Rules on read-across remain hazy

There is still a long way to go before legal certainty is established

As an alternative approach to fulfilling the information requirements under EU laws such as REACH and the biocidal products Regulation (BPR), read-across – the technique where endpoint information from one chemical is used to predict the same endpoint for another chemical which is considered to be similar in some important aspect relating to that endpoint, for example, mode of action, toxicokinetics or metabolism – has gained special attention from the chemical industry. Its importance is also expected to grow with the upcoming changes to REACH, regarding information requirements for nanomaterials. But despite its important role, it remains a challenging area. The problem is threefold: there is little guidance from Echa on assessment of the technique; there is no easily accessible information on accepted read-across justifications; and Echa’s Board of Appeal (BoA) has yet to thoroughly scrutinise read-across from a scientific point of view.

Lack of guidance and access to assessments

Echa has issued various guidance documents on read-across, but none sets out how the agency should assess the read-across criteria in practice and when it should be accepted: its guidance on Qsars and the grouping of chemicals deals mainly with the methodology of analogue searching and focuses on the practical aspects of documenting category approaches, while its practical guide on how to report read-across and categories only addresses the issue of reporting the category concept in Iuclid 5.

Recognising the lack of clear and explicit criteria for the regulatory acceptance of read-across, in late 2012, Echa presented the read-across assessment framework (RAAF) and outlined the steps leading to the establishment of their “expert judgment”. However, the full RAAF has yet to be published.

The framework comprises two tiers of read-across justifications: tier I is relatively well developed, but handles the easy, obvious, or redundant cases; tier II tackles the more difficult issue of the impact of uncertainty.

While providing some explanations on basic read-across types, Echa concludes that “the assessment of a key aspect will in many cases ultimately rely on expert judgment, ie there is no ‘obvious’ conclusion. Ultimately the expert needs to balance the scientific arguments and information to give a ‘best’ opinion.” For stated reasons of transparency, Echa notes that “this analysis and balancing of arguments and information is recorded, with an indication of where subjective choices were necessary.” However, the question of whether REACH registrants actually have access to such records has yet to be tested, since to our knowledge, no registrant has ever directly (via transparency provisions) or indirectly (in an appeal case) requested access to such documents.

Against this background, only one channel of feedback from Echa is currently available – the publication of the non-confidential versions of compliance check decisions on its website. These non-confidential versions, however, only give limited insight into the agency’s read-across assessments. Instead, they usually refer to the deficiencies and weaknesses of the submitted read-across justifications. A review of the endpoint records in the registration section of Echa’s dissemination website doesn’t show whether read-across has been accepted or not, nor does it give the reasoning used in a particular case that positively assessed read-across justifications. Thus, there is no publicly available information on arguments that would have passed Echa’s test.
Expert focus: risk assessment

for evaluating read-across. Moreover, the agency didn’t provide any data on the acceptance rate of read-across justifications in its 2011 or current 2014 report on the use of alternative testing under REACH.

Certainly, there are good reasons for not communicating dossiers that successfully pass the agency’s compliance checks. Nevertheless, Echa publishes a woefully insufficient number of examples of successful read-across justifications (only two such cases, as included in RAAF). Providing more such successful cases would increase legal certainty, and might reduce the number of challenges Echa and its BoA have to deal with.

Furthermore, registrants concerned by the early compliance check decisions have presumably already updated their registration dossiers. Therefore, feedback from Echa would be useful, for example, in the form of a comparison between human and environmental hazard assessment of the substances in the initial state (using read-across justifications) and the updated state (via study summaries of the tests requested by Echa after rejecting read-across). This would not only provide additional guidance on read-across, but would also strengthen the agency’s good administrative practice.

Appeals against compliance check decisions

By way of background, it is worth briefly mentioning the BoA’s powers of review. There are, in principle, two alternatives:
- similar to a court, the BoA may exercise only the right to assess whether Echa misinterpreted REACH or misused its powers (legal review); or
- similar to an administrative review body, the BoA may reassess the facts and law, and therefore replace an Echa decision. * Indeed, according to REACH Article 93(3), the BoA “may exercise any power which lies within the competence of the agency”. At the beginning of its term, the BoA did claim this full power of review by reassessing the facts (Case A-001-2010, NV Elektricity – Produktiemaatschappij Zuid-Nederland EPZ Borssele v Echa, Decision of 10 October 2011, para. 36); substituting Echa’s decision concerning both scientific and legal aspects (Case A-005-2011, Honeywell Belgium NV v Echa, Decision of 29 April 2013, para. 115); and amending or annulling Echa decisions and remitting the case back to the agency for further action. Given such precedents, the BoA also arguably has the power to reassess Echa’s “expert judgment” on read-across justifications.

However, as demonstrated below, the BoA has declined to use this extensive authority in cases in which the applicants allege that Echa erred in assessing read-across justifications:

In Dow Benelux (Case A-001-2012, Dow Benelux BV v Echa, Decision of 19 June 2013, para. 109), the BoA was reticent about assessing the scientific arguments for read-across put forward by the applicant, as this entailed: “[…]the assessment of complex scientific and technical facts.” Consequently, the BoA limited its review solely to “whether […] the agency misused its margin of discretion.” The BoA did not examine the science of read-across or whether the available conditions for using read-across were satisfied, taking a deferential approach to the agency’s margin of discretion. This contrasts with its earlier Honeywell case, where Echa’s margin of discretion did not, as such, prevent the BoA from fully assessing whether such discretion was correctly exercised (Honeywell, para. 76), including reassessing the science of the case. In Dow Benelux, however, the BoA stated that it was for Echa to consider whether the uncertainty linked to a read-across justification is acceptable or not (para. 113).

