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Annual report from the Chairman of the Board of Appeal

46th Meeting of the Management Board 21-22 June 2017

Key messages

- After dealing with more than 100 appeals, ECHA stakeholders perceive the BoA as an independent and effective legal remedy which at the same time can redress practices of the agency ensuring the implementation of the REACH Regulation in line with all of its objectives (BNA Bloomberg, 7 January 2016).
- For the Agency, who is the defendant in appeal proceedings, the BoA is not only a safety net which permits a rectification of flawed decisions without unnecessary litigation but also an opportunity to improve the REACH processes ECHA has to manage. In particular, BoA decisions have helped the Agency to improve the procedure for checking the completeness of submitted registrations, and to apply the principle of 'one substance, one registration'.
- Appeal proceedings, and oral hearings in particular, continue to provide stakeholders with the possibility to be heard directly by the BoA and to interact face-to-face with the Agency. Hearings, which have been numerous in the June 2016 – June 2017 period, are also seen as a forum where the parties may discuss scientific issues present in appeal cases. Interveners, in particular evaluating member state competent authorities in substance evaluation cases, can also shed light on certain scientific aspects of the case. Both in REACH and BPR cases, the possibility to be heard and obtain a fair solution is perceived as contributing to stakeholders' trust in the BoA, and generally in the underlying Regulations.
- Revised Rules of Procedure adopted by the Commission further improved the efficiency of appeal proceedings and strengthened the perception of the BoA as a fair and impartial body. The BoA has also adopted revised Practice directions to parties in appeal proceedings, which will further enhance the smooth and efficient processing of appeals.
- During the reporting period, 25 appeals were closed. This is the highest number of BoA decisions ever adopted in a single reporting period. The final decisions are only the "tip of the iceberg" of a thorough and extensive work by the BoA and its Registry, involving many procedural decisions, communications and procedural measures adopted in the course of each case. The BoA adopted decisions on issues such as nanomaterials, endocrine disruptors, PBT assessment and downstream users' procedural rights. The cases under BPR decided in the reported period concerned data-sharing disputes.
- For the first time, a legal seminar – on '10 years of REACH litigation' – was organised in cooperation with ECHA's Legal Affairs Unit. It brought together distinguished speakers from the EU Courts, the Commission, member states' competent authorities and industry and was followed by more than 150 participants. It was seen as a success and a good opportunity to exchange views and present understandings related to REACH litigation and to hear some of the views presented by lawyers representing appellants in litigation under the REACH Regulation.

Background

As part of ECHA's organisational structure, the BoA reports on its activities in the annual General Report of the Agency[1] and envisages its short term and long-term activities within the planning and reporting cycle of the Agency. The Chairman of the BoA provides more detailed information at every June plenary session of the Management Board. Annex I to this report thus contains a report on the work of the BoA during the reporting period stretching from June 2016 to June 2017.

In addition, the BoA is in regular contact with the Management Board Working Group[2] for the BoA (the 'MBWG-BoA'); three of its members are also reporting officers for the BoA members. The MBWG-BoA also reports to the plenary providing information on BoA developments from a different perspective.

Rationale

The BoA is an independent and impartial body of ECHA. As such, it is accountable to the Management Board specifically, and its stakeholders in general. This report of the Chairman of the BoA to the Management Board constitutes one of the means to carry out this accountability.

Drawbacks

n/a

Attachments:

- Annex I Report from the Chairman of the Board of Appeal
- Annex II List of BoA Members with their terms of office and numbers of staff in the Registry of the BoA
- Annex III Table of Appeals since 2009
- Annex IV Graphics Statistics

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[1] As Activity 9

[2] Mr Hans Meijer (Chair of the MBWG-BoA), Ms Miroslava Bajaníková, Mr Kęstutis Sadauskas and Ms Luminiţa Tîrchilă.

Report from the Chairman of the Board of Appeal

1. Introductory remarks
2. Summary
3. Main BoA findings
4. Maintaining high standards of quality, transparency and efficiency
5. Looking forward

1. Introductory remarks

The BoA is perceived by its stakeholders as a very important element within the regulatory framework under the REACH Regulation[3] (REACH) and the Biocidal Products Regulation[4] (BPR). It acts as the independent administrative review instance of the Agency in certain fields of its competence, including:

1. For REACH: registration (including PPORD exceptions and data-sharing disputes) and evaluation (including compliance checks, testing proposals and substance evaluation);
2. For BPR: fees for the submission and renewal of applications for approval of active substances, fees for Union authorisations and their renewals, technical equivalence, data sharing, and use of data for subsequent applications. So far, appeals under the BPR only concerned data sharing.

As the above indicates, the BoA decides on appeals brought against certain decisions adopted by the Agency. Not all ECHA decisions may be subject to appeal: for instance, company size cases are not admissible before the BoA, and neither are cases regarding substances of very high concern, which are to be brought before the General Court. The Board of Appeal decisions can be, as ECHA decisions, challenged before the General Court.

The BoA carries out an independent review of contested decisions in order to determine if they are legally sound, that is, whether they comply with the applicable Regulations and EU law in general. BoA decisions are decisions of the Agency.

The first action for annulment by an appellant against a BoA decision was brought before the General Court during the reporting period (Case T-125/17, *BASF Grenzach* v *ECHA*[5], related to appeal case A-018-2014).

This report contains information on the main findings included in the BoA decisions adopted during the reporting period but it cannot be an exhaustive description of the findings and BoA conclusions on all the appeals decided. Comprehensive information for each case can be found online in the BoA section of the Agency website.

2. Summary

The numbers presented below cover the period from 10 June 2016 to 10 June 2017.

[3] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1)
[4] Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1)
[5] Announcement of action in Case T-125/17, brought on 28 February 2017.

In the reporting period, 41 appeals have been processed. 25 cases were closed with a final decision and 16 are pending as of 10 June 2017. In these cases, a considerable number of procedural decisions were adopted in the course of the proceedings (11 decisions on intervention, 4 on confidentiality, 6 on stay of proceedings). The number of documents registered (incoming and outgoing documents) in the Register of appeals during the reporting period is close to 900. The average duration of an appeal is 16 months. In the reporting period the BoA has been called to decide upon new issues as for example information obligations on nanomaterials, PBT properties, endocrine disruptors and downstream users' standing to appeal ECHA decisions not addressed to them. In that regard, it should be noted that, as almost all of the appeals received by the BoA are legally and scientifically complex, the Board of Appeal's main objective and aim is to deliver high quality decisions. This may mean that in certain cases the BoA misses its output indicators.

