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Annual report from the Chair of the Board of Appeal and exchange of views

58th Meeting of the Management Board 17-18 June 2020

Key messages

- The new Chairman of the Board of Appeal, Antoine Buchet started in August 2019, following the end of the mandate of Mercedes Ortuño.
- 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 Court, among others, found that decisions under substance evaluation are not decisions of the Member States; they are ECHA decisions adopted according to a specific procedure. 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.
- Currently the most important pending appeal cases include:
    - An appeal on compliance check concerning the interaction between the REACH Regulation and the Regulation on Cosmetics Products;
    - An appeal on the nature and content of a decision taken by ECHA to follow-up a first decision on compliance check;
    - Two data-sharing cases where the Board of Appeal is asked to rule on ECHA decisions adopted after a first annulment followed by the remittance of the case to the Agency;
    - Under BPR, the first appeal case on technical equivalence.
- As ECHA continues to focus on dossier evaluation, it is likely that the number of appeal cases on this topic will increase, whereas appeals concerning substance evaluation could decrease. Under BPR, further appeals on technical equivalence can be expected.
- The Covid-19 crisis brought challenges but did not disrupt the continuity of the Board of Appeal's activities; working methods were adapted to the circumstances and the hearings have been successfully held remotely, using virtual communication technology.
- Early next year, the composition of the Board of Appeal will change again, as both the technically qualified member and the legally qualified member will needed to be replaced. These upcoming changes require that the Board of Appeal relies more frequently on its alternate members.
- The Board of Appeal continues to be both an independent body and an integral part of the Agency.

In addition to the above, the report includes a list of the Board of Appeal members. The Report also includes the latest set of figures on its activity.

Background

Every year, at the Management Board's June meeting, the Chairman of the Board of Appeal (the 'BoA') presents a comprehensive report on the BoA's activities covering, in principle, previous

twelve months. This report was prepared under the auspices of Mr Antoine Buchet, the Chairman of the BoA who took office on 16 August 2019. Annex I contains some personal remarks of the Chairman after his first 10 months in the job. Work of the BoA during the reporting period, stretching from 1 March 2019 to 31 May 2020, is presented in Annex II.

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

Also, the BoA Chairman is in regular contact with the Management Board Subgroup for the BoA (the 'MB BoA Subgroup')1; three of its members are also reporting officers for the BoA members. The MB BoA Subgroup reports to the MB plenary, providing information on any issue related to the activity of the BoA.

Rationale

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

Drawbacks

n/a

Attachments:

- Annex I: BoA Chairman's personal remarks after his first 10 months
- Annex II: Report on the work of the BoA during the reporting period
- Annex III: Table of BoA Members and their terms of office
- Annex IV: Appeals in figures

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[1] MB BoA subgroup is currently composed of: Mr Hans Meijer (Chair), Ms Marie-Laure Metayer, Mr Kęstutis Sadauskas, Mr Oscar Gonzalez Sanchez and Ms Sofia Zisi.

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ANNEX I

BoA Chairman's personal remarks after his first 10 months

1. Introduction
2. BoA at the age of maturity
3. Nature of litigation: between novelty and repetition
4. Efficiency and Fairness at the time of a pandemic: the procedural challenges of the Covid-19 crisis
5. Building a new team

1. Introduction

In April 2019 the Management Board entrusted me with a mission that encompassed a double challenge: changing job, and changing scenery.

Getting to Helsinki was certainly not the hardest part - Finland has been an integral element of my life for over twenty years. In contrast, leaving an institution to join an agency was an important change, which I was probably a little apprehensive about. After spending almost thirty years in the service of big administrations, both in Paris and Brussels, I was going to discover an administrative body of more modest size. It has been so far a very pleasant experience.

There are probably many reasons for the ease with which I have managed to adapt. I will only mention one, which can be summed up in one very simple expression: the sense of ownership. Everyone I have had the opportunity to work with since joining ECHA understands their particular role in achieving the Agency's goals. This is undoubtedly the most basic and common expectation that one can have in his professional life, but this is also the most difficult to realise.

The sense of ownership is contagious, and it is a virus that one should not stray from. Very quickly, I was hit myself and had no trouble getting the feeling that my job's objectives are clear and feasible.

In this new setting, I also had to change job. Of course, I was and remain a lawyer, and I was asked to perform quasi-jurisdictional tasks for which I was trained and which I practiced in the past, exercising in turns the role of the judge and the lawyer. But I had to dive into a new area of expertise.

After my first ten months, I realise that I still have a million things to discover. The regulation of chemicals and biocides is for me a continent, still largely unknown. I am privileged, however, to have met guides of the highest quality.

First of all, I must pay tribute to the remarkable work accomplished by my predecessor, Mercedes Ortuño. It is undoubtedly difficult to succeed her, in the sense that I know that it will take me a long time to reach her level of excellence, but still it is quite pleasant and reassuring to board a ship that is both solid and comfortable.

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.

The Board of Appeal is often described as a hybrid body: 50% administrative, 50% judicial. I leave to the legal doctrine the challenging but fascinating task to analyse its very nature. My point of view, after a few months riding this strange horse, is certainly less sophisticated: the Board of Appeal is 100% in the Agency, and 100% independent. And I have never had the impression that it was self-contradicting.

The legislator, in the REACH Regulation, has established an institutional balance within the Agency. The proper functioning of this clockwork mechanism is in the hands of the various bodies comprised in the Agency. This does not work without frictions – denying it would be counterproductive. But none of those frictions have caused an actual stalemate. Quite the contrary, the conflicts led to discussions, and discussions to improvements. I therefore do not hesitate to also pay tribute to the excellent cooperation I have benefited, from the Executive Director and his team and from the Management Board. Independence is not an obstacle to collaboration; the reverse is the case: independence is a prerequisite for any form of collaboration.

2. The BoA at the age of maturity

Barely more than a month after I took office, a turning point in the young history of the Board of Appeal was awaited from Luxembourg. In two landmark judgments of 20 September 2019, the General Court of the European Union ruled for the first time on the scope and intensity of the power of review of the Board of Appeal in substance evaluation cases.

The first case (T-125/17) was filed by BASF. The BoA had rejected BASF's appeal against a request for further information on the substance triclosan (an antibacterial used in consumer products). BASF argued that the BoA should have carried out a full re-evaluation of triclosan, and not limited itself to the arguments and evidence put forward in the appeal procedure.

