

## **Annual Reports from the Chairman of the Board of Appeal**

42<sup>nd</sup> Meeting of the Management Board 22-23 June 2016

Item	11.3
Action	For information
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#### **Key messages**

- The Board of Appeal (BoA) and its decisions continue to play an important role within ECHA in the implementation of the Biocidal Products Regulation and particularly the REACH Regulation. BoA decisions can also clarify stakeholders' responsibilities under the REACH and BPR regulatory frameworks.
- The appeal proceedings, and in particular the oral hearings, provide stakeholders with the possibility to be directly heard by BoA and to interact face-to-face with the Agency. The possibility to be heard and obtain a fair solution when a dispute exists is an important factor in raising the stakeholders' trust in the REACH processes. BoA decisions and the appeal process itself also help to raise the standards of administration and decision making that ECHA must respect.
- BoA adopted its first decisions related to the substance evaluation process under REACH and the BPR in this reporting period.
- BoA is increasingly a key player in addressing uncertainties in the interpretation of certain parts of REACH and the BPR.
- Amended Rules of Procedure adopted by the Commission will further improve the
  efficiency of appeal proceedings and will allow the BoA to continue to assert its
  independence from the Agency Secretariat, thereby strengthening the perception of
  fairness and impartiality of appeal proceedings before the BoA

### **Background**

As part of ECHA's organisational structure, the BoA reports its activities in the annual General Report of the Agency¹ and envisages its short term and long term activities within the planning and reporting cycle of the Agency (i.e. annual and multi-annual work programme). The Chairman of the BoA gives more detailed information at every June plenary session of the Management Board. Annex I to this report contains a more detailed report on the work of the BoA during the reporting period from June 2015 to June 2016.

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

<sup>&</sup>lt;sup>1</sup> As Activity 9 section

<sup>&</sup>lt;sup>2</sup> Mrss Catherine Mir (Chair), Ana Fresno, Luminiţa Tîrchilă , Miroslava Bajaníková, Messrs Kęstutis Sadauskas, Antonello Lapalorcia and Hans Meijer.

### **Rationale**

The BoA is an independent and impartial body of ECHA. As a public body, it is accountable before the Management Board and stakeholders in general. This report of the Chairman of the BoA to the Management Board serves as one of the tools for 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

For questions: <u>mercedes.ortuno@echa.europa.eu</u> with copy to <u>mbsecretariat@echa.europa.eu</u>

# Report from the Chairman of the Board of Appeal

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- 4. The work on appeals: who, how, when
- 5. Efficiency and Effectiveness
- 6. Looking forward

# 1. Introductory remarks

The BoA is an important component of the regulatory framework under the REACH Regulation (REACH) and the Biocidal Products Regulation³ (BPR). The BoA decides on appeals brought against certain decisions adopted by the Agency; N.B. not all ECHA decisions may be subject to appeal. 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 BoA delivers high quality decisions on often highly legally and scientifically complex issues. The trend observed during the past three years is confirming that the stakeholders are steadily feeling more confident in using the appeal system for challenging decisions adversely affecting them.

With the experience of almost one hundred appeals handled (86 cases; see Annex III) since being established in 2009, the appeal process before the BoA has proven to be an effective remedy for stakeholders affected by an ECHA decision which they believe is not proportionate, well-reasoned, legal or compliant with the applicable legislation or essential principles of EU law. Since the last report to the MB in June 2015<sup>4</sup>, 17 new appeals have been lodged and 17 cases were closed with a final decision, 19 intervention decisions and 4 decisions on stay of proceedings were issued. The number of documents registered in the Register of appeals during the reporting period was 951; this includes all incoming and outgoing documents related to appeal cases during the reporting period. Collectively the decisions were adopted, in the reporting period, within the objective<sup>5</sup> set in the Annual Work programme. It should be noted that the vast majority of the appeals submitted before the BoA are legally and scientifically complex. The first decisions on substance evaluation provided some important findings as to how REACH should be interpreted in this regard. Likewise, the BoA decision from this reporting period related to the 'one substance, one registration' principle has also clarified important aspects of the registration process. During the reporting period, the BoA also adopted its first decisions on appeals lodged against decisions that the Agency adopted under the BPR.6

