

TEXTE

126/2021

# Advancing REACH – ECHA Board of Appeal

Proposals for further development and strategies for  
implementation



TEXTE 126/2021

Ressortforschungsplan of the Federal Ministry for the  
Environment, Nature Conservation and Nuclear Safety

Project No. (FKZ) 3717 67 410 0

Report No. (UBA-FB) FB000108/ENG,ZW,5.7

## **Advancing REACH – ECHA Board of Appeal**

Proposals for further development and strategies for  
implementation

by

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## Imprint

### **Publisher**

Umweltbundesamt  
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06844 Dessau-Roßlau  
Tel: +49 340-2103-0  
Fax: +49 340-2103-2285  
[buergerservice@uba.de](mailto:buergerservice@uba.de)  
Internet: [www.umweltbundesamt.de](http://www.umweltbundesamt.de)

 [/umweltbundesamt.de](https://www.facebook.com/umweltbundesamt.de)

 [/umweltbundesamt](https://twitter.com/umweltbundesamt)

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### **Report completed in:**

March 2021

### **Edited by:**

Section IV 2.3 Chemicals  
Lars Tietjen

Publication as pdf:

<http://www.umweltbundesamt.de/publikationen>

ISSN 1862-4804

Dessau-Roßlau, September 2021

The responsibility for the content of this publication lies with the author(s).

**Abstract: Advancing REACH – ECHA Board of Appeal**

This report is provided in the scope of the project “Advancing REACH”, funded by the research plan of the German Ministry for the Environment. The project aims to develop options to improve the (implementation of) the REACH regulation by analysing various REACH processes and related issues, including substitution, sustainable chemistry, precautionary principle, articles, cost-benefit analyses, socio-economic analyses and financing ECHA.

This report discusses the question, which policy options are available to improve the efficiency of the appeal procedure under REACH and the impacts on the objectives laid down in Art. 1 REACH. It discusses three policy options with regard to streamlining the ECHA procedure. The first option consists of streamlining deadlines, the second option grants the Board of Appeal the discretion to issue an interim order, and the third option includes legislative options to limit the scope and intensity of the review. In light of the overall objectives of REACH and a legal systemic consideration, the second option appears most favourable.

**Kurzbeschreibung: Weiterentwicklung von REACH –Widerspruchskammer der ECHA**

Dieser Bericht ist Teil des Ressortforschungsplan Vorhabens „REACH-Weiterentwicklung“, das basierend auf Analysen verschiedener REACH-Prozesse sowie angrenzender Fragestellungen (Substitution, Nachhaltige Chemie, Vorsorgeprinzip, Erzeugnisse, Kosten-Nutzen Analysen, Sozio-Ökonomische Analysen, Finanzierung der ECHA) Optionen für eine Verbesserung der (Umsetzung der) REACH-Verordnung entwickelte.

Dieser Bericht erörtert die Frage, welche politischen Optionen zur Verfügung stehen, um die Effizienz des Widerspruchsverfahrens unter REACH zu verbessern und welche Auswirkungen dies auf die in Art. 1 REACH formulierten Ziele hat. Er erörtert drei politische Optionen im Hinblick auf eine Straffung des ECHA-Verfahrens. Die erste Option besteht aus einer Straffung der Fristen, die zweite Option gewährt der Widerspruchskammer das Ermessen zum Erlass einer einstweiligen Anordnung und die dritte Option beinhaltet legislative Optionen, um den Umfang und die Intensität der Überprüfung zeitlich zu begrenzen. Im Lichte der Gesamtziele von REACH und einer rechtssystematischen Betrachtung erweist sich die zweite Option als die Beste.

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## List of abbreviations

<b>ACER</b>	Agency for the Cooperation of Energy Regulators
<b>BoA</b>	Board of Appeal
<b>BPR</b>	Biocidal Products Regulation
<b>CCH</b>	Compliance check
<b>CPVO</b>	Community Plant Variety Office
<b>EASA</b>	European Union Aviation Safety Agency
<b>ECHA</b>	European Chemicals Agency
<b>EU</b>	European Union
<b>EUIPO</b>	European Union Intellectual Property Office
<b>NGOs</b>	Non-Governmental Organisations
<b>No</b>	Number
<b>REACH</b>	Registration, Evaluation, Authorisation and Restriction of Chemicals
<b>RoP</b>	Rules of Organisation and Procedure of the Board of Appeal of the European Chemicals Agency
<b>SEv</b>	Substance Evaluation



## Summary

The current report is one of the results of the project “Advancing REACH”, which is funded by the research plan of the German Ministry for the Environment, Nature Protection and Nuclear Safety. Within the project framework, various aspects of the REACH regulation and its implementation are analysed and improvement options developed, including potential changes in the regulatory text and its annexes.

The project “Advancing REACH” consists of 18 sub-projects, which discuss different aspects of (the implementation of) the regulation and related improvement options. Topics of the sub-projects are the REACH processes dossier evaluation, substance evaluation, restriction, authorisation and consultation, as well as the interplay of the processes. In addition, the relation between REACH and sustainable chemistry, the implementation of the precautionary principle, the enhancement of substitution and the assessment of benefits of REACH are evaluated, as well as the procedures of the socio-economic analysis, options to regulate substances in articles and the financing of the European chemicals agency’s (ECHA) tasks.

This piece discusses the question, which policy options are available to enhance the efficiency of the appeal procedure under REACH and the impacts on the aims laid down in Art. 1 REACH. To this end, chapter 2 compiles the status and the development of the BoA since REACH entered into force. Chapter 3 sets the BoA in ECHA into the perspective, on the one hand, of other appellative bodies within European Agencies and, on the other hand, of the national administrative review procedure under German general administrative law.

Against this background chapter 4 discusses three policy options with a view to streamlining the ECHA procedure:

1. The timelines provided for the various steps within the BoA procedures could be tightened. The expected effects entail accelerated decision processes. Indirectly the incentives for the actor to concentrate the exchange of arguments on the most relevant aspects are strengthened.
2. It is advisable to align the suspensive effect of an appeal against a decision issued by ECHA to the procedure before the EU courts: Instead of the “automatic” suspensive effect which is granted by Article 91(2) REACH the discretion to issue an interim order should be assigned to the BoA.
3. The scope and intensity of review were subject to the decisions of the General Court in the Triclosan and Benpat cases. Taking into account the specific function and composition of the Board of Appeal as a body of ECHA, legislative options might be considered to additionally limit the scope and the intensity of review. To this end the Rules of Procedure of the BoA and internal “rules and procedures” of the Agency (Art. 78(3)) would have to be amended accordingly.

In the light of the overall aims of REACH and a systematic legal perspective, the second policy option appears most favourable. The incentive for appellants to prolong the procedure would be reduced, whilst at the same time the BoA has the discretion to grant suspensive effects in justified cases. Stricter timelines (option 1) would also streamline the process and support more focussed legal pleas. The third option would alter the function of the BoA more substantially; as a consequence the leeway for ECHA to assess legal, (eco)toxicological and other scientific issues would be strengthened.

## Zusammenfassung

Der vorliegende Bericht ist ein Teilergebnis des Ressortforschungsplan-Vorhabens „REACH-Weiterentwicklung“, welches im Rahmen des Forschungsplans des Ministeriums für Umwelt, Naturschutz und nukleare Sicherheit gefördert wurde. Im Rahmen dieses Vorhabens wurden verschiedene Aspekte der REACH – Verordnung und ihrer Umsetzung analysiert und Verbesserungsoptionen, einschließlich einer möglichen Veränderung des Verordnungstextes und seiner Anhänge, aufgezeigt.

