Chemical Watch

Decisions of the Echa Board of Appeal – substance evaluation

In the first of three articles outlining the impact of Echa Board of Appeal decisions on key REACH Regulation processes, Andrew Fasey and Luca Bolzonello take a look at the crucial substance evaluation process

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The REACH Regulation gives registrants the possibility of appealing against certain decisions taken by Echa. Appeals are made to the agency's Board of Appeal (BoA), which has taken more than 120 decisions since 2008. These have primarily covered registration, cost and data-sharing disputes, dossier evaluation (compliance checks and testing proposals) and substance evaluation.

Substance evaluation is a process of central importance to the REACH Regulation. It is one of the key ways the authorities can identify the potential risks a substance poses, and clarify whether they are actual or not. Decisions taken under the substance evaluation process involve a wider margin of discretion for the authorities and Echa than other appealable decisions, as the information required is not prescribed in the legislation. This is one of the reasons, perhaps, why the rate of appeals against substance evaluation decisions is higher than for dossier evaluation decisions. Another reason may be that information generated by a substance evaluation decision is more likely to result in regulatory action, including further risk management measures and identification as a substance of very high concern (SVHC).

As a consequence, the BoA has often provided Echa's interpretation of the provisions for substance evaluation, and the implementation of those provisions by both the agency and EU member states.

REACH provides for the evaluation of substances with a view to determining whether they need to be further regulated. If, in order to clarify whether a substance poses a certain risk or not, more standard information is required than the information provided for registration purposes, Article 46 of the Regulation empowers Echa to instruct the registrants to provide it. Such a decision by the agency can be challenged before the BoA.

Requests for further information may be very broad, requiring not only the collection and submission of information available to the addressees of a decision, but also the generation of new information including, sometimes, studies according to modified test guidelines.

Substance evaluation cases therefore tend to raise two types of issues:

- the conditions that must be fulfilled in order for Echa to request further information in a decision; and
- the formal and procedural requirements that the agency and the competent authorities of the EU member state must respect.

In addition, there is an underlying issue concerning the relationship between member state competent authorities, the Echa secretariat and the BoA.

Conditions for requiring further information

The BoA has interpreted Article 46 REACH in light of the objectives of the Regulation, the principle of proportionality and the precautionary principle [cf. A-005-2014, 55-60; A-006-2014, 74-76; A-009-2014, 71]. According to this interpretation – confirmed by the EU's General Court in a 2019 judgment in the case of BASF Grenzach v Echa [T-125/17, para 276] – in order to require registrants to submit further information, Echa must establish that three conditions are fulfilled:

- the substance in question poses a potential risk;
- that the potential risk needs to be clarified; and
- the requested measure – the request for further information – must have a realistic possibility of leading to improved risk management measures.

The first two conditions are satisfied if it can be shown that:

- a substance may have a certain hazardous property;
- humans or the environment may be exposed to it; and
- the concern needs to be clarified.

Echa is not required to show that a risk actually exists provided that it can establish the existence of a potential risk [BoA decisions: A-026-2015, paras 64-72; A-006-2014, para 87; A-005-2014, para 70]. The purpose of a request for further information is precisely to clarify whether a risk actually exists or not.

Further information can be requested in cases in which, for example, there is information to show that a substance might pose a certain hazard, as well as contradictory information to show that a substance does not pose such a hazard. Moreover, if evidence of a hazard is particularly strong, or the hazard is particularly severe, evidence of exposure can be correspondingly less (and vice versa) [cf. A-026-2015, 42; A-015-2015, 82]. However, there needs to be some credible evidence that there is a potential risk – and it is this point which is often at the heart of substance evaluation cases brought before the BoA.

The third condition for requesting further information – that the further information must have a realistic possibility of leading to improved risk management measures – is not limited to the authorisation and restriction provisions in REACH.

In addition to these three conditions, the BoA has consistently held that if Echa requires registrants to provide certain information, the agency must be able to establish that this information is capable of clarifying the potential risk. In other words, the agency must tell the registrants what information is needed and how to provide it. A decision under Article 46 REACH should impose a specific measure and Echa must be able to show that the measure is capable of bringing about the objective sought [cf. A-006-2016, 102; A-026-2015; 118-125; T-755/17, 262].

As is apparent from its decisions, the BoA has found that Echa has considerable latitude ('margin of discretion') on whether to require further information and what that should be. This is essential to allow the agency to clarify potential risks and thereby ensure that substances that pose a risk are adequately managed. However, the BoA has also established the boundaries of the agency's powers by requiring it to demonstrate – in its decisions – that the various conditions are fulfilled.

Substance evaluation as an administrative procedure

Substance evaluation decisions are adopted in accordance with the procedure set out in Articles 50 to 52 REACH. According to these, the competent authority of the evaluating member state drafts a decision. Then, with the unanimous agreement of the member state committee (MSC) – made up of the competent authorities of the member states – this is adopted as an Echa decision. Registrants have the opportunity to comment on the initial draft decision prepared by the evaluating member state and on any proposals for amendment submitted by the member state competent authorities, or by the Echa secretariat.

Registrants frequently raise procedural issues in their appeals. One example is whether, and how, the general principle of the "right to be heard" applies beyond the opportunities for commenting expressly set out in the legislation.

The BoA has held that there are at least two circumstances in which registrants should be heard beyond the commenting possibilities expressly foreseen in Articles 50 to 52 REACH [cf. A-009-2016; A-009-2014]:

- if new information is included in the text of a decision at a late stage, the registrants may need to have the possibility to submit their views on it; and.
- the MSC sometimes resolves differences of view in closed-session meetings. This can result in entirely new or substantially revised information requirements being agreed late on in the procedure. In such cases, registrants must have the possibility to comment on those new or revised information requirements.

