ECHA Will check that the application and data has been submitted in the correct format before informing the competent authority of the Member State to which the application is submitted.

3. The evaluating competent authority will notify the applicant, through R4BP3, of the fees to be paid for the evaluation of their application. These fees must be paid within 30 days of the invoice date.
4. The evaluating competent authority then has 90 days from the date of payment in order to assess the dossier and authorise the placing on the market of the product.

Notification

Although a biocidal product authorised by simplified authorisation can be placed on the market in any Member State without the need for mutual recognition, the authorisation holder most notify any concerned Member State of an intention to place such a product on the market at least 30 days before doing so.

Need further help?

If you manufacture or import biocidal products which you believe qualify for the simplified authorisation procedure, and you wish to know more, why not contact our helpdesk. Email us at enquiries@reachready.co.uk or call +44 (0) 207 901 1444.