# Opinion

# Administrative Precedent and the Application of the REACH Regulation - 10 Years of the ECHA Board of Appeal

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*The REACH Regulation places many of the individual decisions adopted by the European Chemicals Agency ('ECHA') under the competence of its Board of Appeal. Decisions of the Board of Appeal can be challenged before the General Court and, if permission is granted, the judgment of the General Court can be appealed to the Court of Justice. The provisions in the REACH Regulation regarding the Board of Appeal and its powers are quite succinct. In essence, the Board of Appeal is an independent part of ECHA and may exercise any power that falls within ECHA's competence. The Board of Appeal is composed of three members, two of whom are currently legally qualified, and one of whom is technically qualified. The REACH Regulation and the Rules of Procedure of the Board of Appeal ensure they are suitably qualified, independent and impartial. They are assisted by legal and scientific advisors. The legislative history of the REACH Regulation suggests that the Board of Appeal was initially expected to deal with a large number of relatively straightforward cases every year. The cases before the Board of Appeal have turned out to be a fraction of the expected number, but the impact, complexity and importance of the cases has turned out to be considerably greater. This opinion piece will examine four processes under the REACH Regulation in which the Board of Appeal has left a mark, and explore its main contributions and challenges over the last ten years.*

## I. Completeness Checks

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.

In accordance with Article 11 REACH, 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 (the principle of 'one substance, one registration'). Registrants of the same substance must submit most information jointly or else justify that they are allowed to 'opt-out', and submit information individually, for certain specific reasons.

In accordance with Article 20 REACH, once a registration dossier has been 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. These decisions can be appealed before the Board of Appeal.[1]

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1 Decisions withholding a registration number (Art 20(2), para 4, REACH) and decisions granting a registration number (Art 20(3) REACH) can be appealed; *REACheck Solutions* (I) A-022-2013, decision of 15 March 2016 [*REACheck Solutions* (I) hereafter] paras 61 to 64. Decisions requiring a registrant to complete its registration dossier (Art 20(2), para 3, REACH) might also challengeable, but the point has not yet been tested.

There have been mainly two types of completeness check cases before the Board of Appeal: (1) cases concerning registration dossiers that were found to be incomplete because they lacked technical information, and (2) cases concerning registration dossiers that were submitted entirely separately from an existing registration for a substance. An examination of these cases shows that the Board of Appeal has had a considerable impact on the way in which the ECHA Secretariat manages the registration of substances.

## 1. Dossiers Lacking Technical Information

There have been few appeals against decisions finding newly submitted registration dossiers to be incomplete in the sense that they did not contain all the required technical information (10 at the time of writing, which amounts to approximately 0.001% of all registrations).

This may be because Article 20 REACH provides for a procedure in several steps, giving registrants ample opportunity to put their registrations in order before an eventual decision. It may also be because the ECHA Secretariat initially implemented the completeness check procedure as an entirely automated procedure based on an algorithm which verified that the relevant fields of a registration dossier contained text, but not whether that text conveyed meaningful information to satisfy the applicable information requirements. This algorithm was, moreover, made available to registrants as an 'IT tool'. Provided that the relevant fields contained text, therefore, registration dossiers were normally accepted as complete.[2]

The Board of Appeal addressed how the ECHA Secretariat should verify the completeness of registration dossiers in REACheck Solutions (I). In that case, the ECHA Secretariat relied on Article 20(2) REACH, which provides that '[t]he completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted', in order to argue that it could only verify that text was included in the relevant fields of a dossier. The Board of Appeal however found that a completeness check cannot resolve itself in a purely automated verification of whether the relevant fields of a registration dossier contain text. The check must also ensure that the information provided addresses all the applicable requirements and is meaningful.[3]

ECHA subsequently introduced an 'enhanced completeness check', including a manual screening of some newly submitted registration dossiers, and re-examined a number of previously submitted dossiers for completeness. This procedure should ensure that registrants have not abused the registration procedure by filling in registration dossiers without meaningfully addressing the applicable information requirements. This, in turn, should contribute to improving the quality of submitted data.[4]

The Board of Appeal has not yet examined how far a compliance 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, the remarkably low number of appeals in this area may support the view that there is scope for a deeper scrutiny of submitted dossiers under Article 20 REACH.

## 2. Dossiers Contravening the Principle of 'One Substance, One Registration'

There have been a number of appeals concerning registration dossiers which – although not considered by the ECHA Secretariat to be incomplete in terms of the information contained in them – were submitted independently from an existing registration for a substance, contrary to the principle of 'one substance, one registration'.

In the first such case, REACheck Solutions (I), the lead registrant of charcoal challenged an ECHA decision accepting another company's registration of that

2 *REACheck Solutions* (I) para 99; ECHA has made available an IT tool to verify whether a registration would pass the automated completeness check.

3 *REACheck Solutions* (I) paras 103 and 107; See also *REACheck Solutions* (II) A-011-2017, decision of 23 March 2018 [*REACheck Solutions* (II) hereafter] para 47. The Board of Appeal did not address whether and under which conditions administrative decisions can be taken purely by means of algorithms, although the question has exercised scholars for some time; Marion Oswald, 'Algorithm-assisted Decision-making in the Public Sector: Framing the Issues using Administrative Law Rules Governing Discretionary Power' (2018) 376 Philosophical Transactions of the Royal Society A, 2128; Jennifer Cobbe, 'Administrative Law and the Machines of Government: Judicial Review of Automated Public-sector Decision-making' (2019) Legal Studies 1-20.

4 European Commission, 'Commission Staff Working Document Accompanying the Commission General Report on the Operation of REACH and Review of Certain Elements' (2018) SWD(2018)58 final, Section 1.1.6 <https://eur-lex.europa.eu/legal-content/EN/TXT/?uri=SWD:2018:58:FIN> accessed 10 October 2019.

substance on the grounds that the other registrant had submitted its registration dossier entirely independently, thereby breaching the principle of 'one substance, one registration'.[5]

At the outset, the Board of Appeal examined the admissibility of the appeal. It found that a completeness check decision that allows a subsequent registrant to submit a registration dossier entirely independently of an existing registration may have the effect of allowing that subsequent registrant to circumvent its data and cost sharing obligations. In the circumstances of the case, the contested completeness check decision deprived the previous registrant of a possible claim for compensation for vertebrate animal studies included in its dossier that were necessary for the registration of the substance.[6] The previous registrant therefore had standing to challenge the decision before the Board of Appeal as the decision was of direct and individual concern to it.

Having declared the case to be admissible, the Board of Appeal found that adherence to the principle of 'one substance, one registration' is one of the elements which ECHA is required to verify when carrying out a completeness check under Article 20 REACH.[7]

Following REACheck Solutions (I), and the entry into force of Commission Implementing Regulation 2016/9 on joint submission of data and data-sharing,[8] ECHA did not include adherence to the principle of 'one substance, one registration' among the elements verified during the course of a completeness check. However, in order to give substance to that principle, ECHA instituted an additional measure at the point of submission of a registration dossier. After 21 June 2016, it became technically impossible to submit a registration dossier for a substance that was already registered without an alphanumerical code issued by the substance's lead registrant, a so-called 'token for access to a joint submission'.[9]

Starting on 21 June 2016, this 'token' therefore ensured adherence to the principle of 'one substance, one registration'. To this end, the 'token' gave lead registrants the possibility of preventing subsequent registrants from submitting a registration dossier to ECHA. By withholding or threatening to withhold the 'token', a lead registrant could, in effect, police the compliance of subsequent registrants with their data-sharing obligations.