Das Vorhaben REACH-Weiterentwicklung besteht aus insgesamt 18 Teilprojekten, die sich mit unterschiedlichen Aspekten der (Umsetzung der) REACH-Verordnung und Optionen für deren Weiterentwicklung auseinandersetzen. So werden in den jeweiligen Teilprojekten die REACH Prozesse Dossierbewertung, Stoffbewertung, Beschränkung, Zulassung und Konsultationen sowie das Zusammenspiel der Prozesse analysiert. Auch die Verbindung von REACH zur Nachhaltigen Chemie, die Umsetzung des Vorsorgeprinzips, die Förderung der Substitution und die Abschätzung des Nutzens der REACH-Verordnung werden untersucht sowie das Verfahren der sozio-ökonomischen Analyse, Optionen zur Regulierung von Stoffen in Erzeugnissen und die Finanzierung der Aufgaben der Chemikalienagentur ECHA.

Dieser Bericht erörtert die Frage, welche politischen Optionen zur Verfügung stehen, um die Effizienz des Widerspruchsverfahrens unter REACH zu verbessern und welche Auswirkungen dies auf die in Art. 1 REACH formulierten Ziele hat. Dazu stellt Kapitel 2 den Stand und die Entwicklung der Widerspruchskammer seit dem Inkrafttreten von REACH dar. Kapitel 3 ordnet die ECHA-Widerspruchskammer in die Perspektive anderer Beschwerdestellen innerhalb der Europäischen Agenturen und andererseits in die des nationalen verwaltungsrechtlichen Überprüfungsverfahrens nach deutschem allgemeinem Verwaltungsrecht ein.

Vor diesem Hintergrund erörtert Kapitel 4 drei Gestaltungsoptionen im Hinblick auf eine Straffung des ECHA-Verfahrens:

1. Die für die verschiedenen Schritte innerhalb des Widerspruchsverfahrens vorgesehenen Fristen ließen sich straffen. Die erwarteten Effekte sind beschleunigte Entscheidungsprozesse. Indirekt haben die Verfahrensbeteiligten stärkere Anreize, den Austausch von Argumenten auf die relevantesten Aspekte zu konzentrieren.
2. Es ist ratsam, die aufschiebende Wirkung eines Rechtsbehelfs gegen eine Entscheidung der ECHA an das Verfahren vor den Europäischen Gerichten anzugleichen: Statt der „automatischen“ aufschiebenden Wirkung, die Art. 91 Abs. 2 REACH gewährt, sollte es im Ermessen Widerspruchskammer liegen, auf Antrag einen Suspensiveffekt anzuordnen.
3. Der Umfang und die Intensität der Überprüfung durch die Widerspruchskammer war Gegenstand der Entscheidungen des Europäischen Gerichtshofes in den Rechtssachen Triclosan und Benpat. Unter Berücksichtigung der spezifischen Funktion und Zusammensetzung der Widerspruchskammer als Organ der ECHA ließen sich legislative Optionen in Betracht ziehen, die den Umfang und die Intensität der Überprüfung zusätzlich begrenzen. Zu diesem Zweck wären die Geschäftsordnung der Widerspruchskammer und die internen „Regeln und Verfahren“ der Agentur (Art. 78(3) REACH) entsprechend zu ändern.

Im Lichte der Gesamtziele von REACH und einer rechtssystematischen Betrachtung erscheint die zweite Option besonders empfehlenswert. Der Anreiz für die Beschwerdeführer, das Verfahren in die Länge zu ziehen, würde verringert, während es gleichzeitig im Ermessen der Widerspruchsbehörde liegt, in begründeten Fällen aufschiebende Wirkung zu gewähren. Strengere Fristen, wie sie Option 1 beinhaltet, würden außerdem das Verfahren straffen und

dazu beitragen, sich auf die zentralen rechtlichen Argumente zu konzentrieren. Die dritte Option würde die Funktion der Widerspruchskammer stärker verändern; infolgedessen wäre die fachliche Beurteilungsprärogative der ECHA im Hinblick auf rechtliche, (öko-)toxikologischer und andere wissenschaftliche Fragen gestärkt.

## 1 Introduction (with normative target state)

One purpose of REACH is to ensure a “high level of protection of human health and the environment” (Art. 1(1) REACH<sup>1</sup>), while this explicitly includes “the promotion of alternative methods for assessment of hazards of substances”; i.e. methods contributing to reduced tests on animals. In addition, REACH aims for “the free circulation of substances on the internal market while enhancing competitiveness and innovation”. The pivotal administrative body to implement REACH is European Chemistry Agency (in the following ECHA). The agency has the competence to issue legally binding administrative acts, i.a. related to the registration and evaluation processes.

In order “to guarantee processing of appeals for any natural or legal person affected by decisions taken by the Agency”<sup>2</sup> REACH establishes a Board of Appeal (in the following also “BoA” or the “board”) within the Agency. The internal appeal body was established before the Treaty of Lisboa that adjusted the system of legal protection.<sup>3</sup> One main function of the board is providing legal protection for economic actors concerned by ECHA decisions in a more effective and efficient manner, compared to ordinary litigation before the EU courts.<sup>4</sup> The ECHA Board of Appeal plays thus an important role for several REACH processes, notably dossier and substance evaluation. Its decisions not only have a direct impact on the specific cases dealt with but may also have a precedent effect as regards similar disputes and in some cases forced the Agency to review<sup>5</sup> its administrative procedures.

In terms of the normative goals of REACH, timely and well-argued BoA operations may support ECHA and the industrial actors in their effort to ensure a high level of protection by providing clarity on their respective duties. The BoA decisions clarifying the requirements stipulated by the European legislation on chemicals and the means to implement them. Insofar they contribute to assuring a “level playing” field: by putting the actors addressed by the REACH mechanisms in the position to perform their business in a compliant manner. At the same time the decisions reduce leeway for non-compliant “free-riders” within the registration mechanisms. With this the BoA contributes to the effectiveness and efficiency of the data generating processes designed by the legislator to reduce the “toxic ignorance” of the previous regulatory framework.

However, in a relevant number of cases the decision making process from decision issued by the Secretariat (Art. 76 (1) g) until the BoA decision lasted up to two years.<sup>6</sup> Thus, additional measures enabling the BoA to reach final decisions within a reasonable time would help to fulfil the aforementioned functions to a greater extent. In parallel, options to secure the substantive objectives of REACH during the course of the proceedings should be included in the considerations.

<sup>1</sup> Articles, Recitals, Titles, Chapters and Annexes without further indication are those of the REACH Regulation.

<sup>2</sup> Recital 106; in Recital 95 the legislators emphasises “it is vital to ensure its [ECHA’s] independence, high scientific, technical and regulatory capacities, as well as transparency and efficiency”.

<sup>3</sup> During the debate on the Commission proposal interventions from industry highlighted a gap in the legal protection of individual actors against administrative acts issued by EU bodies.

<sup>4</sup> Bronckers and Van Gerven, Legal remedies under the EC’s new chemicals legislation REACH: Testing a new model of European governance, CML Rev. 2009, 1823 (1844).

<sup>5</sup> For instance, as regards ECHA’s automated completeness checks (see WP 5.3 with the charcoal case). Another example can be seen in “a decision on the use of languages in relation to the ECHA’s communications with registrants, in the context of the SME verification process, prompted the ECHA to reassess its processes” (SWD(2018) 58 fin Part 7/7, p. 20.).

<sup>6</sup> See, e.g., in the case A-001-2019, which was decided on 21 October 2020, ECHA sent the initial draft compliance check decision to the applicant on 19 November 2013 leading to the decision contested before the BoA stating (in essence) that the registrant “is ‘...still required to provide a [PNDT] study”, while the procedure before the BoA took more than another year and a half (Feb. 2019 – Oct. 2020).

Against this background, this report analyses different options to enhance the efficiency of the board's decision-making practice. The report addresses the following research questions:

1. How can legal protection for registrants be ensured without undue delays in their legal obligation to provide data?
2. Which policy options are available to enhance the efficiency of the board's decision-making practice?

