

Biocidal Products Regulations

Members may be aware of the Biocidal Products Directive (BPD), in relation to biocides, but may not necessarily have a clear understanding of how the relevant new Biocidal Products Regulations (BPR) are changing from 1st September 2013. This factsheet provides some background details and signposts Members to the relevant HSE website for more information: <http://www.hse.gov.uk/biocides/index.htm>

It is important that Members familiarise themselves with the new EU BPR (EU 528/2012) as this will replace the Biocidal Products Directive (BPD) 98/8/EEC. The BPD and now the EU BPR covers a very diverse group of products, including disinfectants (as well as pest control products and preservatives).

The EU Biocidal Products Regulation

In brief, the EU BPR operates in two stages. First, chemicals known as active substances are assessed on the risks to health, or the environment that they pose when used in biocides. If the risks are found to be acceptable, a decision is taken at EU level whether to approve the active substance and include it on the Union list of approved active substances. Once a substance is on the Union list, companies may apply for authorisation to sell biocidal products (formulations containing the substance that actually goes on the market) in individual Member States, or at EU level, through the European Chemicals Agency (ECHA).

If a decision is taken not to approve the active, then biocidal products containing that substance as an active ingredient must be phased out of the market, by any date specified in the non approval decision.

Whilst the review of the active is ongoing for a particular product type, then products for that usage continue to be regulated under national legislation. In the UK, general disinfectants do not require approval under pesticides legislation for which HSE is responsible (e.g. Control of Pesticides Regulations - COPR) and hence HSE will not have a list of approved PT2 disinfectants (see next page for more details on PT2). Whilst PT2 disinfectants do not require approval under COPR, as discussed on the HSE website, there is still the requirement that the products comply with general chemicals legislation (e.g. Classification and labelling), comply with biocides advertising legislation, that information is supplied to the National Poisons Information Service, and they may need to declare liability for the General Industry Charge.

There are currently no active ingredients for PT2 which have been included onto the Union list and hence as biocidal products only require authorisation under EU BPR when the active in them has been included onto the Union list for that particular product type, HSE do not have any disinfection products currently authorised under EU BPR for PT2.

The new EU Biocides Regulation (EU 528/2012) concerns making available on the market and use of biocidal products. The EU Biocides Regulation can be found at:

<http://eur-lex.europa.eu/LexUriServ/LexUriServ.do?uri=OJ:L:2012:167:0001:0123:EN:PDF>



Whilst the new EU Regulation will bring in a number of changes, the key issue of the assessment of the active, and the subsequent authorisation of the biocidal product will continue as at present, therefore SPATA members may notice little change after September 2013 (when the new EU Regulation applies).

Members should, however, note Article 95 of the EU BPR and its requirements to notify ECHA as alternate suppliers of active substances.

What is PT2?

For information, in Annex V to the EU BPR, the biocidal products are classified into 22 biocidal product-types (PT), grouped in four main areas and swimming pools are classified within PT2 (Disinfectants and algacides not intended for direct application to humans or animals). PT2 is defined as

“Used for the disinfection of surfaces, materials, equipment and furniture which are not used for direct contact with food or feeding stuffs. Usage areas include, inter alia, swimming pools, aquariums, bathing and other waters; air conditioning systems; and walls and floors in private, public, and industrial areas and in other areas for professional activities”

The list of Authorised products that can be used for PT2 can be found at <http://www.hse.gov.uk/biocides/bpd/approved.htm>

Details of the Product Types can be accessed via the ECHA website at: <http://echa.europa.eu/regulations/biocidal-products-regulation/product-types>

Knowing what products, if any, may be at risk from a non-inclusion of the active ingredient (which would require removal of the biocidal product containing it as an active ingredient from the market) will be important as failure to comply with the EU BPR and the conditions of authorisation, may be an offence under the Health and Safety at Work etc. Act 1974 or under the Regulations.

Please note that in terms of the use of copper, a “non inclusion” decision has been taken under BPD the implications of this decision can be found at - <http://www.hse.gov.uk/legionnaires/faqs.htm#silver-copper-systems>. Discussions are ongoing with respect to the essential use application for copper in swimming pools and spas.

The HSE website contains a wealth of information and FAQ's on biocidal products and Members are encouraged to view: <http://www.hse.gov.uk/biocides/eu-bpr/index.htm>

Alternatively, if Members have a specific enquiry that is not covered in the HSE' FAQ's section, then they may wish to email biocides@hse.gsi.gov.uk

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