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Be Ready For Data Sharing Under EU Biocidal Products Rule

Law360, New York (September 24, 2013, 12:15 PM ET) -- Regulation (EU) No 528/2012, known as the biocidal products regulation or BPR, went into effect on Sept. 1, 2013, including several new provisions on data sharing and letters of access. This article seeks to explore some of the pitfalls and difficulties expected in the practical application of these provisions as of Sept. 1. In particular, we review the application of Articles 62 to 64 of the BPR on mandatory data sharing, as well as the transitional provisions of article 95 of the BPR.

In order to avoid unnecessary duplication of animal testing, much like the "inquiry process" under Regulation (EC) No 1907/2006 (the REACH regulation), Article 62 of the BPR requires any prospective applicant intending to perform studies on vertebrate animals (i.e., in need of these studies for the purpose of submitting biocidal product authorization dossiers) to first submit a request to the European Chemicals Agency (ECHA) so that the ECHA can verify whether such tests have already been conducted and, if so, allow the prospective applicant and the original data submitter and/or data owner to enter into contact and negotiate access rights to this data.

The same procedure can also be followed, on a voluntary basis, by applicants wishing to obtain access to data not involving tests on vertebrate animals. The prospective applicant and the data owner then have the obligation under Article 63 to "make every effort to reach an agreement on the sharing of the results of the tests or studies" in question.

Alternatively, the parties can choose to submit the matter to arbitration proceedings. A key aspect of the BPR is that with regard to vertebrate studies, if the parties have not been able to come to an agreement after at least one month has passed since the prospective applicant obtained the contact details of the data submitter or owner from the ECHA, then the prospective applicant may refer the matter to the ECHA, who can then grant permission to the prospective applicant to refer to the requested studies.

The prospective applicant can only benefit from this "forced data sharing," however, if he can demonstrate that every effort has been made to reach an agreement and that he has paid the data owner "a share of the costs incurred" (a payment that cannot be refused by the data owner).

Of course, companies are not required to use the formal process under Articles 62 and 63 to contact data owners, particularly when they already know which companies have the relevant data rights. Also, as in REACH, data sharing is organized in some cases through consortia or other existing data sharing agreements. In most cases, an ECHA decision will not be satisfactory for either party, and they would be better off reaching an agreement.

Indeed, the ECHA can only grant a "right to refer" to the existing studies, and companies wishing to obtain a copy and the right of access to the entire active substance dossier or a given study would not obtain that right from the ECHA. On the other hand, data owners failing to agree would receive only a (probably minimum) share of the data costs and would need to initiate proceedings under national law if they want to obtain a better price for their studies.

It remains, however, that when time is of the essence to submit applications for biocidal products, companies would be well advised to instigate Article 62-63 proceedings sooner rather than later, as the process itself will take some time to be completed, and the right to refer to the active substance dossier/data is a precondition to filing applications for
authorization of the biocidal products containing them for all actors that do not have access to such data.

Another important change brought by the BPR is Article 95, which attempts to establish a level playing field by preventing access to the market for free riders that have not contributed to the data costs associated with the review program for existing active substances started under the framework of the current Biocidal Products Directive (Directive 98/8/ EC, known as BPD).

Essentially, under Article 95, the ECHA will maintain a list of "approved suppliers" from which active substances (and biocidal products) can be obtained. All participants in the review program, i.e., entities that participated in the submission of active substance dossiers under the BPD, will automatically be included in the list of approved suppliers.

Article 95 calls on all EU legal entities holding ownership, a right of access or a right to refer to a dossier or specific data for an existing active substance to submit that information to the ECHA so that they are added to the list of "approved suppliers."

As of Sept. 1, 2015, biocidal products can no longer be made available on the market unless all active substances contained in the biocidal product, or the biocidal product itself, were obtained from an approved supplier included in the Article 95 list.

So far so good? In fact, no. The numerous difficulties in the new application of Article 95 led the commission to propose an amendment to that article. The problem is that this amendment did not enter into force before the BPR becomes applicable on Sept. 1, 2013, but is only likely to be adopted and applicable sometime between the end of 2013 and early 2014, therefore leaving companies in an uncomfortable situation in the interim period.

Without seeking to be exhaustive, below are some of the key issues faced by companies under Article 95 and under the interplay between Article 95 and Articles 62-63 of the BPR:

- Under the previous Article 95, only manufacturers and importers of existing active substances (substance suppliers) could apply to be listed as approved suppliers, only if there were no declared EU substance suppliers for a given existing active substance could importers of biocidal products containing them apply under Article 95 to be listed. By contrast, the revised article 95 will at some stage extend access to the listing to all "product suppliers," including EU formulators of biocidal products. For EU product suppliers, this means that they may have to temporarily import active substances directly or request their EU suppliers to be listed to gain the benefit of such listing.

- Among these benefits, importantly, Article 95 extends the scope of the mandatory data sharing provisions of Article 63.3 (discussed above) to cover not only vertebrate animal studies but all toxicological and ecotoxicological studies. The proposed revision to this article goes even further as it would extend mandatory data sharing to all environmental fate and behavior studies. This is, of course, a very important element to consider in negotiations between prospective applicants and data owners.

- Another benefit of Article 95 is that the relevant person to whom a letter of access to an active substance dossier has been issued "shall be," entitled to allow applicants for authorization of biocidal products containing such a substance to make reference to that letter of access. This means that a substance supplier or biocidal product importer having a right of access can allow any EU biocidal product formulator to apply for a biocidal product authorization. However, this possibility is not yet open to EU formulators of biocidal products, unless they are themselves substance suppliers.

The above evidences the fact that every company involved in the biocides sector, whether as an active substance supplier or biocidal product supplier, needs to reflect upon a series of complex parameters to either seek the necessary access rights to ensure the continuity of its business or to be prepared to respond to data sharing requests that will no doubt increase when the BPR becomes applicable.

These parameters include the following:

- The qualification of the business operator as substance or product manufacturer or importer

- The type of data to which access is needed (vertebrate or nonvertebrate animal data, other toxicological, ecotoxicological, environmental fate or behavior studies)

- The type of access needed or requested (co-ownership, right of access, right of reference)

- The price to be paid or requested based on the combination of the above parameters

- The legal framework under which a request is made (Article 62, Article 95 and others)

Companies should consider benefiting from Article 95 as early as possible. Indeed, even if the lack of an Article 95 "approved supplier" status would only negatively affect companies from Sept. 1, 2015, the rights deriving from such listing, particularly a broad right of access to active substance data, as required to request the authorization of biocidal products containing them, may be needed much earlier than September 2015.

Companies would also be well advised to seek legal advice to fully understand the provisions in place and their impact on their business and to be ready to act in time. This is certainly a complex regulatory and procedural field.

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