With a view to these questions a comparative examination on other European organisations with similar functions (different Boards of Appeals in other EU agencies) might provide illustrative insights. The same applies to the procedural framework for administrative review under German general administrative law. Consequently, the report is structured as follows:

Chapter 2 highlights the legal basis and characterizes the structure of BoA by examining the relevant rules of procedure and the applied standard of review.

Chapter 3 summarizes a survey of EU agencies equipped with a Board of Appeal, including a brief description of the particularities of each. It also looks into the appellate proceedings under German general administrative law.

Chapter 4 analyses improvement options with a view to the research questions.

## 2 ECHA Board of Appeal

This chapter summarizes the relevant provisions with regard to the range of decisions on which an appeal is admissible (section 2.1), other procedural issues (2.2) and competencies (2.3). The overview is completed off by a glance at the available data on the activities of the Board of Appeal (2.4). The assessment of the aforementioned aspects takes into account:

- ▶ Formalised rules of conduct for the BoA: Title X “The Agency” provides for the establishment of the BoA and stipulates some basic procedural rules, which are fleshed out by Commission Regulation No 771/2008 stipulating rules of organisation and procedure (RoP) and by Practice directions to parties adopted in accordance with Art. 27(2) of the RoP;<sup>7</sup>
- ▶ ECHA documents reflecting the boards actual output (“BoA in numbers”)

Finally, section 2.5 discusses development perspectives in the light of the clarification of the organisational status of the BoA within the Agency provided by the implementing regulation (EU) 2016/823.

### 2.1 Admissible appeals

In the REACH context,<sup>8</sup> the BoA hears appeals against ECHA’s decisions listed in Art. 91(1). The list is exhaustive.<sup>9</sup> It entails

- ▶ ECHA decisions on exemptions from the general obligation to register for product- and process-oriented research and development (Art. 9),
- ▶ refusals to register incomplete dossiers (Article 20(2)),
- ▶ decisions on the sharing of existing data in the case of registered Substances (Article 27(6)),
- ▶ specifying which registrant or downstream user is obliged to perform a test (Art. 30(2)),
- ▶ permission to refer to existing information (Art. 30(3)),
- ▶ Decisions in the context of the examination of testing proposals and dossier evaluation in cases where competent authorities do not propose amendments to a draft decision or the Member State Committee reaches an unanimous agreement on the draft decision ((Art. 51(3) and (6)),
- ▶ Decisions within the framework of substance evaluation, under the same prerequisites as under dossier evaluation procedure (Art. 52 in connection with Art. 51 (8)).

If the Member State Committee fails to reach unanimous agreement on the outcome of a dossier or substance evaluation, Art. 51(7) states that “the Commission shall prepare a draft decision to

<sup>7</sup> Commission Regulation (EC) No 771/2008 of 1 August 2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency, OJ L 206, 2.8.2008, p. 5, as amended by Commission Implementing Regulation (EU) 2016/823 of 25 May 2016, OJ L 137, 26.5.2016, p. 4.

<sup>8</sup> Besides, some decisions taken under the realms of the BPR fall into the scope of the BoA. For the state of play in this respect cf. ECHA 2020b, Annex I, BoA Chairman’s personal remarks after his first 10 months, p.6 et subs.

<sup>9</sup> Cf. Andreas Bartosch and Katja Michel, Widerspruchs- und Klageverfahren – der Rechtsschutz gegen Agenturverwaltungshandeln am Beispiel der ECHA, StoffR 2010, 72/73 and Pache/Pieper, in: Führ 2011, chapter 25, para 7.

be taken in accordance with the procedure referred to in Art. 133(3).” These decisions are not admissible before the BoA. Legal remedies might be brought before the general court.

## 2.2 Procedural issues

Legal and natural persons who are addressees of the aforementioned decisions are entitled to appeal. Persons may also appeal against a decision addressed to another person, when it is “of direct and individual concern” to the former (Art. 92).<sup>10</sup> Under specific circumstances,<sup>11</sup> several appellants that are affected by the same administrative act (e.g. several manufacturers of a substance subject to SEv) may lodge a single appeal (“joint application”).

According to Art. 91(2), any appeal lodged has suspensive effect regarding the contested decision<sup>12</sup> – a procedural rule with immediate practical implications that does not exist e.g. in ordinary litigation before EU courts (see section 4.2 below).<sup>13</sup>

Furthermore, pursuant to Art. 8(1)1 RoP an “amicus curiae” option is available: Within three weeks of publication of the announcement, “(a)ny person establishing an interest in the result of the case” at hand “may intervene in the proceedings”. The range of possible interveners includes other registrants, industry associations as well as NGOs (e.g. animal welfare) – also those without the status of an accredited stakeholders.<sup>14</sup> Intervention is limited to “supporting or opposing, in whole or in part, the form of remedy sought by one of the parties” and “ancillary to the main proceedings” (Art. 8(3) RoP). A “Member State whose competent authorities has carried out the substance evaluation may intervene without having to establish an interest in the result of that case” (Art. 8(1)2 RoP).<sup>15</sup>

Addressees<sup>16</sup> need to file the appeal in writing to the Agency within three months of the notification of the decision (92(2)), whereas receipt of Decisions and Communications will be presumed seven calendar days the latest after the date of their notification in the REACH-IT System.<sup>17</sup>

ECHA may rectify the contested decision within 30 days of the appeal if it “considers the appeal to be admissible and well founded”.<sup>18</sup> Besides, the BoA Chairman may invite parties to seek “amicable agreement” (Art. 1a RoP) and applicants may withdraw their appeal at any time (Art. 1b RoP).

<sup>10</sup> Downstream Users as part of a SIEF participants are not directly concerned by SEv decision; it follows the an appeal from a Downstream User is inadmissible, see BoA Decision of 30 May 2017, Case A-022-2015, *Manufacture Française des Pneumatiques Michelin*, para 150 et subs.

<sup>11</sup> Cf. ECHA 2017, Practice directions to parties to appeal proceedings before the Board of Appeal of the European Chemicals Agency, para 27.

<sup>12</sup> See on the practical effect in the different dispute scenarios Bergkamp et al. 2013, *Dispute Resolution and Legal Remedies*, in: *The European Union REACH Regulation for Chemicals. Law and Practice*, para 10.14.

<sup>13</sup> Cf. Eléonore Mullier and Ruxandra Cana, *The ECHA Board of Appeal and the Court of Justice: Comparing and Contrasting Chemicals Litigation*, ICRL 2018, 105 (109).

<sup>14</sup> For details see the eligibility criteria for ECHA’s Accredited Stakeholder Organisations, adopted by the Management Board on 21 June 2011 (MB/34/2011 final).

<sup>15</sup> Cf. Gregor Ischebeck, *ECHA Board of Appeal: First Series of Landmark Decisions on Substance Evaluation under REACH*, *StoffR* 2016, 16 (64).

<sup>16</sup> If the appellant is not the addressee of the decision, the appeal has to be lodged within three months of the day on which the decision became known to the appellant.

<sup>17</sup> Michael Raupach 2015, *Die Widerspruchskammer der Europäischen Chemikalienagentur ECHA*, Vortrag, (1.8.2019); see also ECHA 2017c, “Terms and Conditions of Use and Service of REACH-IT”, section 9 „Notification of Decisions and Communications”.

<sup>18</sup> Art. 93(1) REACH. In practice, ECHA both partially and entirely rectified contested decisions on this legal basis.

Usually, the BoA chairman shall examine whether the appeal is admissible<sup>19</sup> within 30 days after the appeal has being filed. The registrar, in charge of receipt, transmission and custody of documents related to BoA procedures, “shall serve the notice of appeal on the Agency without delay” (Art. 6(5) RoP). A public announcement of the appeal and related key aspects follows (Art. 6(6) RoP).

The Agency shall lodge the defence within two months after service of the notice of appeal, unless the chairperson extended that time limit, under exceptional circumstances (Art. 7(1) RoP).

