Biocides and the REACH and CLP Regulations

Introduction

Although REACH and CLP are applicable to almost all substances manufactured and placed on the market in the EEA, certain product types are controlled by more specific chemical management legislation. Where this occurs, it can create confusion as to which elements of REACH and CLP are still applicable to the substances or mixtures involved. Examples of such materials include pesticides, cosmetics, food ingredients and – the focus of this guidance – biocidal products.

Biocidal products are used to protect humans, animals, materials or articles against harmful organisms such as bacteria and pests through the action of active substances within the product. The Biocidal Products Regulation, No 528/2012 ("BPR") took effect on 1 September 2013 and repeals the previous Biocidal Products Directive (Directive 98/8/EC). Under the BPR the active substance(s) in the biocidal products must be approved for the product type in which they are used. The European Commission maintains a 'Union' list of approved substances[1]. Also, suppliers must have their biocidal product authorised before they can be placed on the market – unless the active substance(s) is still under review, in which case an authorisation would be required once the review is completed.

Companies wishing to place biocidal products on the market can apply for product authorisation at National or Union level. They may also apply for approval of a new active substance by submitting a dossier to ECHA which includes data relating to the health and environmental effects of the substance and information on intended uses.

Registration under REACH

REACH requires any legal entity in the EEA that manufactures or imports substances – on their own or in mixtures – in quantities of one tonne or more per year, to register those substances. Where the substance in question has already been approved under the BPR, however, the information required to be submitted as part of a REACH registration would be a duplication of the dossier already submitted.

Approved active substances listed under the BPR are therefore considered to be already registered under REACH, however it is only for the use in the biocidal product type for which it is approved that the substance is deemed to be registered. If a company manufactures or imports a substance which is approved under the BPR, but places it on the market for another intended use, and does so in quantities of one tonne or more, then REACH registration for this use will still be required. For example, if a company manufactures or imports 10 tonnes per year of boric acid, four tonnes of which is used in biocidal products and six tonnes of which is used in other applications, there will be a requirement to register six tonnes despite the fact that boric acid is approved as an active substance under the BPR.

Prior to the entry into force of the BPR, the Biocidal Products Directive defined and identified 'existing active substances' which are being reviewed for inclusion in the list of approved active

[1] http://ec.europa.eu/environment/chemicals/biocides/active-substances/approved-substances_en.htm

substances. The quantity of those active substances manufactured or imported for use in biocidal products and included in this review program is also exempt from REACH registration. To benefit from the exemption, the manufacturer or importer must ensure they are on the list of companies as set out in Article 95(2) of the BPR.

The exemption from registration also only applies to the active substance within a biocidal product, not co-formulants. Therefore an importer of a biocidal product will be required to register any substances other than the active substance which are imported in quantities of one tonne or more per year. They will also need to gain BPR authorisation to place the biocidal product on the market.

Notification to the Classification and Labelling Inventory under CLP

Legal entities must notify to the Classification and Labelling (C&L) Inventory substances which they place on the market and either:

- ✓ Manufacture the substance and it is subject to registration under the REACH Regulation; or
- ✓ Import the substance – on its own, in a mixture or in an article where there is intended release – and it is subject to registration under the REACH Regulation; or
- ✓ Manufacture or import the substance and it is classified as hazardous, irrespective of the quantity; or
- ✓ Import a mixture which contains the substance that is classified as hazardous and is present above the relevant concentration limit, which results in the classification of the mixture as hazardous according to CLP.

The notification must be submitted within one month of placing the substance on the market.

Active substances contained in biocidal products are regarded as registered under REACH. However, where the respective dossiers do not contain the information required for notification in accordance with CLP Article 40, the legal entity placing the substance on the market is required to submit a separate notification to the C&L Inventory.

Any substance imported as co-formulants within a biocidal product, which contributes to the classification as hazardous, also needs to be notified.

