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Decoding Article 95

Article 95 is the scheme under the Biocidal Products Regulation (BPR) for establishing a list of approved sources of biocidal products. With only a year to go before implementation, clarification on key issues is still required. Darren Abrahams, Indiana de Seze, and Craig Simpson, of Steptoe & Johnson make the case for a re-think.

Although the end of the transitional period for complying with Article 95 of the biocidal products Regulation (BPR) is imminent, key interpretive issues concerning the scope and function of the list of approved active substance and product suppliers remain. Echa's draft guidance on active substances and suppliers, which is currently subject to consultation, has raised concerns about how Article 95 may be administered. However, the agency's position continues to evolve, ahead of the issuing of the final guidance, apparent from its recent announcement that non-EU companies will be included in the final list.

As of 1 September 2015, biocidal products will only be allowed on the EU market if the supplier of either the product or the relevant active substance/product-type combination is included in a list of approved suppliers.

This rule applies to biocidal products, not active substances per se, even though the data access requirements imposed by Article 95 relate to the active substance itself. The prohibition is on making available on the market, which is defined in Article 3(1)(i), as, "any supply of a biocidal product or of a treated article for distribution or use in the course of a commercial activity, whether in return for payment or free of charge".

In most cases, inclusion in the list will result from negotiated agreement. Where no agreement can be reached, Echa may exercise its power to force data sharing pursuant to Article 63(3) of the BPR. This may be invoked within, at a minimum, 90 days from Echa providing the name and address of the data submitter to the prospective applicant. This means that a prospective applicant needs to have been notified of the identity of the data submitter by no later than 1 June 2015 in order to preserve their rights to forced data sharing before the 1 September 2015 deadline. Accordingly, the real deadline is much closer.

Who's list is it anyway?

Article 95 refers to three discernible categories of persons who are eligible for inclusion. They are:

- the data submitter of a "complete dossier", such as those under the Review Programme Regulation (participants), supporters of a new active substance, or "third party" active substance dossiers submitted along with a product authorisation;
- the substance supplier who manufactures in the EU, or imports into the EU a relevant substance, on its own or in biocidal products; and
- the product supplier, who manufactures in the EU or makes available on the market a biocidal product consisting of, containing or generating that relevant substance.

These roles are not mutually exclusive but Echa's draft guidance currently suggests that, while EU data submitters will be on the list, non-EU data submitters will not be able to join. This is not the only possible interpretation of the Article 95 legal text, which distinguishes between data submitters and the other two categories as follows: "For each relevant substance, the list shall also include all persons having made such a submission [i.e. data submitters] or a submission to the agency in accordance with the second subparagraph of this paragraph… [i.e. alternative suppliers who are substance or product suppliers]." However, the agency has recently announced that this position in the guidance will be revised.

How to represent non-EU entities

For now, the draft guidance does not acknowledge the fact that Echa's current provisional list[1] (BiocidesHub 14 April 2014) and the final one to be established serve as an important marketing tool for sellers and buyers to identify legitimate sources. This is understandable, since the agency's function is regulatory not commercial, but the system it develops needs to be sufficiently accommodating of commercial realities. In this regard, non-EU participants and, more widely, those non-EU companies who would want to be listed as alternative suppliers risk being made invisible to the marketplace.

The draft guidance provides that non-EU manufacturers cannot be listed as substance suppliers or product suppliers, as per the legal definition of those roles. However, the importer of an active substance or biocidal product which originates from a non-EU entity could apply to be listed as the "supplier".

This underlines that the BPR has no express equivalent to the "Only Representative" role under REACH, which allows non-EU entities to control REACH registrations via an EU-established representative, and displaces EU importers from having to fulfil a compliance function. The EU legislator acknowledged this as necessary because, while EU importers may be related entities, especially where the non-EU entity is part of a multinational group, this is often not the case for small and medium sized enterprises who may ship to unrelated third parties. Even within multinationals, there may be a reluctance to share information on what is supplied where. Many companies protect this as confidential business information, even within a corporate group.

It is striking that the position in the draft guidance appears to conflict with long established practice. Commission Regulation (EC) No 1896/2000 on the first phase of the review programme already included the idea of a "sole representative" of non-EU actors.

Thankfully, Echa has now indicated that a similar arrangement of representation of non-EU entities will be applied to fill the legislative gap in the BPR. The case is no less compelling than it was under REACH. Indeed, Echa's draft guidance states that the intention of Article 95 is to "ensure the equal treatment of persons placing active substances on the market" and to create a "level playing field […] on the market for existing active substances". So assisting non-EU entities to exploit the EU market makes perfect sense.

The administrative work-around of this issue is only sketched out by Echa. It appears that the list will include "the company names of non-EU entities together with their EU-representatives" and that this will apply without distinction between non-EU companies that are:

- participating in the review programme or supporting new active substances; and
- applying to be alternative suppliers.

Although a welcome development, there is one possible concern about the chosen means of implementation. They will likely reveal supply chain information which should be protected by Echa and national competent authorities under Article 66(2)(c) of the BPR. That provision deems certain information to undermine the protection of commercial interests, including that on "links between a manufacturer of an active substance and the person responsible for the placing of a biocidal product on the market or between the person responsible for the placing of a biocidal product on the market and the distributors of the product".

The most likely choice for a non-EU manufacturer of an active substance who does not have EU affiliates will be to appoint the company who places the substance on the market in a biocidal product. Links between competing EU manufacturers of active substances and those who market products containing them will not have to be disclosed, at least prior to the approval of the active substance in the product. It is not clear why Echa's solution needs to place competitors in a different position based on geographical location.

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1. http://www.chemicalwatch.com/biocideshub/18978

An alternative approach might be to only list the non-EU supplier or manufacturer. The designated EU established representative could be maintained in Echa's records, a measure necessary for enforcement purposes, but need not be declared to the world.

Data sharing implications

Clarification of Echa's approach would help resolve whether the data owner is entitled to refuse requests to negotiate data access where the prospective data accessor is an alternative supplier who is not EU established. The legal definitions in Article 95, noted above, include the notion that such alternative suppliers must be EU established. Notwithstanding the legal text it is a strange outcome given that the non-EU entity may be paying for the letter of access, even if others in the supply chain rely on it. Additionally, the data owner may be a non-EU entity itself. All of this only serves to remind us that the guidance cannot re-write the law but can merely fill in the gaps in a manner which is consistent with it.

Recommendations

Echa's announced change in its administrative practice regarding non-EU companies must be welcomed. It is a further step toward the objective of equal treatment underlying the BPR. However, operators, wherever they are situated, need legal certainty. The current mixture of draft guidance and announcements does not provide this. Given the short period before the list is completed, and the shorter period to conclude negotiations, it is to be hoped that these issues can be resolved promptly. Failure to do so may create opportunities for the Board of Appeal and/or the Court of Justice to address these questions.

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