Whilst adopting decisions quickly is desirable, it is more important that they should be robust and thorough. The scientific complexity of many cases means that the limited scientific expertise in the BoA is sometimes insufficient to deal with a large number of decisions, particularly substance evaluation and compliance check decisions, at the same time. Furthermore, the BoA, as a small unit, does not have the resources to reallocate to ensure that all decisions are taken within 90-working days or that cases are completed within 15 months. This may in certain cases mean that the BoA misses its output indicators with regard to the 90-working day deadline for final decisions and the 15-month KPI[6]. This is to be expected, as the more complex cases can take longer to finalise whilst more straightforward cases (e.g. data sharing) tend to be decided well within 90 working days and with fewer exchanges between the parties, leading to a shorter overall duration. It is also the case that the more cases are being considered at largely the same time, the longer it takes to adopt a final decision. This is largely outside the control of the BoA. The more relevant indicators for the BoA are the robustness and impact of its decisions and the average time taken to adopt final decisions.

The trend observed during the reporting period is the increase in the number of appeals concerning dossier evaluation, which tripled year on year for compliance check cases (including also testing proposals),[7] and a slight decrease in the number of substance evaluation cases, which probably corresponds with the lower number of appealable decisions of that kind taken by the Agency on the same period.

During this reporting period, the BoA adopted numerous procedural measures aimed at making the proceedings transparent and efficient, such as invitations to submit further observations, questions posed to the parties and also administrative measures including requests for time extensions, decisions staying the proceedings, and summons to the hearings. As provided by the Rules of Procedure, the BoA publishes all appeal announcements and final decisions. As transparency values of ECHA require, and after an appeal case is concluded, the BoA also publishes a summary of the final decision.

Seven oral hearings have been held following requests by parties, in particular by appellants. The hearings enabled them to present their arguments orally, and allowed the BoA to put questions directly to the parties and interveners involved. Another hearing will be held at the end of June. As regards the hearings, it should be stressed that the possibility to be directly heard by the BoA and interact with ECHA operational units when a dispute exists is central in maintaining the stakeholders' trust in the in REACH and BPR processes, as further explained in section 4 below.

The **rules of procedure of the BoA (RoP) were amended** by Commission Implementing Regulation (EU) 2016/823, which entered into force on 14 June 2016. The reviewed rules of procedure have ensured the complete independence of the Registry of the BoA from the secretariat of ECHA and introduced some changes in the appeal

[6] Key Performance Indicators

[7] 18 on compliance check vs 6 in previous reporting period. The number of testing proposals cases remained stable, at 2 for this reporting exercise and the previous one.

proceedings, such as for example clarifications on the information that must be included in appeal announcements; the status of privileged intervener in favour of the evaluating member state's competent authority; and the possibility of an amicable solution with the participation of a BoA member.[8]

In light of the experience gained and of the new RoP, the BoA revised the **practice directions to the parties** (initially adopted in 2010) on 28 February 2017. The new practice directions aim to provide guidance and support to the parties in the proceedings. They include, *inter alia*, clarifications on confidentiality requests, recommendations aimed to gain efficiency as regards the written submissions (maximum number of pages in a notice of appeal: 30 pages apart from annexes)[9], and the need to justify any new evidence provided after the first exchange of written pleadings.

As foreseen in Article 89(2) of the REACH Regulation, during the reporting period, four alternate Legally Qualified Alternate Members (LQMs) participated in five appeal cases in the absence of a permanent LQM (they were called before the current LQM was appointed). An alternate Technically Qualified Member (TQM) participated in one appeal case due to a possible conflict of interest of the permanent TQM. In order to ensure that appeals are processed without unnecessary delay, the appointment of LQMs and a TQM helped to ensure the continuous operability of the BoA. The MBWG-BoA was duly informed of those appointments and the Chairman of the BoA reported in detail to the working group on this issue.

3. Findings from BoA decisions during the reporting period[10]

This section summarises some of the key findings and conclusions in decisions that the BoA adopted during the reporting period.

Substance Evaluation

Admissibility of the appeal – Downstream user - Direct concern

An appellant who is not the addressee of a contested decision must be directly concerned by that decision at the time its adoption for an appeal to be admissible. The appellant was a downstream user of the substance targeted by the contested substance evaluation decision and was part of the SIEF together with the manufacturer. This was however not sufficient for the Appellant to be directly concerned by the contested decision. In that regard, the Board of Appeal observed that the contested decision was not addressed to the appellant and that it had neither prepared a CSR nor provided the Agency with a downstream user report. The Board of Appeal noted that, in this particular case, there was no obligation for the Agency and the MSCAs to involve downstream users in the substance evaluation process (Decision of 30 May 2017, Case A-022-2015, *Michelin*, paras 134, 136, and 140).

[8] See section 4, below.
[9] An internal audit found that the average number of pages of appeals varied between 12 and 56 pages per appeal, without annexes.
[10] See Table on Annex III; in addition, all BoA decisions and the case announcements are available on-line on ECHA website

Addressees of a decision – Concerned registrants

The Agency was justified in setting a cut-off point for identifying addressees of a decision. However, registrants known to the Agency before the cut-off point should be included as addressees of a draft substance evaluation decision. The adoption of a substance evaluation decision means that all members of the joint registration for this substance potentially become concerned by its outcomes. Costs should be shared by all co-registrants (present and future) in a fair, non-discriminatory and transparent way (Decision of 7 December 2016, *BASF*, A-013-2014, paras 68, 91).

Scientific merits of a contested decision – Standard of review

Where a ground for concern has been identified there is an uncertainty that may need to be addressed. Under substance evaluation it falls to the Agency to resolve that uncertainty through the exercise of its broad administrative discretion by the adoption of a decision. In the event of an appeal against that decision, the Board of Appeal subsequently verifies whether that discretion was exercised properly. The fact that the Appellant does not share the Agency's view on a scientific point does not in itself suffice to demonstrate that the Agency's exercise of its administrative discretion was flawed. On its own, a difference of scientific opinion is not capable of calling into question the legality of a contested decision (Decision of 19 December 2016, Case A-018-2014*, BASF Grenzach*, para. 133).

This decision is currently challenged before the General Court (Case T-125/17).[11] The applicants before the Court claim that the Board of Appeal was not correct in limiting its role to a review of legality instead of conducting a 'full administrative review'. This is the first time that a BoA decision is challenged by an appellant. The judgment of the Court will be of crucial importance in defining the BoA's role.

Annex XIII – Persistence – 'Relevant conditions'

The Appellant argued that persistence should be tested under 'real life conditions' as this is what is meant in REACH by 'relevant conditions'. The Board of Appeal held that Annex XIII does not suggest that the 'relevant conditions' for the assessment of persistence must be limited to the most frequent patterns of distribution of a substance in the environment. Looking at 'real life conditions' is relevant to risk assessment whereas assessing persistence is about identifying an intrinsic property i.e. hazard assessment. Testing for persistence can be done on a compartment-by-compartment basis (water, sediment, soil) and may be required for different compartments if it is necessary to do so (Decision of 19 December 2016, Case A-018-2014, *BASF Grenzach*, paras 40-51).