However, a lead registrant could abuse the power afforded by the 'token' to prevent a subsequent registrant from submitting a registration dossier even if the subsequent registrant required no data from the lead registrant.[10] Such abuses were prevented by introducing a 'joint submission dispute procedure'[11] under which it assessed whether the subsequent registrant had made 'every effort to join a joint submission'. If so, ECHA would grant the subsequent registration a 'token' in place of the lead registrant.

A decision taken on the basis of the 'joint submission dispute procedure' was challenged before the Board of Appeal for the first time in REACheck Solutions (II).[12] The Board of Appeal dismissed the case as inadmissible for lack of competence. However, the admissibility and the substance of the case were intertwined. In addressing the admissibility of the case, the Board of Appeal examined the principle of 'one substance, one registration' as a part of the wider and coherent administrative system established by the REACH Regulation. Based on this examination, the Board of Appeal found that making a 'token' issued by a lead registrant a condition for submitting a registration dossier to ECHA is neither necessary nor desirable.

Specifically, the Board of Appeal found that the principle of 'one substance, one registration' does not prevent a subsequent registrant from opting out from sharing some, or even all, of a previous regis-

5 *REACheck Solutions* (I).

6 *REACheck Solutions* (I) paras 81, 82, 86 and 92. The wording 'direct and individual concern' is clearly based on what is now Art 263 TFEU. The Board of Appeal held that the case-law on that provision applies, by analogy, to Art 92 REACH. See *REACheck Solutions* (I) para 69; *Manufacture Française des Pneumatiques Michelin*, decision of 30 May 2017, A-022-2015, paras 115 and 116.

7 Under Arts 10 and 20(2) REACH in conjunction with Se 1 of Annex VI REACH; *REACheck Solutions* para 119.

8 Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with the REACH Regulation [2016] OJ L 3, 41.

9 The 'token' was initially introduced as an administrative tool to 'link' registration dossiers of the same substance to each other. That use was and is unobjectionable insofar as it does not amount to preventing a registrant from submitting its dossier. See, to this effect, Case T-806/17 *BASF and REACH & Colours* v *ECHA* [2019] EU:T:2019:724, para 97; *REACheck Solutions* (II) para 44.

10 Art 11(3) REACH allows registrants to opt out from submitting information jointly if certain conditions are fulfilled. A lead registrant could potentially refuse to pass on a token if it disagreed with the subsequent registrant's reasons for opting out.

11 ECHA, 'Guidance on Data-Sharing' (January 2017) 159 <https://echa.europa.eu/documents/10162/23036412/guidance_on_data_sharing_en.pdf/545e4463-9e67-43f0-852f-35e70a8ead60> accessed 10 October 2019.

12 *REACheck Solutions* (II).

trant's data. Article 11 REACH requires data to be submitted jointly, but also allows subsequent registrants to submit data individually if certain conditions are fulfilled. It is the role of ECHA, and not of a lead registrant, to ensure that a registrant adheres to Article 11 REACH both as regards the principle of 'one substance, one registration' and the possibility for a registrant to opt out of submitting information jointly with others. Specifically, completeness checks ensure that registrations that use an opt-out contain meaningful information, whilst compliance checks ensure that opt outs are justified and that registration dossiers using opt-outs meet the full information requirements of the REACH Regulation.

Ultimately, the Board of Appeal considered that the 'token' may be a useful administrative tool to link registrations to each other in an electronic computer system. There is, however, no legal basis in the REACH Regulation to allow lead registrants to prevent subsequent registrants from submitting a registration dossier as part of a joint registration.

The reasoning in REACheck Solutions (II) shows that the Board of Appeal took a different view of the principle of 'one substance, one registration' than either ECHA or the appellant in that case. In essence, the decision is based on the premise that it is incumbent on each registrant to ensure that its own dossier satisfies all the applicable requirements, including the principle of 'one substance, one registration'. ECHA then has mechanisms at its disposal, as specified in the REACH Regulation, to verify the completeness and compliance of every registration dossier submitted to it. The REACH Regulation does not give lead registrants the powers or responsibility to ensure that their fellow registrants comply with their obligations.

REACheck Solutions (II) caused ECHA to change its procedures and provide 'tokens' upon request from a subsequent registrant who wishes to submit all information separately as a 'total opt-out'. Registration dossiers containing opt-outs should also now be prioritised for compliance checks as required by Article 41 REACH.

Interestingly, ECHA adopted two decisions on 'joint submission disputes' shortly before the Board of Appeal issued its decision in REACheck Solutions (II). The two ECHA decisions were challenged simultaneously before the Board of Appeal and the General Court. The judgments of the General Court, which were issued shortly before the publication of this article, confirmed the approach of the Board of Appeal: potential registrants cannot be prevented (for example because they do not obtain a 'token' from the lead registrant) from submitting their registration dossier as part of an existing joint registration.[13]

Following REACheck Solutions (I), in addition to modifying its procedures for new registration dossiers at the point of submission, ECHA sought to address the situation of those substances for which it had already accepted independent registrations. To this end, ECHA sent communications to all the registrants of those substances for which there were several independent registrations. In those communications, ECHA requested all the registrants of a substance to comply with the principle of 'one substance, one registration'. Registrants who failed to do so faced the possibility of revocation of the decisions finding their registration dossiers to be complete, and the subsequent rejection of their registration dossiers. Several appeals were filed against these communications.[14]

In one of these cases, Thor, the Board of Appeal held that ECHA's communication requiring registrants to comply with the principle of 'one substance, one registration' was 'equivalent to a decision adopted pursuant to Article 20(2) [REACH]', and therefore fell within its competence.[15] This approach appears to differ from that of the General Court, which assesses the admissibility of a case based on the legal basis formally stated in an act, whilst the Board of Appeal assesses it based on what the legal basis should have been.[16]

Furthermore, the Board of Appeal found in Thor that breaches of the principle of 'one substance, one

13 T-805/17 *BASF* v *ECHA* [2019] EU:T:2019:723; T-806/17 *BASF and REACH & Colours* v *ECHA* [2019] EU:T:2019:724. The decisions at issue in these cases were also challenged respectively in *BASF* A-015-2017 (pending) and *BASF and REACH & Colours* A-016-2017 (pending).

14 *Thor* A-005-2017, decision of 29 January 2019 [*Sustainability Support Services (Europe)* hereafter]; *Sustainability Support Services (Europe)* A-025-2018 to A-027-2018 (withdrawn after rectification) [hereafter]; *Elkem* A-024-2015 (withdrawn after rectification).

