

## Annual Report from the Chairman of the Board of Appeal

66<sup>th</sup> Meeting of the Management Board 22-23 June 2022

### Key messages

- The new Legally Qualified Member, Marijke Schurmans, started in December 2021
- There is no backlog and the Board of Appeal continued to carry out its activity efficiently
- First annual meeting of all the members of the Board of Appeal since 2019 was held in Helsinki
- The Board of Appeal is preparing a code of conduct applicable to its members who are staff members of the Agency
- The Board of Appeal holds the Chairmanship of the Inter-Agency Appeal Proceedings Network 2022, a subnetwork of the European Agencies Network
- The Registry of the Board of Appeal has published on the website the digest of the decisions of the Board of Appeal, containing a collection of the main findings in the decisions since 2009

### Background

Every year at the Management Board's June meeting, the Chairman of the Board of Appeal reports on the activities of the Board of Appeal over the previous twelve months.

Annex I contains some personal remarks from the Chairman of the Board of Appeal, Mr Antoine Buchet, and information on the organisation of the activity of the Board of Appeal.

Annex II presents the work of the Board of Appeal during the reporting period (1 June 2021 to 31 May 2022).

Annexes III and IV respectively contain information on the members' terms of office and some figures related to appeals.

The Chairman of the Board of Appeal is also in regular contact with the Management Board Subgroup for the Board of Appeal (the 'MB BoA Subgroup'). Three members of the MB BoA Subgroup are also reporting officers for the members of the Board of Appeal. The MB BoA Subgroup reports to the Management Board in full, providing information on any issue related to the activity of the Board of Appeal.

### Rationale

The Board of Appeal is an independent and impartial body of the Agency ('ECHA'). The Management Board acts as the appointing authority of the members of the Board of Appeal. The Board of Appeal is accountable specifically to the Management Board and generally to ECHA's stakeholders and EU citizens. The present report of the Chairman of the Board of Appeal to the Management Board constitutes one of the means to discharge that accountability.

Decisions of the Board of Appeal can be challenged before the Court of Justice of the European Union.

## Drawbacks

N/A

### Attachments:

- Annex I: Remarks of the Chairman of the Board of Appeal
- Annex II: Report on the work of the Board of Appeal during the reporting period
- Annex III: Members of the Board of Appeal and their terms of office
- Annex IV: Appeals in figures

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## ANNEX I

### Remarks of the Chairman of the Board of Appeal

1. Introduction
2. A New and Well Established Team
3. Procedures, Efficiency and Pandemic Constraints
4. New Trends in Litigation

#### 1. Introduction

Perhaps the most salient conclusion from my third year in office is that there is no such thing as a normal year. Last year, in my second annual report, I considered with a certain recklessness that the establishment of a new team was imminent. I also thought that the pandemic was coming to an end and that our previous procedures and working methods would soon be restored. I was maybe too optimistic or, to put it more bluntly, I was simply wrong.

As a matter of fact, it is only at the time of writing this report that I can see that the Board of Appeal has reached a certain stability. And it is therefore only now that I can try to draw some lessons from the three rather turbulent years which constituted the beginning of my mandate.

First lesson: our rules of procedure are efficient, flexible, and fully in line with the general principles of EU law. Despite the pandemic and the long absence of a full-time legally qualified member, the Board of Appeal has managed to eliminate the backlog of the past and to treat more efficiently the new cases, without putting at risk the consistency of its practice or the procedural rights of the parties.

Second lesson: the success of the Board of Appeal is due to a collective effort. The full-time members, the alternate members and the Registry staff have constantly worked as a team. The full commitment of each member of the team is the prerequisite of the consistency of our decisions.

Third lesson: the Board of Appeal can only fully achieve its objectives if it is perfectly integrated into the Agency. It is only thanks to the close collaboration with the secretariat of the Agency and with the Management Board that the Board of Appeal has managed to overcome the various crises it has gone through. Similarly, it is only through an open and constructive dialogue that the decisions of the Board of Appeal can usefully contribute to the progress of the Agency.

In this respect, I would like to take the opportunity of this report to pay tribute to Björn Hansen, who has largely contributed to the full integration of the Board of Appeal in the Agency. His professionalism and open-mindedness greatly facilitated the emergence of a more fruitful relationship between the secretariat and the Board of Appeal.

#### 2. A New and Well Established Team

The new legally qualified member, Marijke Schurmans, joined the Board of Appeal on 1 December 2021, completing the composition of the Board of Appeal (three full-time members who are staff members of the Agency). If fewer alternate members might be designated in future appeal cases, they remain an essential part of the Board of Appeal and consequently of the Agency. As such, they continue to play an important role, ensuring that appeals can be processed efficiently.

On 2 and 3 June 2022, an annual meeting with the alternate members took place at the ECHA premises in Helsinki. It was the first in-person meeting of all members of the Board of Appeal since November 2019. Due to the Covid-19 pandemic, the previous meetings with alternates were held remotely. The annual meeting covered various aspects relating to the internal functioning of the Board of Appeal, its practice and the future of the REACH Regulation.

Following a Commission's request<sup>1</sup> to the Agency to put in place a specific code of conduct applicable to members of the Board of Appeal who are staff members of the Agency<sup>2</sup>, the Board of Appeal had several contacts with the Commission's representatives and with the secretariat of the Agency. The Board of Appeal is currently working on the outline of the code. The main goal is to create a structured document, where all the relevant provisions that apply to the full-time members of the Board of Appeal will be regrouped. Those provisions come notably from the Staff Regulations, which apply to the three full-time members of the Board of Appeal. In addition, the code of conduct could include provisions specific to the activity of the Board of Appeal and further clarifications, for example on the definition and scope of certain terms relating to the secrecy of deliberations and post-employment activities.

The Board of Appeal is considering to adopt the future Code of Conduct as an implementing measure under Article 27(1) of its Rules of Procedure. The Management Board will be regularly informed about the progress made in relation to the preparation of the code of conduct.

### **3. Procedures, Efficiency and Pandemic Constraints**

During the reporting period, the measures related to protection of public health introduced in the context of the Covid-19 pandemic continued to have a considerable impact on the activities of the Board of Appeal. The staff of the Registry and the Board of Appeal were subject to the same working arrangements as the rest of ECHA staff. Almost all the activities of the Board of Appeal were therefore carried out digitally. That impact and the necessary adaptation brought to the working methods of the Board of Appeal did not however have any strong adverse effect on the processing of appeals.

