Annual report from the Chairman of the Board of Appeal and exchange of views
62nd Meeting of the Management Board 23-24 June 2021

Key messages

- The new Technically Qualified Member, Nikolaos Georgiadis, started in March 2021, following the end of Andrew Fasey’s term of office.

- The new Legally Qualified Member will be appointed by the Management Board before the summer of 2021.

- The alternate members of the Board of Appeal were deeply involved in the functioning of the Board of Appeal in order to guarantee the effective processing of appeals.

- Presently, the most important pending appeal cases concern dossier evaluation, and in particular:
  - the limits of the registration obligation on an importer of polymers as regards the monomers that are incorporated in those polymers (A-001-2020);
  - the impact of a tonnage band downgrade after the receipt of a draft decision on a registrant’s obligations to provide the information requested in the final decision (joined cases A-006-2020 and A-007-2020); and
  - the impact of cease of manufacture during a follow-up procedure (A-009-2020).

- Although the number of substance evaluation decisions adopted by ECHA decreased significantly compared with previous years, a relatively high proportion of those decisions is still appealed before the Board of Appeal.

- Six cases against decisions of the Board of Appeal are pending before the General Court; four cases concern the interaction between the REACH and the Cosmetic Products Regulations, one case concerns substance evaluation, and another the examination of a testing proposal. Also, in December 2020, the General Court dismissed an action for annulment brought against a decision of the Board of Appeal in a case related to substance evaluation.

- Although the situation related to the Covid-19 pandemic brought some challenges, the Board of Appeal managed to ensure continuous work on appeal cases, in particular by adapting some of its working methods, most notably by holding oral hearings remotely. The process for submitting procedural documents to the Board of Appeal was also revamped and parties to appeal proceedings are encouraged to submit documents electronically using the webform available on Board of Appeal section of ECHA’s website.

- As an independent body within ECHA’s organisation, the Board of Appeal has demonstrated its effectiveness and resilience. It would welcome any new competences in areas where the legislator may in future entrust further decision-making powers to ECHA.
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 2020 to 31 May 2021).

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: Observations 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: Table of Members of the Board of Appeal and their terms of office
- Annex IV: Appeals in figures

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1 At the time of the submission of this report the MB BoA subgroup was composed of Mr Hans Meijer (Chair), Ms Sharon McGuinness, Mr Kęstutis Sadauskas, Mr Oscar González Sanchez, and Ms Sofia Zisi.
1. Introduction on Efficiency and Independence

The second year in a new job is often more challenging than the first, if only because it becomes more difficult to explain any possible shortcomings as inexperience. Needless to say, the reporting period was full of challenges, some of them quite unpredictable. However, thanks to the team’s hard work and the excellent collaboration with the ECHA secretariat and the Management Board, our ship navigated the murky waters of the various challenges fairly comfortably.

At the end of the reporting period, there is no longer a backlog in the processing of our appeal cases. This success is largely due to the unprecedented mobilisation of all our energies. It was first of all the result of the efforts and sacrifices made by all the members of the team. In this respect, I would firstly like to thank in particular the Registry staff, whose professionalism and expertise are beyond praise. I would also like to thank the alternate members of the Board of Appeal whose involvement in appeal cases, from a distance, allowed our cases to progress effectively, and Andrew Fasey whose last months in office were certainly the most exhausting, but also the most fruitful.

Our success is also due to the flexibility allowed by of our Rules of Procedure. Faced with new challenges and new constraints, we have been able to adapt and even make progress.

Last year, in my first report, I wrote that the Board of Appeal is 100 % in the Agency, and 100 % independent. At that time, with only a few months of experience, it was more intuition than the result of a deep reflection. Today, I can confirm my first impression; the Board of Appeal is a genuinely independent and impartial body, and a full member of the ECHA family.

Our decisions are sometimes criticised from different angles. We are sometimes described as being too strict with the Agency. On other occasions, we are said to be too lenient on the Agency. During the reporting period, those two quite contrasting views gave rise to two different actions before the General Court of the European Union: in one case a Member State challenges a decision where the Board of Appeal was allegedly too demanding on the Agency; in the other case the applicant considers that the Board of Appeal did not perform a sufficiently detailed assessment of the Agency’s decision.

The members of the Board of Appeal do not make their decisions based on what they personally think is right or unfair. Their decisions are based on what the law says. What are the relevant
rules? Are they clear? How have they been interpreted so far by the case-law of the Courts and/or the Board of Appeal? What was the intention of the legislator? These are some of the very basic questions that are always part of our deliberations.

Being independent is certainly not an obstacle to having an actual impact on the Agency’s activities, quite the contrary. The decisions of the Board of Appeal often lead the Agency to modify or adjust its internal practices. Any decision taken by the Board of Appeal is a decision of the Agency. If a decision of the Board of Appeal is challenged before the EU Courts, it is defended by the Agency as a decision of the Agency.

2. A Changing Team

In relation to the composition of the Board of Appeal during the reporting period, two aspects deserve special attention.

First, on 28 February 2021, the second term of office of the technically qualified member, Andrew Fasey, came to an end. Andrew deserves all our thanks and gratitude. He has been one of the pillars of the Board of Appeal during his ten years. He has greatly contributed to the success of the Board of Appeal and to the establishment of its case-law.

Nikolaos Georgiadis was appointed by the Management Board as the new technically qualified member and joined the Board of Appeal on 1 March 2021.

