Chemical Watch

Decisions of the Echa Board of Appeal – the compliance check procedure

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

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The REACH Regulation requires all manufacturers and importers of substances in quantities above one tonne per year to register those substances with Echa by submitting a registration dossier. This dossier must contain all the information required by the applicable provisions and annexes. The compliance check procedure allows the agency to ensure that the information provided by registrants satisfies the applicable rules and requirements. Having a fully compliant base-set of data then makes it possible to assess whether further information on a substance should be requested, or stricter risk management measures are needed. Compliance check decisions can be appealed before the Echa Board of Appeal (BoA).

Compliance checks within the broader system of REACH processes

The compliance check procedure consists of two stages:

- initial decisions under Article 41 REACH, and
- follow-up decisions under Article 42 REACH.

Article 41 REACH empowers Echa to check that registration dossiers are in compliance with the applicable requirements. These information requirements are essentially of two kinds.

Some higher-tier information requirements in the REACH Regulation are worded in an open way, providing for example that a registrant must provide information on a further study if necessary. If this is the case, the BoA has held that Echa must establish in its compliance check decision that the test it requires is proportionate and the last resort in terms of vertebrate animal testing [A-005-2011, 65-71 and 93-97; A-010-2018, 187-190]. The registrant will then be able to challenge, before the BoA, whether the further testing requested by Echa is necessary as well as the choice of the test itself.

The overwhelming majority of information requirements in the REACH Regulation, however, set out precisely what information a registrant must provide and under which conditions. In these cases, the BoA has held that, once Echa has concluded that there is a data gap in a registration dossier – in other words that it is non-compliant in some respect – it has exhausted the extent of its discretion. The consequences of an agency finding of a data gap flow directly from the legislation. Consequently a registrant cannot argue, for example, that it is disproportionate to be requested to fill a data gap. Such an argument would amount to challenging the necessity of information requirements in the REACH Regulation [A-006-2017, 131-135; A-011-2018, 50-52].

REACH, however, provides for adaptations. These are of two kinds:

- general adaptations under Annex XI REACH; and
- specific adaptations under column 2 of the testing annexes.

This means that it is possible for registrants to submit a justified adaptation, instead of carrying out a study, even following a compliance check decision. If registrants submit an adaptation, the initial compliance check decision is followed-up under Article 42 REACH.

The BoA examined the follow-up procedure in a case concerning a communication, called a 'statement of non-compliance' (Sonc), by which Echa informed a national authority that a registrant had not complied with an initial compliance check decision, and requested that authority to impose sanctions [A-019-2013].

The BoA found that the communication should have been adopted under Article 42 REACH because it required the assessment of 'new and substantial information' provided following the initial compliance check decision. Echa cannot avoid the procedure under Article 42 REACH simply by including this assessment in an informal communication.

The General Court subsequently took a similar – but not identical – approach in a different case in which it held that any information provided following a compliance check decision under Article 41 REACH must be assessed under Article 42 REACH, unless it is manifestly unreasonable and therefore an abuse of process [T-283/15, 114].

The Federal Republic of Germany has appealed this judgment to the Court of Justice [C-471/18 P]. A case against a follow-up decision adopted under Article 42 REACH is also pending before the BoA [A-001-2019].

These and other cases show that the BoA has pursued a systematic interpretation of the compliance check procedure within the broader system of the REACH Regulation. According to this interpretation, Article 41 REACH empowers Echa to declare that the information submitted in a registration dossier does not comply with the relevant information requirements, and there is therefore a data gap that the registrant must fill. The registrant then has a choice. It can submit data to satisfy an endpoint – for example, perform and submit a study under Column 1 of the relevant REACH annex. Alternatively, it can submit an adaptation – for example, a specific adaptation under Column 2 of the relevant REACH annex or a general adaptation under Annex IX REACH.

Under Article 42 REACH, Echa must assess whatever information the registrant has provided in consequence of the first decision adopted under Article 41 REACH, and adopt a follow-up decision if necessary. If this decision finds that the submitted information still does not fulfil the information requirement, the relevant member state authorities can, and arguably must, impose proportionate and dissuasive sanctions on a registrant for its incompliance 'at the least' since the expiry of the time period set out in the initial compliance check decision, and possibly since the submission of its registration dossier [T-283/15, 114].

This means that, following an initial compliance check decision, a registrant faces sanctions if it submits an adaptation instead of the requested study and the adaptation is rejected. Provided that sanctions are actually imposed by the member state enforcement authorities, this should prevent registrants repeatedly submitting marginally improved adaptations [cf. the Opinion of AG Tanchev in C-471/18 P, 169]. However, before being sanctioned, the registrant enjoys the protection afforded by the follow-up procedure (Article 42 REACH).

Overall, its decisions show that the BoA has consistently emphasised that it is the responsibility of registrants to ensure that their registration dossiers comply with the requirements of REACH, and the duty of Echa to verify that they do.

Compliance checks as an administrative procedure
Compliance check decisions are adopted in accordance with the procedure set out in Articles 50 and 51 REACH. According to this procedure, a decision is drafted by the Echa Secretariat, and adopted with the unanimous agreement of the competent authorities of the member states. Registrants have the opportunity to comment on the initial draft decision, as submitted by the Secretariat, and on any proposals for amendment submitted by the competent authorities.

