In situ biocides under the BPR

Richard Elsmore and Samantha Wright of JSC International review the regulatory situation for a hitherto ignored class of biocidal systems.

In situ biocides are those biocidal systems where an active substance is generated at the point of use, typically from one or more precursors. They exclude systems where the active substance may be generated via an in situ process during manufacture, which is then bottled for supply to a third party.

The active substance generated from an in situ system is not directly supplied to the user but is generated intentionally via a chemical reaction or other means, such as electrolysis and electrical generation, as a result of direct manipulation on the site of use prior to or during its intended application. As with more conventional active substances the in situ-generated active substance is intended to exert a biocidal activity during its application.

Benefits of in situ biocides

In situ biocides offer many benefits in a wide range of application areas. The active substance is only present at the point of use, as in the case of systems that release an active substance (e.g. releasers of halogens) where the active substance remains bound to a parent molecule until it is needed.

This may allow increased stability in storage or provide more manageable delivery systems where the active substance is released over a longer period of time. In the case of electrolysis systems, such as ozone generated from air or the use of brine in the generation of hypochlorous acid, the precursor does not need to be transported to the point of use.

In the case of more conventional in situ systems where two chemicals are mixed at the point of use, again the active substance is only generated at the point of use and the precursors used may be of low hazard. Typically these systems require sophisticated generating equipment to ensure that the generation and use of the in situ active substance takes place under safely controlled conditions; other systems simply rely on water to activate the generation of the active substance.

Because of these benefits, in situ biocides are widely used in many applications, including swimming pools, industrial water treatment, paper mill slime control and even in anti-bacterial washing powders.

Regulatory background

The regulation of in situ biocides was very unclear under the Biocidal Products Directive (BPD, 98/8/EC). The text of the BPD did not mention in situ biocides specifically, so subsequent guidance documentation tried to provide a framework on how these types of products should be regulated. This guidance proved unclear, resulting in confusion both on the part of industry and of the regulators.1

Under the BPD, certain in situ biocides were deemed to be out of scope, for example those where the precursors were not placed on the market (e.g. ozone generated from the electrolysis of air) or where a general chemical was used, i.e. not one placed on the market as a precursor, such as a stable salt used to generate sodium hypochlorite.

With the introduction of the Biocidal Products Regulation (BPR, 528/2012) a decision was made to include all in situ biocides within the scope of the biocides legislation. The definition of a biocidal product was amended to include active substances that are generated in situ.

Article 3(1)(a) defines a biocidal product as:

- Any substance or mixture, in the form in which it is supplied to the user, consisting of, containing or generating one or more active substances, with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action

- Any substance or mixture, generated from substances or mixtures which do not themselves fall under the first indent, to be used with the intention of destroying, deterring, rendering harmless, preventing the action of, or otherwise exerting a controlling effect on, any harmful organism by any means other than mere physical or mechanical action

The supply of a precursor with the intention that it is to be used to generate an in situ biocide falls under the first definition above, while biocides generated in situ from ambient precursors that are not supplied (e.g. air, seawater) and generated in situ from general chemicals fall under the second definition indent above so all are in scope of the BPR.

Due to the uncertainty surrounding which in situ biocide systems were on the market in the EU, in January 2014 the European Commission (EC) issued a ‘Note for the attention of companies placing on the market or using biocidal products generating active substance(s) and falling within the scope of the BPR’. This called for information on in situ-generated biocidal active substances, in order to identify the systems currently on the market.
Based on over 300 responses the EC published a proposal in May 2014 entitled ‘Management of in situ-generated active substances in the context of the BPR: Way forward on the management of in situ generated active substances in the context of the BPR’. It was intended that this document would provide a system to allow the regulation of in situ biocides but it was not accepted at the May 2014 meeting of Competent Authorities (CAs).

Subsequent proposals were made by the EC and presented at the September 2014 CA meeting. This was subsequently further revised following a workshop held in October 2014 and presented at the March 2015 CA meeting where it was finally accepted. The problems seen in agreeing an acceptable process reflect the complex nature of in situ biocides and the challenges they provide to both regulators and industry.

Despite agreement on most in situ systems the question relating to some specific systems, such as those involving free radicals and photocatalysts, were carried over until the May and September 2015 meetings of CAs.

**Redefinitions & systems not in scope**

As the BPD and subsequent guidance was not clear regarding which in situ systems should have been notified under the Biocides Review Programme, a standard industry approach was not taken, with some companies notifying the active substance and other companies one or more precursors. This resulted in a very inconsistent approach. In many cases, the substance was published in the BPD Review Regulation, providing a poor reflection of what was being supported.²

In the EC document on the management of in situ-generated active substances, the nomenclature of in situ systems is resolved.³ The document proposed that in situ biocides should be defined by the active substance that is formed (e.g. active chlorine, peracetic acid, hydrogen peroxide), followed by the precursors used. In cases where two or more precursors are used, these are specified in the description, for example peracetic acid generated from TAED and sodium percarbonate.

Where only one precursor is used this is also made clear e.g. active chlorine generated from sodium chloride by electrolysis. These systems are listed in Annex I of the EC document. Annex II lists releasers, which are systems where the active substance is released from a parent molecule. These include both halogen releasers and formaldehyde releasers.

