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Biocides and the Board of Appeal: a first assessment

In this expert article Darren Abrahams, Indiana de Seze and Gyöngyi David, of Steptoe & Johnson examine the first cases before the Board of Appeal under the BPR.

The BoA's workload and scope of review

Echa's Board of Appeal (BoA) has announced receipt of five cases under the Biocidal Products Regulation (BPR) since its entry into force in September 2013. All of them concern data sharing. This is perhaps not surprising, since the BPR has more extensive data sharing obligations than any other EU chemicals regime. The BPR also provides remedies in relation to rejection of applications for non-payment of fees in various areas, and determinations on technical equivalence. These areas are yet to generate any BPR cases before the BoA. In contrast REACH has generated some 50 final BoA decisions since its entry into force in June 2007. However, only three of these relate to data sharing.

The BPR provides no explicit BoA remedy as regards aspects of the substantive evaluation of dossiers for active substances or applications for Union authorisation of biocidal products, which are the Commission's prerogative. A company considering a Commission implementing decision for non-approval of an active substance or a Commission decision not to issue a Union Authorisation would have to seek annulment before the General Court of the Court of Justice of the EU (rather than the BoA). This contrasts somewhat with the situation under REACH where key decisions on dossier and substance evaluation are issued by Echa and may be challenged before the BoA.

Analysis of pending cases

Given the relatively early days of the BPR, a number of the cases pending before the BoA have not yet resulted in a final decision. Nonetheless, the "*announcements of appeal*" published by Echa indicate the main issues which arise in each case. This is informative to companies involved in data sharing negotiations, as they can identify the main issues of contention between parties to negotiations and the position of Echa on certain matters of principle. Echa also publishes it data sharing dispute decisions (in redacted form), which provide greater detail on the background of those decisions that are challenged before the BoA. We examine below the four cases which are extant (the fifth was withdrawn by the Appellants in October 2015).

Case A-005-2015: Scope of data sharing & the precautionary principle

This case appears to raise at least two important issues: first, do the mandatory data sharing provisions of the BPR (Articles 62 and 63 and 95) apply where the Prospective Applicant (seeking access to data) is already in possession of those studies and seeks to build a weight of evidence argument to neglect certain results which it already has, rather than to fill a data gap? The BPR is clear that a Prospective Applicant only has to pay "*to share only in the costs of information that it is **required** to submit for the purposes of this Regulation*". Does this mean that it can also ask for *more* than the minimum it actually **requires** for inclusion on the Article 95 list of suppliers? The list is designed to ensure that suppliers are not freeriding. This does not mean that alternative dossiers are qualitatively acceptable. It means that they are substantively complete.

It is true that a qualitatively acceptable Annex II dossier for the active substance (or a letter of access thereto) will be required when a biocidal product application is submitted. However, this is many years away for most products. For 16 of the 22 product types, the deadline for the Biocidal Product Committee to start preparing its opinion on the active substance has not yet arrived. Whilst it may become apparent after an approval decision that an alternative supplier is required to purchase additional studies, there is no obvious

reason to compel this purchase or sharing at this point in time if what the alternative supplier has is sufficient to be included on the Article 95 list. Forced data sharing is an exception to the general principle of exclusive ownership rights and as such should be given the narrowest interpretation necessary to achieve the legitimate objective. Moreover, forced data sharing was introduced into the BPR (over and above Article 95) to avoid duplication of animal testing. If there is no risk that the studies requested will be duplicated (because to do so would breach the BPR) there is no basis for extending the scope of mandatory data sharing.

A second issue in the case is whether the data owner can raise questions of public interest, such as safety - taking a precautionary approach - to justify a refusal to share data. Echa's view (expressed in its Data Sharing Decision in this case) is clearly that these questions of public interest are for Member State enforcement authorities (for biocidal products) and are not relevant to bilateral data access negotiations on the active substance. If this is right, it is hard to see how mandatory data sharing can apply to alternative dossiers in circumstances where access rights are only to improve their quality of the alternative dossier.