15 *Thor* paras 43 to 49; *REACheck Solutions* (II) paras 30 and 60 to 62.

16 T-283/15 *Esso Raffinage* v *ECHA* [2018] EU:T:2018:263, points 33 to 37 (currently under appeal on other grounds). However, see also *Symrise* A-012-2019, decision of the Chairman of the Board of Appeal of 16 September 2019, in which the Chairman dismissed the case on the grounds that the contested decision was not adopted based on one of the provisions listed in Art 91 REACH.

registration' must be addressed under the completeness check or compliance check procedures (Article 20 viz. 41 REACH). ECHA should not circumvent the system and procedures established by the REACH Regulation by issuing informal communications with legal effects.[17]

Finally, the decision of the Board of Appeal in REACheck Solutions (I) also led ECHA to address the situation of those substances for which, at the time when ECHA accepted independent registrations of the same substance, registrants had formed more than one joint registration and one of the lead registrants subsequently refused to relinquish its position. To address these cases, ECHA instituted a 'lead registrant dispute procedure'. An appeal on this issue is currently pending.[18]

In all of its decisions concerning the principle of 'one substance, one registration', and the connected data and cost sharing requirements, the Board of Appeal has consistently placed emphasis on the implementation of the REACH Regulation as a coherent administrative system, and particularly the interplay between the procedures established for registration, data-sharing, and compliance checks. In so doing, it has insisted on the extent of, and limits to, ECHA's legal mandate, taking a critical view of steps which are not specifically foreseen in the REACH Regulation.

## II. Data-Sharing

The REACH Regulation requires registrants and subsequent registrants to share data derived from tests on vertebrate animals, and the costs relating to those data. The data-sharing regime under the REACH Regulation consists of three elements: (i) a prohibition of duplicate testing on vertebrate animals, (ii) a protection period of 12 years during which registrants can refer to each other's data only in return for compensation, and (iii) the possibility of obtaining from ECHA permission to refer to data derived from testing on vertebrate animals submitted by other registrants.

These three elements pursue different, and sometimes conflicting, objectives. On the one hand, registrants who have submitted vertebrate animal studies in their registration dossier may try to abuse the prohibition of duplicate testing and the protection period to 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. Such practices can constitute abuses of a dominant position.[19] On the other hand, subsequent registrants may be tempted to seek a permission to refer from ECHA simply to attempt to make it more difficult for registrants who have submitted vertebrate animal studies in their registration dossier to obtain fair compensation for those studies.

The wording of Article 30(3) REACH might suggest that, once vertebrate animal tests have been submitted to ECHA, ECHA should grant a permission to refer automatically, without any assessment of registrants' efforts. The ECHA Secretariat, however, has given a different, contextual and purposive interpretation to this provision. The Board of Appeal implicitly accepted that interpretation, which is also reflected in Article 5(1) of Implementing Regulation 2016/9 on joint submission of data and data-sharing.[20]

According to this interpretation, if a subsequent registrant files a data-sharing dispute with ECHA pursuant to Article 30 REACH, ECHA will grant it permission to refer only on condition that it has made every effort to reach an agreement with the previous registrant who submitted the information. In REACH & Colours, the Board of Appeal set out criteria for this assessment.[21]

First, ECHA should take account of the negotiations which took place between the parties with regard to those points which engendered the disagreement that led to the filing of the application with ECHA for a permission to refer. Where a subsequent

17 *Thor* paras 63 and 88.

18 *Sustainability Support Services (Europe)* (pending).

19 In the context of phytosanitary products, the Italian Competition Authority fined Bayer Cropscience, who held a study on vertebrate animals that was required by a competitor in order to enter the market for certain phytosanitary product, for its stance in data-sharing negotiations. The phytosanitary products regime prevented the duplication of tests on vertebrate animals and required the sharing of data, but had no mechanism like a permission to refer under Arts 27 and 30 REACH. The decision was based on the essential facilities doctrine under Art 102 TFEU. See AGCM, decision of 28 June 2011, n 22558, A415 – Sapec Agro/Bayer-Helm; ultimately upheld in Cons di Stato, sez VI, sent 29 gennaio 2013 n 548.

20 *Vanadium REACH Forschungs- und Entwicklungsverein* A-017-2013, decision of 17 December 2014 [*Vanadium REACH Forschungs- und Entwicklungsverein* hereafter] para 42; *REACH & Colours and REACH & Colours Italia* A-010-2017, decision of 15 April 2019 [*REACH & Colours and REACH & Colours Italia* hereafter] paras 51 to 59.

21 *REACH & Colours and REACH & Colours Italia* paras 76 to 88.

registrant has challenged specific terms and conditions for cost-sharing proposed by a previous registrant, ECHA's assessment is limited to those specific terms and conditions.

Second, ECHA should assess whether the terms on which a previous registrant has insisted – thereby causing the negotiations to falter – are substantively transparent, fair and non-discriminatory.

'Transparent' means that the conditions proposed by the previous registrant must be clear. Criteria are to be found in Article 30(1) 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. ECHA should then proceed to the next two steps – whether the terms are fair and non-discriminatory – only if the conditions proposed by the previous registrant are clear. If the terms are not clear, neither the subsequent registrant nor ECHA are in a position to determine whether they are fair and non-discriminatory, and the horse falls at the first hurdle.

'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.

'Non-discriminatory' means that registrants who are in comparable situations must not be treated differently and registrants who are in different situations must not be treated in the same way unless such treatment is objectively justified. Registrants are in comparable situations insofar as they need a certain piece of information in order to register a substance.

Finally, following the assessment of the relevant points leading to the dispute against the requirements of transparency, fairness and non-discrimination, ECHA can conclude on whether to grant a permission to refer. The Board of Appeal has not defined the exact extent to which a subsequent registrant must engage in negotiations in order to make 'every effort' as this depends on the context and particular circumstances of each case. However, precedent suggests that if a registrant was right to object to proposed terms on the grounds that they are unclear, unfair or discriminatory, then ECHA should grant it permission to refer.[22]

It has been suggested that the approach taken by the Board of Appeal may lead to greater transparency in data-sharing, and reduce costs for subsequent registrants.[23] Time will tell whether the Board of Appeal has struck the correct balance between the protection of subsequent registrants from abuse by previous registrants, and the compensation of previous registrants for the use of data they generated and submitted.[24] It will also be interesting to see what the Courts will make of the cost and data-sharing provisions in the REACH Regulation if such a case is brought before them.

## III. Compliance Checks

Article 41 REACH empowers ECHA to verify that the information submitted in a registration dossier complies with the applicable information requirements. This assessment goes beyond completeness, as it includes verifying the quality and adequacy of information.

The compliance check procedure is, arguably, the keystone of the REACH Regulation. On the one hand, it follows on from the completeness check of registration dossiers, allowing ECHA to ensure that the information provided by registrants is not only complete, but in fact satisfies all the applicable rules and requirements. On the other hand, the compliance check procedure is an essential first step towards risk assessment and regulatory risk management. Having a fully compliant base-set of data makes it possible to assess whether further information on a substance should be requested or stricter regulatory measures are needed.

