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THE BIOCIDAL PRODUCTS REGULATION (BPR) AND WATER TREATMENT

This article, written by BACS (the British Association for Chemical Specialities), gives some insight into aspects of the Biocidal Products Regulation, the regulatory regime for biocides in the EU, and its relevance to the water treatment sector.

A biocidal product, broadly speaking, is one which controls harmful or unwanted organisms through chemical or biological means. Common examples of such products are disinfectants, wood preservatives, insect repellents and the biocides used in water treatment. The BPR, just as its predecessor the Biocidal Products Directive did, sets out rules for the authorisation of biocidal products to allow them to be made available on the market and to be used in the applications they are intended to be used in, as well as rules for the approval of their active ingredients, in order to ensure a high level of protection for human health, animal health and the environment.

Under the BPR the use applications of biocidal products are classified into 22 product types (PTs), the main PTs and their scope concerning water treatment being as follows:

PT 2	Disinfectants and algaecides not intended for direct application to humans or animals, with usage areas including, inter alia, swimming pools
PT 5	Drinking water disinfection
PT11	Preservatives for water and other liquids used in cooling and processing systems
PT12	Products used for the prevention or control of slime growth on materials, equipment and structures used in industrial processes

As well as biocidal products, articles treated with or incorporating biocidal products, referred to as Treated Articles, fall within the scope of the BPR, examples being some water fittings introduced in recent years especially targeted at healthcare facilities.

The first phase of the BPR concerns the active ingredients used in biocidal products, referred to as Active Substances. All existing Active Substances used in biocidal products must be in the "Review Programme" of the BPR which ultimately leads either to their Approval, allowing them to remain available on the market, or non-Approval and their ultimate withdrawal. To ensure that all sources of Active Substances are supported by dossiers with data on the active substances, Article 95 of the BPR prohibited from 1st September 2015 the making available on the EU market of a biocidal product unless the active substance supplier is included in a list, referred to as the Article 95 list, for the PT to which the product belongs.

There is an exception to this prohibition where, and cases of this are rare, the chemical description of an Active Substance has been redefined since its inclusion in the Review Programme and as a consequence it is not yet included in the Article 95 list. Subject to certain criteria, such a substance may continue to be sourced even though absent from the list.

Apart from this exception, if your supplier of an active substance is not on the Article 95 list as a supplier of that active substance for the product type that covers the intended use of your biocidal product, then it is illegal to use the active substance supplied by that supplier in the biocidal product. Whilst this applies to those who formulate their own products, the principle extends to those who buy them in, and it is important to note that the point of compliance is the making available on the market of the biocidal product.

The Article 95 list of active substances and suppliers can be found on the website of the European Chemicals Agency (ECHA), which, along with authorities in EU member states, manages the implementation of the BPR. An internet search for "ECHA Article 95 list" will provide a link to access the list, which is updated regularly and, therefore, worth checking from time to time.

The second phase of the BPR is the authorisation of Biocidal Products. Once the ECHA Biocidal Products Committee has issued an opinion on an active substance, having evaluated the dossier submitted on it, an Approval date will be set by which date dossiers must be submitted for all biocidal products containing this active substance, for the relevant PTs, to an EU member state Competent Authority (CA), such as the HSE in the UK. In cases where a biocidal product contains more than one active substance, the submission date deadline is the last Approval date for the active substances in the biocidal product.

The compilation of a dossier for a biocidal product requires a substantial amount of information on the chemistry of the product, including Human Health Risk Assessments, Environmental Risk Assessments and efficacy data, to demonstrate safety and effectiveness against target organisms. These data must support any claims made for the biocidal product. For example, if no data are submitted for efficacy against legionella then no claims regarding the control of legionella may be made for the product.

It is also a requirement, for the evaluation of the product dossier, for it to provide data on the active substance. If this data is not in the possession of the submitter of the biocidal product dossier, permission must be obtained from the supplier of the active substance for the CA to access the supplier's data to evaluate the biocidal product dossier, this permission being referred to as a Letter of Access.