Second, the post of the legally qualified member became vacant on 1 July 2020. Pending the conclusion of the selection procedure, alternate members were designated to ensure that appeals are processed at a satisfactory rate. The two alternate legally qualified members – Sakari Vuorensola and Ángel Moreno – have participated in many cases, some of which were the more complex of the reporting period. In addition, thanks to the decision adopted by the Management Board in October 2020 allowing for the designation of the alternate Chairman to act in appeal cases as a legally qualified member², Ekaterina Georgieva has fully participated in our collective efforts to process cases within reasonable timeframes. Our three alternate technically qualified members – Katrin Schütte, Uta Jensen-Korte, and Spyridon Merkourakis – have also all contributed significantly to the success of the Board of Appeal.

Still today, in most of the pending appeal cases, at least one alternate member is in the composition of the Board of Appeal. Considering the circumstances, and as allowed by the Rules of Procedure, in some of the appeal cases there were two technically qualified members in the composition.

I would like to use this opportunity to thank all the alternates for their commitment and dedicated work in appeal cases. They have again proved to be essential to the continued processing of appeals. They are full members of the ECHA family and deserve our deep gratitude.

Although it can be expected that the Management Board’s appointment of a permanent legally qualified member will bring more stability to the composition of the Board of Appeal in future cases, the alternate members will continue to be involved in the work of the Board of Appeal.

Due to the pandemic, the annual meeting of the permanent and alternate members could not take place as foreseen in November 2020. The alternate members therefore participated remotely in two meetings during last autumn. The meetings covered a range of informative sessions and discussions on legal and technical topics. The format of these meetings was a success and it is our intention to repeat the experience in the future.

The members of the Registry staff remained unchanged throughout the reporting period.

Considering the abovementioned changes, this stability was of great help to the Board of Appeal, as it facilitated both the smooth operation of appeal proceedings and the work of the Board of Appeal.

3. Efficiency Increased Despite the Pandemic Constraints

During the reporting period, to combat the effects of the pandemic situation, the Board of Appeal adhered to all measures taken by ECHA, such as teleworking and the cancellation of all physical meetings. Despite this, the Board of Appeal successfully managed to maintain a high level of activity. Appeal proceedings progressed at the same, or even faster, rate as before the Covid-19 crisis.

Such continuity in the processing of appeals has been made possible by the good, pre-existing IT structures available in the Agency and some adaptations made, in compliance with the Rules of Procedure, to the operations of the Board of Appeal and the Registry’s working arrangements.

In particular, as the appellants’ and interveners’ representatives in appeal cases are unable to attend oral hearings in Helsinki, they are, together with the Agency’s representatives, participating in hearings remotely. During the reporting period, the Board of Appeal held 11 hearings remotely using videoconferencing. It seems that the approach of holding remote hearings will continue to be employed as a valuable and less costly alternative to ‘live’ hearings once the pandemic situation is over.

The restrictions put in place by the public authorities in relation to Covid-19 and observed by the Agency mean that alternate members designated in appeal cases, who are not based in Finland, also participate in hearings remotely. This is not ideal as it can affect the effectiveness of communication among the Board of Appeal members during the hearing. In case of future remote hearings, where this is possible considering any public health related constraints, the Board of Appeal will contemplate the possibility of gathering all its members in the same location. In-person communication would contribute considerably to the effectiveness of the Board of Appeal during deliberations. The remote collaboration of the members of the Board of Appeal involved in an appeal case does not in principle pose any issues as such during the steps that are carried out during the written part of appeal proceedings. For the oral part of the proceedings, however, it is much more efficient and practical when the members of the Board of Appeal are all present in the same room and can collaborate ‘face to face’.

The current practice of sending questions to the parties two weeks in advance of the hearing is likely to be continued. This practice has contributed to the more efficient conduct of hearings without compromising the quality of the decision-making process.

As to the Registry of the Board of Appeal, in November 2020 it launched a webform that will facilitate the submission and processing of documents that the parties to appeal proceedings submit to the Board of Appeal.

Using the webform for the electronic submission of often voluminous documents assists the parties and interveners when submitting procedural documents in appeal proceedings as well as the Registry when processing the case file. For the time being, parties are encouraged to use the webform, and they are doing so. Eventually, the use of the webform may replace other means for submitting a document in appeal proceedings.

4. New Trends in Litigation

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 under the relevant REACH process or under the title referring to the BPR.
4.1. REACH Regulation

4.1.1. Dossier evaluation

The clear majority of the cases brought before the Board of Appeal concern appeals against testing proposal and compliance check decisions. Those appeals usually raise complex legal, regulatory and scientific questions. Current ongoing cases include appeals where the Board of Appeal will be considering, in particular, the impact of a cease of manufacture and of a tonnage downgrade during a decision-making process, and the extent of the registration of monomers incorporated in polymers.

Issues that arise in cases currently before the Board of Appeal therefore include the interpretation of the Agency’s application of the REACH Regulation regarding decreases in production of a substance during a dossier evaluation process. In joined cases A-006-2020 and A-007-2020, the main issue concerns the consequences of a tonnage downgrade after the receipt of a draft dossier evaluation decision. Case A-009-2020 concerns the cease of manufacture during a dossier evaluation follow-up procedure. The question of the application of certain cut-off points during a decision-making process can be considered as a recurring issue before the Board of Appeal.3

In a recently lodged appeal – case A-004-2021 – it is again the dossier evaluation follow-up procedure that is at issue4. The contested decision, adopted under Article 42(1) of the REACH Regulation, found that the appellant was still required to conduct a PNDT study and an EORGTS. In that decision, the Agency considered that the appellant’s read-across adaptation did not comply with the rules set out in Section 1.5. of Annex XI to the REACH Regulation. The appellant contests the Agency’s decision based, among other grounds, on an alleged error of assessment and a breach of Annex X to the REACH Regulation.