There are three recurring themes in compliance check cases before the Board of Appeal: (1) the role of compliance checks within the broader system of REACH processes, (2) issues of administrative procedure, and (3) the interpretation of specific information requirements in the REACH Regulation.

22 *REACH & Colours and REACH & Colours Italia* paras 174-176.

23 Chemical Watch, 'BoA Decision Expected to Have Major Impact on EU Data Sharing' (*Chemical Watch*, 9 May 2019) <https://chemicalwatch.com/77358/boa-decision-expected-to-have-major-impact-on-eu-data-sharing> accessed 10 October 2019.

24 For one view, Simon Tilling and Tom Gillet, 'Expert Focus: What is Fair in the Context of Data and Cost Sharing under REACH?' (*Chemical Watch*, 28 June 2019) <https://chemicalwatch.com/79008/expert-focus-what-is-fair-in-the-context-of-data-and-cost-sharing-under-reach> accessed 10 October 2019.

## 1. 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 verify that registration dossiers comply with the applicable requirements. The Board of Appeal has examined the implementation of this provision in a number of cases.[25] It has consistently held that, once ECHA has concluded that there is a data-gap in a registration dossier, it has exhausted the extent of its discretion under Article 41 REACH. In most cases – depending on the wording of the information requirement at issue[26] – the consequences of the finding of a data-gap by ECHA 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 REACH Regulation itself.[27]

This approach might seem hard-hearted, as it might force a registrant to provide information even where it can demonstrate that its uses of a substance pose no risk.[28] Waiving information requirements based on the absence of risk, however, would not be consistent with the scheme of the REACH Regulation. The REACH Regulation is based on the premise that the intrinsic properties of a substance should be investigated separately from the likelihood of exposure to that substance. Additionally, uses and exposure patterns can be different from registrant to registrant and may change over time, whilst the intrinsic properties of a substance do not. Only as a second step are the two kinds of information, hazard and exposure, combined in order to assess risk, for example in a chemical safety assessment.[29]

Article 42 REACH requires ECHA to examine any information submitted following an initial compliance check decision under Article 41 REACH, and take a follow-up decision if necessary. The Board of Appeal examined the implementation of this provision in Solutia Europe.[30] The case concerned a communication, called a 'statement of non-compliance', by which ECHA informed a national authority that a registrant had not filled a data-gap following an initial compliance check decision, and requested that authority to impose sanctions.[31] The Board of Appeal found that the communication should have been adopted under Article 42 REACH because it required the assessment of 'new and substantial information' provided following an 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 Esso Raffinage v ECHA.[32] It annulled another 'statement of non-compliance' on the grounds 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. The Federal Republic of Germany has appealed this judgment to the Court of Justice.[33] A case against a follow-up decision adopted under Article 42 REACH is also pending before the Board of Appeal.[34]

These and other cases show that the Board of Appeal 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

25 For example, *Dow Benelux* A-001-2012, decision of 19 June 2013 [*Dow Benelux* hereafter] paras 112, 116 and 126; *Polynt* A-004-2015, decision of 19 October 2016 [Polynt hereafter] paras 137, 138 and 140; *Climax Molybdenum* A-006-2017 [*Climax Molybdenum* hereafter] decision of 11 December 2018.

26 Some information requirements leave ECHA a margin of discretion as regards the choice of study, or whether a study is necessary. See *Honeywell* A-005-2011 [*Honeywell* hereafter] decision of 29 April 2013, paras 70 and 170.

27 *Climax Molybdenum* paras 118 to 123.

28 This was the essential issue behind *Climax Molybdenum*. The case concerned a study that had been carried out in order to show the absence of risk at a particular level of exposure, and may well have succeeded in that, but provided little information on the intrinsic properties of the substance in question.

29 *Climax Molybdenum* paras 131 to 135.

30 *Solutia Europe* A-019-2013 [*Solutia Europe* hereafter] decision of 29 July 2015.

31 To be precise, the case concerned the follow-up to a request for information under Belgian legislation transposing Council Directive 67/548/EEC on the approximation of the laws, regulations and administrative provisions relating to the classification, packaging and labelling of dangerous substances T-283/15OJ 196, 1. Such requests were considered to be compliance check decisions pursuant to Art 135(1) of the REACH Regulation.

32 T-283/15 *Esso Raffinage* v *ECHA* [*2018*] EU:T:2018:263, para 114.

33 C-471/18 P *Germany* v *Esso Raffinage* (pending).

34 *Solvay Fluor* A-001-2019 (pending) [*Solvay Fluor* hereafter].

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 XI REACH.

Under Article 42 REACH, ECHA should then 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 authorities of the Member States 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.[35]

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 enforcement authorities of the Member States, this should prevent registrants abusing the compliance check procedure by repeatedly submitting invalid adaptations. In other words, a registrant who has received a first compliance check decision (Article 41 REACH) runs a salutary risk of being sanctioned if whatever information it provides to ECHA does not fill the identified data-gap. However, before being sanctioned that registrant enjoys the protection afforded by the follow-up procedure (Article 42 REACH). This offers the registrant greater protection, and arguably encourages the use of adaptations, by giving them a 'second bite at the cherry' rather than the previous ECHA approach whereby a non-compliant adaptation lead to ECHA issuing a statement of non-compliance.

Overall, its decisions show that the Board of Appeal has consistently emphasised that it is the sole responsibility of registrants to ensure that their registration dossiers comply with the requirements of the REACH Regulation, the duty of ECHA to verify that they do, and the Member State enforcement authorities to act on non-compliance.

## 2. 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 prepared by the ECHA Secretariat, and on any proposals for amendment submitted by the competent authorities of the Member States.

The Board of Appeal 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, the Board of Appeal has held that ECHA must give registrants a proper hearing, particularly if there are substantial changes in a draft decision at a very late stage of the decision-making procedure;[36] that ECHA must, in certain circumstances, take into account information that becomes available, or is included in a registration dossier, when the decision-making procedure is already under way;[37] that ECHA must give an adequate statement of reasons for its decision;[38] and that 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.[39]

By emphasising these requirements, the Board of Appeal has – arguably – contributed significantly to ensuring that ECHA's decisions are carefully consid-

35 See *Esso Raffinage* v *ECHA* para 114 (currently under appeal in case C-471/18 P).

36 *Polynt* para 64 to 66.

37 *CINIC Chemicals Europe* A-001-2014 [*CINIC Chemicals Europe* hereafter] decision of 10 June 2016; *BASF* A-017-2014 [*BASF* hereafter] decision of 7 October 2016; *BrüggemannChemical* A-001-2018 [*BrüggemannChemical* hereafter] decision of 9 April 2019.

38 *BASF Personal Care and Nutrition* A-013-2016 [*BASF Personal Care and Nutrition* hereafter] decision of 12 December 2017, paras 35 to 37.