The second case (T-755/17) was filed by the Federal Republic of Germany. The BoA had partially annulled a request for further information on the substance BENPAT (a rubber additive). Germany argued that the Member States have competence to decide what information should be requested under substance evaluation. Therefore, the BoA should not have examined the scientific content of the request at all.

The BoA was actively involved in preparing ECHA's defence.

The General Court fully endorsed the standpoint of the BoA in both cases. Its main findings are the following:

- Decisions on substance evaluation are not decisions of the Member States. They are ECHA decisions adopted according to a specific procedure. The BoA is competent to review the scientific content of these decisions in detail.
- The BoA is not, however, required to re-evaluate a substance when deciding on a case. There is no *de novo* examination by the BoA. Based on the arguments and evidence of the parties to an appeal case, the BoA 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.
- The BoA has the power to, for example, substitute a contested ECHA decision with a different decision if it finds that the ECHA decision contains an error. However, before doing so it must take into account the role of the Member States in ECHA's decision-making procedure, and consider whether it is more appropriate to send the case back.

In addition, the General Court also confirmed the decisions of the BoA on a number of legal/regulatory issues, including the following:

- In order to request further information for a substance evaluation, ECHA must be able to show that there is a potential risk that needs to be clarified, and that the requested information has a realistic possibility of leading to improved risk management measures.

- When ECHA imposes a certain measure in a substance evaluation decision, it must be able to show that this measure is capable of achieving its objective. ECHA cannot set out an obligation of result if it is not sure that this result is achievable.
- Simulation testing for persistence does not have to mimic real life conditions. Its purpose is to see whether the half-life of a substance exceeds the criteria for persistency in Annex XIII of the REACH Regulation.

These important rulings fully vindicate what the BoA has done since its early years of functioning. They clearly and hopefully definitively dissipate most of the hesitations and misunderstandings surrounding the creation of the BoA, and open the door to the age of maturity.

3. Nature of litigation: between novelty and repetition

This section briefly presents some of the key aspects of the ongoing appeal cases at the end of this reporting period. The findings are presented under the relevant REACH or BPR process.

3.1. REACH Regulation

3.1.1. Dossier evaluation

Appeals related to dossier evaluation usually touch upon complex legal, regulatory and scientific questions: for the reporting period, these include cases where the BoA will be considering obligations for monomer substances, the inorganic nature of a substance or the use of a category approach.

Pending cases include appeals on compliance checks decisions, the follow-up procedure to dossier evaluation, and testing proposals.

Compliance check and follow-up

The most recent appeal case concerning compliance check[2] was filed following an Agency decision sent to all registrants under the "new addressee policy" (to all members of the joint submission, including the appellant) – a policy which started taking effect in dossier evaluation from 2019. This means that a greater number of companies can potentially appeal decisions before the BoA.

Two appeal cases currently pending before the BoA relate to the interaction between the REACH Regulation and the Cosmetics Regulation[3,4]. The appellants contend that they use the substances solely as an ingredient in cosmetic products. The question of principle that is raised here is not entirely new, but it is the first time the BoA is really in a position to shed some light on the relation between the two regulations as regards tests on vertebrate animals requested by the Agency.

Another case[5] currently pending before the BoA concerns the "follow-up" process during which ECHA examines how dossiers are updated after a first compliance check decision. Two series of issues are raised before the BoA: scientific issues concerning the weight-of-evidence, together with legal and administrative issues relating to the legal basis of "follow-up decisions", the necessity to grant a second time limit to bring a dossier to compliance after the expiry of a first time limit specified in a first dossier evaluation decision, the right to be heard and the proportionality of the measures taken.

[2] A-001-2020
[3] Regulation (EC) No 1223/2009 on cosmetic products (OJ L 342, 22.12.2009, p. 59)
[4] A-009-2018 and A-010-2018
[5] A-001-2019

Testing proposals (TP)

There are currently three pending cases concerning testing proposals under Article 40 of the REACH Regulation.[6] They raise new issues such as the use of a category approach or the extent to which the Agency should consider the comments submitted following the draft decision publication.

3.1.2. Substance evaluation

For substance evaluation, the only currently pending case[7] raises scientific, regulatory and legal questions that are not very different from those already examined by the BoA in its most recent decisions. The relevance of the concern identified by the Agency, as well as the potential improvement of risk management measures, are again at the core of this case.

3.1.3. Data-sharing cases under REACH

Two years after the last REACH registration deadline, data-sharing appeals still represent a considerable part of the BoA work. However, while several pending cases[8] still relate to data-sharing under Article 30(3) of the REACH Regulation, these are likely to be the last ones, since from the beginning of 2020 data-sharing disputes can only be filed under Article 27.[9]

3.2. Biocidal Products Regulation (BPR)

Under the BPR, the work has been revolving around two main topics: one well known to the BoA, data-sharing, and one which is newer to the BoA, namely the question of technical equivalence.

3.2.1. Data-sharing cases BPR

Over the years, data-sharing cases have formed the large majority of the BoA's work related to BPR, and this reporting period is no exception.

However, in the two cases that are still ongoing before the BoA[10], the subject matter is familiar, but the context is new: in those cases, the BoA already annulled a first decision of the Agency, then remitted the case to the Agency, which then adopted a second decision, containing a similar conclusion that is now challenged again before the BoA. Therefore, both cases concern the margin of manoeuvre the Agency enjoys after the BoA has remitted the case.

3.2.2. First appeal case on technical equivalence

In accordance with Article 77 and 54 of the BPR, technical equivalence is one of the BPR topics for which the BoA has competence. Appeal case A-004-2019 represents the first case brought to the BoA on this topic since the first appeal under the BPR was received in 2015.

This appeal case concerns an active substance that was approved for five product-types. It raises many questions. They are of a legal and procedural nature (e.g. to what extent should be the Agency proactively involved in the assessment of the technical equivalence?; where does the burden of proof lie?; what level of evidence is required?). Other questions are of a scientific nature (e.g. what are the differences between the hazard profile of the applicant's active substance and the hazard profile of the approved reference source for the active substance?).

