Being prepared for litigation under REACH processes

Manufacturers and importers have important opportunities to participate during the adoption of decisions under REACH and to challenge adverse decisions before the European Chemicals Agency's Board of Appeal (BoA) and the European Court of First Instance (CFI). Georg Berrisch and Cándido García Molyneux of law firm Covington & Burling advise.

This article discusses the remedies available to challenge adverse REACH decisions and submits that any company who is subject to a REACH procedure that could result in such an adverse decision needs to think about these remedies early on in the process. Indeed, the foundations of a later successful litigation before the CFI are laid by the company's actions during the REACH administrative procedures before ECHA and the European Commission. In particular, it is important that during these procedures companies make use of their rights to comment, insist on strict observance of their procedural rights, and submit all the pertinent evidence.

A. Challenging decisions

REACH allows companies to appeal to the BoA on a limited number of decisions taken by ECHA, and thereafter, to challenge the decisions of the BoA before the CFI. Companies may also challenge before the CFI other decisions of ECHA without first appealing to the BoA and Commission decisions.

Examples of ECHA decisions that may be appealed before the BoA include decisions regarding:

* imposition of additional conditions on registration exemptions for product and process oriented research and development (PPORD) substances;
* completeness checks of registration dossiers;
* data sharing;
* testing proposals;
* compliance checks of registration dossiers; and
* requests to submit additional information under the REACH evaluation procedures.

Appeals before the BoA have suspensive effect, which may be particularly significant when facing stringent registration deadlines.

The appeals can be lodged by the addressees of the decision and also by other persons with a "direct and individual concern." The latter may include data holders where ECHA allows a third party to continue with his registration despite that party's lack of an agreement with the data holder. Downstream users may also try to claim a direct and individual concern where ECHA rejects the registration of their supplier.

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Third parties with an interest in the result of an appeal may intervene in proceedings before the BoA to support or oppose the remedies sought by appellants. For example, competitors may intervene where a company appeals an ECHA decision denying a PPORD registration exemption.

In addition to appeals before the BoA, registrants may request ECHA to review its own decisions denying confidentiality requests for information submitted in registration dossiers. As with appeals to the BoA, the request that ECHA reviews its own decision suspends the implementation of the decision.

Decisions of the BoA and final ECHA decisions on confidentiality requests may be challenged before the CFI. Furthermore, companies may also challenge before the CFI other ECHA decisions that are not subject to appeal to the BoA as well as Commission decisions.

Examples of ECHA decisions that are not subject to appeal to the BoA but that companies could arguably challenge before the CFI include responses to requests for reduced fees or fee waivers and decisions on requests for access to information. Examples of Commission measures that could be challenged include decisions on testing proposals, rejections of applications for authorisation, and reviews of existing authorisations. As a precaution, any challenge against a decision of ECHA or its BoA before the CFI should also name the Commission as a defendant.

As in the case of appeals to the BoA, an application to the CFI can be lodged by the addressee of the decision and by third parties who demonstrate they have a "direct and individual concern." The latter may include prior authorisation holders where the Commission grants an authorisation to a third party on the basis of the information included in the prior application of the authorisation holder without his permission.

Where a party cannot show a direct and individual concern in a measure, he may try to indirectly challenge it through the so-called preliminary ruling procedure. In particular, a party may challenge the national provision implementing or applying the REACH measure before a national court and ask that court to refer a question on the validity of the disputed REACH measure to the European Court of Justice.

B. Standards of review

REACH provides that in its examination of an appeal, the BoA may exercise any power that lies within the competence of ECHA. This suggests that, in line with practice in other regulatory areas, the BoA may substitute its own assessment of all the technical details for that of ECHA.

In contrast, the case law of the EU Courts suggests the CFI will allow wide discretion to ECHA, the BoA, and the Commission as regards decisions adopted under REACH and will not substitute its own assessment of the technical issues for theirs.

Nevertheless, the CFI is likely to insist

that ECHA, the BoA, and the Commission respect the procedural rights of the parties, that they carefully and impartially examine all relevant aspects of the case, that their decisions be based on cogent and consistent evidence capable of supporting the conclusions reached, and that the reasoning addresses all important aspects of the case and is free of any contradictions. Moreover, the CFI will do so strictly on the basis of the reasoning of the decision and the evidence that was before the authority when it adopted its decision.

This means that the foundations for a successful appeal to the CFI are laid during the company's participation and submission of comments before ECHA, the BoA, and the Commission. Specifically, the quality of the evidence that private parties put forward during these administrative procedures will determine the level of the bar that the three bodies must reach in their decision. Put differently, the stronger the evidence and arguments that a party submits during the administrative procedures, the more difficult it will be for ECHA, the BoA, and the Commission to adopt an adverse decision that will pass the CFI's scrutiny.

Furthermore, the CFI will not set aside an adverse decision on the basis of evidence that the parties failed to submit during the opportunities they had to submit comments to ECHA or the Commission. Moreover, companies must also assert and exercise their procedural rights during the investigation if they want to be able to rely on procedural defects in a subsequent court case before the CFI. For example, where ECHA unjustifiably ignores evidence submitted by an authorisation applicant or fails to investigate relevant information on available substitutes brought by a third party during the authorisation procedure, affected parties should immediately complain about this to ECHA and Commission.

C. Practical steps

On the basis of the above considerations, companies should take the following precautions when trying to ensure the REACH compliance of a substance that is of competitive importance:

1. Identify the REACH procedures to which the substance may be subjected and the opportunities that the company will have to participate.

2. Assess the regulatory implications that any measure resulting from the different REACH procedures may have on the substance.

3. Identify all parties (competitors, Member States, NGOs) who might be interested in the outcome of a procedure affecting a substance. In particular, companies should be aware that REACH also allows third parties to comment and challenge decisions that affect a company's substances.

4. Anticipate the sensitive issues that may end up in REACH litigation.

5. Prepare strong evidence in support of the substance and of the company's position well in advance.

6. Make sure to submit comments and comply with the REACH requirements in due time.

7. Immediately complain to ECHA and the Commission in case of any violation of the company's procedural rights.

8. Document all communications with ECHA, the Commission, and third parties.

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