The appeal procedure has shown a satisfactory degree of flexibility and resilience, particularly, as regards holding hearings and internal meetings, and deciding on appeals. It is expected that new, flexible working arrangements will ensure that internal collaboration becomes easier, whilst, at the same time, gains in efficiency achieved through the digitalisation of the procedure can be maintained. For example, each time a hearing is foreseen, the parties will have the right to attend in person, but will also keep the possibility to prefer that the hearing is held by videoconference.

In addition, the Registry of the Board of Appeal has published a structured collection (digest) of all its findings in its decisions since 2009. This publication is expected to help all interested persons to find relevant precedents easily, thereby simplifying the work of both authorities and registrants.

Finally, the Board of Appeal has continued to hold the chairmanship of the Inter Agency Appeal Proceedings Network that brings together boards of appeals of all EU agencies and is a subnetwork of the European Agencies Network.

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<sup>1</sup> Commission Opinion of 27.7.2021 on the draft Single Programming Document 2022-2024 of the European Chemicals Agency, page 3, paragraph 13.

<sup>2</sup> Code of Conduct applicable to the Board of Appeal's alternate members are subject to a Code of Conduct, which was adopted by the Board of Appeal on 1 February 2018.

## 4. Trends in Pending Cases

This section briefly presents some of the key aspects of the **cases that are pending** at the end of this reporting period. The findings in the closed cases are presented in Annex II under the relevant REACH process or under the title referring to the Biocidal Products Regulation.

### 4.1. REACH Regulation

#### 4.1.1. Dossier evaluation

All of the 7 ongoing cases under dossier evaluation concern appeals against compliance check decisions. This constitutes the clear majority of cases brought before the Board of Appeal in the reporting period.

Two recently lodged appeals, A-002-2022 and A-003-2022, have been joined at the request of the Agency. They both concern a compliance check decision requesting information on an EOGRTS that follows the OECD Test Guideline (TG) 443, and that includes investigations on learning and memory function as described in OECD TG 426. The appellants argue that this specific configuration of the EOGRTS goes beyond the standard information requirements of Annex IX, Section 8.7.3. to the REACH Regulation. Therefore, according to the appellants, ECHA could not request this information in a compliance check decision.

The newest case, A-004-2022, concerns an appeal against a compliance check decision requesting information for a PNDD study following OECD TG 414, and an EOGRTS. The appellant accepts to conduct the PNDD study by means of the oral route, but contests the specific mode of administration prescribed by the decision (gavage). The appellant argues that Sections 8.7.2. and 8.7.3. of Annex IX only refer to the "most appropriate route of administration having regard to the likely route of human exposure", without allowing ECHA to decide on the specific mode of administration (dietary, gavage).

Several other compliance check cases also concern EOGRTS and PNDD studies. Case A-004-2021 concerns the follow-up to a compliance check decision in which ECHA found that the appellant was still required to conduct a PNDD study and an EOGRTS. ECHA had rejected the appellant's read-across adaptation, stating that it did not comply with the rules set out in Section 1.5. of Annex XI to the REACH Regulation.

Case A-011-2021 also concerns a compliance check decision requiring information under Annex X to the REACH Regulation on a PNDD study and an EOGRTS. This case relates more particularly to the obligation to perform a PNDD study on a second species at Annex X level.

Other ongoing appeal cases against compliance check decisions relate to information requirements concerning simulation testing and degradation products.

In case A-005-2021, the contested decision requires information on degradation products under Section 9.2.3. of Annex IX. In appeal cases A-012-2021 and A-001-2022, the appellants contest various information requirements, amongst others simulation testing on ultimate degradation in surface water (OECD TG 309), sediment (OECD TG 308) and soil simulation testing (OECD TG 307).

Overall, the appeal cases concerning dossier evaluation continue to raise complex legal, regulatory and scientific questions. Those questions concern mainly the interpretation of the information requirements in the REACH Regulation, the distribution of responsibilities between the Agency and registrants in developing adaptations, the powers of the Agency in the compliance check procedure, and the follow-up procedure under Article 42.

#### 4.1.2. Substance evaluation

Substance evaluation cases present a wide range of scientific issues. Currently, one appeal brought against a substance evaluation decision is pending before the Board of Appeal, in case A-009-2021. The case concerns a request for information on larval amphibian growth and development assay ('LAGDA') for the substance resorcinol.

If the legal conditions for substance evaluation have now been clarified, both by the Board of Appeal and the EU Courts, substance evaluation decisions continue to raise a variety of scientific and regulatory issues of a high complexity.

#### **4.1.3. Data-sharing cases under the REACH Regulation**

The Board of Appeal did not receive any appeals concerning data-sharing under the REACH Regulation during the reporting period. This can be explained by the low number of data-sharing decisions. Between June 2021 and April 2022, the Agency has adopted only 6 decisions concerning data-sharing under REACH.

#### **4.1.4. Registration**

In December 2021, the Board of Appeal received two appeals (A-013-2021 and A-014-2021) against two separate completeness check decisions rejecting the appellant's registrations and revoking the registration numbers due to the non-payment of the full registration fee following SME (small or medium-sized enterprise) verification performed by the Agency. In both cases, the appellant claims that it is a SME and was therefore entitled to register the substance by paying a reduced registration fee.

### **4.2. Biocidal Products Regulation (BPR)**

During the reporting period, no appeals concerning decisions taken under the BPR have been lodged at the Board of Appeal. During the same period, the Agency adopted 21 technical equivalence decisions. In only three of those decisions the Agency decided that technical equivalence cannot be established and rejected the request made by an applicant. It is therefore in three instances only that there was an actual possibility for an applicant to challenge the findings of the Agency.

### **4.3. Looking forward**

#### ***Dossier and substance evaluation***

As regards dossier evaluation, with an aim to speed up the identification of chemicals needing regulatory action, the Agency continues to direct its resources on the compliance check of registrations, addressing groups of structurally related substances<sup>3</sup>. This means that, in the near future, the majority of appeal cases will likely continue to concern dossier evaluation.