[6] Appeal case A-014-2019, A-015-2019 and Joined Cases A-016-2019 to A-029-2019
[7] Appeal case A-007-2019
[8] Appeal case A-013-2018, Joined Cases A-014-2018 to A-021-2018, appeal case A-023-2018 and A-024-2018
[9] The Commission Implementing Regulation (EU) 2019/1692 of 9 October 2019 on the application of certain registration and data-sharing provisions of Regulation (EC) No 1907/2006 of the European Parliament and the Council after the expiry of the final registration deadline for phase-in substances.
[10] Appeal case A-006-2019 and A-009-2019

3.3. Looking forward

A greater focus on compliance check

As ECHA focuses its efforts on concluding more compliance checks, the relative importance of the substance evaluation process has decreased. Thus, in a period between January and April 2020 the Agency adopted four substance evaluation decisions, whereas, during the same period, it adopted 85 decisions on compliance checks and 33 decisions on testing proposals. These two trends will most likely reflect on the number of appeals the BoA may receive in the coming years. So far, however, and despite the great number of compliance check decisions adopted by the Agency in the beginning of 2020, the BoA has received very few appeals in this field.

Other ECHA approaches, such as the "grouping approach" and "one substance, one assessment", may also have an impact on cases that will be brought before the BoA challenging dossier evaluation decisions, although one can not be certain in what precise way.

If it materializes for appeal cases as well, this ECHA's focus on compliance checks would further underline the long term where since 2009 the majority of all appeal cases have been related to the dossier evaluation process (see, in this regard, Annex IV below).

Relatively fewer data-sharing appeals?

Meanwhile, the number of new data-sharing decisions under REACH remains quite low. Therefore, it can be reasonably expected that the number of new data-sharing REACH appeals will also decrease for the BoA. As explained in section 3.1.3. above, this can be partly explained by the fact that, since January 2020, the only remaining basis for present and future data-sharing disputes decisions is Article 27 of the REACH Regulation ("sharing of existing data in the case of registered substances") and no longer Article 30.

A similar decreasing trend can be observed for data-sharing under BPR, where the number of decisions issued by the Agency have also been low. This will of course mean reduced activity on that topic for the BoA too. For BPR, there is however no regulatory change that could explain such a decrease.

Nanomaterials

The completeness check of nanomaterials started during the reporting period may lead to cases before the BoA both at the level of its Registration (Article 20 of the REACH Regulation) or Evaluation (Article 51) competence, as more nano dossiers should also be subject to compliance check. However, it should be borne in mind that the number of nano dossiers registered in the first months of the obligation has been lower than what the Agency expected.

Under the BPR

Concerning the BPR in general, it can be expected that the process of technical equivalence, mentioned in section 3.2.2. above, could become more frequent among appeal cases, as in the first half of 2020, the Agency has already taken a high number of technical equivalence decisions. Also, one cannot completely exclude that the current Covid-19 related situation (see section 4 below) may bring its own legal challenges in the form of appeals related to the specific issue of placing disinfectants on the market in exceptional circumstances (which has led to an accelerated technical equivalence procedure[11] for two active substances).

4. Efficiency and Fairness at the time of a pandemic: the procedural challenges of the Covid-19 crisis

Since 17 March, the BoA members and its Registry staff members have been mostly, as the rest of ECHA staff, working from home in order to contribute to combating the pandemic.

[11] Under Article 54 of the BPR Regulation.

Owing to certain adjustments made to its internal processes and the use of remote communication technologies, the BoA and its Registry ensured that BoA's activities continue, while paying the necessary attention to the observance of parties' procedural rights and to the need to maintain efficiency of appeal proceedings.

Beside the extension of the procedural deadlines on parties' request, the main effect of the current health situation was in relation to hearings. In the light of the health concerns, and in line with ECHA's measures, the BoA decided to hold remotely all hearings during this period. The BoA even started ahead of time to hold hearings by videoconference, on 27 February and 11 March 2020.

The BoA appreciates the importance that a hearing represents, in particular to a party requesting it. Thanks to the secure video conferencing platforms at disposal of the Agency and the parties, the requirements of the REACH Regulation and of the Rules of Procedure are satisfied also when a hearing is held remotely. The public nature of the hearing is also ensured through the possibility offered to the public to request a link giving access to the hearing.

After the successful hearings of February and March, three other hearings were planned to be held remotely in June. So far all hearings went smoothly, thanks to the great support provided by ECHA's audiovisual colleagues.

In order to fully respect parties' rights during a remote hearing where the BoA members, the parties' representatives and their experts cannot be physically present in the same locations, the BoA shares in advance the questions that it intends to put to the parties during the hearing. In addition, where the BoA wishes to ask additional questions during the hearing, the BoA offers the possibility to any party concerned to interrupt the hearing in order to allow that party to conduct the necessary consultations with its experts before answering the questions.

A remote hearing is technically hosted by the Registry of the BoA and ECHA's audiovisual technicians are readily available to assist the parties with any technical instructions that may be needed before or during the hearing.

The BoA thus adapted the applicable legal rules and principles to the developments relating to the coronavirus pandemic. With the organisation of remote hearings, the BoA is taking the necessary steps to ensure full continuity of its services offered to parties in appeal proceedings, whilst protecting its staff and contributing to the public health objectives of the fight against the pandemic.

5. Building a new team

During the period covered by this report the composition of the BoA went through important changes. Mercedes Ortuño's term of office ended in April 2019, and I joined the BoA in August 2019. At the end of September 2020, the terms of office of three alternate Chairs will end, but this has been partly anticipated by the appointment, in April 2019, of a new Alternate Chair.

The terms of the technically and legally qualified members are also coming to an end.

On 28 February 2021 the second term of office of the technically qualified member will end. Considering that, the Commission published a vacancy notice on 8 April 2020. The selection procedure is currently underway and it will be hopefully finalised in good time.

The term of office of the legally qualified member will end on 31 October 2020 and another selection procedure has to be organised without delay. In the meantime, the BoA will have recourse to the two alternate legally qualified members who are already involved in some of the currently pending appeal cases.

At the end of 2019, the Management Board appointed three new alternate technically qualified members. In order to involve them in the team in a quick and efficient manner, they have already been appointed in three appeal cases.

In this difficult period of time, where several changes in the BoA might have an effect on its efficiency, the alternate BoA members play a crucial role. In the near future, they will be involved

in a more regular manner in the BoA's activities, through organisation of a series of remote meetings on various legal and scientific topics.