Endocrine disruptors – Applicability of test results to humans

The Appellant claimed that an enhanced developmental neurotoxicity study in rats was not appropriate to clarify a potential concern because the results cannot be extrapolated to humans. The Board of Appeal found that the Agency had carefully considered the species differences between rats and humans in the contested decision, and that the Appellant did not establish that the Agency had made an error in this regard. The Board of Appeal also acknowledged that extrapolating the results from one species to another is complex. The test methods requested in the contested decision were however the 'state of the art' at that point in time. The existence of species differences was found not to be sufficient to demonstrate that the requested study would not provide useful information on the effects of the substance on exposed humans (Decision of 19 December 2016, Case A-018-2014, *BASF Grenzach*, paras 161-168).

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[11] See action brought on 28 February 2017 on Curia's website: http://curia.europa.eu/juris/document/document.jsf?text=&docid=189909&pageIndex=0&doclang=EN&mode=req&dir=&occ=first&part=1&cid=1239767

Criteria to be met when requesting additional information – Duty to state reasons

In order to request additional information pursuant to substance evaluation, the Agency must be able to demonstrate the necessity of the requested measure by setting out the grounds for considering that the substance constitutes a risk to human health or the environment. The Agency must also be able to demonstrate that the potential risk needs to be clarified and that the requested measure has a realistic possibility of leading to improved risk management measures. The Board of Appeal found that the standard information requirements set out in Annexes VII to X to the REACH Regulation may, in certain circumstances, be requested under substance evaluation rather than under a compliance check procedure. However, a data gap does not constitute on its own evidence of a potential risk for human health or the environment (Decision of 12 July 2016, Case A-009-2014, *Albemarle Europe and Others,* paras 104 and 142-3*)*.

Compliance Check

Assessment of weight of evidence – Annex IX and XI adaptations

The Board of Appeal found that the Agency had correctly assessed that, in order to meet the conditions in column 2, section 8.7. Annex IX through weight of evidence, the Appellant would need to show that the cumulative conditions of this adaptation were met. However the Appellant had not done so in this case. Further, the Board of Appeal found that it is not for the Agency to develop, justify or improve a weight of evidence adaptation on a registrant's behalf (Decision of 1 August 2016, Case A-014-2014, *BASF Pigment*, paras 38 and 47; and Decision of 1 August 2016, Case A-003-2015, *BASF Pigment,* para 62).

Scope of the environmental exposure assessment and risk characterization

The Appellant argued that Article 14 of the REACH Regulation only requires a registrant to perform the additional steps of risk assessment (exposure assessment and risk characterisation) for hazards that lead to classification under the CLP Regulation.[12] The Board of Appeal however held that classification for one of the hazard classes or categories listed in Article 14(4) acts as a 'trigger' for broader risk assessment. Once the obligation to perform a broader risk assessment has been 'triggered', the risk assessment must include any hazard identified and is not limited to hazards that lead to classification under the CLP Regulation (Decision of 28 June 2016, Case A-015-2014, *BASF SE*).

Procedural requirements during the decision making process – Legitimate expectations - Duties of the Agency

Article 50(1) REACH does not oblige the Agency to request comments from concerned registrants on all amended drafts following the first draft of a compliance check decision. Article 51(5) also only gives the registrant the opportunity to comment once on proposals for amendment and not repeatedly. The Agency is not compelled, in principle, to take into account the registrant's comments after the referral of a draft to the member states' competent authorities. (Decision of 7 October 2016, Case A-017-2014, BASF, paras 41-45 and 55; and Decision of 19 October 2016, Case A-004-2015, *Polynt,* para. 65). However, the Board of Appeal considered that, in certain circumstances, registrants should be given the opportunity to comment in addition to the ones foreseen in Articles 50 and 51. For example, if a decision is based on new elements of fact or law on which the Appellant had not had a prior possibility to make its views known (Decision of 19 October 2016, A-004-2015, *Polynt*, paras 65, 76).

Nanomaterials – Legal certainty

In four cases relating to the same substance, the Board of Appeal found that the terms

[12] Regulation (EC) No 1272/2008 on classification, labelling and packages of substances and mixtures (OJ L 35, 1.12.2008, p.1)

'grade' and 'forms' were not clearly defined in the contested decision. The contested decision did not allow a diligent registrant to know with any degree of certainty what information it was required to provide to ensure compliance with the contested decision. The contested decision therefore breached the principle of legal certainty (Decision of 12 October 2015, Case A-008-2015, *Evonik Degussa*, para. 38, 51; Decision of 12 October 2015, Case A-009-2015, *Iqesil*, para. 35, 48, 50; Decision of 12 October 2015, Case A-010-2015, *Rhodia Operations*, para. 36, 49, 51; Decision of 12 October 2015, Case A-011-2015, *JM Huber Finland*, para. 38, 51).

Nanomaterials – Substance identity information

The Appellants argued that the Agency does not have the power to request detailed substance identity information on nanoforms. The Board of Appeal observed that the Appellants had given a broad definition of their substance (titanium dioxide) for the purposes of their registrations, including the bulk forms as well as all possible nanoforms. In this context, the Board of Appeal held that the Appellants are obliged to provide toxicological and ecotoxicological information covering the entire scope of the broad substance identity. However, the Agency exceeded its powers by requesting detailed substance identity information on the nanoforms of the substance which is not provided for under Section 2 of Annex VI to the REACH Regulation. The Board of Appeal held that it is for the legislator to amend this provision if it considers the requested information is necessary to register nanoforms (Decision of 2 March 2017, A-011-2014, *Huntsman P&A UK and Others*).

Regarding BPR processes

Data-sharing – Permission to refer – Payment of a share of the costs – Real intention to find an agreement

The Agency was correct in granting the prospective applicant, and intervener in the case, access to the Appellant's studies (the data owner). Prospective applicants can pay a share of the costs at any time before the Agency adopts a decision in a data-sharing dispute. The Agency was correct in assessing that the 'every effort' condition set out in article 63(1) BPR is met if a prospective applicant has demonstrated, on the basis of objective criteria, a real intention to find an agreement with the data owner. However, the Agency is not entitled to assess the fairness, transparency and non-discriminatory nature of the cost calculation methods employed by the parties to a data sharing dispute (Decision of 4 April 2017, Case A-001-2016, *Troy Chemical Company*, para. 69, 76, 111, 112, 118 and 120).

Data-sharing – Permission to refer – Assessment of efforts exerted by both parties

When assessing whether the parties to a data sharing dispute have made 'every effort' within the meaning of Article 63(3), the Agency must examine the efforts of both parties in a balanced manner. In this case, the BoA found that the Agency erred in not taking into account some of the data owner's efforts and in not finding that the prospective applicant had also failed to advance with the data sharing negotiations prior to submitting the dispute to the Agency. Although the Agency might have been correct in considering that technical equivalence is not a legal requirement for data sharing under the BPR, in the present case, the Agency erred in finding that the fact that the Appellant (data owner) and the prospective applicant had contractually made technical equivalence a pre-requisite to their data sharing agreement was not relevant for the assessment of the every effort criterion under Article 63(3) (Decision of 23 August 2016, Case A-005-2015, *Thor*, paras 80, 84).

