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Article 95 listing: a level playing field?

In this expert article Darren Abrahams, Indiana de Seze and Eléonore Mullier of Steptoe & Johnson LLP examine recent Court of Justice and Echa Board of Appeal decisions on the operation of Article 95.

In a previous article for BiocidesHub[1] we examined the challenges that Article 95 of the Biocidal Products Regulation (BPR) creates for data accessors and data owners. More than a year after the 1 September 2015 deadline for inclusion on Echa's list of approved suppliers ("the Article 95 list"), the Board of Appeal (BoA) and Court of Justice have provided guidance on some of these issues. The decisions are instructive for the many companies who remain involved in, or are planning to embark upon, data sharing negotiations.

The stated aim of Article 95 is to introduce a level playing field among operators. The BPR's recital (58) declares that such "*level playing field should be established as quickly as possible on the market for existing active substances, taking into account the objectives of reducing unnecessary tests and costs to the minimum, in particular for SMEs, of avoiding the establishment of monopolies, of sustaining free competition between economic operators and of equitable compensation of the costs borne by data owners*". For this reason, it provides for mandatory data sharing to an extent that is unprecedented in EU chemicals regulation.

Since 1 September 2015, companies that are not listed 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. The condition to be listed as an approved supplier is the submission to Echa of a dossier complying with Annex II to the BPR or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive ('the complete substance dossier'). A prospective applicant may at any time submit to Echa either a complete substance dossier for that relevant substance, a letter of access to a complete substance dossier, or a reference to a complete substance dossier for which all data protection periods have expired. Echa has expressed in guidance documents that it also accepts mixed dossiers, comprising a mix of data and letter(s) of access to other data.

Article 95(3) of the BPR imposes mandatory data sharing not only for "data involving tests on vertebrates" but also "all toxicological, ecotoxicological and environmental fate and behaviour studies" for substances listed in the Review Programme Regulation, including any such studies "not involving tests on vertebrates".

Recent decisions from the BoA and the General Court (of the Court of Justice of the EU) shed some light on the extent of the "level playing field" and in particular the role of technical equivalence of their materials, and the extent to which alternative dossiers need to be identical or not. These decisions are discussed below.

Technical equivalence or chemical similarity as a pre-requisite to data-sharing under Articles 63 and 95 of the BPR?

In case A-005-2015 (decided on 23 August 2016), a data owner appealed Echa's decision to grant access to two studies in a data-sharing dispute ("the Contested Decision"). In essence, the reasoning of the Contested Decision was that the data owner had not demonstrated that it had made "every effort" because (according to Echa) the data owner had unilaterally made technical equivalence of the applicant's source to its own, a prerequisite to the sharing of data. The dispute took place in the context of a substance still

under review. During the negotiations, the data owner had sought advice from both Echa and the Commission, which both had stated in similar terms that *"technical equivalence or chemical similarity are not legal requirements for data sharing under Article 62 and 63" and "we take this opportunity to further clarify that technical equivalence or chemical similarity are not conditions for an application to be included on the Article 95 list"*.

The BoA annulled the Contested Decision on the grounds that Echa committed a manifest error of assessment because it failed to *"examine, carefully and impartially, all the relevant facts of the individual case which support the conclusions reached"*. In particular, the BoA observed that Echa was wrong in deciding that the data owner had unilaterally made technical equivalence a prerequisite to data sharing, as the parties *"discussed the relevance of technical equivalence for their negotiations and the applicant agreed that this assessment would be performed"*. In other words, Echa should have considered the fact that parties had expressly agreed to examine technical equivalence as a first step in their negotiations. It is notable that they did not agree to abandon negotiations in the event that equivalence was not found, although the BoA does not focus on this aspect in its decision.

The parties further agreed on the principle and on the modalities of such an assessment, ultimately by using a third party consultant. The BoA further notes that Echa failed to take into account the lack of clarity surrounding the submission of data sharing to technical equivalence at the time the negotiations began, i.e. before the entry into force of the BPR.

Fundamentally, the BoA concluded *"although the Agency might be correct in considering that the technical equivalence assessment is not a legal requirement for data sharing under the BPR, this legal observation cannot constitute an assessment of the parties' efforts to reach an agreement within the meaning of Article 63."* In the first instance, Echa should have made its balanced assessment of whether every effort had been made to reach an agreement and should not have based its decision instead on its own view of whether technical equivalence was required. Importantly, the BoA did not limit this finding to cases where Echa would err in its legal opinion – Echa must conduct a balanced assessment of "every effort" even if the (current) position of the parties goes beyond the legal requirements.

The BoA observed that the prospective applicant failed to respond to the data owner's invitation to discuss further for more than three months, before lodging a data-sharing dispute with Echa. In contrast, the data owner took steps to explain its position to Echa, which counted, according to the BoA, as efforts to be taken into consideration to the credit of the data owner.