39 *Evonik Degussa* A-008-2015 [*Evonik Degussa* hereafter] decision of 12 October 2016; *IQESIL* A-009-2015 [*IQESIL* hereafter] decision of 12 October 2016; *Rhodia Operations* A-010-2015 [*Rhodia Operations* hereafter] decision of 12 October 2016; *J.M. Huber Finland* A-011-2015 [*J.M. Huber Finland* hereafter] decision of 12 October 2016.

ered and thoroughly justified. Anecdotal evidence suggests that this may have increased the acceptance of those decisions by registrants, thereby also reducing the number of appeals against compliance check decisions.

In addition, the appeal procedure itself is an opportunity to ensure that registrants do not suffer the consequences that flow from the finding of a data-gap – i.e. expense and, potentially, sanctions – without ample opportunity to put their registration dossiers in order. Appeals have suspensive effect and, in principle, the Board of Appeal has the power to substitute an erroneous contested decision with a different one.[40] It can moreover include in its assessment new information that a registrant submits to the Board of Appeal even if it was not available to the ECHA Secretariat and the competent authorities at the time of the initial decision-making.[41] In extremis, this may mean that a registrant has the possibility to fill a data-gap in the appeal procedure.[42]

## 3. Interpretation of Specific Information Requirements

The information requirements in the REACH Regulation are not always completely clear. Examples are the substance identity requirements for nanoforms and the definition of intermediates, both of which have been the subject of appeals.

The Board of Appeal addressed the registration requirements for nanoforms in Huntsman P&A.[43] The case concerned the compliance check of a registration dossier for titanium dioxide. The registrant had given a broad definition of the substance, covering several crystal phases and all nanoforms. ECHA had considered that the registrant was required to submit further information on substance identity under Section 2 of Annex VI REACH.

The Board of Appeal found that Section 2 Annex VI REACH contained a clear and closed list of information requirements as regards the identity of a substance and these did not include a requirement to identify precisely the crystal phases and nanoforms.

At the same time, however, the Board of Appeal stated that where a registrant of a substance chooses to give a broad definition of its registered substance, the information provided in its registration dossier must address the intrinsic properties of all forms of the substance covered by the broad substance definition. This may be burdensome, but the extent of the burden on a registrant to provide the relevant information depends on its own choices: the broader the substance definition the more information is required. This interpretation of the relationship between substance identity and information requirements will soon be reflected expressly in the Annexes to the REACH Regulation.[44]

The second example concerns the definition of intermediates, which the Board of Appeal addressed in Nordenhamer Zinkhütte.[45] In that case, a registrant claimed that it was exempted from a number of information requirements because it used the registered substance as an intermediate under strictly controlled conditions. ECHA considered that the registrant did not use the substance as an intermediate because the 'main aim' of its use was not to transform it into another substance, but rather to purify a solution of zinc salts before electrolysis.

The Board of Appeal was therefore called upon to give an interpretation of the definition of 'intermediate' in Article 3(15) REACH. According to this provision, an intermediate 'means a substance that is manufactured for and consumed in or used for chem-

40 T-125/17 *BASF Grenzach* v *ECHA* [2019] EU:T:2019:638, para 118. However, the Board of Appeal is not required to evaluate whether, at the time it rules on an appeal, a new decision with the same operative part as the decision contested before it may lawfully be adopted. Moreover, when deciding how to exercise its powers, the Board of Appeal must take into account the role of the Member States in the decision-making procedure under Arts 50 and 51 REACH; *BASF Grenzach* v *ECHA* paras 88, 89, 94 and 95.

41 *BASF Grenzach* A-018-2014 [*BASF Grenzach* hereafter] decision of 19 December 2016, para 123.

42 *Climax Molybdenum* para 31; *Polynt* para 133; *Dow Benelux* para 46; In those cases, the Board of Appeal assessed information that had not previously been available, and concluded that even with this new information there were still data-gaps in the Appellant's registration dossier.

43 *Huntsman P&A and Others* A-011-2014 [*Huntsman P&A and Others* hereafter] decision of 2 March 2017.

44 Point 3(a) of the Annex to Commission Regulation (EU) 2018/1881 amending the REACH Regulation as regards Annexes I, III, VI, VII, VIII, IX, X, XI, and XII to address nanoforms of substances [2018] OJ L 308, 1 states: 'More than one dataset may be required for one or more information requirements whenever there are significant differences in the properties relevant for the hazard, exposure and risk assessment and management of nanoforms. The information shall be reported in such a manner that it is clear which information in the joint submission pertains to which nanoform of the substance. Where technically and scientifically justified, the methodologies set out in Annex XI.1.5 shall be used within a registration dossier when two or more forms of a substance are "grouped" for the purposes of one, more or possibly all the information requirements.'

45 *Nordenhamer Zinkhütte* A-010-2014 [*Nordenhamer Zinkhütte* hereafter] decision of 25 May 2016.

ical processing in order to be transformed into another substance (hereinafter referred to as synthesis)'.

Based on a literal, contextual and purposive interpretation of this provision, the Board of Appeal held that ECHA had misinterpreted it by adding a requirement that was not in the REACH Regulation, namely that, in order to be considered as an intermediate, a substance must be used with the 'main aim' of transforming it into another substance whose manufacture is the purpose of the industrial process in which the substance at issue is employed as an intermediate.[46]

The General Court addressed the issue in a case, PPG and SNF v ECHA, which concerned ECHA's decision to identify acrylamide as a substance of very high concern. The General Court held that classifying a use as an intermediate use depends on the aim or main purpose of the chemical process in which a substance is used.[47] The Court of Justice however eventually disagreed on that point, holding that the classification of a substance as intermediate does not depend on whether the purpose of use is primary or secondary in nature.[48]

### 4. Conclusions on the Board of Appeal's Approach to the Compliance Check Procedure

The Board of Appeal has consistently emphasised, and differentiated between, the respective responsibilities of registrants, ECHA, and Member State competent authorities under the compliance check procedure.

On the one hand, the Board of Appeal has held ECHA to high and stringent standards. It found that ECHA 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 the REACH Regulation; and that decisions must be written clearly and address the relevant legal criteria.

On the other hand, the Board of Appeal 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 procedure.

## IV. Substance Evaluation

The REACH Regulation provides for the evaluation of individual substances, as opposed to registration dossiers, with a view to determining whether they pose a risk to human health or the environment and therefore need to be further regulated. During the course of this assessment it may become apparent that further information is needed in order to clarify whether a substance poses a certain risk or not. Article 46 REACH empowers ECHA to require the registrants of the substance in question to provide the information needed to clarify the potential risk.

Requests for further information under Article 46 REACH often aim at determining whether a substance fulfils one or more of the conditions to be identified as a substance of very high concern, as set out in Article 57 REACH. However, Article 46 REACH can be used with a view to further regulation under the REACH Regulation as well as, arguably, under other pieces of sectoral EU legislation.[49]

46 *Nordenhamer Zinkhütte* para 45 to 49.

47 T-268/10 RENV *PPG and SNF* v *ECHA* [2015] EU:T:2015:698, para 54. In that case, the issue was that the main purpose of the use of the substance (as a grouting agent) was to achieve a sealing function.