As regards the Registry, in view of the above mentioned changes among the membership of the BoA, it is important that the staff members of the Registry that support and assist the BoA in carrying out its activities remain stable. This greatly facilitates the work of the BoA. In summer 2019 the Registry team was strengthened by a scientific advisor who provides a very valuable support to the BoA members and to the Registry staff.

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ANNEX II

Report on the work of the BoA during the reporting period

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

1. Introductory remarks

The appeals system as setup by the REACH Regulation, is the administrative review mechanism through which a party adversely affected by certain ECHA decisions may turn to the BoA, asking it to review the challenged decision. The BoA is competent to review in an impartial and independent manner ECHA decisions regarding the main REACH processes, namely registration (including data sharing) and evaluation (including both dossier and substance evaluation). The BoA is also competent to review ECHA decisions taken under the BPR, related to data sharing, technical equivalence, SME status and payable fees. The BoA is composed of three members, who have alternates. They are all appointed by the Management Board.

When deciding on a case, the BoA considers the pleas and arguments of the appellants and examines whether the contested decision complies with either with REACH or BPR regulations, associated implementing regulations and with EU law in general. An appeal before BoA has suspensive effect, meaning that the addressee of the contested decision does not have to comply with it until BoA decides on the appeal.

It should be mentioned that the BoA decisions are decisions of the Agency. As such they can be challenged before the General Court of the European Union. In this regard, during this reporting period, four cases before the General Court should be mentioned. There are currently two cases before the General Court where BoA decisions are challenged. In case T-176/19, *3V Sigma* v *ECHA*[12], the applicant is challenging BoA decision in appeal case A-004-2017 related to substance evaluation[13]. In case T-127/20, *France* v *ECHA*, France – whose REACH competent authority acted as an evaluating authority in substance evaluation case – seeks annulment of the BoA decision in appeal cases A-003-2018, A-004-2018 and A-005-2018[14].

In other two cases that were brought against the decisions of the BoA by *BASF Grenzach*[15] and *Germany*[16] respectively, the landmark judgments of the General Court – addressing the powers and scope of the BoA's review in substance evaluation cases – were presented under section 2 of the Annex I.

2. Summary of the BoA activity

During the reporting period, the BoA was processing 58 appeals; 20 cases were closed with a final decision (four after the appeal has been withdrawn); four cases were closed by the decision of the BoA Chairman after the appeal was found to be inadmissible; and 38 are ongoing. The

[12] Application (OJ).
[13] Decision of the BoA of 15 January 2019 in appeal case A-004-2017, *3v Sigma*; [maybe also link to Summary and Decision]
[14] Decision of the BoA of 17 December 2019 in appeal cases A-003-2018 (*BASF SE*), A-004-2018 (*Kemira Oyj*) and A-005-2018 (*Kemira Oyj*); Summary and Decision
[15] Application (OJ).
[16] Application (OJ).

BoA held nine oral hearings (in 20 different appeal cases) in this period. In addition to the final decisions, many procedural decisions were adopted in the course of the proceedings (19 decisions on intervention, one on stay of proceedings decision and one decision joining the cases and one decision on confidentiality). The number of procedural measures (consisting of e.g. questions to parties, inviting them to make submissions) prescribed by the BoA was around 500. The number of documents registered (incoming and outgoing) in the Register of appeals during the reporting period stands at around 1000. The average duration of appeal proceedings that were closed during the reporting period was 15 months.

During 2019 the BoA received 29 appeals. Notices of appeal in 14 cases concern testing proposals of ZDDP substances[17], so the BoA decided to join the cases and those appeals are handled as one case. Although the 29 appeals is the highest number of appeals received in one calendar year, the overall observed trend suggests a decrease in number of appeals. This is in particular evident in relation to appeals on compliance check under dossier evaluation, to substance evaluation appeals and appeals against data-sharing decisions, both under the REACH Regulation and BPR. This is most likely the result of lower number of decisions adopted by the Agency during 2019 in particular on substance evaluation and data-sharing. However, during 2019, the Agency adopted 119 decisions on compliance checks and only two of those decisions were appealed.

The BoA decision-making process remains as transparent as possible. All appeal announcements and final decisions are published online. After an appeal case is concluded, the BoA also publishes a summary of the final decision and the main procedural decisions adopted.

During the reporting period and in order to ensure continuous work of the BoA, its alternate members were designated in 17 cases. In particular, alternate Chairmen were required to participate in those appeals due to the ending of the previous BoA Chairman’s term of office and alternate Legally Qualified Members were asked to replace the Legally Qualified Member during her absence. The Management Board BoA subgroup was duly informed of those designations.

[17] Fourteen different substances derived from zinc dialkyldithiophosphate.

3. Main BoA findings during the reporting period[18]

This section summarises some of the most relevant findings and conclusions in decisions that the BoA adopted during the reporting period. The findings are presented under the relevant

3.1. REACH Regulation

3.1.1 Registration

- (A-005-2017); One substance, one registration – Article 20 – Article 41 – Substance sameness – Right to be heard

  The appellant contested ECHA's communication addressed to all registrants of a substance. In the communication ECHA stated that the joint submission obligation had been breached because separate registrations had been submitted for the same substance.

  The BoA confirmed that both Article 20 and Article 41 of the REACH Regulation allow ECHA to ensure that registrants comply with the principle of one substance, one registration. Since the contested decision was not adopted on the basis of either Article 20 or Article 41, ECHA had acted beyond its powers. Anulling the contested decision, the BoA also held that the appellant's right to be heard had been breached.

- (A-010-2017); Data-sharing dispute – Article 30 – Assessment of 'every effort' – Requirements for data and cost sharing to be fair, transparent and non-discriminatory

  This case concerned a data-sharing dispute under Article 30(3) of the REACH Regulation. ECHA had granted a potential registrant permission to refer to information submitted by a previous registrant, and the previous registrant challenged the decision before the Board of Appeal.

  According to the Board of Appeal, a permission should be granted if, despite a potential registrant's requests and objections, the previous registrant fails to comply with the requirements of fairness, transparency and non-discrimination.

  The appeal was rejected, but for different reasons than the ones in ECHA's decision.

- (A-008-2019); Verification of a registrant's declaration of company size – Registration fee – Administrative charge – Competence of the Board of Appeal – Inadmissibility

  This case concerned the fees and charges imposed by ECHA on a registrant following an incorrect declaration of company size. The Chairman dismissed the case as inadmissible within 30 days of its filing, on the grounds that the Board of Appeal is not competent to review such decisions.