4. Maintaining high standards of quality, transparency and efficiency

The BoA aims to maintain a standard of high quality for its decisions and working methods. Working transparently is also particularly important for an adjudicatory body whose decisions have a great impact on stakeholders and ECHA processes. Improving efficiency without diminishing quality is an important challenge.

4.1 Quality

Stakeholders' feedback: The quality of BoA decisions and their usefulness for stakeholders and the ECHA secretariat are widely recognised. As was stressed in the previous annual report, the main test of the BoA's efficiency is the impact that its decisions have on ECHA's processes, clarifying the requirements placed on all actors under REACH and the BPR, and the impact on Appellants' confidence in the interpretation and implementation of REACH and the BPR.

As regards:

- ECHA: In the evaluation progress report from ECHA it was recognised that the BoA has had a clear impact on REACH processes, such as for example the correct implementation of the REACH principle of 'one substance, one registration', the scope of the technical completeness check, and on evaluation processes.[13]

- Industry in general and appellants: Appeals brought to the BoA come from across the EU, as shown in the graphs in annex. According to feedback from chemical companies, parties to proceedings feel that they are respected by the BoA.[14] Both the BoA and the EU Courts are seen as providers of 'good administration' according to the sector's umbrella organization, CEFIC, and proceedings before the BoA are seen as 'user-friendly' with a very high satisfaction stemming from the opportunity to be heard during appeals. Opinion of the BoA by CEFIC is that it is a 'truly impartial and independent' body and that its decisions are of high quality.[15] The said impact on ECHA processes is also seen by industry as a positive contribution.

- Lawyers involved in BoA cases: based on feedback gathered in the 2016 stakeholder survey, the BoA has consistently treated the lawyers involved in a professional, proactive and helpful way.

Improving quality by reflecting on crucial aspects of the appeals process: A seminar was organised during the reporting period, with many actors involved in REACH and BPR litigation. It was deemed the right moment to look back as ECHA's 10 years anniversary is this year, and as the BoA reached its 100th appeal in 2017. The seminar provided an opportunity to reflect together with the main actors (judges of the Court of Justice and General Court, ECHA legal affairs, industry, lawyers, speakers from the German and Dutch competent authorities). Different opinions were expressed, in particular with regard to the scope of review of the BoA. The two main alternatives are whether the BoA is intended to conduct a *de novo*, full review (i.e. a complete re-evaluation) of contested decisions, or whether it is expected to conduct a legal review with technical expertise. In addition, the question was raised of whether the competences of the BoA in substance evaluation overlap with member state competent authorities, and if so, to what extent.

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[13] See ECHA's Report on the Operation of REACH and CLP 2016, page 67, fourth paragraph: "…*certain BoA decisions have […] provided important clarification on certain REACH requirements and have improved the predictability of SEv processes […]"*

[14] CEFIC's presentation at the seminar on 10 Years of REACH Litigation (held on 24 May 2017)

[15] Ibid

4.2 Working in a transparent manner

The BoA is committed to maintain high levels of transparency in its work. All appeals received by the BoA are announced on ECHA's website, oral hearings are announced on the website one month before they are due to take place, final decisions and summaries thereof are published, and when a case is closed associated procedural decisions are normally published. The public can also attend oral hearings. These measures help ensure that stakeholders can learn from the publicly available information and potentially refine and improve registration dossiers and legal claims.

As regards shedding light on settlements leading to withdrawals of cases, there is a possibility that remains to be tested: the revised RoP provide for an 'amicable agreement' procedure. This procedure aims to enhance the transparency of appeal proceedings that are closed after the appellant and the Agency settle a case and the appeal is withdrawn.

4.3 Efficiency

Resources:

The BoA consists of the three full-time members who can be substituted by alternates (see Annex 2). It is supported by the Registrar, three lawyers acting as legal advisers, two assistants and two secretaries. After the administrative arrangements were revised following the adoption of the revised RoP, the Registry is now under the managerial supervision of the Chairman of the BoA.

Whilst the impact of its decisions on ECHA processes is considerable, the BoA is the smallest unit in ECHA. Due to the quasi-judicial nature of BoA's work, it is impossible to outsource its tasks, nor those of the Registry. Furthermore, the availability of the AAMs is also limited by their availability (e.g. depending on their academic or professional occupations) as well as by the limited payment allowed for AAMs involved in cases. However, so far the BoA is coping efficiently with the resources currently available. The appeals (around 40 simultaneously in this reporting period) are being processed at a reasonable rate of 16 months on average in cases that are concluded by a 'full' final decision. As mentioned above, the time taken to finalise a decision varies considerably due to the complexity of the case and the nature of the decision taken by the BoA. For example, some substance evaluation cases are extremely scientifically complicated and some also raise complicated and novel legal questions. These cases can take considerably longer to prepare, agree and adopt than a relatively straightforward data sharing case. Recording the time taken to take a final decision and comparing it against the KPI is useful insofar as it is a measure of the time being taken on average. It is not however a useful indicator of performance on a case-by-case basis. The average time taken to adopt final decisions is a far more useful indicator of the BoA's performance and efficiency but, even then, it must be used carefully as the time taken is often dependent on the particular cases considered and the decision taken. For example, in cases where there are applications to intervene, interveners, confidentiality claims, requests for extensions, and requests for stays of proceedings, amongst other things, the time taken to finalise the case will also be considerably longer than those in which there are no such complications. The BoA is always looking for opportunities to improve its efficiency by several means:

Streamlining proceedings as much as possible

Many appellants claim confidentiality for, in particular, certain commercially sensitive information, or names of experts contained in their notices of appeals or observations on the defence. This means the Chairman of the BoA and the Registry often have to deal with confidentiality issues that always prolong the processing of appeals, in particular in cases with interveners involved in the proceedings. Parties may submit confidentiality requests at different stages of the proceedings (notice of appeal, defence, observations on statements in intervention, before the scheduled hearing). In the revised practice directions to the parties, the BoA has indicated that the appeal proceedings have their own confidentiality regime which is different from the procedure to request access to public

documents. The claims for confidentiality during an appeal case should be carefully distinguished from objections to the access to public documents.

Improving planning

Medium term planning of case management: At the time of arrival of a new case, the Registry prepares a case calendar for the upcoming 15 months, listing all major steps in the proceedings, attempting to foresee the timeline of the case in relation to other pending cases. This planning tool complements existing tools used by the BoA. One of the main aims of this longer projection is to enable the BoA to better understand and estimate how, which and when the next steps in pending appeals need to be dealt with and what will be the necessary efforts and resources. It is hoped that by doing this the risk of long proceedings and backlog will be minimised. However, it must be recognised that appeal cases rarely follow exactly the anticipated plan and planning as there may be many complications in case. These range from the need for the BoA to take decisions on, for example, confidentiality requests, stays of proceedings and applications to intervene, to the absence of key staff (as such a small unit the ability to cover absences is limited, and for the BoA members it is impossible unless the BoA member is actually replaced). The reality is that even with good planning there are frequently periods of extreme pressure when many cases come to a head at much the same time. When this happens it may be necessary to prioritise certain cases at the expense of others and this may also have an impact on the time taken to finalise a BoA decision.