In another recent appeal – case A-005-2021 - against a compliance check decision, the Board of Appeal will have to examine a series of questions relating to degradation products. In its registration dossier, the appellant sought to waive the information required for two endpoints. The contested decision rejected the information and waivers included in the registration dossier for both endpoints and required the appellant to submit the standard information for these endpoints under Annexes VII and IX to the REACH Regulation. The appellant submits that the contested decision is unlawful insofar as it requires it to submit information on the identification of degradation products under Section 9.2.3. of Annex IX to the REACH Regulation.

The consequences of the exclusion of polymers from registration and the extent of the registration of monomers incorporated in polymers are at the core of ongoing case A-001-2020. Similar – but not identical – questions have been examined in the past, both by the Court of Justice5 and by the Board of Appeal in the context of substance evaluation.6

4.1.2. Substance evaluation

Substance evaluation cases remain an important aspect of the Board of Appeal’s activity, in particular because of the wide range of scientific issues that they often present. Pending appeal cases A-003-2020, A-004-2020 and A-005-2020 concern an alleged failure by the Agency to satisfy the conditions necessary to justify a request for information under Article 46 of the REACH

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4 An important decision was adopted by the Board of Appeal during the reporting period in case A-001-2019 – see below, section 3.1.2. of this report.


Regulation. The appellants also claim that a compliance check procedure should have been conducted and concluded before the substance evaluation procedure. These three related cases led to a relatively high number of applications to intervene (twelve in total, four per appeal).

In appeal case A-002-2021, the appellants claim, in particular, that the Agency committed an error of assessment and breached its duty of good administration by failing to take into account information that became available between the date of the draft decision and the adoption of the contested decision. The appellants also argue that the requested information is not suitable to clarify the concern identified by the Agency.

The appeal in case, A-007-2021, contests a substance evaluation decision in which the Agency requested the appellant to provide information to clarify a potential risk related to the PBT/vPvB properties of a substance (simulation testing for ultimate degradation in surface water). The appellant requests the Board of Appeal to annul the contested decision or modify the required test to allow the appellant to perform it with a different methodology than the one set out in that decision.

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

During the reporting period, three years after the last registration deadline, data-sharing appeals no longer represented a notable portion of the cases brought before the Board of Appeal. Currently, only one appeal related to data-sharing is still pending (case A-002-2020). This case concerns a dispute which was declared inadmissible by the Agency since the data and cost-sharing negotiations took place after the deadline foreseen in Article 29(3) of the REACH Regulation (1 June 2018). This case raises issues concerning the interpretation of Commission Implementing Regulation (EU) 2019/1692 of 9 October 2019 on the application of certain registration and data-sharing provisions of REACH after the expiry of the final registration deadline for phase-in substances.

### 4.2. Biocidal Products Regulation (BPR)

Under the BPR, the Board of Appeal has worked on two main topics: data-sharing and technical equivalence. At the end of the reporting period, there is one pending appeal case concerning the BPR. In the most recent appeal case A-008-2021, received on 31 May 2021, the appellants contest the Agency’s actions and acts related to the evaluation of the renewal of an active substance, including an opinion of the Biocidal Products Committee.

### 4.3. Looking forward

In the period between 1 January and 1 May 2021, the Agency adopted two substance evaluation decisions, whereas, during the same period, it adopted 71 decisions on compliance checks and 43 decisions on testing proposals. Those are the decisions that are most often appealed to the Board of Appeal.

**Dossier evaluation**

ECHA continues to focus its efforts on the compliance check of registrations, with dossiers now being evaluated in groups.

This means that, in the near future, the majority of appeal cases will likely continue to concern dossier evaluation, as has also been the case for the past twelve years.

Compliance check appeals may raise issues related to the interpretation of the REACH Annexes, both before and after they are revised.

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Also, implementation of the “one substance, one assessment” principle, which aims at better coordinating the assessment of the same substance under different processes by different agencies (especially ECHA and EFSA), could have an effect on the future decisions that can be appealed to the Board of Appeal.

**Substance 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. As the proportion of appealed substance evaluation decisions remains relatively high (almost a quarter of ECHA substance evaluation decisions are appealed), the Board of Appeal is still dedicating a lot of its time and efforts in this area.

**Data-sharing: still more under the REACH Regulation than under the BPR**

Article 27 of the REACH Regulation is the sole remaining basis for data-sharing disputes under that Regulation. However, the Agency adopted a significative number of data-sharing decisions in the early months of 2021. Nonetheless, the only ongoing data-sharing appeal case concerns the transitional period for phase-in substances under Article 30 (see section 3.1.3 above).

Under the BPR, only two data-sharing decisions have been adopted by the Agency during the reporting period. No BPR data-sharing appeals are currently pending.

**Under the BPR**

In the first five months of 2021, the Agency adopted 10 decisions on technical equivalence and those decisions account for the majority of BPR appealable decisions. It remains to be seen if some of those decisions will be appealed. So far, the Board of Appeal has adopted only one decision on technical equivalence (case A-004-2019, decision adopted during the reporting period).

**Possible new competences?**

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.

The Board of Appeal is looking forward to contributing, where appropriate, to the upcoming review of the REACH Regulation, including the preparation of a possible Founding Regulation that will be entirely dedicated to ECHA’s structures, functioning and competences, especially if that review could include the possibility of extending the scope of competence of the Board of Appeal.

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8 See "Main findings of the Board of Appeal" Annex below.
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

Closed Court case during the reporting period

Final decisions of the Board of Appeal are decisions of the Agency. Those decisions can be challenged before the Court of Justice of the EU.

During the reporting period, the General Court delivered its judgment in Case T-176/19, 3V Sigma v ECHA concerning an action for annulment against a decision of the Board of Appeal in case A-004-2017, upholding an ECHA substance evaluation decision. In its judgment, the Court confirmed the Board of Appeal’s finding that the assessment of substances under Annex XIII to the REACH Regulation (persistence, bioaccumulative and toxic properties) must be based on data obtained under ‘relevant’ conditions that enable an objective assessment of the properties of a substance, instead of using ‘real life’ or ‘realistic’ conditions.