If quality issues are not relevant how can they be relied upon to enlarge the scope of mandatory data sharing? Indeed, this is why Echa's guidance has consistently maintained that technical equivalence (and the impurity profile) is not relevant to the Article 95 data sharing process. The oral hearing in this case was held on 21 April 2016 so we will not have long to wait for an answer from the BoA.

Cases A-020-2015 and A-19-215: Absence of BoA Remedy for Errant Article 95 Listings

In two similar cases the BoA rejected as "*manifestly inadmissible*" a challenge to the inclusion of a company in the Article 95 list by Echa (as updated regularly on Echa's website). The Appellants (a task force) considered that the inclusion was an error because of data gaps which it argued must exist in the alternative supplier's dossier. The Appellant has been required to generate an *in vivo* study by the evaluating competent authority but Echa had not required an equivalent or a letter of access to this study to be included in the alternative dossier in order to judge it complete. The Appellants argued there had been *de facto* mandatory data sharing i.e. Echa had treated the alternative supplier as if it had been granted data access pursuant to Article 63(3) of the BPR outside a data sharing dispute procedure. There had been negotiations between the Appellants and the alternative supplier and no formal decision by Echa to force data sharing.

In rejecting the appeal, the BoA noted that it had no powers to examine:

- claims of Echa having failed to act – which is the competence of the General Court of the Court of Justice of the EU;
- any Echa decision which "is not explicitly listed in Article 77(1) of the BPR and its implementing legislation of Article 91(1) of the REACH Regulation"; and
- *de facto* challenges to the legality of the BPR – which is the competence of the Court of Justice of the EU.

The BoA also rejected the claim for reimbursement of the Appellants' legal costs, restating its Rules of Procedure that do not provide for such a possibility (except where related to taking of evidence). The hope underlying these cases, that the BoA would assert wider powers than those set out expressly in the BPR, has been firmly quashed. Companies who question the merits of the listing of competitors will nonetheless want to consider the other remedies which potentially exist. In our experience there are other levers that may be of assistance to address these issues.

Case A-001-2016: The timing of payments to the data owner and pre-BPR data sharing

The most recent case to be lodged with the BoA raises at least two important issues. First, the case concerns Echa's practice of issuing **draft** decisions granting mandatory access. These are made final decisions conditional upon payment of "a share of the costs incurred". The Appellant argues that the terms of Article 63(3) require this payment to have been made **before** a data sharing dispute is initiated and cannot be undertaken after the event. Second, the case concerns whether data compensation received under the Biocidal Products Directive is material for the purpose of calculating fair, transparent and non-discriminatory compensation under the BPR.

What next?

It is apparent that the BoA is already active on data sharing under the BPR. Its decisions will be important for all of the many data sharing negotiations which are ongoing and will remain a feature of the biocides world for many years to come.

The BoA seems unlikely to seek to extend its influence by inferring additional powers from a purposive reading of the BPR. It is to be hoped that future revisions to the BPR (and any other chemicals legislation which is placed under Echa's wing) will provide for a wider scope for recourse to the BoA.

The current narrowly focused list of areas where the BoA can act under the BPR will also drive companies towards other venues for recourse such as the Court of Justice (and national courts where possible) and the European Ombudsman, who is playing an ever increasing role in addressing issues of real concern for which there is no more conventional 'tribunal' solution. The recent successes of the biotechnology industry in a complaint against the European Commission, resulting in a finding of "systemic" maladministration, may be a model which biocides companies may want to emulate. The BoA continues to do important work, but companies will have to think out of the box if they are to maximise opportunities for filling the gaps in the BPR for effective recourse.

Darren Abrahams, Partner, Indiana de Seze, Senior Associate, and Gyöngyi David, Associate, Steptoe & Johnson LLP

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