Hearing planning: hearing dates are now planned by looking six months ahead. For example, five hearings are currently planned to take place in September – December 2017. This also helps the parties to make their arrangements as early as possible. The parties also have the possibility to attend the hearing using remote access (e.g. by WebEx).[16]

5. Looking forward

5.1. As regards BPR cases

The common factor in appeals brought under the BPR is that they concern data-sharing disputes. The inclusion of companies on the 'Article 95' list of suppliers of biocidal active substances remains the main issue, and the appellants are concerned by either protection or gaining the market access. The question of whether and to what extent the Agency can define objective criteria on the 'every effort' condition will be interesting to follow up. So far, there were no appeals on BPR decisions other than data-sharing cases.

5.2. As regards REACH

Certain changes related to new scientific guidance by ECHA, inter alia in relation to nanomaterials, as explained below, as well as EOGRTS (extended one-generation reproductive toxicity study)[17] redesign could see the BoA deal with these matters.

New appeals may also come in relation to registration as a result of:

- ECHA's new approach towards the technical completeness check, and stricter implementation of the 'one substance, one registration' (OSOR) principle. Such checks that may culminate in the rejection of registrations or revocation of registrations. Those decisions, as well as possible resulting data sharing disputes

[16] The WebEx opportunity to attend a hearing from another location than Helsinki was used by several member state competent authorities as interveners in various cases.

[17] See "How ECHA identifies the design for the extended one-generation reproductive toxicity study (EOGRTS) under dossier evaluation of September 2016

under REACH may then be contested before the BoA.

- The 2018 registration deadline: it is estimated that up to 60 000 registrations will be submitted to ECHA for up to 25 000 substances; this process may engender new appeals.

- Substance evaluation of nanomaterials: five appeals related to dossier evaluation and compliance checks of nanomaterials led to final decisions, all of which were upheld. In the meantime, in May 2017 ECHA published guidance on nanoforms.[18] Two new decisions of the BoA in appeals where appellants are challenging substance evaluation decisions of nanomaterials are expected soon. It is expected that the issues surrounding nanomaterials and REACH Regulation will continue to be present in appeals.

5.3. Other

Revision of the Code of Conduct of the Board of Appeal: The current Code of Conduct of the BoA dates back to 2010, and the BoA is finalising its update. Changes will include clarifications concerning members' outside activities, their relations to the media and with the public.

Term in office of BoA members approaching end: The second term in office of the Chairman will expire in April 2019. In addition, the terms in office of two alternate legally qualified members will expire earlier (see Annex II) and those of the three alternate TQMs will all end before the end of 2020. In order to ensure continuation of BoA's activities the necessary selection procedures should commence in good time.

[18] The *Nano-specific Appendix to Chapter R.6 of the Guidance on Information Requirements and Chemical Safety Assessment (QSARs and grouping of chemicals)* ; *How to prepare registration dossiers that cover nanoforms - best practices* and updates to three of existing ECHA guidance on nanomaterials, which are the appendices for nanomaterials to *Chapter R.7a, R.7b and R.7c of the Guidance on IR&CSA (Endpoint specific guidance*

ANNEX II

Table of BoA members: 'regular' and alternate and additional members (June 2017)

Name	Role	Term started	Term ends
Mercedes **ORTUÑO**	Chairman	15 Apr 2009	14 April 2019**
Andrew **FASEY**	TQM	15 March 2011	14 March 2021**
Sari **HAUKKA**	LQM	1 November 2015	30 October 2020*
Christoph **BARTOS**	Alt Chair	15 Oct 2010	14 October 2020**
Ioannis **DIMITRAKOPOULOS**	Alt Chair	15 Oct 2010	14 October 2020**
Cristopher **HUGHES**	Alt Chair	15 Oct 2010	14 October 2020**
Harry **SPAAS**	TQAAM	01 Dec 2010	30 November 2020**
Jonna **SUNELL-HUET**	TQAAM	16 May 2009	15 May 2019**
Arnold **VAN DER WIELEN**	TQAAM	16 May 2009	15 May 2019**
Barry **DOHERTY**	LQAAM	15 Oct 2008	14 Oct 2018**
Rafael **LÓPEZ PARADA**	LQAAM	15 Oct 2008	14 Oct 2018**
Angel M. **MORENO MOLINA**	LQAAM	1 December 2014	30 November 2019*
Sakari **VUORENSOLA**	LQAAM	1 December 2014	30 November 2019*

***- First mandate**
****- Second mandate**

Registry Unit supporting BoA's work in the reporting period

- 1 Registrar: Alen Močilnikar
- 3 Legal Advisors and 1 interim lawyer
- 2 Legal Assistants
- 2 secretaries

ANNEX III

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
101	**A-005-2017** **OPEN**	15/05/2017	Thor GmbH	Registration	
100	**A-004-2017** **OPEN**	20/03/2017	3v Sigma S.p.a	Substance evaluation	
99	**A-003-2017** **OPEN**	20/03/2017	Cardolite Specialty Chemicals NV	Testing proposal	
98	**A-002-2017** **CLOSED**	20/03/2017	Cardolite Specialty Chemicals NV	Testing proposal	Final Decision 22/05/2017 Withdrawal by Appellant
97	**A-001-2017** **OPEN**	20/03/2017	Cardolite Specialty Chemicals NV	Testing proposal	
96	**A-014-2016** **OPEN**	16/12/2016	Solvay Solutions UK Limited	Data Sharing, BPR	
95	**A-013-2016** **OPEN**	16/12/2016	BASF Personal Care and Nutrtion GmbH	Testing proposal	
94	**A-012-2016** **CLOSED**	28/11/2016	Zschimmer & Schwarz Italiana	Testing proposal	Final Decision 13/03/2017 Withdrawal by Appellant
93	**A-011-2016** **CLOSED**	22/11/2016	KTR Europe GmbH	Registration	Final Decision 09/03/2017 Withdrawal by Appellant
92	**A-010-2016** **CLOSED**	22/11/2016	KTR Europe GmbH	Registration	Final Decision 09/03/2017 Withdrawal by Appellant
91	**A-009-2016** **OPEN**	29/09/2016	Symrise AG	Substance evaluation	
90	**A-008-2016** **CLOSED**	13/09/2016	Emerald Kalama Chemical B.V. and Others	Compliance Check	Final Decision 14/11/2016 Withdrawal by Appellant
89	**A-007-2016** **OPEN**	11/08/2016	Sharda Europe BVBA	Data Sharing, BPR	
88	**A-006-2016** **OPEN**	28/07/2016	SI Group-UK Ltd and Others	Substance evaluation	
87	**A-005-2016** **OPEN**	26/07/2016	Cheminova A/S	Testing proposal	
86	**A-004-2016** **OPEN**	28/04/2016	Huntsman P&A UK Limited	Compliance Check	
85	**A-003-2016** **OPEN**	13/04/2016	Solutia Europe SPRL/BVBA	Substance Evaluation	
84	**A-002-2016** **CLOSED**	02/02/2016	Bolton Manitoba S.p.A.	Data Sharing, BPR	Final Decision 12/05/2016 Withdrawal by Appellant