48 C-650/15 P *PPG and SNF* v *ECHA* [2017] EU:C:2017:802, paras 35 to 38.

49 For example, the Board of Appeal implicitly accepted that a study can be required under Art 46 REACH with a view to determining whether the substance under evaluation should be classified as a developmental toxicant under Regulation (EC) No 1272/2008 on classification, labelling and packaging of substances and mixtures [2008] OJ L 353 1; *Akzo Nobel Chemicals and Others* para 55 ff.

By contrast to the compliance check procedure, Article 46 REACH gives ECHA a discretion not only as regards whether to request further information, but also which information to request.[50] Requests for further information under Article 46 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 studies according to modified test protocols.

Furthermore, a request for further information under Article 46 REACH may concern any information that is needed in order to clarify a potential risk posed by a substance, including information on substances other than the one being evaluated. An example is SI Group UK and Others (I), in which Board of Appeal held that ECHA can request information on substances other than the one under evaluation – namely on the polymers derived from an evaluated monomer – insofar as information on other substances is needed in order to clarify a potential risk posed by the substance under evaluation.[51]

Given the extent of ECHA's power under Article 46 REACH, the breadth of administrative discretion involved, and the amount of information assessed, appeals in substance evaluation cases tend to raise many pleas in law and stir up very large numbers of scientific arguments. In general, however, there are two types of issues facing the Board of Appeal: the conditions which must be fulfilled in order for ECHA to request further information under Article 46, and the formal and procedural requirements which ECHA and the competent authorities of the Member States must respect.

## 1. Conditions for Requiring Further Information

The Board of Appeal has interpreted Article 46 REACH in light of the objectives of the REACH Regulation, the principle of proportionality and the precautionary principle. According to this interpretation, in order to require registrants to submit further information, ECHA must establish that two conditions are fulfilled: (i) the substance in question must pose a potential risk that needs to be clarified, and (ii) the requested measure must have a realistic possibility of leading to improved risk management measures.[52] This interpretation has recently been confirmed by the General Court.[53]

The first condition – whether a substance poses a potential risk that needs to be clarified – is satisfied if it can be shown that a substance may have a certain hazardous property, and humans or the environment may be exposed to it.[54] Provided that it can establish the existence of a potential risk, ECHA is not required to show that a risk actually exists: the purpose of requests for further information under Article 46 REACH is precisely to clarify whether a risk actually exists or not.

The REACH Regulation does not set a high bar in this respect. 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.[55] Moreover, if evidence of a hazard is particularly strong or the hazard particularly severe, evidence of exposure can be correspondingly less (and vice versa).[56]

The Board of Appeal has also emphasised repeatedly that, whilst requests for further information under Article 46 REACH require the assessment of all available information on a substance, they are not based on a 'weight of evidence' assessment within the meaning of Annexes XI and XIII REACH. Contrary to those annexes, a request for further information under Article 46 REACH is not based on a firm

50 According to one view, this discretion does not lie with ECHA but with the Member States. The General Court and the Board of Appeal have however taken a different view; T-755/17 *Germany* v *ECHA* [2019] EU:T:2019:647, para 76.

51 *SI Group-UK and Others* (I) A-006-2016 [*SI Group-UK and Others* (I) hereafter] decision of 6 June 2018, paras 42 to 53.

52 See for example, *Akzo Nobel Industrial Chemicals* paras 55 to 60; *International Flavors & Fragrances* A-006-2014 [*International Flavors & Fragrances* hereafter] decision of 27 October 2015, paras 74 to 76; *Albemarle Europe and Others* A-009-2014 [*Albemarle Europe and Others* hereafter] decision of 12 July 2016, para 71; The Board of Appeal sometimes also referred to three distinct conditions – that there is a potential risk, that it needs to be clarified, and that clarifying it may lead to improved risk management measures.

53 T-125/17 *BASF Grenzach* v *ECHA* [2019] EU:T:2019:638, para 276; T-755/17 *Germany* v *ECHA* [2019] EU:T:2019:647, para 287.

54 *Akzo Nobel Industrial Chemicals*, para 59; T-125/17 *BASF Grenzach* v *ECHA* [2019] EU:T:2019:638, paras 271 and 272.

55 For example, *Envigo Consulting and DJChem Chemicals Poland* A-026-2015 [*Envigo Consulting and DJChem Chemicals Poland* hereafter] decision of 8 September 2017, para 64 to 72; and *International Flavors & Fragrances* para 87; However, see also *Akzo Nobel Industrial Chemicals* para 70, where the Board of Appeal held that the evidence did not justify a request for further information.

56 *Envigo Consulting and DJChem Chemicals Poland* para 42; *Evonik Degussa and Others* para 82.

conclusion, based on the weight of the evidence and expert judgment, on whether a substance has or has not a certain property. Under Article 46 REACH, it is sufficient for ECHA to establish that a substance might have a certain property.[57]

This approach is consistent with the purpose of Article 46 REACH, which is to obtain further information in cases in which existing information – especially the information derived from the application of the standard information requirements in the REACH Regulation – shows that a substance might pose a risk.

The second condition for requesting further information under Article 46 REACH – that the further information required by ECHA must have a realistic possibility of leading to improved risk management measures – should not be problematic in most cases. As mentioned above, these improved risk management measures can arguably be of any kind and need not be limited to the authorisation and restriction provisions in the REACH Regulation. This condition is intended to ensure that requests for further information demonstrably aim to protect human health or the environment by regulating the use of a substance, preventing so-called 'fishing expeditions' or 'research projects'.

In addition to these two conditions – that there is a potential risk, and that clarifying the risk has a realistic possibility of leading to improved risk management measures – the Board of Appeal has consistently held that if ECHA requires registrants to provide certain information, it must also be able to establish that the requested information is capable of clarifying the potential risk.

Indeed, under Article 46 REACH, ECHA has a discretion as to the measures to be imposed. As a consequence, it must be able to show that any measure which it does impose – such as a certain test or a requirement to provide exposure information – is proportionate, in particular, in the sense that it is capable of achieving its objective. In other words, where ECHA obliges registrants to provide further information under Article 46 REACH, it cannot simply set out an obligation of result and leave it to the registrants to find the means. A decision under Article 46 REACH should impose a specific measure, and ECHA must be able to prove that measure is capable of bringing about the desired result (i.e. to clarify the potential risk).[58] This approach was recently confirmed by the General Court.[59]

As is apparent from its decisions, the Board of Appeal has accepted that ECHA has a considerable latitude under Article 46 REACH as to whether to require further information, and what information to require. This is essential to allow ECHA to clarify potential risks, and thereby ensure that substances that pose a risk are adequately managed. This is consistent with the primary objective of the REACH Regulation, namely protection of human health and the environment, and the precautionary principle that underpins it.[60] However, the Board of Appeal has also marked the boundaries of ECHA's powers under Article 46 REACH by requiring ECHA to establish – in its decisions – that certain conditions are fulfilled.