3.1.2 Dossier evaluation (compliance check and testing proposal)

- (A-006-2017); Compliance check – Pre-natal developmental toxicity study (OECD TG 414) – Assessment of compliance with Column 1 of Section 8.7.2. of Annex IX – Setting of dose levels

  The case concerned a compliance check decision by which ECHA rejected a study because that study had not been carried out in accordance with the relevant test method (the dose levels were set too low).

  The Board of Appeal held that ECHA is competent to verify whether a study was carried out

[18] All BoA decisions and the case announcements are available on-line on ECHA website.

correctly in accordance with the relevant test method. If the study was not carried out correctly, there is a data-gap and the registrant must bring its registration dossier into compliance with the REACH Regulation by performing a new study or developing an acceptable adaptation. ECHA is not required to consider whether the information requirements in the REACH Regulation are proportionate. The appeal was dismissed.

- (A-001-2018); Dossier evaluation – Compliance check – Registration dossier update during the decision–making procedure – Cut-off points for considering dossier updates – Legal certainty – Duties of the Agency

  The appellant contested ECHA's practice of not taking into account dossier updates received after the draft decision has been sent to the registrant for comments (the 'cut-off point for updates').

  The Board of Appeal upheld the appeal. It decided that, in the case at hand, ECHA's notification of the cut-off point for updates failed to meet the fundamental requirement of the principle of legal certainty. ECHA had expressed the cut-off point for updates inconsistently and confusingly in a news alert, in a practical guide, in the letter accompanying the draft decision, and during the appeal proceedings. ECHA also acted contrary to its own communications regarding the cut-off point for updates. It was therefore unclear whether, and in what circumstances, a dossier update submitted after the draft decision was notified to the appellant would be taken into account.

  ECHA also breached the requirement for legal certainty by failing to ensure that the exact cut-off point applicable in the present case was communicated in a timely manner so that the appellant could know precisely the time at which the measure came into being and began to have legal effects.

- (A-006-2018); Dossier evaluation – Compliance check – Read-across – Error of assessment – Alternative metabolic pathways – Conflict of opinion with another European Union body – Legal certainty – Right to good administration

  The appeal concerned a compliance check decision rejecting read-across adaptations that were justified by the rapid metabolism of benzaldehyde to benzoic acid via its primary metabolic pathway.

  The Board of Appeal found that the potential other metabolic pathways of benzaldehyde had not been adequately addressed in the read-across adaptations. Therefore ECHA had not made an error of assessment in rejecting the read-across adaptations.

  The Board of Appeal also found that ECHA and European Food Safety Authority (EFSA) had not carried out a similar task in their assessments concerning benzaldehyde. Consequently, there was no potential conflict of opinion between the contested decision and the previous findings of EFSA within the meaning of Article 95 of the REACH Regulation.

- (A-011-2018); Compliance check – Section 1.2. of Annex XI – Weight-of-evidence adaptation – Article 13 – Compliance with the relevant test method – Section 9.1. of Annex IX – Requirements for aquatic toxicity testing on fish

  The case concerned a compliance check decision by which ECHA found that a registration dossier had a number of data gaps. ECHA consequently required the appellant to provide information on pre-natal developmental toxicity (PNDT) studies in a first and second species, an extended one generation reproductive toxicity study (EOGRTS), tests on algae and invertebrates, and a fish early-life stage (FELS) test.

  The Board of Appeal decision addressed, amongst other things, the requirements for weight-of-evidence adaptations, the requirements for the proportionality of compliance check decisions, the conditions under which ECHA can reject tests if they have not been carried out in accordance with the relevant test guidelines, and the interpretation of the information

requirements for aquatic toxicity in Annexes VIII and IX to the REACH Regulation. The appeal was dismissed in its entirety.

- Appeals dismissed as inadmissible by Chair's decisions (A-012-2019 and A-013-2019; Follow-up to dossier evaluation – Failure to respond to a dossier evaluation decision – Admissibility – Competence of the Board of Appeal)

  The Chairman of the BoA dismissed as inadmissible two appeals against acts adopted by ECHA in follow-up to dossier evaluation decisions. In those acts ECHA requested the relevant competent authorities to take action against the registrants in question because they had not complied with earlier compliance check decisions.

  The Chairman decided that the Board of Appeal is not competent to review such acts. The acts in question could only be challenged before the General Court.

3.1.3 Substance evaluation

- (A-004-2017); Substance evaluation – PBT assessment – Grounds for concern – Bioaccumulation – Proportionality – Error of assessment – Annex XIII; Challenged before General Court in T-176/19

  The appellant contested a substance evaluation decision requesting sediment simulation study (OECD TG 308) and further information on uses and environmental emissions.

  ECHA had requested the OECD TG 308 in order to identify the transformation and/or degradation products of the substance under evaluation. The QSAR data used by ECHA showed that the substance may form transformation and/or degradation products that may be PBT or vPvB substances. The Board of Appeal therefore found that the request for OECD TG 308 was proportionate and dismissed the appeal as regards this requirement.

  However, the Board of Appeal annulled the requirement in the Contested Decionn to submit further information on uses and environmental emissions as ECHA had not demonstrated the necessity and appropriateness of this requirement.

  The appellant before the Board of Appeal is now challenging decision of the Board of Appeal before the General Court.

- (Joined Cases A-003-2018, A-004-2018 and A-005-2018); Substance evaluation – Potential risk – Read-across – Risk management measures; Challenged before General Court in T-127/20

  The appeals concerned separate decisions on the substance evaluation of aluminium chloride, aluminium sulphate and aluminium chloride basic. In the contested decisions, ECHA requested information on a combined in vivo mammalian erythrocyte test and in vivo mammalian comet assay to clarify a concern for genotoxicity.

  The BoA annulled the contested decisions on the ground that ECHA had not demonstrated that the requested information was necessary. The BoA found that there was a lack of clarity, and in some respects consistency, regarding the substance(s) of concern. The BoA also found that ECHA had failed to demonstrate clearly that, based on the evidence as a whole, there is a potential risk which requires further investigation under substance evaluation. The BoA also found that ECHA did not adequately examine, or explain, in the contested decisions how the contested information requirement could lead to improved risk management measures.