After the first exchange of written pleadings, parties may not introduce further evidence or new pleas in law – unless the BoA approves of it, see Art. 12 RoP.<sup>20</sup>

The BoA notifies the parties of the closure of the written part of the proceedings. It may decide to hold an oral hearing. In addition, within two weeks from notification of closure, parties can request the BoA to hold a hearing (Art. 13 RoP). In what follows, a time-limit for the BoA to render its decision does not exist.

Appellants may contest BoA decisions before the EU courts.<sup>21</sup>

## 2.3 Competencies

The BoA is an integral part of the Agency.<sup>22</sup> Specific provisions ensure the board’s independence.<sup>23</sup> Its interdisciplinary composition – “Each appeal shall be decided by three members”, whereas “at least one member shall be legally qualified and at least one member shall be technically qualified”<sup>24</sup> – allows it to deal with cases complex both in legal and technical<sup>25</sup> terms.<sup>26</sup>

Art. 93(3) confers to the BoA the mandate to “exercise any power which lies within the competence of the Agency or remit the case to the competent body of the Agency for further action”, whereas in the latter case the Agency as a principle rule “shall be bound by the reasoning in the decision”.<sup>27</sup> From its legal mandate, the board concludes it “can carry out a new, full examination as to the merits of the appeal, in terms of both law and fact”.<sup>28</sup> It follows that the BoA can not only annul contested decisions, in part or entirely, but can also render its own

<sup>19</sup> See Art. 11 RoP for formal grounds as regards inadmissibility.

<sup>20</sup> Art. 12 RoP; cf. ECHA 2017, Practice directions to parties to appeal proceedings before the Board of Appeal of the European Chemicals Agency, “Only where invited to do so by the BoA may the parties provide further observations on the submissions of the other party”, para 35.

<sup>21</sup> Art. 94 REACH; jurisdiction is laid down in Article 263 TFEU. The Court of Justice examines whether appeals raised after 1 May 2019 directed against General Court decisions as appeal against BoA decisions are admissible, i.e. whether the appeal raises “an issue that is significant with respect to the unity, consistency or development of Union law”, cf. Art. 58a Regulation (EU, Euratom) 2019/629 of 17 April 2019 amending Protocol No 3 on the Statute of the Court of Justice of the European Union, OJ L 111 of 25.4.2019, p. 1.

<sup>22</sup> Art. 76(1)(h) REACH.

<sup>23</sup> Art. 90(3) to (7), Art. 89(3) REACH, cf. Eléonore Mullier and Ruxandra Cana, The ECHA Board of Appeal and the Court of Justice: Comparing and Contrasting Chemicals Litigation, ICRL 2018, 105 (109).

<sup>24</sup> Art. 1(2) RoP, Art. 89(3) REACH.

<sup>25</sup> Defined in Art. 1(2) RoP as: „substantial professional experience in hazard assessment, exposure assessment or risk management with regard to human health or environment risks of chemical substances or in related fields”.

<sup>26</sup> Besides three permanent full time members, i.e. one scientific and two legal experts, additional “alternates” are involved on ad hoc basis depended on case specific needs.

<sup>27</sup> Art. 18 RoP.

<sup>28</sup> BoA, decision of 10.10.2011, Case A-001-2010, EPZ, para 36.



decision, formulating specific requirements in an evaluation case that derogate from those requirements initially formulated by the Agency.<sup>29</sup>

In accordance with its mandate to “exercise any power” conferred to the Agency, the BoA considers the scope of its “administrative review” not limited “by the need to establish that the [contested] decision is ‘manifestly inappropriate’ to the objective pursued”.<sup>30</sup> The latter, in contrast, determines the scope of judicial review of the EU courts.<sup>31</sup> In the Benpat-case the Court

“noted that, admittedly, in the context of an action for annulment under Article 263 TFEU, the review conducted by the EU Courts is limited where it concerns the assessment of highly complex scientific and technical facts. As regards such assessments, the EU Courts are limited to reviewing whether they are vitiated by a manifest error, a misuse of powers or whether the decision-maker manifestly exceeded the limits of its discretion”.<sup>32</sup>

The court continued

“However, that case-law is not applicable to the review conducted by the Board of Appeal of the ECHA. In that regard, regarding the members of that body, it should be noted that, under the second subparagraph of Article 1(1) of Regulation No 771/2008, at least one member is legally qualified and at least one member is technically qualified, in accordance with Regulation No 1238/2007. Under Article 1(2) of the latter regulation, the technically qualified members are to hold a university degree or an equivalent qualification and are to have substantial professional experience in hazard assessment, exposure assessment or risk management with regard to human health or environment risks of chemical substances or in related fields. It must be deduced from those provisions that the legislature intended to provide the Board of Appeal of the ECHA with the expertise necessary in order to allow it to itself carry out assessments of highly complex scientific and technical facts.

Therefore, the review, by the Board of Appeal, of scientific assessments included in an ECHA decision is not restricted to verifying the existence of manifest errors. On the contrary, in that regard, by relying on the legal and scientific competences of its members, that board must examine whether the arguments put forward by the applicant are capable of demonstrating that the considerations on which that decision is based are vitiated by error.”<sup>33</sup>

It follows that the BoA needs to “consider all circumstances and facts applicable during the administrative procedure that led to the adoption of the contested decision. As such, and by reason of the concept of administrative continuity, the examination of the appeal by the Board of Appeal is not limited to the arguments of facts and law raised by the parties” but the board may use additional evidence acquired “on its own motion”.<sup>34</sup>

<sup>29</sup> Eléonore Mullier and Ruxandra Cana, *The ECHA Board of Appeal and the Court of Justice: Comparing and Contrasting Chemicals Litigation*, ICRL 2018, 105 (106).

<sup>30</sup> BoA, decision of 29.4.2013, Case A-005-2011, Honeywell, para 117.

<sup>31</sup> General Court, judgement of 07.03.2013, Case T-93/10, *Bilbaina de Alquitranes, SA and Others v European Chemicals Agency* [2013] ECLI:EU:T:2013:106, para 76; cf. Marcus Navin-Jones, *A Legal Review of EU Boards of Appeal in Particular the European Chemicals Agency Board of Appeal*, *European Public Law Journal* 2015, 143 et subs..

<sup>32</sup> General Court, judgment of 20.09.2019, *BENPAT*, parap 192; the Court referred to judgment of 21 July 2011, *Etimine*, C-15/10, EU:C:2011:504, paragraph 60 and the case-law cited.

<sup>33</sup> General Court, judgment of of 20.09.2019, *BENPAT*, parap 193.

<sup>34</sup> BoA, decision of 10.10.2011, Case A-001-2010, *EPZ*, para 37-38; cf. on the concept of “functional continuity” Luca Bolzonello, *Independent Administrative Review Within the Structure of Remedies under the Treaties: The Case of the Board of Appeal of the European Chemicals Agency*, 2016 (22) *European Public Law*, 569-581 (575).

However, in the Triclosan case the Court of First Instance held that BoA is not obliged to exercise a full review (“de novo”<sup>35</sup>) of the merits of the appeal. The new Chairman of the Board of Appeal (Antoine Buchet), who started in August 2019, following the end of the mandate of Mercedes Ortuño summarises the essence of the Triclosan- and Benpat-cases as follows:<sup>36</sup>

On 20 September 2019, the General Court of the EU handed down two landmark judgments, deciding for the first time on the scope and intensity of the power of review of the Board of Appeal. (...) The Board of Appeal is competent to review the scientific content of these decisions in detail. However, the Board of Appeal is not required to re-evaluate a substance when deciding on a case. Based on the arguments and evidence of the parties to an appeal case, the Board of Appeal verifies if an ECHA decision *contains errors*. Appellants must put forward detailed arguments and evidence in order to prove that the ECHA decision they challenge is incorrect.