By so doing, the Board of Appeal has contributed to structuring ECHA's assessment in the context of substance evaluation, arguably to the benefit of both the persons carrying out the assessment within authorities, and registrants. Establishing a structure for the assessment of substances subject to evaluation alleviates the main challenges of that procedure, namely the sheer quantity of information to be taken into account and the degree of scientific uncertainty comprised in that information. Ultimately, this makes it possible for ECHA to ensure – and for the Board of Appeal to verify – that the legal conditions for requiring further information are satisfied, and that information requests are proportionate.

## 2. Substance Evaluation as an Administrative Procedure

The decision-making procedure under Article 46 is similar to that for compliance check decisions. The biggest difference from the compliance check proce-

57 To this effect see, *BASF Grenzach* paras 54, 64, 151 and 152; *Evonik Degussa and Others* para 123; *Envigo Consulting and DJChem Chemicals* para 64.

58 For example, in the circumstances of one case, this meant that ECHA could not oblige the registrants of a monomer to achieve the aim of obtaining information on polymers derived from that monomer unless they manufacture or import those polymers themselves; *SI Group UK and Others* (I) para 102. In another case, the Board of Appeal held that ECHA cannot oblige registrants to achieve the aim of identifying all the metabolites of a substance if it is not certain that there are appropriate analytical methods available; *Envigo Consulting and DJChem Chemicals Poland* para 118-125; T-755/17 *Germany* v *ECHA* [2019] EU:T:2019:647, para 262.

59 ibid.

60 Recital 9 and Art 1 REACH; Also, for example, *SI Group UK and Others* (I) para 51.

dure is that it is the competent authority of a Member State, and not the ECHA Secretariat, that carries out the evaluation and drafts the decision. Registrants then have the possibility to comment on that draft, and on any proposals for amendment made by competent authorities or by ECHA. The decision is finally adopted with the unanimous agreement of all the Member State competent authorities.

Registrants frequently raise procedural issues in their appeals. One example, is whether, and how, the principle of the right to be heard applies beyond the opportunities for commenting expressly set out in Articles 50 to 52 REACH.[61]

Strictly speaking, Articles 50 to 52 REACH only foresee two such opportunities: registrants may comment on the initial draft decision prepared by the evaluating Member State competent authority, and on any proposals for amendment submitted by other Member State competent authorities or by the ECHA Secretariat.[62] Articles 50 to 52 REACH do not, therefore, allow registrants to comment on the revised draft of a decision that is prepared following their first set of comments.

However, the Board of Appeal found that registrants must sometimes be given additional opportunities to comment. The Board of Appeal went to great lengths to explain that the right to be heard is not a mere procedural formality. It is a fundamental right and serves the interests of both registrants and authorities. On the one hand, it allows the addressees of decisions that significantly affect their interests to defend themselves by influencing the decision-making process. On the other hand, it ensures that decisions are taken with all due care and prudence and the decision is substantively correct. Based on these considerations, the Board of Appeal concluded that registrants must have the opportunity to comment not only on the factual basis of a decision, in accordance with the settled case-law, but also on the information requirements ECHA intends to impose.[63]

In practice, this means that there are at least two circumstances in which registrants must be heard beyond the commenting possibilities expressly foreseen in Articles 50 to 52 REACH.[64] Firstly, substance evaluation is based on a very large amount of information and additional information may become available during the process. Therefore, it is sometimes the case that the evaluating Member State competent authority rebuts an argument made by a registrant with reference to new information. In such a case, registrants must have the possibility to comment on that information, even at a late stage of the decision-making procedure. Secondly, Member State competent authorities tend to resolve differences of view in closed-session meetings of the Member State Committee.[65] This sometimes results in entirely new or substantially revised information requirements being agreed at a late stage of the decision-making procedure. In such cases, registrants must have the possibility to comment on those new or revised information requirements.

A further procedural issue which the Board of Appeal has repeatedly addressed is whether, and under which conditions, ECHA can request standard information for a registration under Article 46 REACH (substance evaluation) instead of Article 41 REACH (compliance check). The Board of Appeal held that, as a rule, compliance checks should precede the evaluation of a substance.[66] It is only as an exception that information required for the registration of a substance should be requested under Article 46 REACH.[67] This is a necessary consequence of the way the REACH Regulation 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 Article 46 REACH, however, must be shared between all registrants of a substance. Therefore, if the substance evaluation procedure is used to request standard information, this

61 For example, *Symrise* A-009-2016 [*Symrise* hereafter] decision of 8 August 2018; *Albemarle Europe and Others* A-009-2014 [*Albemarle Europe and Others* hereafter] decision of 12 July 2016.

62 Whether the ECHA Secretariat can make proposals for amendment under Article 52 REACH is a matter of interpretation. The Board of Appeal has found that it can. *Akzo Nobel Chemicals and Others*, para 185.

63 *Symrise* paras 67 to 69.

64 *Symrise* paras 66, 75 to 84 and 95 to 108.

65 The Member State Committee is composed of representatives of the Member States; Arts 76(1)(e) and 85(3) REACH.

66 *Akzo Nobel and Others*; *Albemarle Europe and Others Infineum UK*; A-008-2017, *SI Group-UK and Oxiris Chemicals*.

67 This can only be the case if the choice of the substance evaluation procedure does not prejudice the rights of any existing registrants of the substance in question. For example, a decision under Article 46 REACH must not oblige registrants of a substance in low tonnage bands to contribute to the costs of generating information which, had the compliance check procedure been followed, would only have to be shouldered by registrants in higher tonnage bands; *SI Group UK and Others* (II), para 56 ff.

can upset the balance of rights and obligations established by the legislature. 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.

These examples show that, under Article 46 REACH, the Board of Appeal has consistently held ECHA and the Member State competent authorities to high formal and procedural standards.

Moreover, where it has found a formal or procedural shortcoming the Board of Appeal has consistently remitted the case to ECHA (viz. the evaluating Member State competent authority) for re-examination. This practice is the result of the need to balance the powers of the Board of Appeal and the role of the Member States in the context of substance evaluation.

According to Article 93(3) REACH the Board of Appeal can exercise 'any power that lies within the competence of the Agency'. The Board of Appeal therefore has the power to annul a contested decision, improve or substitute its reasons, or even revise or replace its operative part. The Board of Appeal might therefore be able to 'cure' formal or procedural shortcomings of a contested decision. For example, the Board of Appeal might find that a decision adopted under Article 46 REACH was affected by a breach of the right to be heard because the registrants had no possibility to comment on some crucial piece of information which, according to ECHA, proves the existence of a potential risk. In such a case, the Board of Appeal would have to set the contested decision aside. Assuming that it has at its disposal all the required information, the Board of Appeal could then evaluate the scientific aspects of the case, and determine whether, and which, further information should be requested.

This would however require the Board of Appeal to perform – and set out in its decision – a scientific assessment of its own. Would such an assessment on the part of the Board of Appeal be compatible with the role of the Member States in the decision-making procedure under Article 46 REACH?