The BoA did not examine the other four pleas raised in the appeal:

- mandatory data sharing should not apply where the prospective applicant already has sufficient data;
- (2) the prospective applicant failed to inform the data owner of the lodging of the dispute and the Agency failed to adopt the Contested Decision within 60 days;
- (3) the Agency failed to take into consideration letters sent by the data owner to the Echa and the Commission but not to the prospective applicant; and
- (4) the Agency infringed the precautionary principle by failing to consider technical equivalence as necessary in view of the alleged presence of hazardous impurities in samples of the prospective applicant's source tested by the data owner. Some of these issues will no doubt resurface in future data sharing decisions and BoA cases.

It is noteworthy that, pending the appeal, the applicant successfully applied to be included in the Article 95 list, despite the suspensive effect of the appeal on the Contested Decision, because in the end it did not actually seek to rely upon the mandatory data sharing granted by Echa. This confirms that even when granted a right to refer to data by Echa, the prospective applicant does not have to rely on that right (or pay compensation) if it considers that it can submit a sufficient alternative dossier without relying upon it. Only use of those citation rights triggers an obligation to provide compensation (as agreed between the parties or decided by national courts).

Equivalence of technical dossiers as a prerequisite to inclusion in the list of active substance suppliers under 95 of the BPR

Two related cases address claims by a data owner (a consortium) that a prospective applicant had failed to submit a complete dossier because it did not contain (proof of access to) a Comet Assay which the data owner was itself requested to submit during the pending review of its active substance.

The data owner brought two actions, in parallel, against Echa's decision to include the prospective applicant on the Article 95 list: one before the BoA (case A-020-2015) and one before the General Court (Case T-669/15). Both tribunals dismissed the data owner's actions as inadmissible.

In BoA case A-020-2015, within 30 days of the initiation of the appeal, the Chairman adopted an order on the inadmissibility of the appeal (the Chairman's Order). The Chairman's Order is based on the scope of the jurisdiction of the BoA, which is limited to appeals against decisions adopted in accordance with the provisions exhaustively listed under Article 77 of the BPR. The latter does not include Echa's decisions to accept an alternative dossier and include a prospective applicant on the Article 95 list. The Chairman's Order thus dismissed the appeal. This suggests that whilst the BoA is willing to use its powers to their full extent, it is not willing to push beyond the boundaries of the powers expressly provided to it by Article 77.

In Case T-669/15, the order of the President of the General Court (the President's Order) is based on the absence of ***direct*** concern of the data owner in the annulment of the contested decision. When applying to the Court for the annulment of an individual decision addressed to another party, the claimant must establish its direct and individual concern, i.e. that its own legal situation is affected by the contested decision. In this case, the data owner failed to establish it had such direct and individual concern in the annulment of Echa's decision to include the prospective applicant on the Article 95 list.

Notwithstanding the decision, the President's Order contains several elements worth further consideration by data owners dissatisfied with similar decisions of Echa to include their competitors on the Article 95 list: First, the President's Order observes that the data owner was not prevented from placing on the market biocidal products containing the active substance in question, as it was a participant in the review programme and thus, automatically included in the Article 95 list itself.

The data owner's rights to compensation for the Comet Assay – which would have arisen if the competing prospective applicant relied upon it – was thus considered not infringed. This was because the data owner had not shown that a reference to the Comet Assay was ***necessary*** for the prospective applicant's dossier to be complete. The President's Order discusses how Echa had demonstrated that the Comet Assay was not necessary (because of presence of three in vitro studies). This raises the question of whether - in future cases where it could be shown that the study was necessary - the approach of the Court might be different.

Second, the data owner failed to establish that the prospective applicant's dossier was ***incomplete*** with regard to the requirements laid down in Article 95 (1) of the BPR, i.e. a "*dossier complying with Annex II to the BPR or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive*". The data owner had not shown that the Comet Assay was required under Article 13 of Regulation No 1451/2007 (now replaced by the new Review Programme Regulation (EU) 1062/2014). On the contrary, the rapporteur Member State had informed the data owner that, as participant in the review programme, its dossier was complete, before it requested the Comet Assay.

Third, the data owner's plea of unfair competitive advantage could not succeed because the Comet Assay was not necessary for the completeness of the alternative dossier, and thus the ***costs*** borne by the data owner for the Comet Assay did not have to be shared. This confirms that each prospective applicant building an alternative dossier has its own responsibility to determine what it needs, which will be reviewed by Echa and ultimately the General Court. If the data accessor is wrong in its assessment, it will bear the consequences of this error by not being included on the Article 95 list.

Finally, the data owner has not established that the Contested Decision amounted to unlawful "State Aid" because, in particular, there was no unfair competitive advantage by granting access to the Comet Assay without compensation nor a proven need for it in any event.

The President's Order, contrary to the BoA Chairman's Order, leaves the door open to a challenge of an Echa decision based on Article 95 of the BPR, provided the claimant successfully proves a competitive disadvantage and demonstrates its direct and individual concern. This is a high, but perhaps not impossible, standard to achieve.

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1. Article 95 and beyond https://chemicalwatch.com/biocideshub/37108