Ongoing Court cases

When a decision of the Board of Appeal is challenged before the General Court, the preparation of the Agency’s defence is prepared jointly by the Registry of the Board of Appeal and the Legal Affairs Unit. The members of the Board of Appeal are also involved in the preparation of Agency’s submissions.

In cases T-655/20 and T-656/20, Symrise v ECHA, and T-663/20 and T-664/20, OneVoice v ECHA, the appellant before the Board of Appeal and an NGO respectively are 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 and REACH legal frameworks.

In case T-127/20, France v ECHA, the French Republic is challenging the decision of the Board of Appeal in joined appeal cases A-003-2018, A-004-2018 and A-005-2018 which annulled three substance evaluation decisions on three aluminium salts.

In the most recent Court case, T-207/21, Polnyt v ECHA, the appellant before the Board of Appeal submitted an action for annulment against the decision in A-015-2019 in which the Board of Appeal upheld an ECHA testing proposal decision requiring information on an EOGRTS.

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10 3V Sigma S.p.A., Decision of the Board of Appeal of 15 January 2019
12 The Cosmetics Regulation is regulation (EC) No 1223/2009.
2. Summary of the activity of the Board of Appeal

During the reporting period, the Board of Appeal was processing 32 appeals; 19 cases were closed with a final decision.

The average duration of appeal proceedings that were closed with the decision of the Board of Appeal during the reporting period was 19 months. The duration of these cases was affected by the absence of a permanent legally qualified member since 1 July 2020 which led to alternate members being designated during several ongoing appeals.

14 appeals are currently pending before the Board of Appeal. During the reporting period, the Board of Appeal held 11 oral hearing. All hearings were held remotely.

In addition to final decisions, many procedural decisions were adopted in appeal proceedings during the reporting period (15 intervention decisions, one decision joining cases, and one confidentiality decision). The Board of Appeal prescribed around 150 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 750.

From 1 June to 31 December 2020, the Board of Appeal received 7 appeals. The notices of appeal in 4 of those cases concern compliance check decisions.2 Two of the appeals were joined on Board of Appeal’s own motion. The remaining 3 notices of appeal related to substance evaluation decisions.16

So far in 2021 (1 January to 1 June 2021), the Board of Appeal has received 8 appeals. 2 of the appeal cases were closed after the appellants withdrew their appeals following the Executive Director’s rectification of the contested decisions - a compliance check decision and a decision under the review programme related to biocidal products.17 Another case related to an examination of a testing proposal was closed after the appellant informed the Board of Appeal that it was withdrawing its appeal.18 Another 4 appeals concern two compliance check decisions and two substance evaluation decisions. The remaining appeal related to Biocidal Products Regulation, more particularly to the evaluation of the renewal of an active substance.21

The Board of Appeal’s decision-making process remains as transparent as possible, taking into account any confidentiality requests that the parties may submit. Every appeal is announced and final decisions are published online. Following the adoption and publication of the final decision in an appeal case, a summary of that decision and the main procedural decisions adopted in the case are also published on ECHA’s website.

During the reporting period, in order to ensure the continuous processing of appeals by the Board of Appeal, the Chairman designated alternate members in 16 appeal cases. This was necessary due to the circumstances related to the legally qualified and technically qualified members (see section 2 of Annex I above). The Chairman duly informed the members of the MB BoA Subgroup before designating alternate members.

21 Appeal Case A-008-2021.
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. The findings are presented under the relevant

3.1. REACH Regulation

3.1.1. Registration

3.1.2. Dossier evaluation (compliance check and testing proposal)


  The Board of Appeal dismissed an appeal against a testing proposal decision requesting the appellant to perform a PNDT study on a second species and an EOGRTS with the extension of Cohort 1B and the Cohorts 2A and 2B.

  The Board of Appeal rejected the appellant’s arguments that ECHA had made several errors in the decision-making procedure and had failed to take all the available information into account. The appellant’s comments on the draft decision as regards the revision of the prescription of the substance type from a UVCB substance to multi-constituent substance were not substantial new information that would have required ECHA to re-start, or repeat certain steps of the decision-making process. Moreover, the appellant had not established that ECHA failed to take into account the observations made by a third party in a public consultation under Article 40(2) or that ECHA erred in defining the study design of the EOGRTS.

- **Case A-009-2018** (Compliance check – Sections 8.6.2., 8.7.2. and 8.7.3. of Annex IX – Substance used exclusively as an ingredient in cosmetic products – Relationship between the REACH Regulation and the Cosmetics Regulation – Studies on vertebrate animals – Route of administration for an EOGRTS) and

  - **Case A-010-2018** (Compliance check – Sections 8.7.2. and 8.7.3. of Annex IX – Substance used exclusively as an ingredient in cosmetic products – Relationship between the REACH Regulation and the Cosmetics Regulation – Studies on vertebrate animals – Route of administration for an EOGRTS – Section 9.1.6. of Annex IX – Aquatic toxicity testing).

  Compliance checks of registration dossiers for two substances used exclusively in cosmetic products. Given that the relationship between the information requirements in REACH and the marketing and testing ‘bans’ in the Cosmetics Regulation (Regulation (EC) No 1223/2009) have been an issue for many years with several different interpretations, the two decisions are among the most important decisions taken thus far by the Board of Appeal.

  The registrant argued before the Board of Appeal that ECHA cannot require studies on vertebrate animals for human health endpoints because the substances are used exclusively as ingredients in cosmetic products. The Board of Appeal found that the REACH Regulation can require registrants to perform studies on vertebrate animals even if the substance is used

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22 All the decisions of the Board of Appeal and the case announcements are available on-line on ECHA website.
exclusively as an ingredient in cosmetic products. The Board of Appeal based its decision mainly on two tenets.

