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PEER REVIEWED

The Authorisation of Biocidal Products under the BPR

KEYWORDS: Biocides, Biocidal Products Regulation, BPR, Regulation (EU) 528/2012, Biocidal Products Directive, BPD, 98/8/EC, biocidal products, biocidal product authorisation, national biocide authorisation, Union authorisation, mutual recognition, simplified authorisation.

Abstract Over recent years the legislation concerning the placing of biocidal products on the market within the EU has changed significantly. We are seeing the gradual transition from national requirements to a harmonised European system of regulation. While the new EU wide system is based on a two phase approach, initially focussing on active substances, the second phase of this process is now impacting many companies who place formulated biocidal products, such as disinfectants, on the market. The change over from the diverse national approval systems to the BPR product authorisation process is triggered by the approval of the active substances that a product contains and product authorisation will now become essential if existing products are to remain on the market or before new products can be launched.
While certain biocidal products have traditionally been regulated under the old national rules in some Member States, the BPR requirement for product authorisation will impact all biocidal products that fall within scope of the BPR and represents a major change particularly for some products that may only have been lightly regulated in the past. As such, the requirements for BPR product authorisation can represent a significant challenge for companies who market these types of products. This article examines the process of product authorisation and some important considerations when planning to place a biocidal product on the market.

INTRODUCTION

Historically the regulation of biocidal products has varied considerably within the various Member States of the EU. Nationally some groups of product such as rodenticides and insecticides have been regulated in most Member States, other types of biocide such as disinfectants and preservatives have been regulated in some Member States but not in others. Even where different Member States have had systems in place for biocidal products, the requirements have not been consistent and have varied considerably from country to country.

Because of this lack of a level playing field within the EU a harmonised system of control was proposed in the early 1990's along the same lines as the harmonised system for agricultural pesticides (1). This draft non-agricultural legislation was introduced as the Biocidal Products Directive (2), or BPD, which was published in 1998 and implemented in Member States on 14 May 2000. The BPD was subsequently repealed and replaced by the Biocidal Products Regulation, or BPR (3), in 2012. The BPD and the BPR are both based on a two phase process. The first phase involves the evaluation and assessment of active substances. This process was originally expected to be completed over a 10 year period with completion in 2010, but this timeline was extended initially to 2014 and, more recently, under the BPR to the end of 2024. While active substances remain under evaluation the existing national rules for biocidal products remain in Member States with only certain aspects of the BPD/BPR having effect.
The second phase of the European biocide legislation impacts biocidal products directly. Once an active substance successfully completes its evaluation and a positive decision is made regarding its safe use in biocidal products, a deadline is set for product dossiers to be submitted for all biocidal products that are based on that active substance. Under the BPR this deadline is referred to as the Approval date for the active substance and this is published in the Official Journal of the EU as an Approval Regulation. For products that are based on more than one active substance, it is the Approval date for the last active substance in the formulation to be approved that triggers the deadline for product authorisation. A phased active substance submission timetable was used based on the product type in which the active substance is used (starting in 2004 and running through to 2008).

The timing of active substance approval has been reflected in the timings for product authorisation, with active substances that were submitted earliest (e.g. wood preservatives and rodenticides) tending to gain approval first. Other factors have impacted when an active substance was approved such as the resources available to the evaluating member state and where additional data have needed to be generated. Because of this, active substance approvals have been staggered. Under the BPR the Biocidal Product Committee (BPC) of ECHA must come to an opinion on an active substance. The likely timing of this can be determined from the BPC working programme which is published on the ECHA website; the website also includes the opinions once they are made. Without going into the legislative details of the process, in principle the Approval Regulation is published approximately 6 months after the BPC opinion (although this can be later) and the approval date is 24 months after the BPC opinion.

A target has been set for at least 50 active substance / PT ECHA opinions and Commission decisions to be made per year to allow the 2024 completion deadline to be met.

Some of the active substance approval dates in 2016/17 are listed below (not exhaustive):

Active substance	Product Type (PT)	Approval Date (this is the date by which product dossiers must be submitted for products to remain on the market*)	Commission Implementing Decision
Permethrin	8,18	01/05/2016	(EU) No 1090/2014
Propan-2-ol	1,2,4	01/07/2016	(EU) 2015/407
Glutaral (Glutaraldehyde)	2,3,4,6,11,12	01/10/2016	(EU)2015/1759
MIT	13	01/10/2016	(EU)2015/1726
5-chloro-2-(4-chlorphenoxy)phenol (DCPP)	1,2,4	01/12/2016	(EU)2015/1727
Hydrogen peroxide	1,2,3,4,5,6	01/02/2017	(EU)2015/1730
C(M)IT/MIT	2,4,6,11,12,13	01/07/2017	(EU)2016/131
Biphenyl-2-ol	1,2,4,6 & 13	01/07/2017	(EU)2016/105
PHMB	4, 2,3 &11	01/07/2017	(EU) 2016/124 & (EU) 2016/125
Peracetic acid	1,2,3,4,5,6	01/10/2017	(EU)2016/672

*for biocidal products containing a single active substance, for products containing more than one active substance the deadline is triggered by the last active substance in the formulation being approved.