The General Court recently held that the Board of Appeal has a discretion when deciding whether to replace a contested decision vitiated by an error, or whether to remit it to ECHA for further action. When exercising this discretion, the Board of Appeal must 'take into account' the role of the Member States in the decision-making procedure.[68] So far, the Board of Appeal has remitted decisions affected by formal or procedural shortcomings to ECHA. It remains to be seen whether this practice will remain unchanged. Depending on the circumstances of a case, the Board of Appeal might be able to 'cure' some types of formal or procedural shortcomings.

## 3. Conclusions on the Board of Appeal's Approach to Requests for Further Information under Article 46 REACH

Substance evaluation cases tend to be more complicated both scientifically and legally – and contentious – than compliance check cases. There appear to be three obvious reasons for this. First, substance evaluation cases involve the assessment of a much larger amount of information than the other procedures which fall under the competence of the Board of Appeal. Second, substance evaluation decisions often require substantially more information than a compliance check decision. And third, there may be several ways to clarify a potential risk. Many appeal cases raise the question of whether the approach which ECHA chose is the best and/or the least onerous. Ultimately, substance evaluation cases often hinge on the difference between the need to know and the wish to know.

In addition, there appears to be a degree of confusion as regards the nature and purpose of a request for information under Article 46 REACH. Some registrants – though by no means all – appear to believe that a request for further information already constitutes a conclusion as to whether a substance actually poses a risk to human health or the environment.[69] This, however, is not the case. The purpose of a request for further information under substance evaluation is to clarify whether a potential risk exists in practice. It may well be that, once further information is generated, a substance is proven not to pose

68 T-755/17 *Germany* v *ECHA* [2019] EU:T:2019:647, para, 88 and 89; T-125/17 *BASF Grenzach* v *ECHA* [2019] EU:T:2019:638 para 118.

69 In the same vein, applicants for interim measures before the General Court have raised the argument that the request for further information damages their reputation. See order of the President of the General Court, T-176/19 R *3v Sigma* v *ECHA* [2019] EU:T:2019:547, paras 25 and 33 dismissing the application for interim measures.

a risk. And even if the information shows that a substance does pose a risk, registrants may have the opportunity to challenge this conclusion at the stage of the identification of a substance of very high concern under Article 59 REACH, and at the stage of its inclusion in Annexes XIV or XVII REACH.

Finally, the evaluation of a substance is carried out largely by the competent authority of the evaluating Member State. Requests for further information are adopted on proposal by that authority, with the unanimous agreement of the competent authorities of the other Member States. Due to the number and diversity of the actors involved, such a system tends to produce a variety of different approaches, practices and interpretations. These inconsistencies can, in turn, lead to disputes.

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

On the one hand, Article 46 REACH 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 Board of Appeal, 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.

## V. Conclusion: Contribution and Challenges

The legislature has conferred on ECHA considerable powers vis-à-vis individual natural and legal persons. ECHA must be able to exercise those powers to their full extent so that it can achieve the aim for which it was set up in the first place, namely to ensure a high level of protection of human health and the environment. However, it is not love of procedural formality that has led the Board of Appeal to take a critical view of any procedural imperfections. The reason underlying this is that strong powers must be accompanied by strong safeguards to ensure that they are exercised properly.

In this quest for balance between these two elements – power and safeguards – the Board of Appeal has been remarkably consistent in its approach to the various processes within its competence. It has paid particular attention to interpreting those processes as part of a coherent system, and has taken a consistently critical view of any steps taken outside the formal procedures established in the legislation.

This was, arguably, more by design than by accident. The set-up and working methods of the Board of Appeal provide strong incentives for consistency. First of all, precedent – whether administrative or judicial – is always seen as a guide. As departure from a line of precedent has to be expressly reasoned, even administrative precedent acquires a traction of its own.[70] Secondly, the composition of the Board of Appeal has been stable thanks to the use of permanent members.[71] A consistent approach could therefore be achieved with greater ease than might have been the case if the composition of the Board of Appeal had varied frequently. Finally, the low turnover in the staff of the Registry of the Board of Appeal has contributed to the development of a strong organisational memory.

Furthermore, the Board of Appeal has enjoyed the benefit of several other advantages which ought to be recognised. The legal framework gives the Board of Appeal the inestimable advantage of time and, consequently, thoroughness in its deliberations. The pace of appeal proceedings can be rather measured. Proceedings typically involve several rounds of written pleadings, much internal discussion, a hearing and an iterative drafting process. This procedural thoroughness is compounded by the fact that the pro-

70 C-240/18 P *Constantin Film Produktion* v *EUIPO* ('*Fack Ju Göhte*') [2019] EU:C:2019:553, Opinion of Advocate General, paras 110, 111 and 125; See also, in the same vein, C-521/09 P *Elf Aquitaine* v *Commission* [2011] EU:C:2011:620 para 155.

71 In most other boards of appeal, members are called upon *ad hoc* in specific cases but are not employees of the relevant agency. The members of ECHA's Board of Appeal are have five-year mandates, renewable once.

cedure before the Board of Appeal is adversarial in nature[72] and the submissions of all parties in appeal proceedings – the ECHA Secretariat, Member State competent authorities, registrants, non-governmental organisations – are often of a high quality. Consequently, the Board of Appeal has been able to delve deeply into each case, considering all the aspects that might be relevant, with the benefit of detailed submissions. The result, it would appear, has been that appeal proceedings are thorough and their outcome is balanced. The decisions may be correct or not, but they are always thoroughly considered and extensively reasoned. It appears that this has also banished any remaining concerns about the independence of the Board of Appeal.

There have, of course, also been challenges. The main of these has been identifying the applicable scope and intensity of review in evaluation cases. The General Court has addressed this issue in two recent cases. In BASF Grenzach v ECHA, the applicant claimed that the Board of Appeal should carry out a full and fresh de novo evaluation of each case. In Germany v ECHA, the applicant claimed that the Board of Appeal is competent to examine only procedural issues and not the substantive content of evaluation decisions. The Board of Appeal pursued a middle way between these two extremes, and its approach was confirmed by the General Court by two judgments issued shortly before the publication of this article.

Another challenge arises from the fact that the Board of Appeal is a relatively small body with few staff and a sensitive role in the REACH system. Its institutional legitimacy stems mainly from the quality of the reasoning in its decisions, which must for this reason be maintained at a consistently high standard. In order to achieve this, the Board of Appeal has been fortunate to rely on a high degree of commitment from institutional actors (e.g. the ECHA Management Board, Member States and EU institutions) and stakeholders (e.g. industry and non-governmental organisations).

In conclusion, when the Board of Appeal was established in the REACH Regulation no one was sure how it would work and what its impact would be. However, during the first ten years of its existence the Board of Appeal has clarified many grey areas in the REACH Regulation. More importantly perhaps it has helped to develop the REACH Regulation from a set of complex legal and scientific provisions into a coherent system, and to anchor that system within broader EU law. It has done so for the benefit of all, and set a high standard for ECHA and its stakeholders to abide by in complying with the REACH Regulation.

72 T-125/17 *BASF Grenzach* v *ECHA* [2019] EU:T:2019:638 paras 61 to 66; T-755/17 *Germany* v *ECHA* [2019] EU:T:2019:647, para 86.