Decisions of the Echa Board of Appeal – registration and data sharing

In the third of three articles outlining the impact of Echa BoA decisions on key REACH processes, Andrew Fasey and Luca Bolzonello take a look at the registration of substances and the sharing of data and costs

02 December 2020

The REACH Regulation requires all manufacturers and importers of substances in quantities above one tonne per year to register them with Echa by submitting a registration dossier. This dossier must contain all the information required by the applicable provisions and annexes.

Echa has two procedures that relate to registration:

- the completeness check; and
- that for examining applications for permission to refer when data- and cost-sharing negotiations have failed.

Completeness checks

In accordance with Article 20 of REACH, once a registration dossier is submitted, Echa verifies whether it is complete, gives the registrant a reasonable time to put the dossier in order if needed, and eventually makes a decision to accept or reject the registration. Decisions under Article 20 can be appealed before the Echa Board of Appeal (BoA).

There have been very few completeness check cases before the BoA. They concerned mainly registration dossiers that were found to be incomplete because they lacked technical information, and those that were submitted entirely separately from an existing registration for a substance, in other words not following the principle of 'one substance, one registration'.

The interpretation of Article 20(2) which provides that 'the completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted' has caused some controversy.

The Echa secretariat initially verified only that information was included in the relevant fields of a dossier. The BoA, however, found that a completeness check cannot only consist of a purely automated verification of whether these fields contain text. It must also ensure that the information provided addresses all the applicable requirements and is meaningful [A-022-2013].

Echa subsequently introduced the manual screening of some newly submitted registration dossiers, and re-examined a number of those previously submitted for completeness. This procedure should ensure that registrants have not abused the registration procedure by filling in dossiers without meaningfully addressing the applicable information requirements.

The BoA has not yet examined how far a completeness check can enter into technical detail short of assessing the quality or adequacy of submitted information, which must be addressed under the compliance check procedure. However, with a view to ensuring the quality of data, there is arguably scope for a deeper scrutiny of submitted dossiers under Article 20.

Furthermore, Article 11 of REACH provides that there can only be a single registration for each substance and no registration dossier may be submitted entirely independently from an existing registration for the same substance – in accordance with the principle of 'one substance, one registration'. Registrants of the same substance must submit information jointly or else justify their opting-out, and submit information individually, for certain specific reasons.

There have been a number of appeals concerning registration dossiers that were submitted independently from an existing registration for a substance. In the first such case, REACheck Solutions (I) [A-022-2013], the lead registrant of charcoal, challenged an Echa decision accepting another company's registration of that substance. The appeal was on the grounds that the other registrant had submitted its registration dossier entirely independently, thereby breaching the principle of 'one substance, one registration'. The BoA found that adherence to this principle is one of the elements Echa is required to verify when carrying out a completeness check under Article 20 in conjunction with section 1 of Annex VI of REACH. This ensures that registrants that opt out from sharing data and costs with other registrants must justify this, which can, and should then, be checked by Echa. After some initial teething problems [A-011-2017; T-805/17; T-806/17;] the system now appears to be running satisfactorily.

Data and cost sharing

Article 25 of REACH and the following articles require registrants, and subsequent registrants, to share data derived from tests on vertebrate animals and the costs relating to those data. The application of these provisions has caused considerable difficulties.

The wording of Articles 27 and 30 might suggest that once vertebrate animal tests have been submitted to Echa, the agency should grant a permission to refer automatically. The Echa secretariat, however, has given a different, contextual and purposive interpretation to this provision. The Board of Appeal implicitly accepted that interpretation [A-017-2013; A-010-2017], which is also reflected in Article 5 of Implementing Regulation 2016/9 on joint submission of data and data sharing.

According to this interpretation, if a subsequent registrant submits an application for permission to refer to Echa, the agency will grant that permission only following an assessment of the negotiations between the parties. Determining the criteria to be applied has proved a significant challenge.

The Echa secretariat developed them, based on the behaviour of the parties in the negotiations. It would verify whether the potential registrant applying for permission to refer had made 'every effort' by adopting a constructive attitude, exploring every avenue and generally demonstrating a genuine intention to find an agreement with the previous registrant.

The BoA initially left open whether this approach is in principle correct, and focused on the specific circumstances of the cases brought before it [for example A-017-2013]. More recently, however, it has clarified what the agency's approach to its assessment of cost- and data-sharing negotiations should be. This seeks to balance the following three competing objectives, or considerations, of the relevant rules [A-014 to A-021-2018, 77-93; cf. A-010-2017; A-013-2018; A-023-2018; A-024-2018].