Consequently, in cases where the BoA identifies a broad margin of discretion on the part of ECHA – e.g. in relation to assessing and deciding whether the uncertainty inherent to a read-across proposal is acceptable or not – the board reduced its review to finding whether the Agency misused its margin of discretion.<sup>37</sup> In such cases, lack of proportionality and errors of assessment are the two main pleas that applicant can put forward.<sup>38</sup>

The decision of the General Court can be summarised under the follow Guideline: The BoA is not obliged to carry out a new assessment (“de-novo”) of the merits of the case; within the scope established by “pleas in law and the arguments of fact and law relied on” (Art. 61)(e) RoP) and based on the related „evidence of the parties to an appeal case“ BoA examines whether and to which extent the decision issued by ECHA is incorrect.

## 2.4 BoA in numbers

This section discusses data presented by the BoA chairman at 58<sup>th</sup> meeting of the ECHA Management Board (as of 18.06.2020).<sup>39</sup>

Every year, applicants lodge around 20 appeals (Figure 1<sup>40</sup>) – a case load significantly below expectations when REACH went into force.<sup>41</sup>

<sup>35</sup> On this issue see also Luca Bolzonello, Independent Administrative Review Within the Structure of Remedies under the Treaties: The Case of the Board of Appeal of the European Chemicals Agency, 2016 (22) European Public Law, 569-581 (576 et subs).

<sup>36</sup> ECHA 2020, Annual report from the Chairman of the Board of Appeal. MB/32/2020 final, p. 1. Helsinki, 58th Meeting of the Management Board 18 June 2020; download [here](#).

<sup>37</sup> BoA, Decision of 19.6.2013, Case A-001-2012, Dow, para 109; cf. Marcus Navin-Jones, A Legal Review of EU Boards of Appeal in Particular the European Chemicals Agency Board of Appeal, European Public Law Journal 2015, 143.

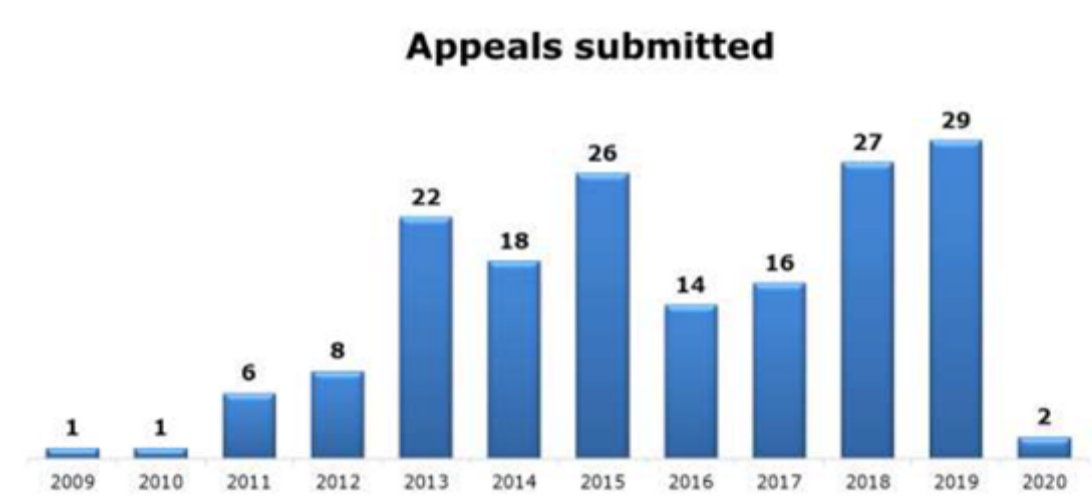
<sup>38</sup> Luca Bolzonello, Independent Administrative Review Within the Structure of Remedies under the Treaties: The Case of the Board of Appeal of the European Chemicals Agency, 2016 (22) European Public Law, 569-581 (577 et subs).

<sup>39</sup> ECHA 2020b, Annual report from the Chair of the Board of Appeal, MB/32/2020 final, Helsinki, 18.06.2020.

<sup>40</sup> ECHA 2020b, p. 17.

<sup>41</sup> SWD(2018) 58 fin Part 7/7, p. 20.

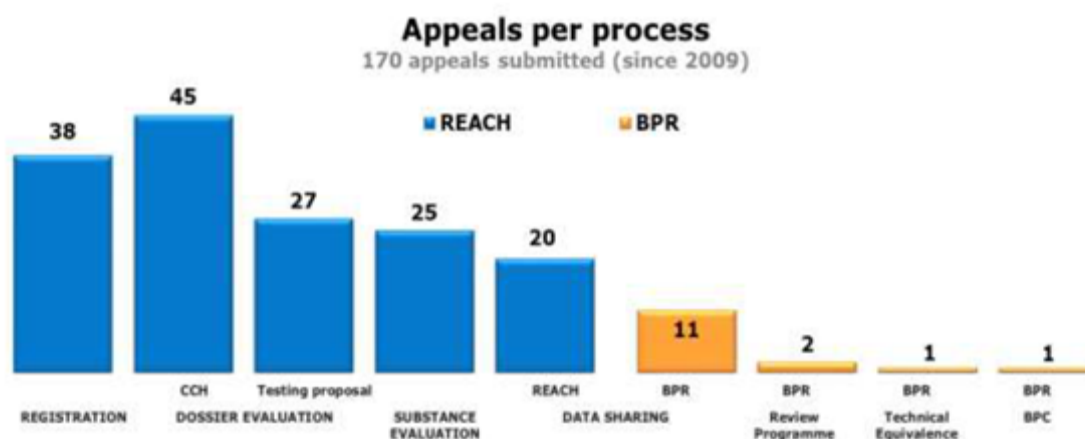
**Figure 1: ECHA BoA Appeals lodged between 2009 and 2020 per year, including 15 appeals under the BPR**



Source: ECHA 2020b

Most appeals concern CCH decisions and other issues linked to the registration process (Figure 2). Until June 2020 in total 25 appeals against substance evaluation decision were lodged.

**Figure 2: ECHA BoA Appeals lodged between 2009 and 2020 per regulatory process**



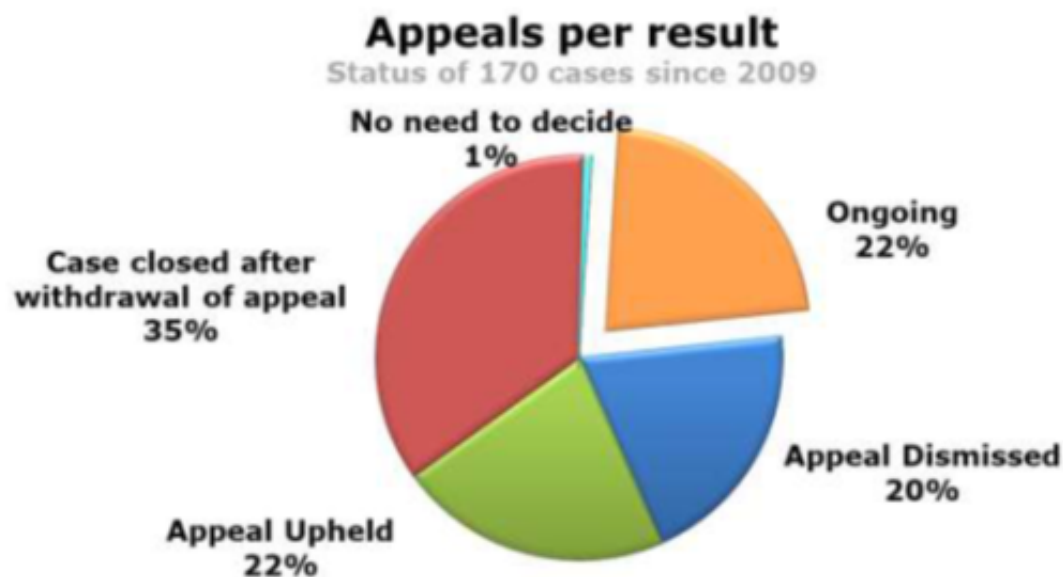
Source: ECHA 2020b

Not every appeal triggers comprehensive proceedings. Rather, the BoA decision database lists 50 withdrawals,<sup>42</sup> often after ECHA has rectified the decision according to Art. 93(1). In the BoA chairmans report to the ECHA Management in 2020 this holds true for 35% of the 170 BoA cases since 2009 (Figure 3).<sup>43</sup> In 22% of the cases the BoA upheld the appeal, while in 20% the appeal was dismissed. 22% of the cases were still ongoing in June 2020.