The appeal system established by REACH works well and serves the foreseen aims. It provides an effective access to legal review to stakeholders, in particular registrants, with many having their interests met through a combination of decisions being annulled, rectified, and withdrawn. In some cases, even though an Appellant may have had their appeal dismissed, the clarifications obtained through the appeals process and the possibility to present their arguments to both BoA and ECHA has been seen as being helpful and productive by the Appellant. In other cases both parties (ECHA Secretariat and appellants) have their respective interests met if there is a mutually acceptable solution leading to a withdrawal of the appeal. Many BoA decisions are however important not only to the parties involved in appeal proceedings but also to other stakeholders with an interest in REACH, as the decisions help to clarify the interpretation of

<sup>&</sup>lt;sup>3</sup> Regulation (EU) 528/2012

<sup>&</sup>lt;sup>4</sup> The present report outlines the period and numbers related to the appeal proceedings spanning between 10 June 2015 and 10 June 2016.

<sup>&</sup>lt;sup>5</sup> 90% of the final decisions have been taken within the 90 working days<sup>5</sup> that the BoA set for itself as a performance indicator in the annual Work Programme.

<sup>&</sup>lt;sup>6</sup> See Table of all appeals since 2009 in Annex III and graphics in Annex IV

certain aspects of REACH and the BPR and their implementation by ECHA. BoA decisions importantly contribute towards the legally sound implementation of REACH and BPR and in helping to achieve the objectives pursued by those two Regulations.

## 2. Summary

The number of appeals lodged from June 2015 to June 2016 (reporting period) is 17, which is lower than the number of appeals received during the previous reporting period when 24 appeals were submitted before the BoA. During the reporting period, the BoA adopted 17 final decisions which is a higher number than the one adopted during the previous period (11 decisions). Six more final decisions are due to be adopted before August. This output indicates that the BoA is reaching 'cruising speed' as a consequence, among others, of the stability in its composition gained at the end of 2015 after a prolonged period of unstable formation. As regards the outcomes, in 4 cases the appeal was dismissed, in 4 cases the BoA decided in favour of the appellant, and 9 cases were closed after the appellants withdrew their appeals (in four cases because the Executive Director rectified the contested decision and in five cases because the parties settled the case during the appeal proceedings). There are currently 27 appeals pending before the BoA.

The feedback received from stakeholders confirms that the BoA has made a number of high quality decisions covering some difficult and complex ground. In particular, regarding registrations, it could be mentioned the positive echo in the media and the impact that the decision in the appeal case A-022-2013 (the 'OSOR' case) had on the registration process and on completeness check in particular. This decision, which annulled a registration granted in breach of the one substance one registration principle, has had an impact not only on the registrants involved in the dispute but also on more than one hundred other registrants that registered the same substance outside the joint registration. Following the decision of the BoA, the Agency announced that, after the BoA confirmed its competence to revisit previously granted registrations, it intends to commence the review of many dossiers submitted outside the joint registration. Importantly, this BoA decision means that dossiers which are devoid of real content should no longer pass the completeness check thereby contributing to safe use of chemicals. And, significantly, ECHA has put in place a new completeness check strategy, showing that the impact of BoA decisions is often much wider than the particular case under adjudication. Subsequently, ECHA could adopt revocation decisions if a dossier is found incomplete or the OSOR principle has not been respected. It seems that the Agency has taken this decision as an opportunity to refine and improve its activities related to the completeness check procedure. This is an important development considering the 2018 registration deadline where thousands of new registrations will be made. These developments clearly show how BoA decisions are helping to achieve the objectives of REACH.

It should be also remarked that by considering that an appeal by a registrant which is not the addressee of the contested decision is admissible, this in principle promotes the "private enforcement" of REACH by a company which is not the addressee of the contested decision, the "private enforcement" of REACH. This again serves to other objective of the REACH in particular enhancing fair competition between registrants of the same substance. More recently, and following the OSOR case, there have been two further appeals lodged by non-addressees of an ECHA decision.