Substance evaluation is a slower and more complex process, where the burden of proof and the allocation of tasks are different than in dossier evaluation. Given the complexity and importance of these cases, the Board of Appeal is still dedicating considerable efforts to this area.

Overall, the Board of Appeal continues to be called upon to examine both scientific and regulatory aspects of evaluation cases, and the functioning of the evaluation procedures.

As regards the first aspect, namely the scientific and regulatory review of cases, the Board of Appeal has acquired much experience and has struck an effective balance between reviewing the scientific content of decisions and respecting the role and prerogatives of the various actors of the procedure (Agency and Member States). This balance was confirmed by the EU Courts as being constitutionally mandated and correct, and the Board of Appeal will continue to maintain this balance in the future.

As regards the second aspect, namely the functioning of the evaluation procedures, the Board of Appeal has paid particular attention to ensuring that the respective responsibilities of registrants and of the Agency are clearly delineated, and the relevant rules are as clear as possible. This has contributed to simplifying the Agency's work under both dossier and substance evaluation, whilst at the same time ensuring that the REACH Regulation is implemented in full compliance with the principles of good administration. This aspect will also continue to play an important role in future cases.

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<sup>3</sup> <https://echa.europa.eu/working-with-groups>

### ***Efficiency and duration of the appeal procedure***

The Board of Appeal has put considerable emphasis on ensuring that the appeal procedure is as fast and effective as possible, without compromising the quality of its decisions. Despite changes in composition, the extensive use of alternate members in the reporting period, and the constraints of the Covid-19 pandemic, the duration of appeal proceedings, ending with a Board of Appeal's decision on a substance, decreased compared to the pre-pandemic average (from 19 to 14 months on average).

The Board of Appeal will continue to pay attention to speeding up its procedures. This is particularly important as the suspensive effect of appeal proceedings is an essential element of the system, particularly as regards testing on vertebrate animals. In that regard, the appeal procedure is and will remain a safety net for the entire Agency. However, the suspensive effect also requires that appeals be decided within a reasonable time so as not to delay testing where necessary, thereby ensuring a high level of protection of human health and the environment.

To that end, the Board of Appeal intends to improve its procedures further, in order to make them more efficient and further reduce the duration of appeals. Some of those changes will be implemented directly, others will be proposed in due time in the framework of the revision of the Rules of Procedure.

### ***Review of the REACH Regulation***

The Board of Appeal has a role wherever the Agency has decision-making powers. Following the Chemicals Strategy for Sustainability, ECHA's competences may be strengthened. If this leads to additional decision-making powers for the Agency, this should in turn result in further competences for the Board of Appeal.

Where appropriate, the Board of Appeal is contributing to the Agency's input in relation to the review of the REACH Regulation in those fields which fall, or may fall, within its competence.

## ANNEX II

# Report on the work of the Board of Appeal during the reporting period

1. Introductory remarks
2. Summary of the activity of the Board of Appeal
3. Main findings of the Board of Appeal during the reporting period

## 1. Introductory remarks

### *Two closed Court cases during the reporting period*

Final decisions of the Board of Appeal are decisions of the Agency. They can be challenged before the General Court, and then before the Court of Justice if the strict conditions introduced in 2019 in the Statute of the Court of Justice of the EU are fulfilled.

During the reporting period, the General Court delivered its judgment in Case [T-127/20](#), *France v ECHA*. That case concerned an action for annulment against a Board of Appeal decision in joined cases [A-003-2018](#), [A-004-2018](#) and [A-005-2018](#)<sup>4</sup> partially annulling three separate ECHA decisions on the substance evaluation of aluminium chloride, aluminium chloride basic and aluminium sulphate. In the challenged decision, the Board of Appeal had found that, for four separate and independent reasons, ECHA had not demonstrated that the requested information was necessary. However, before the General Court, the applicant only challenged two of the grounds for annulment identified by the Board of Appeal. The two uncontested grounds would have been sufficient on their own to annul ECHA's decision. Therefore, the General Court found that the arguments raised by the applicant were ineffective, as they could not on their own affect the validity of the Board of Appeal's decision to annul ECHA's decisions. The Court dismissed the applicant's action.<sup>5</sup>

The General Court also delivered an order in cases [T-663/20](#) and [T-664/20](#), *OneVoice v ECHA*, concerning an action for annulment against Board of Appeal decision in case [A-010-2018](#)<sup>6</sup>. The main issues of the cases were the applicability of the REACH Regulation to ingredients used exclusively in cosmetics products and more generally the relationship between the cosmetics<sup>7</sup> and REACH regulation. The court dismissed the action as inadmissible due to the fact that the appeal had been lodged after the prescribed two-month time period starting from publication of the decision on the ECHA website.<sup>8</sup> An action on the same subject-matter is currently pending before the General Court in cases [T-655/20](#) and [T-656/20](#) (see below).

### *Ongoing Court cases*

When a decision of the Board of Appeal is challenged before the General Court, the Registry of the Board of Appeal and the Legal Affairs Unit of the secretariat prepare the Agency's defence jointly.

In the most recent Court case, [T-29/22](#), *Polynt v ECHA*, an action for annulment was brought against Board of Appeal decision [A-009-2020](#)<sup>9</sup> concerning a cessation of manufacture that occurred after the adoption of a compliance check decision, during the follow-up process. The applicant's main argument is that it was not required to submit the information requested in the compliance check decision after having ceased the manufacture of the substance in accordance with Article 50(2) of the REACH Regulation.

<sup>4</sup> *BASF SE/Kemira Oyj*, Decision of the Board of Appeal of 17 December 2019.

<sup>5</sup> Judgment of the General Court of 15 September 2021 in Case T-127/20, *France v ECHA*, EU:T:2021:572.

<sup>6</sup> *Symrise AG*, Decision of the Board of Appeal of 18 August 2020.

<sup>7</sup> Regulation (EC) No 1223/2009.

<sup>8</sup> Order of the General Court of 8 June 2021 in Cases T-663/20 and T-664/20, *OneVoice v ECHA*, EU:T:2021:346, EU:T:2021:345.

<sup>9</sup> *Polynt S.p.A.*, Decision of the Board of Appeal of 9 November 2021.