A further procedural issue which the BoA has repeatedly addressed is whether, and under which conditions, Echa can request standard information for registration purposes under REACH Article 46 (substance evaluation) instead of Article 41 (compliance check). The BoA has held that,

as a general rule, compliance checks of the relevant registration dossiers (dossier evaluation) should precede substance evaluation [cf. A-005-2014; A-009-2014; A-007-2017; A-008-2017]. It is only as an exception that information required for the registration of a substance should be requested under substance evaluation (Article 46 REACH) [cf. A-008-2017, 56 ff.]. This is a necessary consequence of the way REACH is structured: it imposes standard information requirements and data-sharing obligations so that the higher a registrant's tonnage, the more information it is required to provide and the more costs it will have to bear.

The cost of further information required under substance evaluation, however, must be shared between all registrants of a substance. Therefore, if the substance evaluation procedure is used to request standard information, this can upset the balance of rights and obligations established in REACH. An example of this is where a registrant in a low tonnage band might be obliged to provide, and pay for, information which only its fellow registrants in higher tonnage bands would otherwise be bound to provide.

The relationship between the BoA, Echa secretariat and MSCAs

Each substance evaluation appeal concerns three independent institutional actors:

- the member state competent authorities, which carry out the substance evaluation, draft decisions under Article 46 and agree on those decisions unanimously in the MSC;
- the Echa secretariat, which supports the member state competent authorities in their tasks, including by providing scientific expertise, adopts the decisions and defends those decisions when they are challenged before the BoA; and
- the BoA, which is called upon to hear an appeal.

The interaction between these three has consequences on how the appeal process works and on the content of BoA decisions.

On the one hand, the BoA has been established to review appealed decisions as regards both formal issues and the content of them. If the BoA were simply to defer to the assessment set out in a decision, it would fail to exercise its responsibilities under REACH and also under the Treaties (Article 263(5) TFEU and Article 58 of the Statute of the Court of Justice).

Similarly, if the BoA were limited to reviewing the formal and procedural aspects of a substance evaluation decision, then the General Court – which reviews the BoA decision – would also be prevented from reviewing the scientific content of substance evaluation decisions. This would be contrary to the EU Charter of Fundamental Rights [cf. T-755/17, 57-72].

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On the other hand, it is clear the member states and their competent authorities have an essential role in the substance evaluation process. It is they, and not the Echa secretariat or the BoA, that carry out the substance evaluation and determine initially which further information is needed. The scientific assessment set out in a substance evaluation decision must therefore be treated with care and respect and the BoA cannot overturn the reasoning in a decision simply because it disagrees with it.

These two elements – the purpose of the BoA and the respect due to the member state competent authorities – are reflected and carefully balanced in the standard of review of the BoA and in exercise of its powers to annul or modify substance evaluation decisions.

As regards the standard of review, the boards of appeal of most EU agencies are required to carry out a full re-examination of a contested decision (a de novo review). In the case of Echa and its BoA, however, this approach would not be consistent with the structure of the REACH Regulation in general, and the role of the member state competent authorities in particular. The BoA has therefore consistently held and the courts have confirmed – in the BASF Grenzach judgment – that it does not carry out a de novo review of substance evaluation decisions, but limits itself to verifying whether the arguments and evidence put forward by an appellant show that the contested decision is vitiated by an error [cf. A-018-2014; T-125/17; T-755/17]. A simple difference in scientific opinion will therefore not lead to the BoA annulling a substance evaluation decision. An appellant can only be successful if it manages to prove that the contested decision contains an actual legal and/or scientific flaw.

As regards the powers of the BoA to annul or modify

substance evaluation decisions, Article 93(3) REACH gives BoA the possibility of exercising the same powers as the agency. This includes the power not only to annul a contested substance evaluation decision, but also the power to substitute the reasons set out in it, or to modify its requirements (the dispositive part). The Board therefore has a power of discretion in determining what to do following its examination of the grounds of an appeal. However, in exercising this discretion, the BoA must take into account the role of the member state competent authorities in the decision-making process [cf. T-755/17, 89]. This means that there are some situations in which it could modify a substance evaluation decision itself, for example by substituting the reasoning justifying a decision while upholding the information requirements set out in its dispositive part. However, respect for the role of the member state competent authorities requires that the BoA may have to refrain from substantively modifying the information requirements in a substance evaluation decision, rather remitting the case to the agency and the member state competent authorities for re-examination.

Conclusions

Substance evaluation cases tend to be more complicated both scientifically and legally – and contentious – than other types of appeal.

On the whole, the practice of the BoA in substance evaluation cases shows an underlying need to balance two competing considerations.

On the one hand, Article 46 places considerable power in Echa's hands. A request for further information can be very broad (and expensive) and require not only the collection and submission of information available to the addressees of a decision, but also the collection, generation and submission of new information. It would not be far off the mark to say that, according to the practice of the BoA, Echa has the power to require from registrants a broad range and depth of information, provided that:

- the information is necessary to clarify a potential risk;
- that it might lead to improved risk management measures; and
- that it is demonstrably possible for registrants to provide that information.

On the other hand, Echa must exercise its considerable power with all due care. It must have particular regard to ensuring that requests for further information are adopted in a way that is procedurally correct and that the requests are appropriately justified, and that they can demonstrably achieve their aim.

This article is the first 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 in 2021

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