<sup>42</sup> See the [search results](#) as of 07.11.2020.

<sup>43</sup> ECHA 2020b, p. 17.

**Figure 3: Status of the 170 BoA cases since 2009**



Source: ECHA 2020b

Earlier versions of the ECHA annual “General Reports” referred to a performance indicator related to the board, i.e. “Percentage of final decisions made within 90 working days of the closure of the written or oral procedure.” Measured by that, in the reporting periods 2013, 2014 and 2015 the BoA exceeded its target.<sup>44</sup> More recent reports for the years 2016, 2017 and 2018 provide indications on the average overall length of the dispute cases closed in the respective reporting periods, which is “a little over a year” – 18 months.<sup>45</sup> Particular complex cases, notably in the SEv context, took “between one and two years” according to the 2017 report.<sup>46</sup>

Increased use of joint appeals marks a more recent trend, which likely increases efficiency of the boards operations. For instance, in 2015 altogether, 80 appellants brought 16 appeals<sup>47</sup> and 15 cases closed in 2017 involved 62<sup>48</sup> companies.

The ECHA database show 119 final decision related to REACH in the time from 2009 to October 2020.<sup>49</sup>

## 2.5 Organisational structure and development perspectives

The BoA is part of the organisational structure of the Agency and an independent body from the rest of ECHA. It reports directly to ECHA's Management Board.<sup>50</sup> Whilst the members of the BoA are appointed in a dedicated procedure the staff supporting the work of the BoA is hired and paid by the Secretariat. At the same time BoA oversees the decisions of the ECHA Secretariat (Art. 76 (1) g), led by the Executive Director (Art. 83), insofar as they are contested by the

<sup>44</sup> Deloitte and VVA 2016, Review of the European Chemicals Agency (ECHA), Final Report, p. 51.

<sup>45</sup> 18 months according to ECHA 2017a, General Report 2016, p. 67; “a little over a year” according to ECHA 2018a, General Report 2017, p. 96; 15 months ECHA 2019, General Report 2018, p. 33.

<sup>46</sup> ECHA 2018a, General Report 2017, p. 96.

<sup>47</sup> ECHA 2016, General Report 2015, p. 74.

<sup>48</sup> ECHA 2018a, General Report 2017, p. 97.

<sup>49</sup> In addition, 13 final decision on Biocidal Products Regulation and overall 94 procedural decisions; see [here](#) as of 10.11.2020.

<sup>50</sup> Discussions on the organisational structure and composition of the BoA take place within a specific Working Group of the Management Board; for details in this respect cf. SWD(2018) 58 fin Part 7/7, p. 20.

applicants. During the first nine years of ECHA this organisational structure created a permanent area of tension. In addition, the BoA consists of only three permanent members having equal voting rights. Thus the “solid performance” of each of its members “as well as their interpersonal relationships” led the Commission services to the conclusion, “that the BoA is a vulnerable body”.<sup>51</sup>

The Regulation (EU) 2016/823<sup>52</sup> strengthened the status of the board within the agency. The amended “rules of organisations” made clear that the Chairman of the board not only appoint the Registrar of the BoA but also has “have managerial and organisational powers to give directions to the Registrar” and thus also towards the supporting staff within the registry.<sup>53</sup>

The new Chairman of the BoA appears to be confident that the three permanent members, supported by the registry are able to cope with the challenges ahead.<sup>54</sup> However, the BoA staff nevertheless are under the jurisdiction of the Executive Director. To the extent that the BoA personal considers promotion to other posts within the agency a potential “conflict of interests” still might influence their attitude towards the cases brought to the BoA, which – by its very nature – call the Agency’s decisions erroneous. Putting forward arguments in line with the appellant’s pleas thus are not likely to arouse enthusiasm on the side of the ECHA staff, including the competent directors and the head of the agency.

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<sup>51</sup> SWD(2018) 58 fin Part 7/7, p. 21.

<sup>52</sup> Cf. Commission Implementing Regulation (EU) 2016/823 of 25 May 2016 amending Regulation (EC) No 771/2008 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency, OJ L 137 of 26.5.2016, p. 4; in particular Recital 6 and the amended paragraphs 4 and 5 of Art. 5 RoP clarifying that the Registrar “shall be appointed by the Chairman”, who also “have managerial and organisational powers to give directions to the Registrar on matters relating to the exercise of the functions of the Board of Appeal”.

<sup>53</sup> Art. 5 RoP (see also Art. 76(1)(h) REACH).

<sup>54</sup> ECHA 2020b, p. 3, Annex I, BoA (second) Chairman’s personal remarks after his first 10 months: “On board this ship, a competent and dedicated team was waiting for me. The objective of this report is not to thank them all individually, but to underline that the Board of Appeal is a structure whose balance should be preserved: three permanent members, whose varied skills and experiences are complete, and a registry composed of the registrar, legal and scientific advisors, as well as administrative and legal assistants.”

### 3 Benchmarks in EU and national administrative law

This chapter presents the results of a comparative survey of EU agencies equipped with a Board of Appeal (section 3.1). Furthermore, section 3.2 describes the appellate proceedings under German general administrative law.

#### 3.1 Overview of appellate bodies in other EU agencies

Five EU agencies have appellate bodies comparable to ECHA's Board of Appeals:

- ▶ EUIPO – European Union Intellectual Property Office<sup>55</sup>
- ▶ CPVO – Community Plant Variety Office<sup>56</sup>
- ▶ EASA – European Union Aviation Safety Agency
- ▶ ACER – Agency for the Cooperation of Energy Regulators<sup>57</sup>
- ▶ Joint Board of Appeal of the European Supervisory Authorities (Banking)

Table 1 shows a comparison of these five boards vi-á-vis ECHA's BoA using criteria related to procedural economy.<sup>58</sup>

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<sup>55</sup> Former Office for Harmonisation in the Internal Market (OHIM); cf. Commission Delegated Regulation (EU) 2018/625 of 5 March 2018 supplementing Regulation (EU) 2017/1001 of the European Parliament and of the Council on the European Union trade mark, and repealing Delegated Regulation.

<sup>56</sup> Art. 67 of Council Regulation (EC) No 2100/94.

<sup>57</sup> Art. 19 of Regulation (EC) No 713/2009.

<sup>58</sup> Source, unless otherwise indicated, Oliver Streckert 2016, Verwaltungsinterner Unionsrechtsschutz. Kohärenter Rechtsschutz durch Einführung eines Widerspruchskammermodells für die Europäische Kommission, Mohr Siebeck, p. 72-75.

**Table 1: Comparison of different BoA**

	Suspensive effect	Possibility to rectify contested Decision within 30 days	Full administrative review <sup>59</sup>	Mandate to replace contested decision	No of legal grounds to appeal	Right to intervene	Legal (and ~ factual) time of proceedings	~ No of appeals lodged	~ No of decisions
ECHA	Yes	Yes	Yes	Yes	4	Yes	(~12 – 24 months, section 2.4)	131 (2009 – March 2019) <sup>60</sup>	103 (2009 – July 2019) <sup>61</sup>
ACER	If BoA decides so	No	Yes	Yes		Not stipulated		13 (Nov 15 – Feb 19) <sup>62</sup>	5 (Dec 15 – Feb 19) <sup>63</sup>
CPVO	Yes	Yes	Yes	Yes	14			185 (2009 – 2018) <sup>64</sup>	85 (1996 – 2018) <sup>65</sup>
EASA	If BoA decides so	Yes	Yes	Yes			(~ 4 Months)	3.248 (2014)	2.783 (2014)
EUIPO	Yes	Yes	Yes	Yes					
Banking	If BoA decides so <sup>66</sup>		Not clear	No <sup>67</sup>	See Art. 60(1)		2 Months <sup>68</sup>		

<sup>59</sup> Of the disputed decision, taking into account all legal and factual details relevant for the case.