  The French Republic is challenging the decision of the Board of Appeal before the General Court.

- (A-008-2018); Substance evaluation – Legal basis – Potential risk

  The appeal concerned a decision on the substance evaluation of Ziram requesting information on a combined developmental neurotoxicity study (OECD TG 426) and neurotoxicity study in rats (OECD TG 424). The request for information was based on concerns for developmental neurotoxicity and parkinsonian disorders.

  The Board of Appeal annulled the OECD TG 424 part of the combined study as ECHA had not demonstrated that there is a potential risk of parkinsonian disorders being caused by exposure to Ziram.

  However, the Board of Appeal did not decide whether ECHA had established a concern for developmental neurotoxicity for the purposes of requesting the OECD TG 426 part of the combined study. This is because the Board of Appeal did not possess sufficient information to replace ECHA's decision with its own decision, if necessary. The Board of Appeal therefore remitted the case to ECHA for further action.

3.2. BPR regulation

3.2.1 Data sharing

- (A-013-2017 and A-014-2017); Scope of the Biocidal Products Regulation – Review Programme Regulation – Notification procedure – Food and feed

  The appellant contested ECHA decisions rejecting the notifications submitted for peanut butter (A-013-2017) and brandy (A-014-2017) under the Review Programme Regulation[19].

  The Review Programme Regulation sets out criteria for food and feed that were eligible for inclusion in the Review Programme. The Board of Appeal found that ECHA had accepted the appellant's declarations of interest to notify peanut butter and brandy without properly assessing whether the eligibility criteria was fulfilled. Accepting the declarations of interest was a preparatory act to the contested decisions and an error in that preparatory act could in turn affect the legality of the contested decisions.

  The Board of Appeal therefore annulled the contested decisions and remitted the case to ECHA.

- (A-007-2018); Biocidal Products Regulation – Data-sharing – Decision granting permission to refer – Intention to perform tests on vertebrate animals – Deadline for adopting a decision – Time of payment – Every effort

  The case concerned a data-sharing dispute under the BPR. The appellant contested, amongst other things, ECHA's procedures for deciding on data-sharing disputes and ECHA's assessment of the facts of the case.

  The Board of Appeal held that ECHA failed to issue a decision within 60 days, as required by the BPR. However, the Board of Appeal did not consider that the decision should be annulled because of this. Moreover, the Board of Appeal confirmed that ECHA did not make an error in its assessment. The case was therefore dismissed.

- (A-011-2019); Opinion of the Biocidal Products Committee – Admissibility – Competence of the Board of Appeal

  The case concerned an opinion of the Biocidal Products Committee on the approval of an active substance. The Chairman of the Board of Appeal dismissed the case within 30 days of its filing as the Board of Appeal is not competent to review these opinions.

[19] Commission Delegated Regulation (EU) No 1062/2014 on the work programme for the systematic examination of all existing active substances contained in biocidal products referred to in Regulation (EU) No 528/2012 of the European Parliament and of the Council (OJ L 294, 10.10.2014, p. 1).

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ANNEX III

Table of BoA Members and their terms of office

Name	Role	Term started	Term ends
Antoine **BUCHET**	Chairman	16 August 2019	15 August 2024*
Andrew **FASEY**	TQM[1]	1 March 2011	28 February 2021**
Sari **HAUKKA**	LQM[2]	1 November 2015	31 October 2020*
Christoph **BARTOS**	Alt Chair	15 Oct 2010	14 October 2020**
Ioannis **DIMITRAKOPOULOS**	Alt Chair	15 Oct 2010	14 October 2020**
Christopher **HUGHES**	Alt Chair	15 Oct 2010	14 October 2020**
Ekaterina **GEORGIEVA**	Alt Chair	15 April 2019	14 April 2024*
Ángel Manuel **MORENO**	LQAAM[3]	15 December 2014	14 December 2024**
Sakari **VUORENSOLA**	LQAAM	15 December 2014	14 December 2024**
Uta **JENSEN-KORTE**	TQAAM	14 December 2019	13 December 2024*
Spyridon **MERKOURAKIS**	TQAAM	14 December 2019	13 December 2024*
Katrin **SCHUTTE**	TQAAM	14 December 2019	13 December 2024*

*- First term of office
**- Second term of office
[1] – Legally Qualified Member
[2] – Technically Qualified Member
[3] – Alternate (Additional) Member