Firstly, the Cosmetics Regulation prohibits testing on vertebrate animals, and imposes a marketing ban, if such testing is carried out ‘in order to meet the requirements of [the cosmetics] regulation’. The purpose and requirements of the Cosmetics Regulation are narrower than those of the REACH. The Cosmetics Regulation seeks to ensure that finished cosmetic products, whatever ingredients they contain, are safe for the end user, for example the consumer applying the product. The REACH Regulation, by contrast, aims to ensure the safety of substances throughout their lifecycle. The REACH Regulation therefore covers elements that the Cosmetics Regulation does not cover, for example risks to workers. Testing carried out under the REACH Regulation on a substance used as a cosmetic ingredient is not, therefore, automatically carried out ‘in order to meet the requirements of [the Cosmetics Regulation]’.

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

The Board of Appeal therefore held that ECHA was correct in requiring the registrant to provide the vertebrate animal tests in question.

Case A-010-2018 (keywords are the same as above on p. 12)

ECHA had required the registrant to conduct a fish sexual development test, which is not one of the fish tests listed as a standard information requirement. The registrant argued that ECHA did not have the power, in a compliance check, to go beyond the standard information requirements. The Board of Appeal consequently needed to address the interpretation of the requirements for long-term aquatic toxicity testing under Section 9.1. of Annex IX.

Column 1 of Annex IX requires, as a standard information requirement, one of three specific fish tests. In addition, Column 2 of Annex IX allows for an adaptation. The wording of this adaptation, however, is not entirely clear and gives rise to three different possible interpretations.

One interpretation – proposed by the registrant – was that one of the three standard tests needs to be carried out only if there is existing information showing that the registered substance might pose a concern with regard to aquatic toxicity. The Board of Appeal rejected this interpretation because it is incompatible with the scheme of the REACH Regulation. In particular, this interpretation would allow registrants to avoid providing information on a substance if they have no information on that substance.

Another interpretation – set out in ECHA’s guidance – was that the three standard tests could be waived if there is information to show that the testing is not necessary. The Board of Appeal could not accept this interpretation because it is incompatible with the wording of the legal provision at issue (Column 2 of Section 9.1. of Annex IX). Moreover, this interpretation would be an unnecessary repetition of other waiving possibilities that are foreseen in other parts of the REACH Regulation (Annex XI).

A third interpretation – adopted by the Board of Appeal – is that one of the three listed fish tests must be conducted as a standard information requirement, but may have to be replaced by a more extensive (‘further’) study if existing information shows that this is necessary. The
Board of Appeal considered that this is the only interpretation that is compatible with the wording, context and purpose of Section 9.1. of Annex IX.

In this case, ECHA had demonstrated that further testing was necessary because the registered substance might be an endocrine disruptor. The Board of Appeal therefore held that ECHA was entitled to require the registrant in the case to carry out a further test instead of one of the three standard fish tests.

- **Case A-001-2019** (Follow-up to dossier evaluation – Article 42(1) of the REACH Regulation – Weight-of evidence – Error of assessment)

Appeal against an ECHA decision taken under Article 42(1) of the REACH Regulation in follow-up to a compliance check decision.

In an earlier compliance check decision, ECHA found that the appellant’s registration dossier was missing information on a pre-natal developmental toxicity ('PNDT') study (Section 8.7.2. of Annex IX to the REACH Regulation). To fill this data-gap, the appellant updated its dossier with a weight-of-evidence adaptation. However, in the follow-up compliance check decision, ECHA rejected the adaptation and found that the appellant’s registration dossier still does not comply with Section 8.7.2. of Annex IX.

In its decision, the Board of Appeal dismissed the appellant’s claims that ECHA had breached its right to be heard and made an error of assessment in rejecting the weight-of-evidence adaptation.

The Board of Appeal also decided that, in the follow-up compliance check decision, which was rightfully based on Article 42(1), ECHA was not required to set a new time limit for the appellant to provide the information on a PNDT study missing from its dossier.

- **Joined cases A-016-2019 to A-029-2019** (Dossier evaluation – Article 40 – Read-across testing proposals – Conduct of the decision-making procedure – Duties of the Agency – Article 25 – Addressees of a testing proposal decision)

The Board of Appeal upheld appeals in 14 of the 16 joined cases brought against testing proposal decisions for a group of substances. The registrants of those substances had proposed to apply a category approach and to carry out certain tests under Annex IX to the REACH Regulation only on four of those substances.

In the contested decisions, ECHA rejected the category approach and required the lead registrant of each substance to carry out the tests at issue on its own substance. The Board of Appeal found that ECHA is entitled to assess adaptations in the context of the examination of the testing proposals. It also found that, by rejecting the category approach in the context of these cases, ECHA did not commit an error. In particular, when examining a testing proposal ECHA is not bound to require registrants to generate, gather and submit information to substantiate an adaptation.

However, the Board of Appeal also found that most of the contested decisions contained a procedural flaw, as they were addressed only to the lead registrant and not to the other registrants of each substance. The Board of Appeal consequently annulled the contested decisions containing that procedural flaw and remitted the corresponding cases to ECHA for further action.


The Board of Appeal dismissed an appeal against a testing proposal decision requesting the appellant to carry out an EOGRTS, including Cohort 3.
The Board of Appeal rejected the appellant’s claim that under the specific rules for adaptation contained in Column 2 of Section 8.7. of Annex X to the REACH Regulation, the EOGRTS was not necessary. In particular, and contrary to the appellant’s arguments, the requirement to perform the EOGRTS could not be omitted on the basis that the substance had been identified as an SVHC due to its respiratory sensitising properties.

