Transitional Measures

Introduction

On 1 September 2013, the European Commission implemented the Biocidal Products Regulation (BPR), in doing so repealing the Biocidal Products Directive (BPD) and the Member States' national legislation implementing it. The new Regulation retained the basic principle of the Directive – that the permissioning regime is a two-step process involving first the approval of active substances and then the authorisation of biocidal products – however it also introduced new processes and broadened the scope. Whilst the transition from the BPD to the BPR was largely smooth for applicants therefore, a number of transitional measures needed to be put in place to ensure the transition of applications submitted under the Directive to the evaluation process of the Regulation.

These transitional measures are covered under Articles 89-95 of the Regulation and are summarised below.

Approval of Active Substances

The Biocidal Products Regulation defines two groups of active substances. Existing active substances are those that were on the market, as an active substance of a biocidal product, on 14 May 2000 for any purposes other than scientific or process-orientated research and development. New active substances are those which were not. Applications for existing active substances were submitted under the Biocidal Products Directive and, whilst some active substances were approved under that Directive, many applications are still to be evaluated.

For those active substance dossiers which have not yet been evaluated, a programme has been developed to ensure the review is complete by 2024. This program is structured so that active substances incorporated into the same product type are evaluated in the same year allowing, therefore, for a similarly structured approach to the authorisation of biocidal products. As these applications were submitted to comply with the requirements of the Biocidal Products Directive, but are being reviewed against the requirements of the BPR, it is possible that there will be required data missing from the dossiers. Where such a case occurs, the applicant will be given the opportunity to provide the additional information required.

As well as the above stated transitional measures relating to the evaluation of submitted dossiers, measures also exist under Article 95 of the Regulation concerning access to these dossiers by other applicants. This provision is intended to prevent so called 'free-riders' from benefitting from the time and expense put in by applicants, without paying fair compensation. Those manufacturers or importers who wish to place an active substance on the market for use in a biocidal product type must submit to ECHA either a dossier for that active substance, or a letter of access to such a

dossier. Those organisations who have done so, either under the Biocidal Product Directive, or subsequent to 1 September 2013, will be identified on a list of 'approved active substance suppliers' maintained by ECHA and accessible online.

Authorisation of Biocidal Products

As, under the BPR, biocidal products cannot be placed upon the market unless the active substances have been approved, and approval of all existing active substances is not going to be completed until 2024, an unintended market freeze would have been the consequence for certain products unless transitional measures were in place. These measures, detailed under Articles 89-93 of the BPR, allow biocidal products containing an active substance which is still under review to continue to be made available on the market provided applications for their authorisation are submitted no later than the date of approval of the last active substance for that product type. If no application for authorisation is made, the biocidal product shall no longer be made available on the market with effect from 180 days after this date, whilst disposal and use of existing stocks may continue until 365 days after this date.

The authorisation of any biocidal products granted in accordance with the Biocidal Products Directive remains valid until the expiry date of the authorisation, however in the case of applications submitted under the BPD for which the evaluation has not yet been completed the applicant may be required to submit further information.

Finally, there are some biocidal products which fall under the scope of the BPR but were not under the scope of the BPD, such as those generated from devices when no precursors are placed on the market. For such products, available on the market on 1 September 2013 and where existing active substance approval has already been granted, an application for authorisation must be submitted by 1 September 2017.

Treated articles

Unlike active substances and biocidal products, treated articles were not within the scope of the Biocidal Products Directive. A transition period is therefore created to allow those who were placing treated articles on the market when the Biocidal Products Regulation came into force (1 September 2013) to bring their products, and themselves, into compliance. For such manufacturers and importers an application for the approval of any active substance/product-type combination used for a treated article, and not currently supported in the review programme, must be made by 1 September 2016. If such an application is not made, the treated article must be removed from the market by 1 March 2017.

Finally, if the active substance/product-type combination is subject to a non-approval decision, the treated article must be removed from the market by the 1 September 2016 or 180 days following the decision – whichever is later.

Need further help?

If you submitted an application for the approval of an active substance or authorisation of a biocidal product under the BPD, or import materials which may have undergone biocidal treatment, why not contact our helpdesk to see how you are affected by the BPR. Email us at enquiries@reachready.co.uk or call +44 (0) 207 901 1444.