The BoA has emphasised that, during the course of this decision-making procedure, Echa must assess registration dossiers with care and attention, and to a high standard of procedural correctness. For example, registrants must be given a proper hearing, particularly if there are substantial changes in a draft decision at a very late stage of the decision-making procedure [A-004-2015, 64-66]; in certain circumstances, information that becomes available when the decision-making procedure is already under way must be taken into account [A-001-2014, A-001-2018]; and decisions should be drafted in a clear and comprehensible way, so that registrants can understand the reasons for the decision and what they have to do in order to bring their registration dossiers into compliance with the applicable information requirements [A-008-2015 to A-011-2015].

Interpretation of specific information requirements

The information requirements in the REACH Regulation are arguably not always completely clear. There are examples of this in the decisions of the BoA. The most recent example, and one of the most interesting, concerns the registration requirements for substances used as ingredients in cosmetic products. In two cases, Echa had required a registrant of substances used exclusively as an ingredient in cosmetic products to carry out studies on vertebrate animals or submit an acceptable adaptation [A-009-2018, A-010-2018]. The registrant argued before the BoA that it could not be required to carry out such studies, because doing so would contradict the cosmetics Regulation [Regulation (EC) No 1223/2009] which prohibits the testing of cosmetic ingredients on vertebrates and sanctions it with a marketing ban.

The BoA examined the respective requirements of REACH and the cosmetics Regulation in much detail. It based its decision mainly on two tenets.

Firstly, the cosmetics Regulation prohibits testing on vertebrate animals, and imposes a marketing ban, if such testing is carried out 'in order to meet the requirements of this regulation'. The purpose and requirements of the cosmetics Regulation are narrower than those of REACH. The cosmetics Regulation seeks to ensure that finished cosmetic products, whatever ingredients they contain, are safe for the end user, for example the consumer applying the product. The REACH Regulation, by contrast, aims to generate and make available information on essentially all chemical substances on the European market, so that their safety can be ensured throughout their lifecycle. REACH therefore covers elements that the cosmetics Regulation does not cover, for example protecting workers from risks arising from the manufacture of a substance, and environmental risks. Testing carried out under REACH on a substance used as a cosmetic ingredient is not, therefore, automatically carried out 'in order to meet the requirements of [the cosmetics Regulation]'. Indeed, as the Court of Justice held in a different case [C-592/14], the cosmetics Regulation prevents producers of cosmetic products from relying on vertebrate animal tests in order to prove that their products are safe for end users – it does not prohibit them from carrying out tests altogether.

Secondly, the REACH Regulation contains a single relevant exemption for substances used as cosmetic ingredients from (some) vertebrate animal testing requirements: under Section 3 of Annex XI REACH, a registrant of a substance used as a cosmetic ingredient may be able to waive those studies if it can show that there is no (or no significant) exposure other than through the use of finished cosmetic products by end users. In effect, if a registrant can show that the risk posed by a substance arises only from the use covered by the cosmetics Regulation and there is no other potential exposure (for example to workers), it may be able to waive a test. In the two cases at issue, however, there was in fact potential worker exposure. The BoA therefore held that Echa was justified in requiring the registrant to provide the vertebrate animal tests in question.

This example shows how the BoA has been called upon, over the years, to address not only scientific issues, but also highly complex questions of law. Further examples, that would exceed the confines of this article, are the registration requirements for nanomaterials [A-011-2014], the definition of intermediates [A-010-2014], the requirements for long-term aquatic toxicity testing [A-011-2018], the setting of dose-levels in certain tests [A-006-2017], the trigger for the obligation to carry out an in-depth risk assessment [A-015-2014], and the general requirements for weight-of-evidence adaptations [A-011-2018]. The decisions of the BoA in compliance check cases have arguably had a considerable impact on the interpretation and application of the information requirements in the REACH Regulation.

Conclusions on the BoA's approach to the compliance check procedure

The BoA has consistently emphasised, and differentiated between, the respective responsibilities of registrants, Echa, and national authorities under the compliance check procedure.

On the one hand, the BoA has held Echa to high and stringent standards. It found that the agency must give registrants ample opportunity to be heard and submit information; that the compliance check procedure (Article 41 REACH) and its follow-up (Article 42 REACH) cannot be circumvented by the use of informal communications; that Echa has no power to go beyond the information requirements set out in REACH; and that decisions must be written clearly and address the relevant legal criteria.

On the other hand, the BoA has held registrants to their own responsibility, which is to submit a fully compliant dossier. It has held that the information requirements in the annexes to the REACH Regulation cannot be circumvented or avoided, and that it is not Echa's role to compile or improve adaptations on a registrant's behalf, or to consider whether the standard information requirements are proportionate.

These two aspects are two sides of the same coin. Echa's role in the compliance check procedure is to verify that

registration dossiers comply with the relevant information requirements, not to 'nurse' registrants by compiling or improving adaptations on their behalf. Registrants bear the burden of ensuring that their dossiers are compliant, but must be put in a position where they can take full advantage of the several possibilities to 'get it right' during the course of the compliance check procedure.

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