Active substance approvals that are expected to trigger product authorisations in 2017, but where the Approval Regulation has not been published at the time of writing, include Biphenyl-2-ol (PT 3), Formaldehyde (PT3), L(+) Lactic acid (PT1).

Equally important is when active substances are not approved for particular product types as this will mean that products will need to exit the EU market. Recent examples include Triclosan in PT1, 2, 7 & 9 (Decision (EU) 2016/110 & 2014/227/EU), PHMB in PT 1, 6 & 9 ((EU) 2016/109), Glutaral (Glutaraldehyde) in PT 1 & 13 (Decision 2014/227/EU). Once a decision has been published Member States will follow Article 89(2) of the BPR regarding any products that are on the market and the applicable sell through time. This Article states that *'in the case of a decision not to approve an active substance, a Member State may continue to apply its current system or practice of making biocidal products available on the market for up to 12 months after the date of the decision not to approve an active substance in accordance with the third subparagraph of paragraph 1, and may continue to apply its current system or practice of using biocidal products for up to 18 months after that decision'*. This means that products can continue being placed on the market for 12 months with a further 6 months to allow products to be used up.

ECHA also published a list of upcoming deadlines relating to the ability to notify active substances which, for example, had been redefined or were not considered to be active substances under the BPD (4).

APPROVED SUPPLIER LIST (ARTICLE 95)

In addition to containing an active substance that is being supported through the Review programme it is also a requirement of the BPR that, after 01 September 2015, only biocidal products consisting of, containing, or generating a relevant substance, can only be made available on the EU market if the substance supplier or product supplier is included in the approved supplier list (Article 95 list) for the product type to which the product belongs. This list is regularly updated by ECHA and can be found on the ECHA website.

PRODUCT AUTHORISATION OPTIONS

Under the BPR there are a number of options available for product authorisation. These include:

National authorisation and mutual recognition
Companies planning to sell their products in one EU Member State must apply for product authorisation in that country. The Member State competent authority evaluates the application and makes a decision on the authorisation within 3 years of the date of approval.

If a company wishes to extend the national product authorisation to other markets, it can ask other Member States to recognise it. Companies can apply for mutual recognition (MR) either in sequence or in parallel. To apply for MR in sequence, a company will first need to get their product authorised in one Member State. After this, they can request other Member States to recognise this authorisation.

For MR in parallel, the company can submit an application for product authorisation in one Member State (called the reference Member State) and simultaneously ask other countries to recognise the authorisation as soon as it is granted. If the concerned Member States do not agree to MR, the case will be referred to the coordination group, which has 60 days to seek agreement. If the coordination group cannot reach an agreement, the matter is referred to the Commission which may ask ECHA for an opinion on the scientific or technical aspects of the case.

Union authorisation (UA)
Certain biocidal products can be authorised at Union level. This will allow companies to place their biocidal products on the market throughout the entire Union, EEA and Switzerland, without the need to obtain specific national authorisations. Union authorisation can be granted to biocidal products with similar conditions of use across the Union, except those containing active substances meeting the exclusion criteria. The timeframe for initiating the authorisation process differs depending on whether the product contains new or existing active substances.

For existing active substances UA will be possible in three different stages, depending on the product-type:
For product-types 1, 3, 4, 5, 18 and 19 - from 1 September 2013
For product-types 2, 6 and 13 - from 1 January 2017
For the remaining product-types (7, 8, 9, 10, 11, 12, 16 and 22) – from 01 January 2020
UA is not applicable to products in PT 14, 15, 17, 20 and 21.

Simplified authorisation
The simplified authorisation procedure aims to encourage the use of biocidal products that are less harmful for the environment, human and animal health. Simplified authorisation applies only to products that contain active substances that appear in Annex I of the BPR (and comply with the specified restrictions listed in Annex I). There are also specific requirements that the product does not contain any substance of concern or any nanomaterials and that its intended use does not require personal protective equipment. In addition the biocidal product must be sufficiently effective.

Same Biocidal Product Authorisation
The Same Biocidal Product Regulation is a similar system to the back-to-back process under the BPD or national requirements. This procedure can be utilised when a biocidal product or product family has been authorised or has been submitted via R4BP, and authorisation is sought for an identical product. The application of the Same Biocidal Product, once submitted will be validated within 30 days. This includes a check of the LoA to the related reference product and review of the specified differences and evidence of being identical on all other aspects between the Same Biocidal Product and the related reference product. The application will be granted or refused within 60 days after the validation of the application, or, where applicable, from the subsequent date of adoption of the corresponding decision concerning the related reference product. The Same Biocidal Product will be independent of the reference dossier with the authorisation number being held by the applicant. The procedure is provided in the Commission implementing Regulation (EC) 413/2013 (5).