In cases [T-655/20](#) and [T-656/20](#), *Symrise v ECHA*, the appellant before the Board of Appeal is challenging the decisions of the Board of Appeal in appeal cases [A-009-2018](#) and [A-010-2018](#). Among other issues, the cases relate to the applicability of the REACH Regulation to ingredients used exclusively in cosmetics products and more generally the interface between the cosmetics<sup>10</sup> and REACH legal frameworks.

In case [T-207/21](#), *Polynt v ECHA*, the appellant before the Board of Appeal submitted an action for annulment against the decision in case [A-015-2019](#)<sup>11</sup> in which the Board of Appeal upheld an ECHA testing proposal decision requiring information on an EOGRTS.

## 2. Summary of the activity of the Board of Appeal

During the reporting period, the Board of Appeal was processing 24 appeals; 13 cases were closed with a final decision.

The average duration of appeal proceedings that were closed with a substantive decision of the Board of Appeal during the reporting period was around 14 months. The duration including cases that were closed due to inadmissibility or after rectification and withdrawal of the appeal is 11 months.

10 cases are currently pending before the Board of Appeal. During the reporting period, the Board of Appeal held 5 oral hearings. Out of these, 4 hearings were held remotely and one hearing in case A-005-2021 was held in person in the ECHA Conference Centre.

In addition to final decisions, 3 intervention decisions were adopted during the reporting period. One decision to join two appeals was taken in cases A-002-2022 and A-003-2022. The Board of Appeal prescribed around 100 procedural measures (consisting of, for example, questions to the parties and requests for additional submissions). The number of documents registered (incoming and outgoing) in the Register of appeals during the reporting period stands at 475.

From 1 June to 31 December 2021, the Board of Appeal received 7 appeals. The notices of appeal in 4 of those cases concern compliance check decisions<sup>12</sup>. One notice of appeal related to a substance evaluation decision.<sup>13</sup> Two notices of appeal concerned completeness check of registrations pursuant to Article 20(2).<sup>14</sup>

So far in 2022 (1 January to 1 June 2022), the Board of Appeal has received 4 appeals. They all concern compliance check decisions.

Two of the appeal cases were closed after the appellants withdrew their appeals following the ED's withdrawal or rectification of the contested decisions.<sup>15</sup>

During the reporting period, the Chairman designated two alternate members in two new appeal cases (i.e. legally qualified member in case A-002-2021 and technically qualified member in case A-011-2021). Compared to the previous reporting period, the number of newly designated alternate members has therefore decreased. This is because in March and December 2021 respectively, the new technically qualified member and the new legally qualified member of the Board of Appeal started their terms at the BoA, completing the composition of the Board of Appeal. Between June 2021 and June 2022, six alternate members were involved in 13 appeal cases.

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<sup>10</sup> The Cosmetics Regulation is regulation (EC) No 1223/2009.

<sup>11</sup> Polynt S.p.A., Decision of the Board of Appeal of 9 February 2021.

<sup>12</sup> Appeal Cases A-010-2021, A-011-2021, A-012-2021 and A-015-2021.

<sup>13</sup> Appeal Case A-009-2021.

<sup>14</sup> Appeal Cases A-013-2021 and A-014-2021.

<sup>15</sup> Appeal Cases A-010-2021 and A-015-2021.

## 3. Main findings of the Board of Appeal during the reporting period

This section summarises some of the most relevant findings and conclusions in decisions that the Board of Appeal adopted during the reporting period.<sup>16</sup> The findings are presented under the relevant REACH process or under the title referring to the BPR.

### 3.1. REACH Regulation

#### 3.1.1. Registration

There were no decisions in appeals concerning registration under the REACH Regulation during the reporting period.

#### 3.1.2 Dossier evaluation

##### ➤ Case [A-001-2020](#)

(Dossier evaluation – Compliance check of a registration for a monomer – Unreacted monomer in a polymer – Monomer as a degradation product of a polymer – Exposure-based adaptation – Error of assessment – Powers of the Agency – Data-sharing – Organic or inorganic nature of a substance – Duty to state reasons)

The appeal concerned a compliance check decision of the appellant's registration dossier for the substance cyanoguanidine. The appellant had submitted all information separately from the other registrants of the Substance under Article 11 (3) of the REACH Regulation. ECHA rejected the adaptations by which the appellant had sought to fulfil the standard information requirements of a 90-day (subchronic) toxicity study, a PNDT study and a surface water simulation study (OECD TG 309).

The Board of Appeal annulled the contested decision insofar as it required the appellant to fulfil further information requirements on stimulation testing on ultimate degradation in water and found that ECHA breached its duty to state reasons in rejecting the appellant's adaptation.

##### ➤ **Joined cases** [A-006-2020](#) and [A-007-2020](#)

(Dossier evaluation – Compliance Check – Tonnage downgrade – Cut-off point for considering dossier updates – Substantial new information – Duties of the Agency – Proportionality – Article 25)

The appeal concerned the compliance check of the appellants' registration dossiers for the substance reaction product of [29H, 31 H-phthalocyaninato (2-)-N29, N30, N31, N32] zinc, sulphuric acid and caustic soda. The appellants requested the Board of Appeal to annul the contested decision insofar as it concerned the information requirements set out in Annex IX to the REACH Regulation. According to the appellants, REACH does not define any cut-off point that would allow ECHA to disregard new facts in the decision-making process. The appellants argued that since they downgraded their tonnage band after receiving ECHA's draft decision on the compliance check of their dossier, the requirements in Annex IX should not have applied to their respective dossiers.

The Board of Appeal held that the REACH Regulation does not preclude ECHA from taking into account tonnage downgrades during a compliance check process. According to the Board of Appeal, the tonnage downgrades constituted substantial new information, which ECHA should have considered in the decision-making process under Article 41 of the REACH Regulation. ECHA thus breached its duty to take into consideration all the relevant facts and circumstances of the case and further breached its duty to ensure that studies on vertebrate animals are carried out only as a last resort under Article 25 (1) of the REACH Regulation. Consequently, the Board of Appeal annulled the contested decision insofar as it concerned the information requirements set out in Annex IX of the REACH Regulation.

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<sup>16</sup> All the decisions of the Board of Appeal and the case announcements are available online on [ECHA website](#).