Authorisation and Restriction under REACH

One of the principle aims of REACH is the substitution of high-risk substances with safer alternatives, through the processes of Authorisation and Restriction. Under the Authorisation process, Substances of Very High Concern (SVHCs) may be added to Annex XIV of REACH. The inclusion of a substance on this Authorisation List requires anyone who places on the market or uses that substance, on its own on in mixtures, to obtain (or be covered by) an authorisation to do so. The use of substances in biocidal products, both as active substances and co-formulants, is exempt from this process however, and thus the substances may continue to be used – provided the biocidal product has, as and where required, been authorised under the BPR.

Restrictions are a different matter, and manufacturers, importers and suppliers of biocidal products must comply with any restrictions placed upon their ingredients in Annex XVII of REACH.

Hazard communication under REACH

REACH requires suppliers of both substances and mixtures to inform their recipients of both hazard information and suitable measures to control any risks. For industrial and professional

uses, this communication is through the safety data sheet (SDS), compiled in accordance with Annex II of REACH, and those who supply active substances for inclusion in biocidal products, or biocidal products themselves, must also comply with this requirement.

For substances which have been registered in quantities of 10 tonnes or more per year the REACH registrant was required to create a Chemical Safety Report. Where the substance is hazardous, this 'CSR' elaborates the risk management measures to be utilised to achieve adequate control of exposure in a given use. These risk management measures are communicated downstream in the form of an 'exposure scenario' supplied as an annex to the substance SDS, thus creating an extended SDS. Distributors must pass on relevant exposure scenarios when compiling their own SDS; formulators of mixtures must include relevant exposure scenarios when compiling their own SDS. Although the active substance in a biocidal product will not have a REACH Chemical Safety Report (and therefore will not have an extended SDS) if a formulator of a biocidal product receives an exposure scenario for any of the co-formulants in their mixture, they must include it in their SDS for that mixture, either by including them in an annex, or incorporating the information appropriately into the main sixteen sections.

Labelling under CLP

Article 69 of the Biocidal Product Regulation states specific elements that must be included on the labels of biocidal products authorised under the BPR. Inclusion of this information does not absolve the supplier of their duty to label hazardous mixtures in accordance with the CLP Regulation, however. Rather, the required elements under the BPR should be included in the supplemental label information allowed for under CLP.

The BPR doesn't just set labelling requirements for biocidal products however; it also sets requirements for the labelling of substances or mixtures which have been treated with a biocidal product, so called 'treated articles'. If any claim is made by the supplier as to the effect that biocidal product has on the 'treated article', or the conditions of the approval of the active substance require it, then additional labelling is required under article 58(3) of the BPR. Such a claim may be, for example, 'contains a preservative to prevent microbial deterioration' appearing on a paint product treated with an in-can preservative.

N.B. For any treated articles imported into the EEA, it must be ensured that the active substance within the biocidal product used to treat them has been approved, or is in the review program for the particular product type.

Articles

Whilst most articles are outside the scope of CLP, the REACH Regulation looks to track the usage of, and potential exposure to, chemical substances throughout their lifecycle including any eventual inclusion in articles. There is a registration requirement placed on those who import articles containing a substance intended for release which is present in quantities exceeding one tonne per year. In addition, there are communication requirements around SVHCs: suppliers of articles are obliged to inform their recipients of their presence above 0.1% by weight and provide (as a minimum, the name of the SVHC) information on safe use; importers and producers of such articles must also notify ECHA where these goods contain more than one tonne per year.

Under the BPR, there are also obligations relating to articles. First, if an article has a primary biocidal function (for example a mosquito net treated with insecticide, or an antibacterial wipe), the article is regarded as a biocidal product and must be authorised under the Regulation. Second, duties under the BPR apply also where an article is treated with a biocidal product but where it either gives no biocidal function to the article, or the function provided by the treatment is

secondary to the primary function. Articles which fit this second criterion are termed 'treated articles' and there are two requirements placed on those that produce or import them:

- ✓ The active substance within the biocidal product used to treat them must have been approved, or is in the review program, for the particular product type;
- ✓ If any claim is made about the effect of the treatment on the article (for example, contains a preservative to control wood-destroying insects), then labelling of the article is required. The label must include a statement that the article has been treated with a biocidal product; the name of the active substance within that product, and any precautions required for safe use. Any such claim must also be substantiated through efficacy testing.

Need further help?

If you manufacture or import biocidal products, or you import articles 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.