<sup>60</sup> ECHA 2019, Final report from the outgoing Chairman of the Board of Appeal, MB/10/2019 final, access [here](#) (15.7.2019).

<sup>61</sup> See [search results](#) (15.7.2019).

<sup>62</sup> See [here](#) (15.7.2019).

<sup>63</sup> See [here](#) (15.7.2019).

<sup>64</sup> CPVO, Consolidated Annual Activity Report 2018, p. 91, access [here](#).

<sup>65</sup> CPVO, Consolidated Annual Activity Report 2018, p. 93, access [here](#).

<sup>66</sup> Art. 60(3) Regulation (EU) No 1093/2010 of 24 November 2010 establishing a European Supervisory Authority (European Banking Authority).

<sup>67</sup> Art. 60(5) Regulation (EU) No 1093/2010.

<sup>68</sup> Art. 60(2) Regulation (EU) No 1093/2010.

The comparison (Table 1) shows extensive similarities in terms of procedural economy. Notably, all but one of the assessed boards share a wide standard of review and related competencies.

Three of the examined appeal procedures entail a suspensive effect. Under the other three procedural frameworks the BoA has the competence to issue an interim order.

### 3.2 German administrative procedural law

Under German administrative procedural law, the addressees of an administrative act have the possibility to gain a judicial review of the decision. In most cases,<sup>69</sup> the first step is an appeal to be lodged with the administrative body, which issued the decision (“preliminary proceeding”) within a period of one month, see § 70 (1) VwGO. The appeal is handled either by the same authority or by the superior authority. A “Board of Appeal” or a functional equivalent does not exist.

Based on the appeal the authority has to reconsider the decision based on legal and factual grounds including the use of discretionary power.<sup>70</sup> The internal review might lead to an adjusted decision based on the aforementioned grounds. Thus, the scope in the preliminary proceedings is rather wide.

After the “preliminary proceeding” took place – or after a time-period of three months without a decision on the appeal (§ 75 VwGO) – the appellant can file a remedy at the administrative courts. The court is obliged to assess the factual basis of the case on its own behalf (§ 86(1)1 VwGO). It is not bound to the evidence presented by the parties (§ 86(1)2 VwGO).

The appeal – as well as a remedy before the court – has suspensive effect (§ 80(1)1 VwGO); at least in principle. However, sectoral legislation has increasingly ruled out the suspensive effect of an appeal. In addition, the authority is entitled to issue an administrative order of immediate execution (§ 80(2)4 VwGO). In these cases, the applicant has to lodge a separate proceeding asking for an interim order by the court establishing the suspensive effect of the remedy (§ 80(5) VwGO).

Compared to the legal grounds on which the BoA is acting it has to be stated that the German model follows the “principle of administrative enquiry”, whilst the BoA procedure is of “adversarial nature”. It follows that the scope of the review is limited to legal arguments and the related evidence put forward by the appeal. Only within this scope, the board is entitled to issue a new decision of the case (see section 2.3); insofar the intensity of review does not differ. According to Article 93(3) the BoA has the competence to “exercise any power which lies within the competence of the Agency”.

<sup>69</sup> At least before the several waves of “streamlining” the review processes. In the last years the administrative review was abolished; the appeal has to be lodged directly at the court.

<sup>70</sup> § 68(1)1 VwGO (Law on Administrative Court Proceedings) asks for an internal review in terms of legality and expediency (“Rechtmäßigkeit und Zweckmäßigkeit”).



## 4 Policy options

In normative context of REACH the ECHA BoA should be, on the one hand, a control instance close to the Agency, which has to test both legal and "technical" (i.e. toxicological or exposure related) aspects on the basis of the REACH requirements, and, on the other hand, has to make timely but nevertheless well-founded decisions. The scope of the review is defined by the pleas raised by the appellant. The challenge to be met by BoA is ultimately the same as for the Agency: The provisions of the Regulation must be applied to the individual case. Where there is room for interpretation, it must be filled in in relation to the objectives of the Regulation: Article 1(1) mentions the "high level of protection" in the first place; this aim must be balanced with the other objectives of the Regulation. Where further animal testing is to be conducted, the objective to "promote alternative methods" must be taken into account.<sup>71</sup>

The following policy options consider these legislative requirements in respect of the research questions outlined in section 1. The central question is how legal protection for registrants can be ensured without undue delays in their legal obligation to provide data? In this respect, three main options can be considered. From a status quo perspective, tighter timelines would be the least invasive modification (section 4.1). Moreover, the rules on suspensive effect could be aligned with those of the Court of Justice (4.2). The most significant change would be to limit the scope of review in appeal proceedings (4.3).

### 4.1 Timelines

Section 2.2 introduced timelines for applicants to lodge their appeal and for ECHA to provide a written defend. The appeal has to be filed "within three months of the notification of the decision to the person concerned" (Art. 92(2)). Taking the German provisions as a benchmark where a period of a month is provided, a quarter of a year seems relatively long. The reason for this might be seen in the fact, that at the beginning of the REACH implementation a company had to meet the phase-in deadlines for a large number of substances, which implied that consequently a bunch of ECHA decisions are to be reviewed by the company experts.

The situation in 2020 and beyond, however, is rather different. Now the CoRAP process serves as an early warning mechanism. In addition, before ECHA issues a final decision the addressees have 30 days to comment on any draft decision according to Art. 50(1), Art. 51(5) as well as Art. 52(1) and Art. 52(2) in conjunction with Art. 51(5). Thus, in those cases, which cover most of the appeals to BoA, the addressees are already aware of the forthcoming administrative act and the respective reasoning. Thus, a period of one month should suffice to file an appeal (to be introduced in Art. 92(2)).

Accordingly, the Agency would have to lodge the defence in one month (Art. 7(1) RoP).

Up to now, no time limits have been laid down for the BoA to render its decision. This is in marked contrast to other bodies of the Agency. An option would be, to introduce a period of three month as a time limit for BoA (e.g., in Art. 21 RoP). If that period expired, the appellant could bring an action to the General Court for failure to act.

In order to legally implement these changes both, the REACH Regulation and the RoP will have to be amended as described in this section.

<sup>71</sup> It is worth mentioning that ECHA in 2015 accepted the findings of a European Ombudsman's inquiry (Case 1606/2013/AN). The Ombudsman proposed to ECHA (i) that it require all registrants to show that they have tried to avoid animal testing and (ii) that it provide registrants with all the information at its disposal which could allow them to avoid animal testing.

## 4.2 Suspensive effect

The suspensive effect of the appeal serves different functions. On the one hand, it makes sure that substance manufacturers do not perform legally not required animal tests based on an Agency decision that is later repealed. Besides, during suspension, economic actors may usually proceed with their business. On the other hand, suspension postpone the duties to gather data, which authorities deem necessary to put the registrant(s) into a position to assess adequately the unintended effects of the substance according to the information requirements laid down by REACH. The task to be tackled is thus to find an appropriate balance between the different legally protected issues.

For the length of the appeal proceedings, the appellant takes advantage of the fact that he has not to conduct additional tests for the substance. This provides benefits in terms of cost savings for this period. Depending on the test results, he might also be obliged to enhance the risk management measures in the exposure scenario and to amend the safety data sheet accordingly. This will trigger the general safety obligation of the downstream users according to Art. 37(5)(a) who has to apply additional measures to adequately control the risks identified by the new tests results. This usually causes additional costs for the downstream users with effect that the use of the substance is less attractive and he might prefer other options. Thus, the suspensive effect brings a competitive advantage against competing substances for which the registrant fulfilled all information requirements. Moreover, the absence of the requested test results postpone possible regulatory action by the authorities. In the meantime, the appellant may place the substance on the market although the “no data, not market” rule is suspended for the entire scope of the decision. The suspensive effect, thus, also postpone the first of those three objectives of REACH<sup>72</sup> to “to ensure a high level of protection of human health and the environment”.

