Comparative Assessment

Introduction

During the evaluation of an application for the approval of an active substance under the Biocidal Products Regulation (BPR), the European Chemicals Agency (ECHA) will establish an opinion as to whether the substance meets the criteria to be considered a 'candidate for substitution'. If this criteria is met, then subsequent applications for the authorisation of biocidal products containing this active substance will be subject to a process of 'comparative assessment'. This process involves the evaluating Member State competent authority assessing the product against other authorised products of the same product-type, as well as non-chemical controls, in order to establish whether an alternative prevention method exists which "*presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages*". If such an alternative is identified, and there is sufficient diversity of active substances used in the given product-type to minimise the occurrence of resistance in the target species, the making available on the market of the biocidal product will be prohibited or restricted.

Candidates for substitution

For an active substance to be identified as a 'candidate for substitution', it must meet one of the criteria given in Article 10(1) of the BPR. These criteria are:

- Meets one or more of the exclusion criteria listed in Article 5 (Category 1A or 1B CMR; PBT; vPvB; or considered as having endocrine-disrupting properties);
- Classified, under the CLP Regulation, as a respiratory sensitiser;
- Acceptable daily intake, accurate reference dose or acceptable operator exposure level significantly lower than the majority of approved active substances for the same product-type and use scenario;
- Meets two of the criteria for being persistant, bioaccumulative and toxic (PBT) under the REACH Regulation;
- Gives reason for concern linked to the nature of the critical effects which, in combination with the use patterns, amount to use that could still cause concern, such as high potential of risk to groundwater, even with very restrictive risk management measures;
- Contains a significant proportion of non-active isomers or impurities.

Before providing an opinion to the Commission on the potential approval of an application, ECHA will establish whether any of the given criteria are met and, if deemed to be, the substance will be the subject of a public commenting period. Information provided during this period will be taken into account in the opinion provided by ECHA. Where an active which is a candidate for substitution is approved, the approval period will be limited to a maximum of 7 years.

Comparative Assessment

The comparative assessment itself is carried out during the evaluation of an initial application for product authorisation, or an application for the renewal of an existing authorisation. As such, it is the receiving competent authority (in the case of a National Authorisation) or the evaluating competent authority (in the case of a Union Authorisation) who will undertake the evaluation. Where the comparative assessment poses a question relevant to more than one competent authority or the consequence of a decision may be felt at Union level (e.g. second-generation anticoagulants), the question may be referred to the Commission.

Although the comparative assessment is the responsibility of the Member State, the competent authority may require the applicant to submit additional information to assist in the evaluation of alternatives, whilst ECHA will also organise a public consultation to allow interested third parties to submit information on available substitutes. With this in mind, and whilst not a requirement, an applicant whose product will be subject to comparative assessment may wish to include in their application further information which will assist in establishing that the benefits of the product outweigh the risks associated with its use.

Approval

Article 23(3) of the BPR states that:

"*The receiving competent authority or, in the case of a decision on an application for Union authorisation, the Commission, shall prohibit or restrict the making available on the market or the use of a biocidal product containing an active substance that is a candidate for substitution where the comparative assessment…demonstrates that both of the following criteria are met:*

(a) for the uses specified in the application, another authorised biocidal product or a non-chemical control or prevention method already exists which presents a significantly lower overall risk for human health, animal health and the environment, is sufficiently effective and presents no other significant economic or practical disadvantages;
(b) the chemical diversity of the active substances is adequate to minimise the occurrence of resistance in the target harmful organism."

Where these criteria are not both met and the authorisation is granted, it will be for reduced period of up to 7 years. It is possible however, for such a product to be authorised for a period of up to 4 years without a comparative assessment if an exceptional case and the comparative assessment cannot be undertaken without first gaining experience through using the product in practice.

Need further help?

If you manufacture or import biocidal products, the approval of which will be subject to comparative assessment, 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.