➤ **Case [A-009-2020](#)**

(Follow-up to dossier evaluation – Article 42(1) of the REACH Regulation – Cessation of manufacture – Legal certainty – Proportionality – Read-across)

The appellant sought the annulment of a decision taken by ECHA under Article 42 (1) of the REACH Regulation in follow up to an initial compliance check decision concerning the appellant's registration dossier. Following the initial compliance check decision by ECHA, the appellant submitted an updated read-across adaptation for the sub-chronic toxicity study endpoint and notified ECHA that it had ceased the manufacture of the substance. According to the appellant, it could no longer manufacture the substance as no suitable raw material was available due to a fire at its supplier's production site. ECHA rejected the updated read-across adaptation and found that the appellant's registration dossier still did not comply with Section 8.6.2 of Annex IX to the REACH Regulation. The appellant argued that ECHA should not have addressed to it the contested decision and that ECHA committed an error of assessment in rejecting its read-across adaptation.

The Board of Appeal found that the appellant continued to be bound to provide information requested in the initial compliance check decision even if it had ceased the manufacture of the substance after the adoption of that decision. The Board of Appeal also held that ECHA was correct in finding that the information provided by the appellant was not sufficient and that ECHA did not make an error of assessment in rejecting the appellant's read across adaptation. Consequently, the Board of Appeal dismissed the appeal.

➤ **Case [A-010-2021](#)**

(Closure of the proceedings – Withdrawal of the Contested Decision by the Executive Director – Withdrawal of the appeal by the Appellant)

The appeal concerned a compliance check decision that did not take into account a tonnage downgrade.

Having regard to the Board of Appeal's decision in joined cases in [A-006-2020](#) and [A-007-2020](#), the Executive Director withdrew the contested decision. This resulted in the appellant's withdrawal of the appeal. The case was then closed by the Chairman.

➤ **Case [A-015-2021](#)**

(Rectification of the contested decision – Withdrawal of the appeal by the Appellant)

The appeal concerned a compliance check decision that did not take into account a tonnage downgrade.

The Executive Director rectified ECHA's contested decision by withdrawing the contested information requirements, also having regard to the Board of Appeal's decision in joined cases [A-006-2020](#) and [A-007-2020](#). Following this, the appellant withdrew the appeal and the Chairman of the Board of Appeal closed the case.

### 3.1.3 Substance evaluation

➤ **Cases [A-003-2020](#), [A-004-2020](#) and [A-005-2020](#)**

(Substance evaluation – Error of assessment – Potential risk – Improved risk management measures – Proportionality – Article 25)

The Board of Appeal dismissed three appeals against separate substance evaluation decisions concerning three antimony metals.

In cases A-003-2020 and A-004-2020, the appellants were required to perform a 90-day (sub-chronic) inhalation toxicity study in rats (OECD TG 413). In case A-005-2020, the appellant was required to perform a 90-day (sub-chronic) toxicity study in rats, oral route (OECD TG 408).

The Board of Appeal rejected the appellants' arguments that the requested studies were not necessary or appropriate to clarify the concerns identified by ECHA.

The Board of Appeal also clarified that ECHA did not infringe a procedural requirement of the

REACH Regulation by not completing a compliance check on the substances prior to carrying out the substance evaluation. The Board of Appeal found that it does not follow from the REACH Regulation nor from previous Board of Appeal decisions that ECHA must always perform a full compliance check before carrying out a substance evaluation on that substance.

The Board of Appeal also found that ECHA was under no obligation to wait for the appellants to develop their respective grouping approach and read-across proposals before requesting additional information under substance evaluation. The Board of Appeal held that ECHA did not give the appellants assurances that their grouping approach would be accepted and the appellants therefore could not rely on the principle of the protection of legitimate expectations.

➤ **Case [A-007-2021](#)**

(Substance evaluation – Admissibility – Simulation testing on ultimate degradation in surface water – <sup>14</sup>C-radiolabelling)

The Board of Appeal dismissed an appeal against a substance evaluation decision requiring information on simulation testing on ultimate degradation in surface water (OECD TG 309) or alternatively simulation testing in sediment (OECD TG 308). Both tests additionally required radiolabelling of the molecules in order to identify and quantify the transformation and/or degradation products.

The Board of Appeal held that the appellant failed to demonstrate that radiolabelling of the substance was not necessary and did not provide evidence to show that the relevant transformation and/or degradation products can be predicted by reference to similar substances. The Board of Appeal also found that ECHA took the appellant's comments into account in an objective manner and provided reasons as to why it was not persuaded by those.

➤ **Case [A-002-2021](#)**

(Substance evaluation – Error of assessment – Good administration – Proportionality)

The appeal concerned a substance evaluation decision on diuron requiring information on a Larval Amphibian Growth and Development Assay ('LAGDA'), according to OECD TG 241. The request for information was based on a concern that diuron may be an endocrine disruptor in the environment. According to the contested decision, the LAGDA was necessary to examine the concern in relation to the (anti)androgenic and (anti)estrogenic ('EA') modes of action, as well as the thyroid mode of action.

The Board of Appeal rejected the appellants' arguments that ECHA failed to take into account in its decision certain information that was published during the substance evaluation decision-making procedure. The appellants' argument that the LAGDA is not suitable to investigate the thyroid mode of action was also rejected.

However, the Board of Appeal found that ECHA had failed to demonstrate that there is a potential hazard related to the EA modes of action. In particular, the results of a Fish Sexual Development Test ('FSDT') - submitted by the appellants in response to an earlier substance evaluation decision on diuron - did not show any endocrine disruption mediated adverse effects. In addition, to justify a potential hazard related to the EA modes of action, the contested decision did not refer to any other information which would suffice on its own to contradict the FSDT study findings.

The contested decision was therefore annulled and the case remitted to ECHA for further action.

### **3.1.4. Data Sharing**

➤ **Case [A-002-2020](#)**

(Article 30(3) of the REACH Regulation – Article 4(1) of Commission Implementing Regulation 2019/1692 – application for permission to refer filed after the expiry of the final registration deadline for phase-in substances)

The appeal concerned an ECHA decision rejecting the appellant's application for permission to refer under Article 30 of the REACH Regulation on the ground that the application was submitted

after the final registration deadline for phase-in substances (i.e. 1 June 2018). According to ECHA, since the relevant data and cost-sharing negotiations took place after 1 June 2018, the registrant did not fulfil the admissibility criteria for the permission to refer under Article 30 (3) of the REACH Regulation.