The document provides guidance and clarity to determine:

- Precursor(s)/active substance(s)/Product Type(s) combinations that are included in the Biocides Review Programme
- Precursor(s)/active substance(s)/Product Type(s) combinations that are newly in scope of the EBPR and are eligible for inclusion in the Biocides Review Programme under Article 93 of the EU BPR (these were not in scope of the BPD)
- Precursor(s)/active substance(s)/Product Type(s) combinations that are eligible for inclusion in the biocides review programme under Article 13 of the Biocides Review Regulation (EC) 1062/2014 following the redefining process (more details below)

Based on the status of an in situ system – existing, new or redefined – it will determine the actions required for these systems to remain on the market.

Existing systems should be covered by current dossiers that have been or are under evaluation. For new systems, companies need to submit applications for approval of the precursor(s)/active substance(s)/Product Type(s) combination by 1 September 2016. If this deadline is met the system can continue to be used until a decision on approval for the combination.

For redefined systems ECHA has published an ‘open invitation’ to allow companies to submit a notification, under Article 13 of the Review Regulation, via R4BP by 27 April 2016. This will allow the relevant precursor(s)/active substance/Product Type combinations to be included in the biocides review programme.

The open invitation includes a table of the precursor(s)/active substance/Product Type combinations eligible for notification. This is not an exhaustive list but notifications are only possible for precursor(s)/active substance/Product Type combinations not already covered by the new redefinition.

**Impact of Article 95**

Article 95 of the BPR is intended to ensure that the costs of generating data and supporting active substances are shared fairly. To this end, the BPR puts in place a system which allows organisations supporting active substances under the review programme and alternative suppliers to appear on a list of companies (the Article 95 list).

The BPR states that, as of 1 September 2015, only biocidal products consisting of, containing or generating a relevant substance, included in the Article 95 list, shall be made available on the market if either the substance supplier or the product supplier is included in this list for the Product-Type(s) to which the product belongs.

The list has been updated to include the redefined in situ system names listed in the EC’s document on the management of in situ-generated active substances. Inclusion of precursors in the Article 95 list depends on two situations which are distinguished depending on the precursor used to generate the active substance:

1. **Active substances generated from one or more precursors supplied with the intention to generate them for a biocidal use.** These precursor(s) will be regarded as biocidal products as they are supplied with the intention of generating an active substance and therefore meet the definition of a biocidal product as laid down in the BPR. In such cases, the provisions of Article 95 apply.

2. **Active substances generated from ambient air, sea water or from precursors not supplied with the intention to generate them for a biocidal use.** These are still regarded as biocidal products as defined under the BPR but as no biocidal product (i.e. the precursor) consisting of, containing or generating a relevant substance is made available on the market, the provisions of Article 95 do not apply.
Compliance with Article 95 is therefore only relevant for precursors supplied with the intention to generate an active substance. For systems (i.e. combination of active substances and precursors) already supported under the review programme of existing active substances, the provisions of Article 95 apply in full to the precursors of these systems from 1 September 2015. For example, for peracetic acid generated from TAED and sodium percarbonate, Article 95 will apply to both precursors when they are placed on the market with the view to generating an active substance.

For systems not supported under the review programme but eligible for taking over under Article 13 of the BPR Review Regulation or for approval under Article 93 of the BPR, the provisions of Article 95 will apply to these precursors from the date of inclusion of such systems in the Article 95 list (i.e. from the date of validation of the application submitted for the approval of a system).

**Summary**

The position of *in situ*-generated active substances and the precursors from which they are generated was very unclear under the BPD. Guidance documentation was developed but in many aspects this guidance was also unclear. Some systems were also deemed to be out of scope of the BPD, such as systems where no precursor was placed on the market.

Under the BPR all *in situ* systems are in scope, including those where no precursor is placed on the market. A process has been put in place concerning how these previously out of scope active substances can now be supported. This does require action from industry to allow these systems to remain on the market.

In an effort to clarify the situation many *in situ* systems have been redefined, requiring action from industry to support those systems so as to ensure that they can remain on the market.

The Article 95 obligations of the BPR are now defined, for systems where the precursor(s) are placed on the market for the intention to generate an active substance then the Article 95 obligations do apply to the precursors and active substance. In cases where systems are being newly supported for example following redefinition, then compliance with the Article 95 list from 1 September 2015 will not apply. It will, however, apply as soon as a ‘complete substance dossier’ has been submitted and accepted.

For those systems where the precursors are not supplied with the intention to generate an active substance (e.g. commodity chemicals) the precursors do not need to appear on the Article 95 list. For example, for chlorine dioxide generated from sodium chlorite by acidification, Article 95 will apply only to sodium chlorite and not to the many acids (considered as commodity chemicals), which can be used to generate chlorine dioxide.

Finally, the introduction of the BPR has introduced new challenges for both industry and regulators not least of which is the regulation of *in situ* biocides. Due to the complex nature of these systems (often comprising a number of precursors), how they should be regulated has proved difficult for both regulators and industry.

*In situ* systems can provide safe and effective biocides which can deliver both safety and operational benefits. The new system of regulation, while providing challenges, will offer a mechanism for inclusion within the regulatory framework presented by the BPR.

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