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ANNEX IV

Appeals in figures

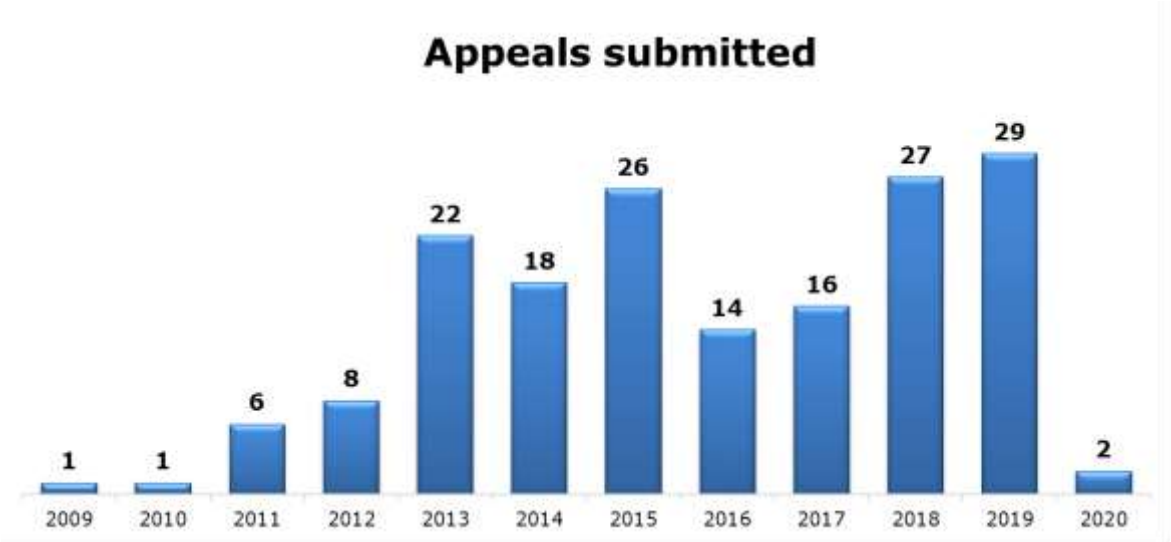

Figure 1: Appeals submitted since 2009

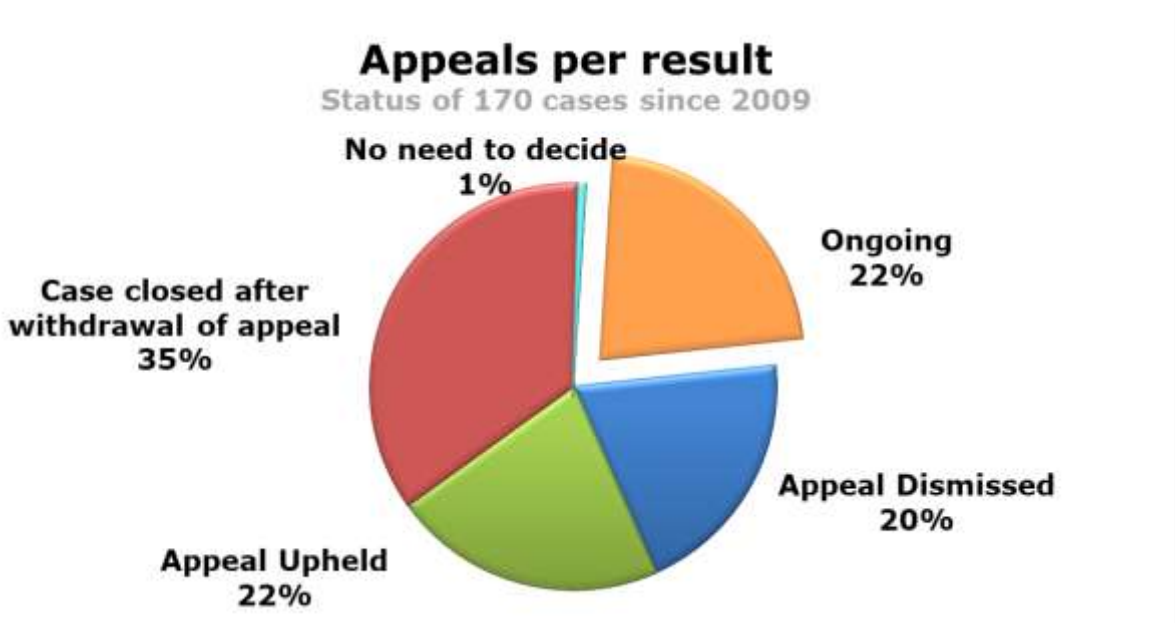

Figure 2: Appeals per result since 2009

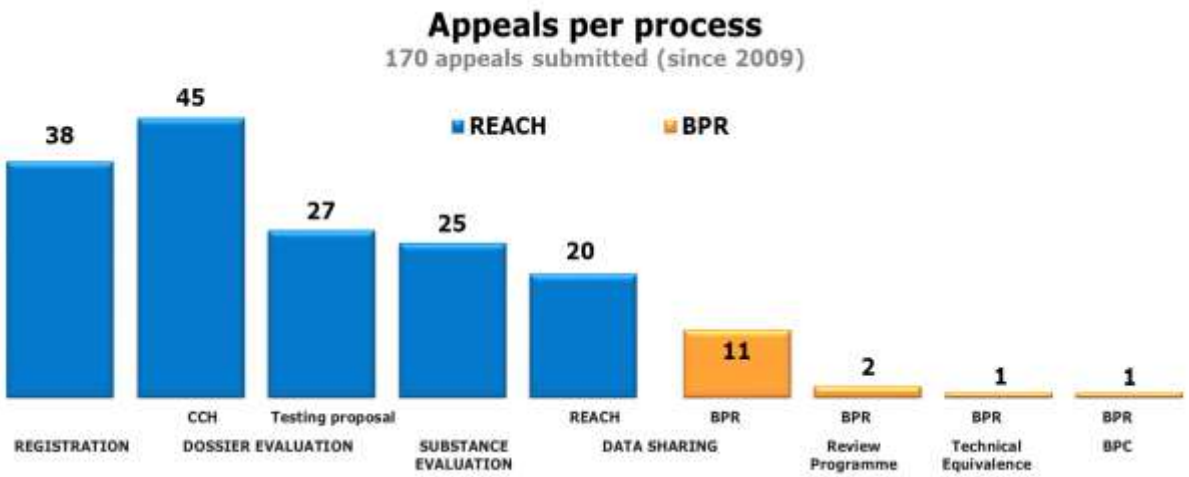

Figure 3: Appeals per process since 2009

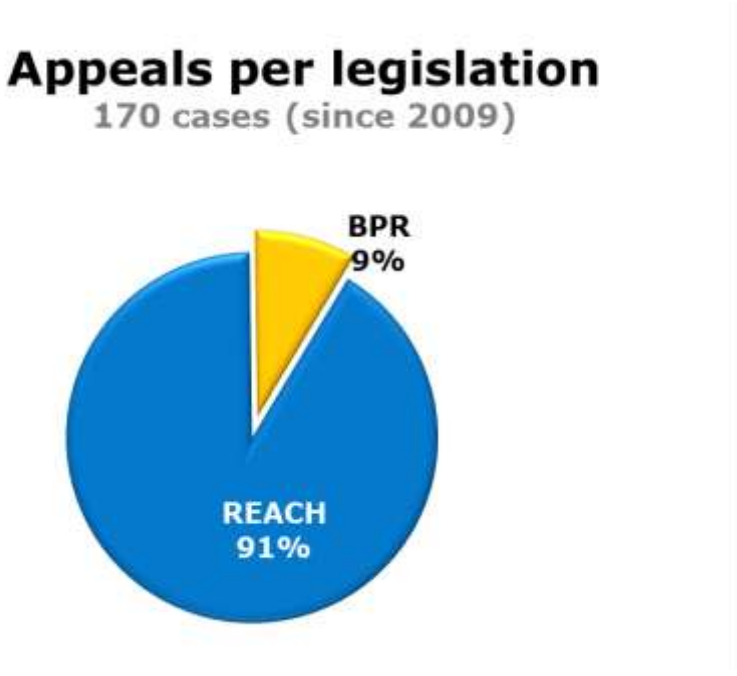