The Board of Appeal held that neither Article 30 (3) of the REACH Regulation nor Article 4 (1) of the Implementing Regulation 2019/1692 contained rules concerning the admissibility of an application for permission to refer. According to the Board of Appeal, Commission Implementing Regulation 2019/1692 allowed former SIEF participants to submit applications for permission to refer under Article 30 of the REACH Regulation until 31 December 2019, even if no actual negotiations took place before 1 June 2018. It therefore annulled ECHA's decision and remitted the case to ECHA for further action.

### **3.2. BPR regulation**

#### **➤ Case [A-008-2021](#)**

(Opinion of the Biocidal Products Committee – Admissibility – Competence of the Board of Appeal)

The appellant challenged an Opinion of the Biocidal Products Committee on the application for renewal of the approval of the active substance creosote. According to the appellant, the Board of Appeal is under the general duty to review administrative acts and therefore is the competent body to review the appeal under Article 77 of the BPR.

The Board of Appeal found that, since the opinion was adopted under Article 14 (3) of the BPR and not under any of the provisions listed in Article 77 (1) of the BPR, it lacked competence to review the appeal. Consequently, the Board of Appeal dismissed the appeal as inadmissible under Article 93 (2) of the REACH Regulation.

## ANNEX III

### Members of the Board of Appeal and their terms of office

Name	Role	Term started	Term ends
Antoine <b>BUCHET</b>	Chairman	16 August 2019	15 August 2024*
Nikolaos <b>GEORGIADIS</b>	TQM <sup>1</sup>	1 March 2021	28 February 2026*
Marijke <b>SCHURMANS</b>	LQM <sup>2</sup>	1 December 2021	30 November 2026*
Ekaterina <b>GEORGIEVA</b>	Alternate Chair <sup>3</sup>	15 April 2019	14 April 2024*
Uta <b>JENSEN-KORTE</b>	TQAAM <sup>3</sup>	14 December 2019	13 December 2024*
Spyridon <b>MERKOURAKIS</b>	TQAAM <sup>3</sup>	14 December 2019	13 December 2024*
Katrin <b>SCHÜTTE</b>	TQAAM <sup>3</sup>	14 December 2019	13 December 2024*
Laura <b>DE SANCTIS</b>	LQAAM <sup>3</sup>	27 May 2021	26 May 2026*
Ángel Manuel <b>MORENO</b>	LQAAM <sup>3</sup>	15 December 2014	14 December 2024**
Marcus <b>NAVIN-JONES</b>	LQAAM <sup>3</sup>	27 May 2021	26 May 2026*
Christian <b>SCHULTHEISS</b>	LQAAM <sup>3</sup>	27 May 2021	26 May 2026*
Sakari <b>VUORENSOLA</b>	LQAAM <sup>3</sup>	15 December 2014	14 December 2024**