The Board of Appeal also found that the appellant had not demonstrated that ECHA made an error of assessment in requiring the inclusion of Cohort 3 in the EOGRTS based on the results of a sub-chronic toxicity study on the substance submitted by the appellant.

- **Case A-010-2019** (Dossier evaluation – Compliance check – Section 9.1. of Annex IX – Requirements for aquatic toxicity testing on fish)

The Board of Appeal dismissed an appeal against a compliance check decision requesting a fish early-life stage (FELS) toxicity test. The appellant argued that it was not required to submit any of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX as the chemical safety assessment of the substance did not indicate a need to investigate further the effects on aquatic organisms.

The Board of Appeal rejected the appellant’s arguments and confirmed its previous interpretation in cases A-011-2018 and A-010-2018 that Column 2 of Section 9.1. of Annex IX to the REACH Regulation is neither a ‘trigger’ nor a ‘waiver’ for the requirement to submit information on one of the three long-term toxicity tests on fish under Column 1 of Section 9.1.6. of Annex IX.

Instead, Column 2 of Section 9.1. of Annex IX is a specific adaptation rule that requires registrants to submit information on a further study than one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX if the chemical safety assessment indicates that it is necessary to investigate the effects of a substance on aquatic organisms beyond the information that any of those three studies would provide.

Column 2 of Section 9.1. of Annex IX allows a registrant to forgo submitting information on one of the three studies listed in Column 1 of Section 9.1.6. of Annex IX, only if it provides, instead, a longer-term and/or more extensive toxicity test on fish.

ECHA was correct in finding that the appellant’s registration dossier has a data-gap as regards long-term toxicity testing on fish. ECHA made no error in requiring the appellant to submit information on the FELS test.

- **Case A-001-2021** (Rectification of the contested decision – Withdrawal of the appeal by the appellant)

The appellant withdrew its appeal after the rectification of the Contested Decision by the Executive Director of ECHA pursuant to Article 93(1) of the REACH. The reason for the rectification was that certain information provided by the appellant was not taken into account during the decision-making procedure.

### 3.1.3 Substance evaluation

- **Case A-007-2019** (Substance evaluation – Error of assessment – Potential risk – Improved risk management measures – Proportionality – Article 25)

The Board of Appeal dismissed an appeal against a decision on the substance evaluation of ammonium 2,3,3,3-tetrafluoro-2-(heptafluoropropoxy) propanoate requesting information on a carcinogenicity study in mice. ECHA had concluded that, based on the tumours observed in a carcinogenicity study in rats with the substance, there is a concern for carcinogenicity...
related to the substance.

The Board of Appeal rejected the appellant’s claim that ECHA made an error of assessment in concluding that there is a carcinogenicity concern based on the available information on the substance. In particular, The Board of Appeal rejected the appellant’s claim that the tumours observed in the carcinogenicity study in rats are not relevant to humans because, according to the appellant, those effects were induced by the peroxisome proliferator-activated receptor alpha (‘PPARa’) mode of action.

The Board of Appeal also rejected the appellant’s claim that ECHA committed an error of assessment in concluding that the requested information could lead to improved risk management measures. The Board of Appeal found that the results of the requested study could lead to the substance being classified as a Category 1B carcinogen which could in turn lead to the substance being included in the candidate list of SVHCs and eventually authorisation.

### 3.1.4. Data Sharing

- **Case A-013-2018** (Article 30(3) of the REACH Regulation – Article 5 of Implementing Regulation 2016/9 – Permission to refer to studies on vertebrate animals – Requirements for data and cost-sharing to be transparent, fair and non-discriminatory) and
- **Joined cases A-014-2018 to A-021-2018** (Article 30(3) of the REACH Regulation – Article 5 of Implementing Regulation 2016/9 – Permission to refer to studies on vertebrate animals – Requirements for data and cost-sharing to be transparent, fair and non-discriminatory)

Sharing of data and costs for the registration of the substance fatty acids, C18-unsatd., dimers, 2-ethylhexyl esters. The appellant was a potential registrant of the substance. The intervener was the lead registrant for the substance.

The two new decisions covered 9 appeals. They were notified to the Parties on 27 July 2020 and published on the ECHA website on 28 July 2020.

ECHA had made 9 decisions refusing a potential registrant (appellant before the Board of Appeal) ‘permission to refer’ to certain vertebrate animal studies on the basis that it had not made ‘every effort’. The Board of Appeal decisions address the conditions that apply, from the REACH Regulation and Commission Implementing Regulation 2016/9, to the granting of a ‘permission to refer’. The Board of Appeal also made a decision more than a year ago in case A-010-2017 addressing the conditions that need to be met before a ‘permission to refer’ should be granted. The three decisions together give a clear interpretation of how The Board of Appeal sees the requirements in the REACH Regulation and Commission Implementing Regulation 2016/9 [on joint submission of data and data-sharing in accordance with the REACH Regulation] and how they should be implemented by ECHA.

These are important decisions as they make clear that the assessment of ‘every effort’ must be largely based on the objective criteria established in COM Regulation 2016/9; namely that the conditions for data and cost-sharing are transparent, fair, and non-discriminatory. ECHA has previously applied a more subjective approach, assessing the behaviour of the parties to a data and cost-sharing dispute, whether they are making a real attempt to reach an agreement, and also ‘balancing’ the efforts of the parties concerned.

Earlier decisions on the Board of Appeal on data and cost-sharing were perhaps not as clear as they might have been. The three decisions mentioned above however are clear and unambiguous on how the efforts of the parties need to be considered in an assessment of whether ‘permission to refer’ should be granted.