First, registrants that have submitted vertebrate animal studies in their registration dossiers could abuse the prohibition of duplicate testing and the protection period for study results (Article 25(3)) to potentially exclude later registrants from a market, hamper or delay their market access, or seek to generate an unfair level of compensation for the use of data they submitted to Echa. For example, a previous registrant could include in its data- and cost-sharing model inflated 'cost' evaluations which do not correspond to the actual cost of studies, unjustified administrative costs, double counting, etc. Not only is the legality of such practices questionable, but they are likely, if pursued systematically, to have a detrimental effect on competitiveness in the relevant markets. Seen from this perspective, it is clear that the purpose of permissions to refer under Articles 27 and 30 is to make it impossible for previous registrants to impose abusive conditions.

Second, subsequent registrants may be tempted to seek a permission to refer from Echa simply to attempt to make it more difficult for those that have already submitted vertebrate animal studies in their registration dossier to obtain fair compensation, that is, to force 'data owners' to resort to a national court for a decision on the costs to be paid for data. To the authors' knowledge, no such case has been filed in any national court, so the problem appears hypothetical. Moreover, the costs involved in pursuing a claim this way will, presumably, also be recovered by the same means. Nevertheless, in order to prevent potential abuses by potential registrants (and existing registrants updating their registration dossiers) and to provide an incentive to find an agreement on data and cost sharing, permissions to refer should not be granted automatically, but only where certain criteria are fulfilled.

Third, whatever criteria are applied must be as clear and as easy to understand as possible, so that existing and future registrants can plan and act accordingly. An approach that focuses on the behaviour of the parties rather than on the objective content of the terms proposed, is excessively case-specific, complicated to apply, and unforeseeable in outcome.

As a result of these considerations, the BoA has tied the granting of an application for permission to refer to the criteria of fairness, transparency and non-discrimination which are provided for in Articles 27 and 30 of REACH, and further defined in detail in Implementing Regulation 2016/9.

According to the BoA findings, Echa must grant a potential registrant permission to refer if, despite the potential registrant's requests and objections, the previous registrant fails to comply with the requirements for data and cost sharing to be transparent, fair and non-discriminatory [A-010-2017; A-013-2018; A-014 to A-021-2018; A-023-2018; A-024-2018].

'Transparent' means that the conditions proposed by the previous registrant must be clear. Criteria are to be found in Article 30(1) of REACH and in Implementing Regulation 2016/9. The former simply uses the word 'transparent', giving scope for interpretation in specific cases. The latter contains an open list of examples, such as an obligation for the previous registrant to list the costs relating to each available item of information.

'Fair' means that a subsequent registrant can only be required to pay a share of the actual costs of the information that it requires for the purposes of its own registration. Costs are actual if they can be determined either by proof or by approximation. For example, a risk premium and annual surcharges are not actual costs, and applying them would not therefore be 'fair' [A-010-2017, 126 ff. and 159 ff.].

'Non-discriminatory' means that registrants in comparable situations must not be treated differently, and those in different situations must not be treated in the same way, unless such treatment is objectively justified. For example, a blanket exemption for registrants' affiliates from sharing in the costs is discriminatory [A-013-2018, 39 ff.].

In effect, a potential registrant will be granted permission to refer:

- if it requests information which it is entitled to obtain for registration purposes and that request is not complied with (by the previous registrant and/or data owner) to the extent required by Implementing Regulation 2016/9; or
- if it objects to terms transparently proposed by the previous registrant on the grounds that those terms are unfair or discriminatory, and it is right in its objection.

If, however, the previous registrant's terms comply with all the legal requirements in spite of a potential registrant's protestations, then Echa might reject the application for permission to refer.

It will be interesting to see what the courts – European or national – will make of the cost- and data-sharing provisions in the REACH Regulation if such a case is ever brought before them.

This article is the third of three in which Andrew Fasey and Luca Bolzonello explain the impact of BoA decisions on, first, the substance evaluation process, second, dossier evaluation, and, third, registration and cost and data sharing. In a fourth article, Andrew Fasey will reflect on his role as the technically qualified member of BoA for the past ten years. Andrew will be stepping down from that position next year.

The authors' views are their own and cannot be attributed to Echa or the BoA.