\*- First term of office

\*\* - Second term of office

<sup>1</sup> – Technically Qualified Member

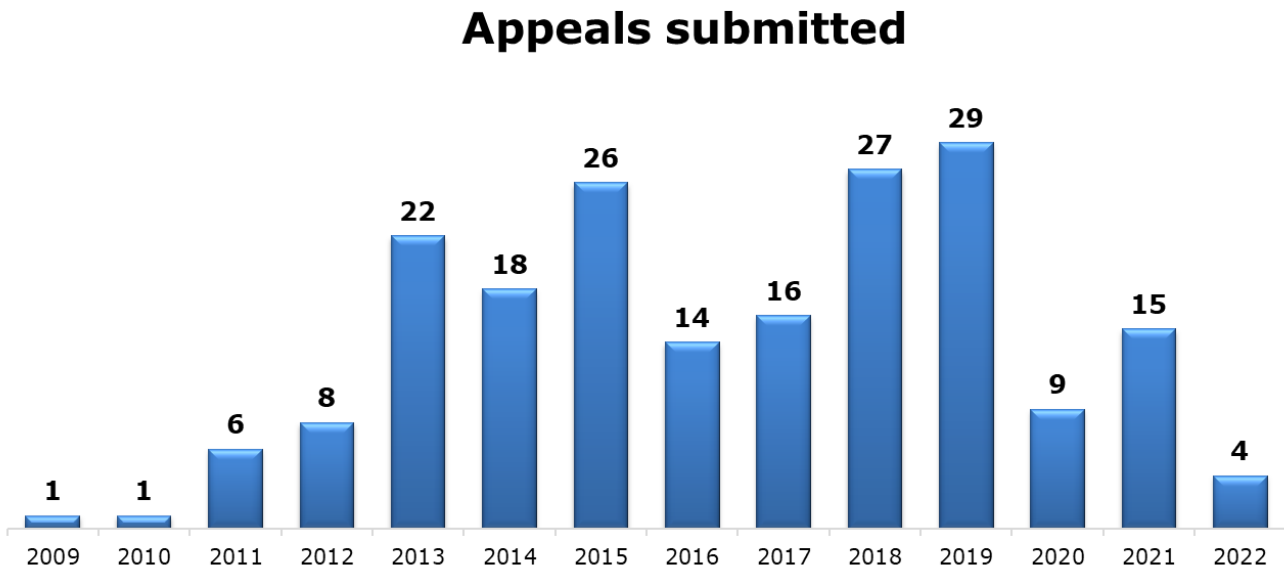
<sup>2</sup> – Legally Qualified Member

<sup>3</sup> – Alternate (Additional) Member

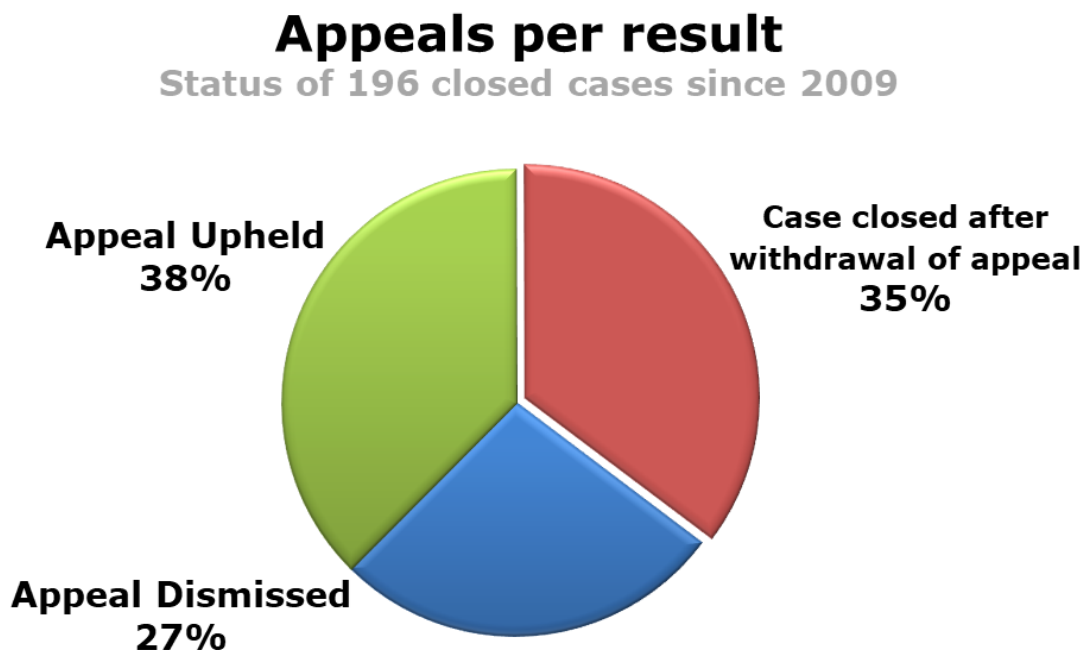
**ANNEX IV**

**Appeals in figures**

**Figure 1: Appeals submitted since 2009**



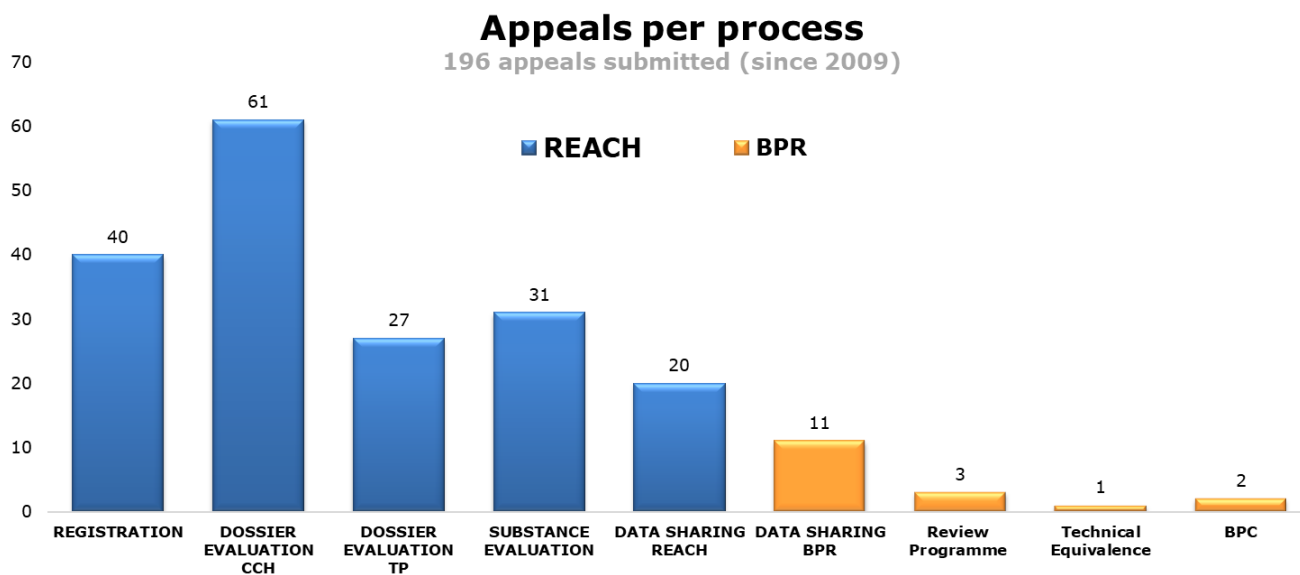
**Figure 2: Appeals per result since 2009**



