Overview
On September 1, the deadline established for active substance and biocidal product suppliers to be on the list of active substances provided by Article 95 of the BPR expired. The European Chemicals Agency (ECHA) published the legally binding list on its website on September 2, 2015. It will be updated again later in September and then on a monthly basis. This has an immediate impact on the ability of all companies to continue to participate lawfully in the European Economic Area (EEA) market for biocidal products.

As of September 1, 2015, those companies who are not an approved supplier or purchasing exclusively from an approved supplier (and able to demonstrate this) do not have lawful access to the EEA market for biocidal products.[1] This applies irrespective of whether a company is established in the EEA or outside. In the latter case the non-EEA company should be listed in Article 95 list via an “EU representative.”[2]

Some companies have been included on a ‘list of pending Article 95(1) applications’ published by ECHA (the Pending List). The Pending List, which is not provided for under the BPR, was intended to “increase transparency for the industry”[3] in the run-up to the legal deadline. It contains information about applications for inclusion on the actual Article 95 List for which ECHA has not yet taken a decision. There are currently over 50 applications on this pending list. This means that these applications can still be rejected (or accepted at a later date) by ECHA. ECHA has taken an average of about 3 ½ to 4 ½ months to assess applications for inclusion in the Article 95 list (though some assessments have taken substantially longer).

The fact that a company is on the Pending List gives no certainty as to a possible inclusion on the Article 95 List in the future – though it shows a commitment to being on the market. The Pending List does not change the legal situation of companies who were not included on the Article 95 List by September 1, 2015, as required by the BPR. Accordingly, national authorities may not lawfully rely on the Pending List to allow the placing on the market of biocidal products incorporating active substances from non-Article 95 List suppliers. However, enforcement practice may provide up to six months for companies to demonstrate compliance.[4]

ECHA itself stresses this lack of legal value or certainty in the explanatory note to the Pending List:

“WARNING: The list of pending Article 95(1) applications creates no legal rights or obligations for the entities listed. The list of pending Article 95(1) applications should not be confused with the [Article 95 List] and the presence of a company (per substance/PT/role) on the list of pending applications does not guarantee that the application will be successful and that the company will ultimately be included in the [Article 95 List].” (emphasis added)

It appears that the Pending List will be maintained by ECHA as an ongoing indication to the market of the progress in the assessment of dossiers which it receives. It will be closely monitored by the supply chain.
Those companies now included in the Article 95 list, and which are concerned about competitors who they know to be in the biocidal product market and not listed on the Article 95 list or are not sourcing active substances from an Article 95 listed supplier, might now consider notifying national enforcement authorities. Consortia, which may often represent all of the lawful sources of an active substance, may be particularly effective in pursuing unlawful free-riding. 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 might consider pursuing the most effective means to complete steps necessary for listing, including, for example, completing alternative dossiers and/or concluding negotiations with data owners.

A small class of market players have further 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

- **New active substances**

Companies who supply active substances or biocidal products falling under the above classes have additional time to achieve compliance. It is expected that these companies aim for cooperating to achieve their objectives in the most efficient and effective manner possible. This cooperation (between competitors) is often pursued within the framework of consortia which should act under clear rules of a consortium agreement.

To discuss your Article 95 and product authorisation needs please contact a member of Steptoe’s Environment & Life Sciences team.

[1] Article 95(2) of the BPR.

[2] “Non-EU companies to be indicated in the list of biocidal active substances and suppliers,” ECHA/NA/14/36.

[3] See the explanatory note on page 1 of the list of pending Article 95(1) applications.

[4] See “Note for discussion with Competent Authorities for Biocidal Products (CA-May15-Doc.4.13-Final)”

**Practices**

**Chemicals**

**Chemicals & Environment**