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
83	**A-001-2016** **CLOSED**	13/01/2016	Troy Chemical Company	Data Sharing, BPR	Final Decision 04/04/2017 Appeal dismissed
82	**A-026-2015** **OPEN**	18/12/2015	Envigo Consulting Ltd & DJChem Chemicals Poland SA	Substance Evaluation	
81	**A-025-2015** **CLOSED**	18/12/2015	Rutgers Novares GmbH	Substance Evaluation	Final Decision 07/03/2016 Rectified by ED
80	**A-024-2015** **CLOSED**	15/12/2015	Elkem AS	Registration Decision appealed by a non-addressee	Final decision 29/06/2016 Withdrawal by Appellant
79	**A-023-2015** **OPEN**	13/11/2015	Akzo Nobel Chemicals N.V. and others	Substance Evaluation Tert-butyl perbenzoate (TBPB)	
78	**A-022-2015** **CLOSED**	10/11/2015	Manufacture Française des Pneumatiques Michelin	Substance Evaluation	Final Decision 30/05/2017 Appeal dismissed
77	**A-021-2015** **CLOSED**	28/09/2015	CARUS EUROPE S.L.	Compliance Check	Final Decision 03/03/2016 Withdrawal by Appellant
76	**A-020-2015** **CLOSED**	28/08/2015	Lysoform Dr. Hans Rosemann GmbH and others	Data Sharing BPR	Final Decision 25/09/2015 Appeal dismissed
75	**A-019-2015** **CLOSED**	28/08/2015	Lysoform Dr. Hans Rosemann GmbH and others	Data Sharing BPR	Final Decision 25/09/2015 Appeal dismissed
74	**A-018-2015** **CLOSED**	19/08/2015	TPP Registrants	Substance Evaluation	Final Decision 09/03/2016 Rectified by ED
73	**A-017-2015** **CLOSED**	12/06/2015	Dow Corning Limited	Compliance check	Final Decision 24/07/2015 Rectified by ED
72	**A-016-2015** **CLOSED**	12/06/2015	AlzChem AG	Testing proposal	Final Decision 17/09/2015 Withdrawal by Appellant
71	**A-015-2015** **OPEN**	10/06/2015	Evonik Degussa GmbH and others	Substance Evaluation	
70	**A-014-2015** **OPEN**	10/06/2015	Grace GmbH & Co. KG	Substance Evaluation	
69	**A-013-2015** **CLOSED**	23/04/2015	Evonik Degussa GmbH	Compliance check	Final Decision 17/12/2015 Withdrawal by Appellant
68	**A-012-2015** **CLOSED**	18/03/2015	SHARDA EUROPE B.V.B.A.	Data Sharing BPR	Final Decision 05/11/2015 Withdrawal by Appellant
67	**A-011-2015** **CLOSED**	16/03/2015	J.M. HUBER FINLAND OY	Compliance check	Final Decision 12/10/2016 Appeal upheld
66	**A-010-2015** **CLOSED**	16/03/2015	RHODIA OPERATIONS SAS	Compliance check	Final Decision 12/10/2016 Appeal upheld
65	**A-009-2015** **CLOSED**	16/03/2015	IQESIL SA	Compliance check	Final Decision 12/10/2016 Appeal upheld

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
64	**A-008-2015** **CLOSED**	16/03/2015	Evonik Degussa GmbH	Compliance check	Final Decision 12/10/2016 Appeal upheld
63	**A-007-2015** **CLOSED**	12/03/2015	Celanese Chemicals Europe GmbH	Compliance check, Read-across	Final Decision 04/02/2016, Withdrawal by Appellant.
62	**A-006-2015** **CLOSED**	11/03/2015	UNITED INITIATORS GmbH & Co. KG	Compliance check	Final Decision 04/05/2015 Rectified by ED
61	**A-005-2015** **CLOSED**	03/03/2015	THOR GmbH	Data sharing BPR	Final Decision 23/08/2016 Appeal upheld
60	**A-004-2015** **CLOSED**	27/02/2015	Polynt S.P.A.	Compliance check	Final Decision 19/10/2016 Appeal dismissed
59	**A-003-2015** **CLOSED**	24/02/2015	BASF Pigment GmbH	Compliance check	Final Decision 01/08/2016 Appeal dismissed
58	**A-002-2015** **CLOSED**	17/02/2015	Lubrizol SAS	Compliance check	Final Decision 04/05/2015 Rectified by ED
57	**A-001-2015** **CLOSED**	17/02/2015	Lubrizol SAS	Compliance check	Final Decision 04/05/2015 Rectified by ED
56	**A-018-2014** **CLOSED**	17/12/2014	BASF Grenzach GmbH	Substance Evaluation	Final Decision 19/12/2016 Appeal dismissed
55	**A-017-2014** **CLOSED**	17/12/2014	BASF SE	Compliance check	Final Decision 07/10/2016 Appeal dismissed
54	**A-016-2014** **CLOSED**	17/12/2014	Oxiteno Europe SPRL	Compliance check	Final Decision 11/02/2015 Withdrawal by Appellant
53	**A-015-2014** **CLOSED**	15/12/2014	BASF SE	Compliance check	Final Decision 28/06/2016 Appeal dismissed
52	**A-014-2014** **CLOSED**	11/12/2014	BASF Pigment GmbH	Compliance check	Final Decision 01/08/2016 Appeal dismissed
51	**A-013-2014** **CLOSED**	10/12/2014	BASF SE	Substance Evaluation	Final Decision 07/12/2016 Appeal dismissed
50	**A-012-2014** **CLOSED**	21/11/2014	HUNTSMAN HOLLAND BV	Compliance check	Final Decision 29/06/2016 Withdrawal by Appellant
49	**A-011-2014** **CLOSED**	16/09/2014	Tioxide Europe Ltd and others	Compliance check	Final Decision 02/03/2017 Appeal upheld
48	**A-010-2014** **CLOSED**	28/08/2014	Nordenhamer Zinkhütte GmbH	Compliance check Intermediate	Final Decision 25/05/2016 Appeal upheld
47	**A-009-2014** **CLOSED**	22/08/2014	Albemarle Europe SPRL and others	Substance evaluation	Final Decision 12/07/2016 Appeal upheld
46	**A-008-2014** **CLOSED**	14/08/2014	CROSFIELD ITALIA S.r.l.	SME status	Final Decision 11/01/2017 Withdrawal by Appellant