Regarding the other REACH major process related appeals under the BoA's competence, dossier and substance evaluation, it is important to highlight that during the reporting period the BoA also made its first substance evaluation (SEv) decision. In its decision, the BoA identified, in line with the REACH aims, objectives and specific requirements, the criteria that ECHA need to satisfy in order to demonstrate the necessity of a testing requirement in a SEv decision. In addition, in the first decisions on SEv (A-004-2014, A-005-2014 and A-006-2014), the BoA has started to clarify the interaction and links between dossier and substance evaluation.

In an important decision related to a follow up evaluation case and a statement of non-compliance letter (SONC; A-022-2013) the BoA has clarified the duties of the Agency in following

up the results from a dossier evaluation decision. The decisions on evaluation to date go to the core of the REACH system.

Many appeals contained claims for confidential treatment of certain information. And many cases, following the publication of announcements, have resulted in applications to intervene. During this reporting period the BoA also adopted procedural measures aimed at optimizing its operability and transparency. Those measures included for example the staying of proceedings when the circumstances of the case so dictated (e.g. where the appellant challenged the same ECHA decision before the General Court of the EU) or the parties so requested in order to start negotiations for a settlement in parallel to the appeal; and also joining certain procedural steps during the case handling of similar cases to manage them more efficiently.

11 oral hearings were held as a result of the parties' requests, in particular by the appellants, where the hearings enabled them to orally present their arguments and the BoA to put questions directly to the parties and interveners involved. The number of hearings has increased considerably and was higher in this reporting period than the total number of hearings held in the preceding seven years. It is the perception of the BoA, also confirmed informally by appellants attending hearings, that appellants welcome the possibility to be directly heard by BoA and ECHA and to interact face-to-face with the Agency. The possibility to be heard and obtain a fair solution when a dispute exists is an important factor in raising the stakeholders' trust in the Agency and in the REACH processes.

During the handling of each appeal case, the BoA adopts a considerable number of procedural decisions. These decisions relate in particular to applications to intervene, requests for observations of the parties and interveners, requests for time extensions, posing specific questions to the parties, decisions staying the proceedings, joining similar cases, and summons to the hearings. The Chairman also dealt with other requests, in particular for information to be kept confidential. As provided by the Rules of Procedure, the BoA publishes all appeal announcements and final decisions. Further to the transparency values of ECHA, and after an appeal case is concluded, the BoA also publishes a summary of the decision and other relevant procedural decisions, for example related to confidentiality requests and applications to intervene. These are published on ECHA's website (see also Annexes III and IV).

As foreseen in Article 89(2) of the REACH Regulation, during the reporting period, four Legally Qualified Alternate Members of the BoA (LQMs) were appointed in six cases. This was due to the fact that the position of the regular Legally Qualified Member was vacant during some of the reporting period (the current LQM was appointed in November 2015). Appointing LQMs helped to ensure the continuous operability of the BoA in order to ensure that appeals are processed without unnecessary delay. The MBWG-BoA was duly informed of those designations and the Chairman of the BoA reported in detail to the working group on this issue.

Finally, the REACH Regulation defines the BoA as a part of ECHA. As such BoA decisions are, and should be seen as, part of the process of continuous improvement of ECHA's operations, complementary to the many other activities taking place in this regard in ECHA. As any responsible body ECHA aims to be a 'learning organisation' and the BoA's decisions have certainly contributed to this end.

# 3. Findings from BoA decisions to date<sup>7</sup>

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

<sup>&</sup>lt;sup>7</sup> See Table on Annex III; in addition, all BoA decisions and the case announcements are available on-line on ECHA website.

#### 3.1 Confirming the Agency's Position

# Dossier evaluation – Compliance check – exposure assessment and risk characterisation

#### Substance Evaluation; different scientific opinion is not an error of assessment

The Appellants' claim that the Agency acted illegally when choosing the testing material and the tests to be performed cannot succeed when the Appellants' arguments demonstrate a difference of scientific opinion between them and the Agency but do not demonstrate an error of assessment on the part of the Agency (Decision of 9 September 2015, Case A-004-2014, MCCP Registrants, paragraphs 54, 70, and 82).