- **Case A-023-2018** (Data-sharing dispute – Legal basis – Requirements for data and cost-sharing – Transparency – Every effort – Sharing of costs – Duties of the Agency)
Data and cost-sharing under the REACH Regulation. The appellant contested ECHA’s decision to granting the data claimant a permission to refer to vertebrate animal studies available in the appellant’s registration dossier.

The Board of Appeal found that even though the contested decision was adopted after the SIEFs had ceased to be operational on 1 June 2018, the rules set out in Article 30 of the REACH Regulation applied to the case as the relevant facts in this data-sharing dispute took place prior to that date. Article 30(3) of the REACH Regulation was a valid legal basis for the contested decision.

The Board of Appeal also found that ECHA had not made an error in its assessment of the parties’ efforts during the data-sharing dispute. The appellant had failed to comply with the requirement for data and cost-sharing to be transparent as it had failed to itemise and justify the administrative costs incurred by the appellant as a lead registrant and by the external consultants.


Data and cost-sharing under the REACH Regulation.

The contested decision, in effect, consisted of three separate decisions. The appellant appealed against each of those decisions. In relation to the decision on access to the joint submission, the Board of Appeal confirmed its previous case law that it was not competent to decide on appeals against such decisions as they are adopted on the basis of Article 11 of the REACH Regulation. Such decisions do not fall within the list of appealable decisions set out in Article 91(1) of the REACH Regulation.

The Board of Appeal decided that the appeal against the part of the contested decision granting the data claimant a time limit to update its registration dossier was inadmissible. This is because that part of the decision was not of direct and individual concern to the appellant as required by Article 92(1) of the REACH Regulation.

The third and main part of the contested decision concerned ECHA’s decision to grant the data claimant permission to refer to information in the appellant’s dossier.

The data sharing negotiations focused on an agreement concerning the right for the data claimant to refer in its registration dossier to information available in the appellant’s registration dossier (a ‘letter of access agreement’). The parties also discussed the possibility of the data claimant purchasing certain data and submitting that information separately (an ‘opt-out agreement’).

The Board of Appeal dismissed the appellant’s arguments that ECHA had acted outside the scope of its powers by assessing and deciding on the efforts made by the parties to agree on the sharing of data and costs, including as part of an opt-out.

The Board of Appeal also found that ECHA had not made an error in its assessment of the parties’ efforts during the data-sharing dispute.

In relation to the opt-out agreement, the Board of Appeal found that, contrary to the appellant’s claims, a reimbursement mechanism must be included in a cost-sharing model, unless the parties agree otherwise. Therefore, ECHA did not make an error in concluding that, in refusing to discuss the inclusion of a reimbursement mechanism, the appellant had not made every effort to reach an agreement.

In relation to the letter of access agreement, the Board of Appeal found that the appellant had failed to comply with the requirement of transparency as it did not provide the data
claimant with sufficient itemisation or proof of the administrative costs incurred by the appellant. The appellant also abused its position by requesting the data claimant to pay a fee to continue negotiations.

The Board of Appeal also decided that a clause in the cost-sharing model according to which registrants who are affiliates of a previous registrant are not required to bear a share of costs if they submit their own registration dossier was discriminatory.

In view of the above, the Board of Appeal decided that ECHA had not made an error of assessment in finding that the appellant had not made every effort to reach an agreement that would be fair, transparent and non-discriminatory. The Board of Appeal therefore dismissed the appeal.

Case A-005-2019 (Article 30(3) of the REACH Regulation – Article 5 of Implementing Regulation 2016/9 – Permission to refer to studies on vertebrate animals – Requirements for data and cost-sharing to be transparent – Itemisation of data and costs)

The Board of Appeal annulled the contested decision on data and cost-sharing under the REACH Regulation. In that decision, ECHA had refused several potential registrants of dye substances permission to refer to vertebrate animal data on those substances on the grounds that they had not made ‘every effort’ to share data and costs.

The Board of Appeal held that ECHA had made an error of assessment because it had not examined whether the previous registrants had complied with their obligations as regards transparency, fairness and non-discrimination. Although the potential registrants had not made clear precisely which of them intended to register which substance, the information they provided to the previous registrant was sufficient to trigger the previous registrant’s obligation to provide an itemisation of data and costs. As the previous registrant did not provide an itemisation of data and costs, it breached the requirement of transparency. Consequently, the Board of Appeal annulled the contested decision and ordered ECHA to grant the potential registrants permission to refer.

3.2. BPR regulation

Case A-004-2019 (Technical equivalence – Similarity of hazard profiles – Right to good administration – Duties of the Agency)

The first appeal against a decision of ECHA on technical equivalence under the BPR Regulation.

The appellant sought to establish technical equivalence between its alternative source of active substance ‘active chlorine released from sodium hypochlorite’ and the reference source defined in the Implementing Regulation (EU) 2017/1273 by which the Commission had approved ‘active chlorine released from sodium hypochlorite’ as an existing active substance. ECHA rejected the appellant’s application finding that the appellant had not provided sufficient evidence to show that the difference in the composition between the appellant’s alternative source and the reference source does not result in an unacceptable change of the hazard profile.

The Board of Appeal found that ECHA had breached the appellant’s right to good administration in two respects.

First, in its additional information request under Article 54(5) of the BPR, ECHA failed to specify clearly and comprehensively the additional information needed to assess the appellant’s application. The Agency merely stated that the appellant should provide more information on ‘local toxicity’ without specifying what information was needed and on which effects.
Second, ECHA breached the appellant’s right to be heard, as it rejected the application partly on considerations on which the appellant did not have an actual opportunity to make its views known. ECHA referred to the need for information on respiratory irritation for the first time in an informal teleconference that took place only eight days before the expiry of the deadline granted to the appellant to submit comments on the draft decision. Therefore, the appellant had no actual opportunity to make known its views on the need for information on respiratory irritation before the adoption of the contested decision.

