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# Article 95 and beyond

The establishment of the list of lawful suppliers under Article 95 of the Biocidal Products Regulation (BPR) is a watershed moment. But there remains much to do in building a complete BPR compliance strategy. In this expert article Darren Abrahams, Indiana de Seze, and Blandine Gayral of Steptoe & Johnson look ahead.

Companies that are not listed on Echa's website as an approved supplier or who are not purchasing exclusively from approved suppliers (and are able to demonstrate this) do not have lawful access to the EU market for biocidal products containing the supplied active substance (as provided by Article 95(2) of the BPR). This applies irrespective of whether a company is established in the EU or outside. In the latter case the non-EU company should be included in the Article 95 list via an 'EU representative' (see Echa/NA/14/36, *Non-EU companies to be indicated in the list of biocidal active substances and suppliers*).

Those companies who have not yet been successful in being included in the Article 95 list but who wish to minimise disruption to market access will have to focus on the most effective means to complete steps necessary for listing, including, for example, completing alternative dossiers and/or concluding letter of access negotiations with data owners.

Certain market players have additional transition time to be in compliance:

- active substances contained in certain products not covered by the scope of Directive 98/8/EC (the BPD) but falling under the scope of the BPR - such as those previously subject to a derogation for food and feed that are intended for use as repellents or attractants of product type 19 under Regulation (EC) 1451/2007 or food contact materials falling under the scope of Directive 89/109/EEC replaced by Regulation (EC) No 1935/2004 - available on the market before 1 September 2013;
- *in situ* generated active substances and their precursors which are not part of the Review Programme, and where the BP did not fall within the scope of the BPD; and
- new active substance/PT combinations.

Companies that operate downstream from Article 95 listed suppliers will need to ensure that they can demonstrate to their customers and enforcement authorities that they are part of a compliant supply chain. In supply chains where there are multiple parties this will be a more complex exercise (as it has been under REACH). Many of the 'good faith' statements of intention that were given in the run up to 1 September 2015 will need to be supported by binding written undertakings. In our experience the scope and nature of these undertakings may require some negotiation.

For those active substances contained in certain products not covered by the scope of the BPD, but falling under the scope of the BPR, consortia and other forms of cooperation can be established within the next few months.

As regulators decided to make population of the Article 95 list a 'paper exercise' namely, having the correct letter of access rights or alternative dossier, this in itself, does not ensure that what will be marketed actually corresponds to what is in the dossier under review. Ensuring technical equivalence will remain an essential condition for product authorisation.

## The review programme marathon

The evaluations of 80% of the existing active substance product combinations under the Review Programme remain to be completed. Deadlines apply for the 1st priority list (PTs 14, 18 19 and 21) and the 2nd priority list (PTs 3, 4 and 5) for which evaluating competent authorities (eCAs) must submit reports, by 31 December 2015 and 31 December 2016 respectively.

The Commission has concluded that progress is slow. Evaluating competent authorities have been asked to indicate, to Echa, potential issues that may have arisen in the course of their work that could explain delays. Our own experience has shown that new issues can be raised by an eCA at an alarmingly late stage in the process. Moreover, the potential consequences of such last minute concerns for market access may not always have been fully considered by the eCA. These unwelcome surprises may be exacerbated by the fact that the dossiers under evaluation were submitted with information which addressed the requirements of the BPD, but now face the full force of the BPR (subject to the transitional rules in Article 90).

These new requirements include exclusion criteria (Article 5) and substitution (Article 10). Under the CLP Regulation (EC) No 1272/2008, the classification of active substances feeds into these new requirements. Whilst the parallel procedures under the CLP Regulation and the BPR are intended to be coordinated, we have already seen examples where there is a disconnect between them, since they may involve different competent authorities.

Hazard classifications are sometimes being proposed or reached precipitously, in the absence of additional information that is in the process of being evaluated or even generated as part of the risk assessment process (in response to requests by eCAs). This can result in overly conservative hazard classifications, that in turn, lead to market bans or *de facto* exclusion. For example, CLP guidance on how to address substances that emit other substances during normal use is notably lacking.

This has resulted in classification proposals which ignore "the forms or physical states in which the substance is placed on the market and in which it can reasonably be expected to be used" (contrary to Article 5(1) of the CLP Regulation) and are based on fictitious presumptions about what is releasable in the real world. In the years ahead, we expect to see an increasing number of legal challenges to implementing regulation that classify substances used as actives in biocidal products.

## Treated articles

Many of the issues of concern to industry have been addressed by revisions to the guidance. However, the supply chain will have to focus on verifying that only an article treated with, or incorporating, active substances (contained in the biocidal products) that are "included in the list drawn up in accordance with Article 9(2), for the relevant product-type and use, or in Annex I" are placed on the market (whilst also respecting "any conditions or restrictions specified therein").

These rules apply from 1 September 2016 (as set out in the transitional rules in Article 94). In many cases this will mean that article manufacturers will need to secure undertakings from upstream in their supply chain to ensure compliance. For some companies this will also mean negotiating a change of suppliers.

Beyond the question of what may be used lawfully to treat an article, companies will need to be attentive to the labelling that will have to be attached to their articles. A feature of the BPR is that specific labelling requirements for treated articles may be determined when an active substance is approved, rather than being left to the good judgment of the person responsible for the placing the treated article on the market with a biocidal claim, subject to Article 58(3) of the BPR. The potential for a disproportionate negative impact on the use of certain active substances seems inevitable given the uneven pace at which competing active substances go through the Review Programme.

## Article 3(3): a path to clarity

The BPR presents a long list of interpretative and implementation questions – even after the extensive work on developing guidance from the Commission, Echa and eCAs. The ability to have legally binding interpretations adopted by the Commission is a new and welcome feature of the BPR. Companies have begun to use this mechanism – submitting their requests to Member States who act as gatekeepers to this mechanism. The results generate clarity across the EU market and this is a welcome departure from the more informal approach under the BPD Manual of Decisions and other non-binding Frequently Asked Questions guidance. Those companies who are unconvinced by the decisions issued also have an effective legal remedy against these "implementing acts".

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*The views expressed in contributed articles are those of the expert authors and are not necessarily shared by Chemical Watch.*