Biocidal Product Families (BPF)
Biocidal Product Families build on the 'Frame formulation' concept under the Biocidal Products Directive (BPD). BPF allow for the replacement of a non-active substance with another of the same or lower risk. All products within the biocidal product family are covered by the one authorisation for the family as a whole; each individual product does not have a separate authorisation. There is no limit to the number of products within each family, and no notification is required if a new product is placed on the market as a result of a change in the pigment, perfume or dye, as long as these are incorporated into the biocidal product family composition.

If a new product has a variation in the active or non-active components, already in the biocidal product family composition, there is a 30 day notification period before placing new products in the family on the market.

R&D Permits
Any tests and experiments carried out for research and development purposes using unauthorised biocidal products and their (not approved) active substances must be recorded and may require notifications if a release in the environment is possible.

Parallel Trade Permits
This type of application allows a company to import, and place on the market in a second member state, a product already authorised in another Member State under the BPR, when an identical product is already authorised under the EU BPR in the second member state.

IMPACT OF THE BPR ON PRODUCT AVAILABILITY

It has long been recognised that the BPR will result in a reduction in the number and diversity of biocidal products on the EU market as companies continue to rationalise their product ranges. This is primarily driven by the cost and resources required. A recent AISE/CEFIC survey published in December 2015 (6) indicated that, overall, about 26% of the products currently on the market (covered by the survey) were expected to be withdrawn in the future. The same withdrawal rate was observed across the different biocidal product main groups with the trend equally affecting SME's and large companies.
In addition the survey indicated that 74% of biocidal products expected to be supported in the future would be grouped into families which reconfirms the high interest of industry for the BPF concept, as it enables a considerable reduction of the total number of dossiers to be evaluated in the future, thus reducing the workload for both industry and authorities.
Of concern for smaller national organisations was that the survey indicated that less than 10% of the products currently on the EU market are sold at local level, i.e. only in one or two Member States. Around half of the products are sold in more than 10 countries, i.e. 30% in 11 to 15 Member States, and another 25% in more than 15 Member States. This would tend to suggest the dominance of products sold in many Member States.

The intention to use UA seems to have decreased slightly since the last survey (undertaken in 2011), as in this survey around 44% of the future dossiers (58% individual products and 42% families) were thought to be submitted for UA, versus 56% in 2011. This reduction is thought to be due to the perceived UA costs which are seen as too high by a majority of companies, regardless of their size.

DOSSIER PREPARATION

The BPR product dossier will include specific data on individual products or on product families. This data will include phys chem studies, storage stability data and efficacy studies to support any claims made. These studies must be conducted to strict guidelines and may need to be done under GLP. The product dossier will also include details on the use of the product in the form of specific risk assessments looking at how the product is used and the routes of exposure; this must show that the product use is safe for both humans and the environment before it can be authorised. Typically no data is required with the product dossier on the active substance as this is usually captured in a letter of access from the active substance supplier. It should be noted, however, that the available active substance data may not necessarily be sufficient to cover a specific product's use and additional studies may be required. Because of this, it is advisable to start discussing letters of access and what they cover with suppliers at an early stage.

It is important to realise that generating the required data and risk assessments does take time and should be planned well in advance of the dossier submission date to allow for refinement of risk assessments and reporting of studies. Storage stability tests (depending on the claimed shelf life) can take several years to complete. In addition the importance of efficacy testing should not be overlooked as only products that are sufficiently effective will be authorised. As new efficacy test methods and efficacy guidance are developed it should not necessarily be assumed that products that have been on the market for many years and may have been tested under different methods, will pass the new standards required by the BPR. In some cases this may only result in changes being required to label claims, but under other circumstances can require product reformulation or even product withdrawal.

SUMMARY

The BPR puts in place an EU wide system for the regulation of biocidal products and the active substances that they contain. The system is a two stage process initially focusing on active substance approval followed by the second stage which involves product authorisation. While many of the first active substances that were approved triggered the authorisation of products that have traditionally been heavily regulated throughout the EU (such as rodenticides, wood preservatives and insecticides), more recent approvals are affecting products that may have been only lightly regulated in many Member States. It is important that companies which formulate and supply biocidal products such as disinfectants, water treatment biocides and slimicides track the status of the active substances that they use and plan for how they will approach product authorisation. While the BPR provides a number of options to reduce costs, such as same product authorisations, the use of product families and union authorisation, the costs associated with regulatory compliance are significant and rationalisation of product lines can provide a good starting point for companies with extended portfolios of products.

It is also important to realise that until the time for BPR product authorisation for a particular product, national rules continue to apply in Member States and these must be complied with. Companies should develop strategies for their product authorisations well in advance of the deadline for BPR product submission and determine which is the best regulatory route towards product authorisation for their company and their product ranges.

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