The BPR provides for various ways of making a product available on the market. The submission of a biocidal product dossier allows the applicant to maintain control of all branding and product names on the packaging. This of course comes at a high cost. There are alternatives to the full submission route and these usually include working closely with your supply chain. One such alternative is known as a Same Biocidal Product Authorisation. With this, the applicant has an identical product to that of the supplier he is being supplied by but becomes the person holding the Authorisation. This gives a degree of freedom over what is actually placed on the market and, more importantly, the opportunity to make minor changes over time. This route requires a letter of access to the supplier's product dossier. A further alternative is to "piggy back" on the supplier's Authorisation by using "parallel trade" where the Authorisation holder lists the seller's brand on his own Authorisation. This is probably the lowest cost route but it must be remembered that the seller is never the Authorisation holder and that the Authorisation holder's details must appear on the packaging.

Some may choose to resell branded products the authorisations for which are owned by others and lose their own branding in the market.

Whichever route is chosen, products can only be used in accordance with their Authorisation which may mean changes to applications products are sold for and methods of dosing.

The above gives a picture of some elements of the BPR, whose impact is now being felt by BACS Water Treatment Group (WTG) members, who include active substance manufacturers, blenders and service providers. Whilst Approval dates have still to be determined for some Active Substances in the Review Programme, focus has moved to the authorisation of biocidal products themselves. The Approval dates, past and future, for some Active Substances of interest to the water treatment sector and, therefore, the deadlines for the submission of dossiers for the authorisation of Biocidal Products based on them, for the main water treatment (and other) PTs, are shown in the table below.

Active Substance	PTs	Deadline
Iso-propyl alcohol	2 (also 1 & 4)	1 July 2016
Glutaraldehyde	2, 11 & 12 (also 3, 4 & 6)	1 October 2016
Hydrogen peroxide	2 & 5 (also 1, 3, 4 & 6)	1 February 2017
Mixture of CMIT and MIT	2, 11 & 12 (also 4, 6 & 13)	1 July 2017
Peracetic acid	2 & 5 (also 1, 3, 4 & 6) 11 & 12	1 October 2017 1 July 2018

If a biocidal product dossier deadline is missed, the product supplier can continue to supply the product for 180 days, after which the end user has a further 185 days to stop using it, unless of course the biocidal product contains a second active substance with a later deadline for product dossier submission. Whilst a dossier can be submitted after the deadline, this product withdrawal process still applies resulting in the product effectively being off the market for around three years.

BACS sector groups, particularly the Biocides and Biosciences Group (BBG) regarding the BPR, provide forums for discussing developing regulatory issues and to help members understand regulatory requirements, such as the process for biocidal product dossier submission and what needs to be done both in principle and in detail.

As well as providing members with a wide range of information, BACS represents their interests by working to shape and mitigate the impact of legislation and regulatory policies through engagement in the UK and involvement at the European level. Data demonstrating the efficacy of a biocidal product is a key element of a product dossier. BACS has been, and continues to be, very active in the development of efficacy guidance for the product types relevant to the water treatment sector, such as PT11, which includes biocides used for cooling towers and closed systems, via its involvement with both EBPF, the European Biocidal Products Forum sector group of Cefic, the main voice of the chemical industry in Europe, and CEN, the European Committee for Standardization, the European organisation which develops test methods and standards.

And of course there is Brexit. BACS has been working since the referendum to try to shape Brexit negotiations and the post-Brexit landscape, directly with BEIS and Defra, and with other associations in the Alliance of Chemical Associations. In the context of the BPR post-Brexit, the mutual recognition of Active Substance Approvals and Biocidal Product Authorisations and options for a selective approach to the implementation of the BPR in the UK in areas not relating to requirements for trade with the EU, where regulating differently would benefit companies operating in the UK, are examples of key considerations.

So in conclusion, as the choice of biocidal active substances in the formulator's armoury continues to be reduced, BACS remains active at both the UK and EU levels in lobbying to try to influence the implementation of the BPR and the post-Brexit landscape to the benefit of members' interests.

The British Association for Chemical Specialities (BACS) is a trade association whose members operate in the speciality chemicals sector of the chemicals supply chain.
BACS has around 130 members, from multi-nationals to SMEs and sole traders, including chemical manufacturers, ingredient suppliers, product formulators, distributors, retailers and service providers.
BACS operates a range of sector groups to cater for the diversity of members' interests, one being the Water Treatment Group (WTG), which provides a forum for members manufacturing and supplying speciality chemicals, equipment and support services for all aspects of water treatment to keep abreast of and influence legislation and industry standards which affect their businesses. The WTG chairman, Tom Laffey, will be known to many WMSoc members.

More information on the Association and membership may be found on its website at:

www.bacsnet.org

or from the BACS office at:

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