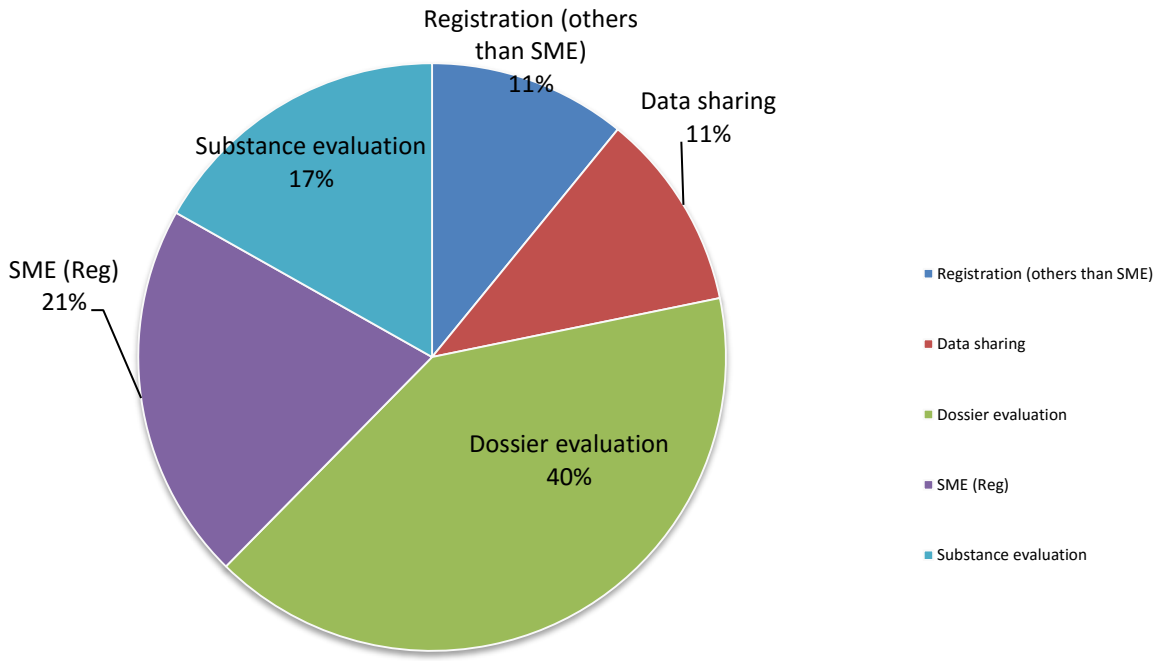
No.	Case No.	File Date	Appellant	Keywords	Result/decision date
45	**A-007-2014** **CLOSED**	27/05/2014	SA Azko Nobel Chemicals NV	Testing proposal	Final Decision 11/07/2014 Rectified by ED
44	**A-006-2014** **CLOSED**	26/05/2014	International Flavours & Fragrances B.V.	Substance evaluation	Final Decision 27/10/2015 Appeal dismissed
43	**A-005-2014** **CLOSED**	26/05/2014	Collective appeal representing several Appellants	Substance evaluation	Final Decision 23/09/2015 Appeal upheld
42	**A-004-2014** **CLOSED**	16/05/2014	Collective appeal representing several Appellants	Substance evaluation	Final Decision 09/09/2015 Appeal dismissed
41	**A-003-2014** **CLOSED**	17/04/2014	Aluwerk Hettstedt GmbH	SME status	Final Decision 16/12/2014 Withdrawal by Appellant
40	**A-002-2014** **CLOSED**	17/04/2014	Richard Anton KG	SME status	Final Decision 15/12/2014 Withdrawal by Appellant
39	**A-001-2014** **CLOSED**	15/01/2014	CINIC CHEMICALS EUROPE SARL	Testing proposal Information in other dossiers	Final Decision 10/06/2015 Appeal upheld
38	**A-022-2013** **CLOSED**	12/12/2013	REACheck Solutions GmbH	Registration Completeness check Absence of data sharing	Final Decision 15/03/2016 Upheld
37	**A-021-2013** **CLOSED**	20/11/2013	Zementwerk Hatschek GmbH	Revocation of registration number	Final Decision 5/11/2014 Withdrawal by appellant
36	**A-020-2013** **CLOSED**	11/11/2013	Ullrich Biodiesel GmbH	Rejection of registration	Final Decision 13/11/2014 Appeal dismissed
35	**A-019-2013** **CLOSED**	25/10/2013	Solutia Europe sprl/bvba	Statement of non-compliance	Final Decision 29/07/2015 Appeal upheld
34	**A-018-2013** **CLOSED**	23/10/2013	BASF SE	Compliance check	Final Decision 05/12/2013 Rectified by ED
33	**A-017-2013** **CLOSED**	14/10/2013	Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein	Data-sharing Permission to refer	Final Decision 17/12/2014 Appeal dismissed
32	**A-016-2013** **CLOSED**	15/10/2013	Marchi Industriale SpA	SME status 'Linked enterprises'	Final Decision 14/11/2016 Withdrawal by Appellant Stay of proceedings General Court case T-620/13
31 30 29 28 27	**A-015-2013** **A-014-2013** **A-013-2013** **A-012-2013** **A-011-2013** **CLOSED**	09/09/2013	Confidential	Revocation of registration number	Final Decision 01/04/2014 Withdrawal by Appellant
26	**A-010-2013** **CLOSED**	29/08/2013	Tecosol GmbH	Revocation of registration number SME status	Final Decision 22/01/2014 Withdrawal by Appellant