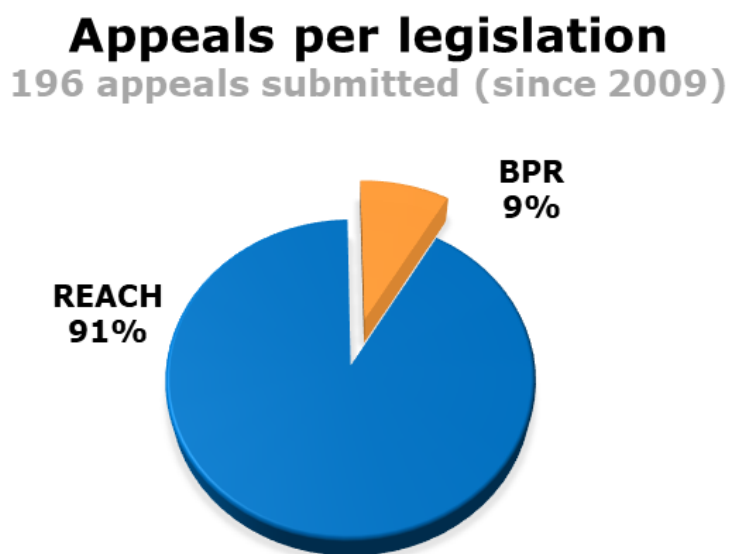




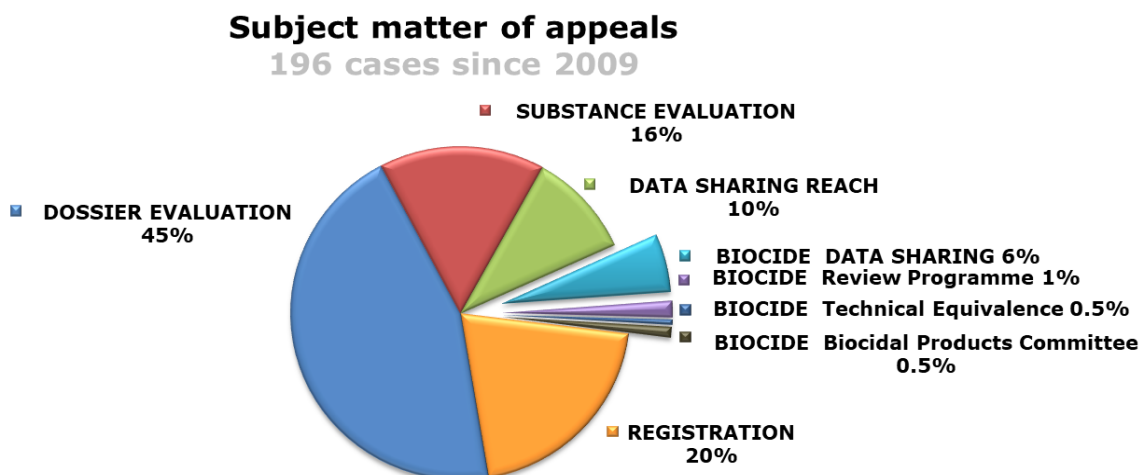
**Figure 3: Appeals per process since 2009**



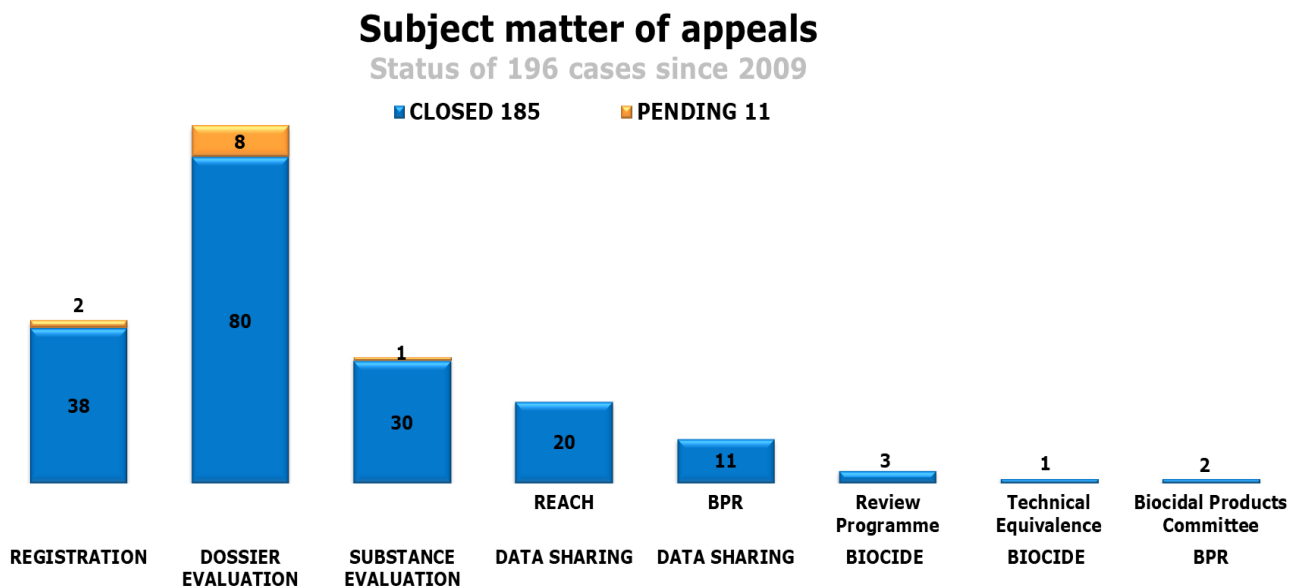
**Figure 4: Appeals per legislation since 2009 (REACH and BPR)**

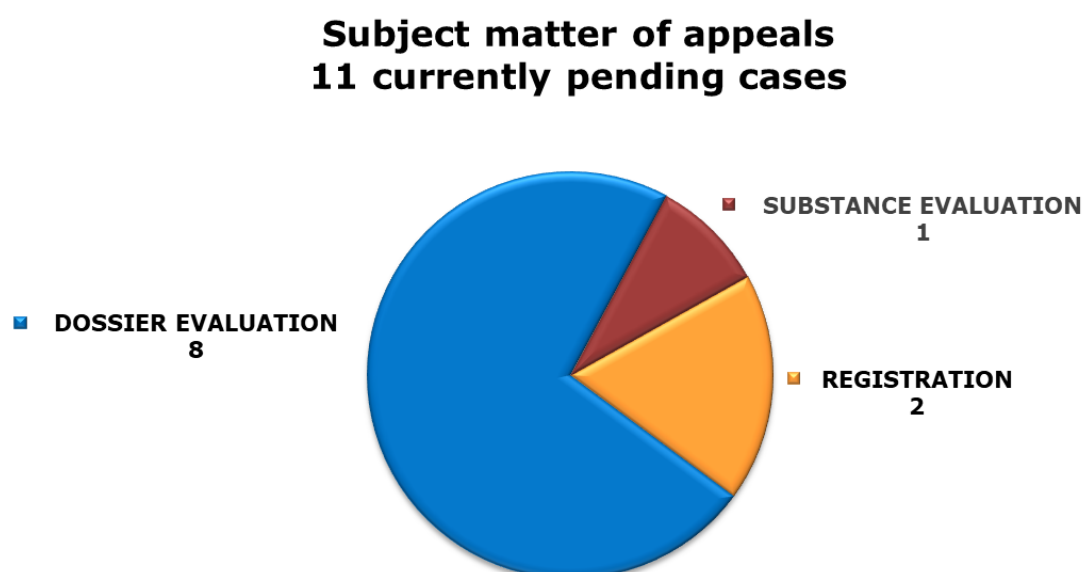


**Figure 5: Share of all appeals per subject matter and legislation since 2009**



**Figure 6: Number of all appeals per subject matter and legislation (REACH or BPR) since 2009 (pending cases in yellow)**



**Figure 7: Number of appeals per subject matter (pending cases)****Figure 8: Duration of appeal proceedings**