The Board of Appeal annulled the contested decision and remitted the case to ECHA for further action.

- **Case A-003-2021** (Rectification of the contested decision – Withdrawal of the appeal by the appellant)

The appellant withdrew its appeal after the rectification of the Contested Decision by the Executive Director of ECHA pursuant to Article 93(1) of the REACH. The reason for the rectification was that the appellant’s right to be heard was not sufficiently respected in the decision-making process leading to the contested decision, and the reasoning provided in the contested decision was insufficient.

### 3.2.1 Data sharing

- **Case A-006-2019** (Biocidal Products Regulation – Data and cost-sharing – Interest in pursuing a case – Right to be heard – Replacement of a contested decision by the decision of Board of Appeal – Conclusion of a data-sharing agreement)

The Board of Appeal upheld an appeal against a decision on data and cost-sharing under the BPR. This decision was the second decision taken by the Board of Appeal on the same case: a first decision of ECHA, denying permission to refer to certain studies, was annulled by the Board of Appeal in a previous case. That case was remitted to ECHA, which issued a second decision denying again the permission to refer. This decision was again contested by the prospective applicant.

In its new decision, the Board of Appeal held that ECHA infringed the prospective applicant’s right to be heard because it did not hear its views, before the adoption of the second decision, on the implications of the first decision of the Board of Appeal. The Board of Appeal therefore annulled the second ECHA decision.

The Board of Appeal then adopted its own decision. It found that as the prospective applicant had since concluded a data-sharing agreement on the data at issue with the data owner, it could no longer obtain permission to refer under Article 63(3) of the BPR. The Board of Appeal therefore rejected the prospective applicant’s application for permission to refer.

- **Case A-009-2019** (Biocidal Products Regulation – Data and cost-sharing – Right to be heard – Every effort – Contractual agreement making the sharing of data conditional on the prior establishment of chemical similarity – Payment of a share of the cost – Manifestly unreasonable amount)

The Board of Appeal upheld an appeal against a further decision on data and cost-sharing under the BPR. This decision was also the second decision taken by the Board of Appeal on the same case: a first decision of ECHA, granting permission to refer to certain studies, was annulled and the case was remitted to ECHA, which issued a second decision granting again the permission to refer. This decision was again contested by the appellant who was the data owner.
The Board of Appeal held that ECHA infringed the data owner’s right to be heard because it did not hear the appellant on the implications of the first the Board of Appeal’s decision. The Board of Appeal therefore ECHA’s decision again.

The Board of Appeal then adopted its own decision and rejected the prospective applicant’s application for permission to refer for two reasons: first, the prospective applicant failed to make every effort before filing the application for permission to refer; second, the sum paid by the prospective applicant was manifestly unreasonable and therefore insufficient to be seen as ‘a share of the costs incurred’ in accordance with Article 63(3) of the BPR.
### Members of the Board of Appeal with their terms of office

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
<th>Term started</th>
<th>Term ends</th>
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<tbody>
<tr>
<td>Antoine BUCHET</td>
<td>Chairman</td>
<td>16 August 2019</td>
<td>15 August 2024*</td>
</tr>
<tr>
<td>Nikolaos GEORGIADIS</td>
<td>TQM1</td>
<td>1 March 2021</td>
<td>28 February 2026*</td>
</tr>
<tr>
<td>[appointment currently ongoing]</td>
<td>LQM2</td>
<td></td>
<td></td>
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<tr>
<td>Ekaterina GEORGEIEVA</td>
<td>Alt Chair3</td>
<td>15 April 2019</td>
<td>14 April 2024*</td>
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<tr>
<td>Ángel Manuel MORENO</td>
<td>LQAAM3</td>
<td>15 December 2014</td>
<td>14 December 2024**</td>
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<tr>
<td>Sakari VUORENSOLA</td>
<td>LQAAM3</td>
<td>15 December 2014</td>
<td>14 December 2024**</td>
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<td>Uta JENSEN-KORTE</td>
<td>TQAAM3</td>
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<td>TQAAM3</td>
<td>14 December 2019</td>
<td>13 December 2024*</td>
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<tr>
<td>Katrin SCHÜTTE</td>
<td>TQAAM3</td>
<td>14 December 2019</td>
<td>13 December 2024*</td>
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* - First term of office  
** - Second term of office  
1 – Technically Qualified Member  
2 – Legally Qualified Member  
3 – Alternate (Additional) Member

### Board of Appeal members’ terms that ended during the reporting period

<table>
<thead>
<tr>
<th>Name</th>
<th>Role</th>
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<th>Term ended</th>
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<tbody>
<tr>
<td>Andrew FASEY</td>
<td>TQM1</td>
<td>1 March 2011</td>
<td>28 February 2021</td>
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<tr>
<td>Sari HAUUKKA</td>
<td>LQM2</td>
<td>1 November 2015</td>
<td>30 June 202023</td>
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<tr>
<td>Christoph BARTOS</td>
<td>Alt Chair3</td>
<td>15 Oct 2010</td>
<td>14 October 2020</td>
</tr>
<tr>
<td>Christopher HUGHES</td>
<td>Alt Chair3</td>
<td>15 Oct 2010</td>
<td>14 October 2020</td>
</tr>
<tr>
<td>Ioannis DIMITRAKOPOULOS</td>
<td>Alt Chair3</td>
<td>15 Oct 2010</td>
<td>14 October 2020</td>
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23 Term ended after the member left the Agency.
Appeals in figures

Appeals submitted

Figure 1: Appeals submitted since 2009

Appeals per result

Status of 171 closed cases since 2009

Case closed after withdrawal of appeal 37%
Appeal Dismissed 25%
Appeal Upheld 38%

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: 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)