It is worth noting that when Echa’s Member State Committee considered the Dow Benelux case in a meeting in 2011, one member state competent authority said the issues were borderline for read-across justification for the two implicated tests, while another competent authority said the read-across arguments for these endpoints were justified. In light of the committee’s discussions, it is clear that the appellant, as well as some committee members, challenged Echa’s “expert judgment”.

Following the BoA’s decision in Dow Benelux, various scientific commentators also argued that the read-across justifications in this case seemed “overwhelmingly strong” (GBB July/Aug 2013). Therefore, this should have given the BoA adequate incentive to more thoroughly scrutinise such justifications. In Momentive Specialty Chemicals (Case A-006-2012, Momentive Specialty Chemicals BV v Echa, Decision of 14 February 2014), the BoA appeared to conduct a full analysis of the plea challenging ECHA’s interpretation of the requirements to permit read-across justification, but the assessment was only pure legal analysis. The BoA did not address the scientific value of the presented evidence. It only indicated several times that the opinions of the appellant’s experts had merely identified a certain degree of uncertainty, thus allowing the BoA to conclude that Echa was not “incorrect in considering that further information […] was required”. The BoA did not assess the acceptability of such a degree of uncertainty. Nor did it balance the objectives of REACH with the inherent uncertainty and need to predict toxicology, although this was identified as one of the agency’s tasks when assessing read-across (paras. 62 and 85). Additionally, the BoA supported Echa’s conclusion that “simply stating that a substance is a member of an OECD category is not by itself a sufficient justification for a read-across.” However, it is unsatisfactory to have rejected the OECD’s approach simply on the basis of a mere statement that such approaches to read-across were “different” from those of the agency and REACH (para 77). Clearly, the BoA chose to shy away from full re-assessment.

Unfortunately, to date the European courts (General Court or Court of Justice) have not been tasked with deciding any cases assessing the BoA’s largely hands-off practice in reviewing Echa decisions. Only one annulment action, currently pending, has been brought against a BoA decision (Case T-673/13, European Coalition to End Animal Experiments v Echa). Here, the applicant, an intervenor in the BoA case, claims the BoA erred in interpreting REACH provisions; however, read-across is not an issue in the case.

In light of the above, it appears that for the time being, a prospective appellant may at best hope for an assessment of whether Echa abused its margin of discretion, or committed a blatant error. When the agency rejects read-across, the BoA appears likely to accept that choice, unless it is a clear-cut case of a manifest error of assessment or a procedural mistake by Echa. The more complicated cases, where the agency’s expert judgment is brought under scrutiny, are likely to be upheld under the current line of precedents.

Finally, attempts to rely on the proportionality principle would appear to be of little use to appellants, other than in cases of “unusual” information requests (see Honeywell case). As REACH lists these information requests in detail, Echa generally need not justify the proportionality of these information requirements. Furthermore, as the precautionary principle
underpins the provisions of REACH, this provides the agency with the discretion to request further data in case of doubt (i.e. to reject read-across), in order to achieve REACH’s objective of ensuring a high level of human and environmental protection.

**Read-across for nanomaterials and biocides**

For nanomaterials, read-across is not only used from one substance to another, but also on a form to form basis within the same substance (for example, bulk versus nano form). However, the technique’s applicability is part of the current review of REACH. In a paper presented to the November 2013 meeting of competent authorities for REACH and CLP (Caracal), the European Commission stated that any future amendment of REACH should specify that non-testing methods are a priority for nanoforms, and clarify form-to-form read-across for nanoforms; and the use of read-across between forms within a dossier should be subject to the same procedures, as concerns the need to provide scientific justification, as in cases where REACH Annex XI is applied across dossiers.

The use of read-across for the purposes of biocidal applications is currently based on Echa’s guidance on information requirements under the BPR. All sections relevant to specific endpoints contain a general reference to the availability of guidance within the agency’s guidance on the application of the CLP criteria. However, it seems the agency is preparing BPR specific guidance, focusing on use of read-across in human health effects assessment that will further develop read-across for health-related endpoints, and possibly additional guidance to address a “more systematic approach” for biocidal applications.

**‘Transparency has yet to be achieved, both in substance and statistically’**

Transparency has yet to be achieved, both in substance and statistically, on the acceptance of read-across. Existing guidance on when read-across may be used is of little help in this regard, which is also regrettable from the perspective of Echa’s commitment to good administrative practice. This situation is worsened by BoA’s apparent reluctance to scrutinise the agency fully. Establishing transparency would be highly desirable towards increasing legal certainty both for industry and for Echa itself, in view of diminishing future challenges to its administrative practice. In the meantime, in light of this current state of affairs, REACH registrants and biocide notifiers will be in practice forced to conduct more (animal) testing.

*For further details, see article by Marcus Navin-Jones, Keller and Heckman LLP, A legal review of EU boards of appeal, in particular the European Chemicals Agency Board of Appeal, European Public Law Journal, publication due in early 2015 (see abstract).

This publication should not be construed as legal advice on any specific facts or circumstances. The authors would like to thank Ursula Schliessner, partner at Jones Day Brussels, for her review.

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