Figure 4: Appeals per legislation since 2009 (REACH and BPR) since 2009

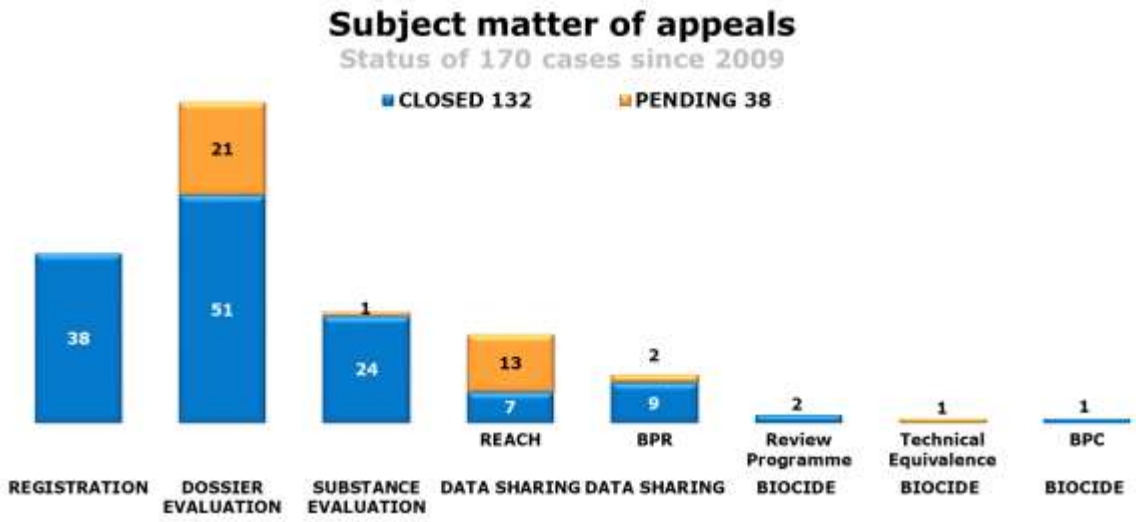

Figure 5: Subject matter of appeals (closed and pending cases) since 2009

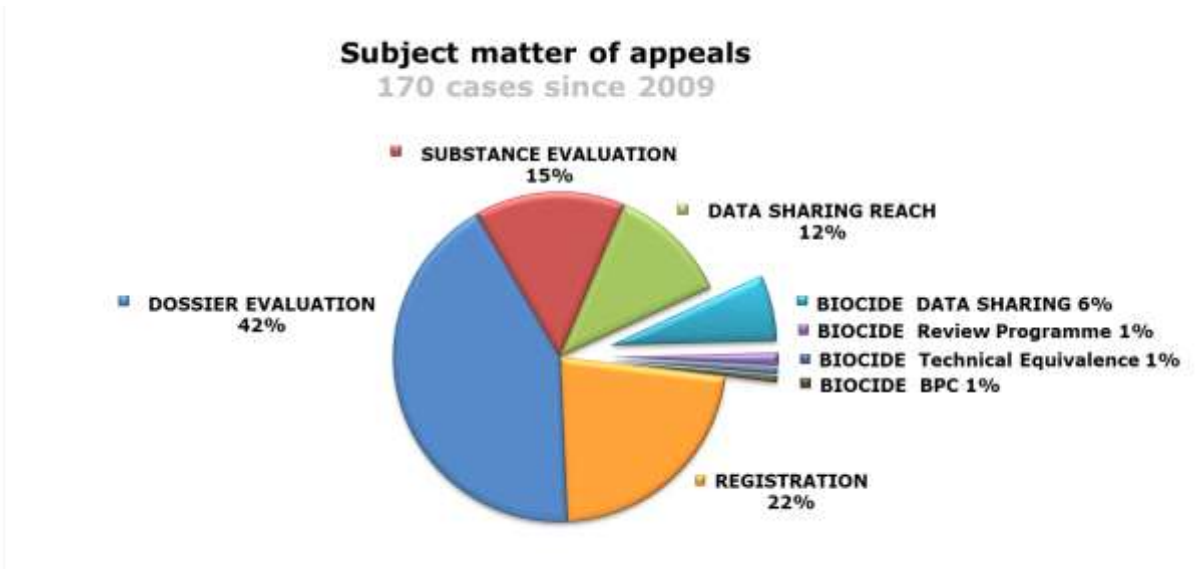

Figure 6: Subject matter of appeals (legislation) since 2009

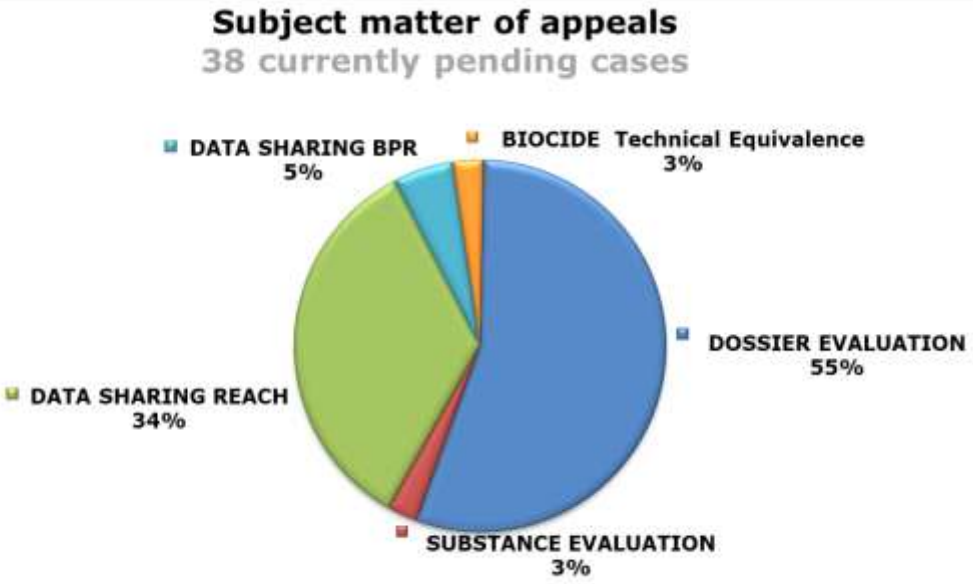

Figure 7: Subject matter of appeals (currently pending cases)