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
25 24 23	**A-009-2013** **A-008-2013** **A-007-2013** **CLOSED**	15/08/2013	Hermann Trollius GmbH	Revocation of registration number SME status	Final Decision 08/01/2014 Withdrawal by Appellant
22	**A-006-2013** **CLOSED**	15/08/2013	Hermann Trollius GmbH	SME status Language of communication	Final Decision 08/01/2014 Withdrawal by Appellant
21	**A-005-2013** **CLOSED**	07/08/2013	Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein	Data sharing Permission to refer	Final Decision 03/12/2014 Appeal dismissed
20	**A-004-2013** **CLOSED**	01/08/2013	Cromochim SpA	Revocation of registration number SME status	Final Decision 05/12/2013 Withdrawal by Appellant
19	**A-003-2013** **CLOSED**	08/05/2013	Poudres Hermillon Sarl	Revocation of registration number SME status	Final Decision 14/01/2014 Withdrawal by Appellant
18	**A-002-2013** **CLOSED**	19/04/2013	Distillerie DE LA TOUR.	Revocation of registration number SME status Administrative charge	Final Decision 21/05/2014 Appeal upheld
17	**A-001-2013** **CLOSED**	08/02/2013	Infineum UK Ltd	Compliance check Substance identity	Final Decision 09/04/2014 Appeal dismissed
16	**A-008-2012** **CLOSED**	02/10/2012	PPH UTEX Sp. z o.o.	Compliance check Substance identity	Final Decision 02/04/2014 Appeal upheld. Appeal fee refund
15	**A-007-2012** **CLOSED**	28/09/2012	Italcementi Fabbriche Riunite Cemento S.p.A. Bergamo	Substance identity UVCB Compliance check	Final Decision 25/09/2013 Appeal upheld
14	**A-006-2012** **CLOSED**	20/09/2012	Momentive Specialty Chemicals B.V.	Compliance check Use of read-across data	Final Decision 13/02/2014 Appeal dismissed
13	**A-005-2012** **CLOSED**	01/08/2012	SEI EPC ITALIA SpA	Administrative charge SME status	Final Decision 27/02/2013 Appeal dismissed
12	**A-004-2012** **CLOSED**	05/07/2012	Lanxess Deutschland GmbH	Compliance check Testing involving animals	Final Decision 10/10/2013 Appeal dismissed
11	**A-003-2012** **CLOSED**	25/05/2012	THOR GmbH	Compliance check Updated dossier	Final Decision 01/08/2013 Appeal upheld
10	**A-002-2012** **CLOSED**	30/04/2012	BASF SE	Testing proposal Updated dossier	Final Decision 21/06/2012 Rectified by ED
9	**A-001-2012** **CLOSED**	24/01/2012	Dow Benelux B.V.	Compliance check Rejection of suggested read-across	Final Decision 19/06/2013 Appeal dismissed
8	**A-006-2011** **CLOSED**	03/08/2011	5N PV GmbH	Administrative charge SME status	Final Decision 30/11/2011 Withdrawal by Appellant
7	**A-005-2011** **CLOSED**	21/06/2011	Honeywell Belgium N.V.	Compliance check Testing involving animals	Final Decision 29/04/2013 Appeal upheld
6	**A-004-2011** **CLOSED**	11/04/2011	Kronochem GmbH	Rejection of registration Registration fee	Final Decision 07/10/2011 Appeal dismissed
5	**A-003-2011** **CLOSED**	21/02/2011	BASF SE	Data-sharing Permission to refer	Final Decision 27/05/2011 Withdrawal by

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
					Appellant
4	**A-002-2011** **CLOSED**	11/02/2011	Feralco (UK) Ltd	Rejection of registration Incomplete dossier	Final Decision 31/03/2011 Rectified by ED
3	**A-001-2011** **CLOSED**	11/02/2011	Feralco Deutschland GmbH	Rejection of registration Incomplete dossier	Final Decision 31/03/2011 Rectified by ED
2	**A-001-2010** **CLOSED**	21/12/2010	N.V. Elektriciteits – Produktiemaatschappij Zuid-Nederland EPZ	Rejection of registration Registration fee	Final Decision 10/10/2011 Appeal upheld
1	**A-001-2009** **CLOSED**	16/09/2009	Specialty Chemicals Coordination Center sa/nv	Rejection of registration Incomplete dossier	Final Decision 30/10/2009 Rectified by ED

CHARTS

Chart 1: Proportion of submitted appeals per type of contested decision since 2009



Last update: 24 May 2017

Chart 2: Number of lodged cases per calendar year (REACH and BPR) since 2009

Chart 3: Appeal outcomes since 2009 as of 30 May 2017

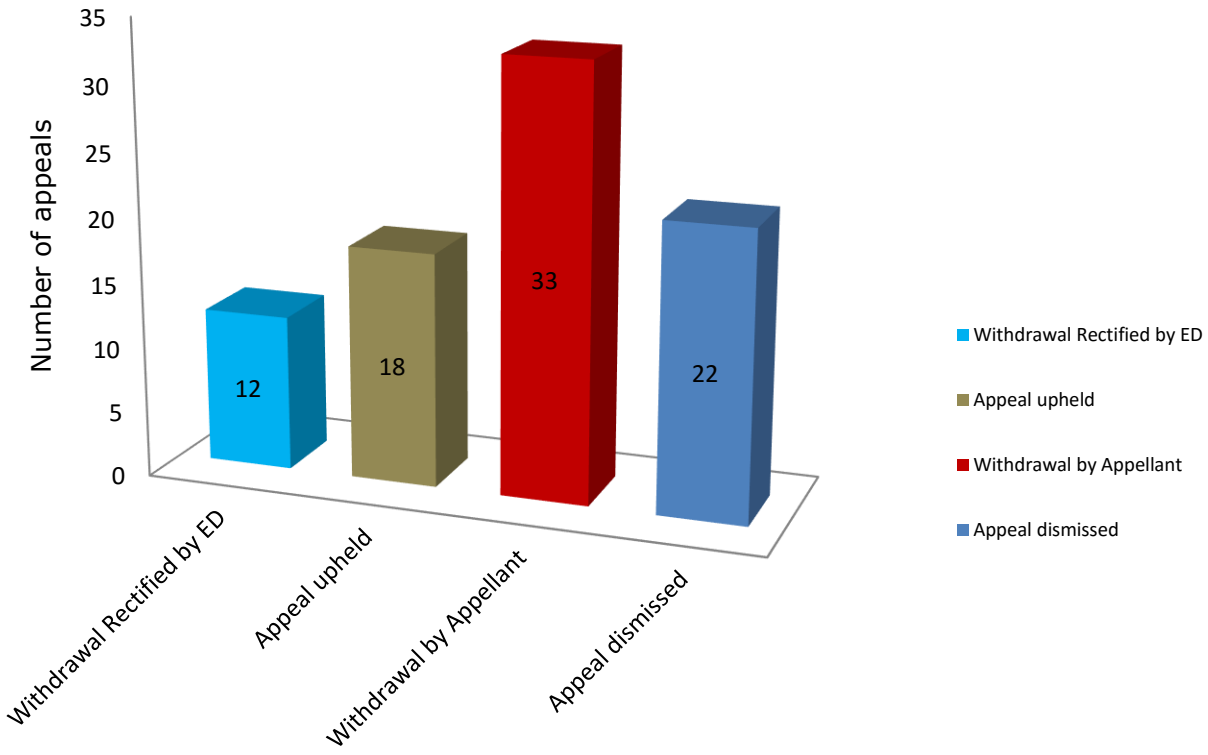


Chart 4 Pending cases as of 30 May 2017 as a proportion of all cases since 2009

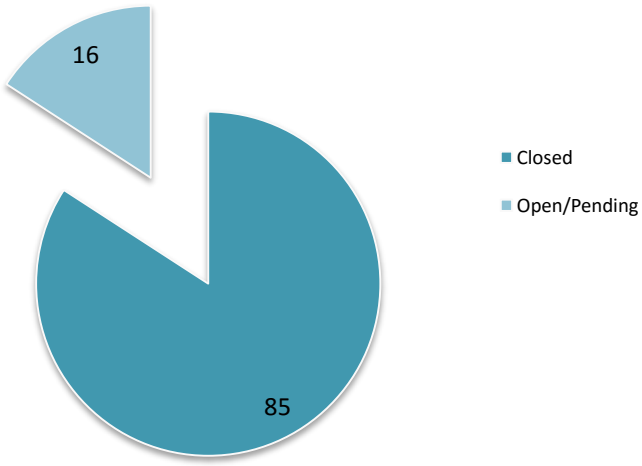


Chart 5 Origin of appeals by member state, as of 10 June 2017