Remarkably, a structural incoherency occurs when comparing this to decisions taken under REACH before the Court of Justice. Considering that results from the identical REACH evaluation processes have to be heard both before the Board of Appeal and – in proceedings involving the Commission – the Court of Justice; and for the latter no “automatic” suspensive effect applies, this divergence is surprising: For decisions under dossier evaluation as well as under substance evaluation the identical provision pave the path towards a Commission decision (51(7) and 52(2)):

*If Member State Committee fails to reach unanimous agreement, the Commission shall prepare a draft decision to be taken in accordance with the procedure referred to in Article 133(3).<sup>73</sup>*

It follows, that in those cases the consequences of the respective evaluation procedure is contested by at least one Member State. Consequently, it is for the Commission services to prepare and issue the final decision. In this case, the duty holder can file a complaint only to the General Court. In the other instance, in which all Member State representatives unanimously agreed on the subject matter ECHA issues the decision and the duty holder has to lodge an appeal to the BoA. In both cases, the ECHA bodies had to follow the identical examination procedures. Thus, the scientific basis does not differ. Only the lack of consensus in the Member State Committee triggers the path towards a decision issued by the Commission.

<sup>72</sup> See Court of Justice, decision as of 7 July 2009, S.P.C.M., C-558/07, EU:C:2009:430, para 45, 49, 54. “the main purpose of the obligation to register laid down in Article 6(3) thereof, the first of those three objectives, namely to ensure a high level of protection of human health and the environment”

<sup>73</sup> Art. 113(3) stipulates the regulatory procedure laid down in “Articles 5 and 7 of Decision 1999/468/EC (...) having regard to the provisions of Article 8 thereof. The period laid down in Article 5(6) of Decision 1999/468/EC shall be set at three months.”

In the light of the institutional framework on EU level it makes sense that a decision issued by the Commission cannot be contested before the body of a regulatory Agency like ECHA.<sup>74</sup> Insofar the different routes of legal remedies appear reasonable; what is questionable, however, are the diverging effects with regard to the obligation to comply with the administrative act during the ongoing legal appeal procedure. This unequal treatment would be avoided from the outset if only one appeal to the Court of First Instance were possible in each case. The alternative option would be to align the suspensory effects.

Under the current system the context can be summarized as follows: The procedural framework suggests that evaluation findings brought to European Commission's regulatory procedure contain more elements that are controversial since the disagreement among the Member State experts with regard to the findings of the evaluation process is the precondition for an evaluation decision from the European Commission. Nevertheless, under the rules of procedure of the European Court of Justice a legal remedy does not stipulate by itself a suspensory effect. It is for the court to decide on interim measures, including an order to suspend the effects of the contested decisions. In all cases, the court rejected any application by the appellant for granting of interim measures, whether they were originally decisions of the Commission<sup>75</sup> or those by the BoA.<sup>76</sup>

An appeal against a decision taken by ECHA based on a unanimous agreement in the MSC, on the other hand, automatically triggers a suspensive effect.

It is worth mentioning, that in none of the interim proceeding cases decided by the Court of Justice did animal welfare aspects play a decisive role. The Court obviously considers this aspect not as a relevant argument to put an evaluation decision with animal testing requirements on hold until the final ruling of the court.

All in all, the option at hand would be to adjust the situation before the BoA to the rules of procedure of the European Court of Justice. This could be achieved by deleting Art. 91(2) of REACH.

The implementing regulation consequently should entail the possibility for the BoA to grant interim measures in analogy to the court procedures. This option would allow the BoA to consider animal welfare aspects in its decision on interim measures.

### 4.3 Scope of review

A third option to streamline the procedure could be to limit the scope of the review. Once again, the procedure before the Court of Justice might serve as a benchmark. The EU Courts restrict their scope of review when it comes to the "assessment of highly complex scientific and technical" to "manifest errors", whereas the BoA due to the "the legal and scientific competences of its members (...) must examine whether the arguments put forward by the applicant are capable of demonstrating that the considerations on which that decision is based are vitiated by error."<sup>77</sup> The legal context in the REACH Regulation, however, might be subject to amendments by the EU legislators. The most likely options would be to align to composition of the BoA with

<sup>74</sup> On the status of ECHA as a "mature" regulatory agency that "shall perform [its] duties in the interests of the Community, and independently of any specific interests" (Art. 83(1)) and that is not a subordinate body of the European Commission, see Führ, *Vom Wesen Europäischer Agenturen*, in: Ewer/Ramsauer/Reese/Rubel (Hrsg.), *Methodik - Ordnung - Umwelt (Festschrift für Hans-Joachim Koch)*, Berlin 2014, S. 229 (236 et subs.).

<sup>75</sup> Cf. Order of the President of the Court as of 30 April 2020 – T-868/19 R – *dimethyl ether*.

<sup>76</sup> Cf. Order of the Vice-President of the Court as of 28 May 2018 – C-565/17 P(R) – *Tricolosan*; Order of the President of the Court as of 15 July 2019 – T-176/19 R – *UVASORB HEB*.

<sup>77</sup> General Court, judgment of 20.09.2019, BENPAT, para 193; see also section 2.3 for further details.

the EU courts. After all, a technically qualified member is hardly likely to keep up with the competence of several hundred ECHA experts.

The General Court has clarified, that the procedure before the BoA is of “adversarial nature”, therefore “the applicant must put forward detailed arguments calling into question the ECHA’s findings” in the sense “it is for the applicant to put forward detailed arguments to show that the considerations relied on by the ECHA are incorrect”.<sup>78</sup> The General Court holds, thus, that the BoA decision is not based on the principle of investigation, but on an adversarial procedure, so that the applicant must substantiate his own arguments in order to undermine the challenged ECHA decision.<sup>79</sup> The Board of Appeal thus is confined to examining the applicant’s detailed arguments.<sup>80</sup> With this judgement, the General Court underlined the limited scope for BoA to examine an appeal as laid down in Art. 12(1) and (2) RoP. The Court explicitly rejected the argument of the applicant that “the Board of Appeal is to conduct a ‘de novo’ evaluation”.<sup>81</sup>

With this clarification a streamlined decision making process is supported. However, the question remains to which extent within this scope of review the “intensity of review” might be limited. If the EU legislator intends to limit the review competence of the Board of Appeal, then Art. 93(3) would also have to be adapted. Only in simple cases the Board of Appeal would be empowered to replace the decision of ECHA, whereas as a matter of principle it would “remit the case to the competent body of the Agency for further action”. This option would limit the “intensity of review” thus contributes to a streamlined decision making.

In constellations where the BoA remits the case to the ECHA bodies the internal rules of procedure apply. According to Art. 78(3) the Management Board has the competence to “adopt the internal rules and procedures of the Agency”.

Taking into account the specific function and composition of the Board of Appeal as a body of ECHA, it must therefore be concluded that there are legislative options available to additionally limit the scope and the intensity of review in a way that goes beyond the current Rules of Procedure. This would reflect the division of “technical” expertise, e.g. with regard exposure assessment and (eco-)toxicological issues, between the BoA on the one hand and the staff of ECHA and the aggregated competence in the ECHA committees on the other hand.

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<sup>78</sup> General Court, judgement of 20.09.2019, T-125/17 – *Triclosan*, para. 280; see also para 59 et seq.

<sup>79</sup> General Court, judgement of 20.09.2019, T-125/17 – *Triclosan*, para. 279 et seq.

<sup>80</sup> General Court, judgement of 20.09.2019, T-125/17 – *Triclosan*, para. 465.

<sup>81</sup> General Court, judgement of 20.09.2019, T-125/17 – *Triclosan*, para. 59 et seq.

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