#### **Biocidal Products Regulation – Admissibility of the appeal**

A decision of the Agency to include a company on the Article 95 List is not appealable before the Board of Appeal as this type of decision is not listed as an appealable act under Article 77 of the BPR. The failure for the Agency not to take a data sharing decision under Article 63(3) of the BPR in the context of an Article 95 inclusion is not appealable before the Board of Appeal as it would amount to a review of the legality of the BPR which can only be performed by the Court of Justice. (Decision of 25 September 2015, Case A-019-2015, Lysoform Dr. Hans Rosemann and Decision of 25 September 2015, Case A-020-2015, Lysoform Dr. Hans Rosemann).

#### 3.2. Areas for Improvement

#### **Registration – Completeness Check – OSOR**

It is a fundamental pillar of the REACH Regulation that for each substance there should be only one joint submission (the principle of 'one substance, one registration' or 'OSOR'). A registrant cannot 'opt out' from a joint submission in its entirety by submitting a wholly separate registration for the same substance. It may only submit the information for certain endpoints separately for the reasons listed in Article 11(3) of the REACH Regulation, and only if it provides an explanation for doing so (Decision of 15 March 2016, Case A-022-2013, REACheck Solutions GmbH, para. 73).

If a registration breaches the OSOR principle, the Agency can and must consider it incomplete and set a reasonable deadline for the registrant to complete its registration. The Agency may eventually reject the registration (Decision of 15 March 2016, Case A-022-2013, *REACheck Solutions GmbH*, paras. 120 and 127).

#### Registration - Completeness Check - Scope of checking

The fact that the IT system used for completeness checks does not recognise a difference between 'text' and 'information' does not exonerate the Agency from its obligation to check the completeness of dossiers. Moreover, ascertaining that all the elements required for a registration are provided in a dossier does not constitute an assessment of the quality or the adequacy of any information submitted (Decision of 15 March 2016, Case A-022-2013, *REACheck Solutions GmbH*, paras. 106 and 107).

#### **Dossier evaluation – Compliance check – Statement of Non-Compliance**

Pursuant to Article 42(1) of the REACH Regulation, where the Agency adopts a fresh decision following the evaluation of substantial new information provided by a registrant in response to a previous decision the Agency must follow the decision-making process set out in Articles 50 and 51 of the REACH Regulation (Decision of 29 July 2015, Case A-019-2013, *Solutia Europe sprl/bvba*).

#### **Dossier evaluation - Compliance check - Intermediate**

The definition of intermediate under Article 3(15) of the REACH Regulation is not a matter of extensive or restrictive interpretation but a matter of ascertaining whether two cumulative requirements are met: (i) the substance must be manufactured for, and consumed in, a chemical process and (ii) the substance must be intentionally transformed into another substance. The wording of Article 3(15) does not include a reference to 'the main aim of a production process' as a consideration for a substance to qualify as an intermediate. The legislator took into account all the objectives pursued by the REACH Regulation in establishing the definition of intermediate and decided that, if certain criteria are met, intermediates shall benefit from a less stringent regime under the REACH Regulation due to the limited risks for human health and the environment. It is neither for the Agency nor for the Board of Appeal to take on the role of the legislator and to add supplementary requirements to the definition of intermediate under Article 3(15) (Decision of 25 May 2016, Case A-010-2014, Nordenhamer Zinkhütte GmbH, paragraphs 39 to 49).

# Substance Evaluation – Test to be performed when requesting additional information – Proportionality

In order to request additional information consistent with the proportionality principle, the Agency must inter alia be able to demonstrate the necessity of the requested measure by setting out the grounds for considering that a 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 (Decision of 23 September 2015, Case A-005-2014, *Akzo Nobel Industrial Chemicals GmbH and Others*, paragraphs 52 to 73; Decision of 27 October 2015, Case A-006-2014, *International Flavors & Fragrances*, para. 76).

#### DOSSIER AND SUBSTANCE EVALUATION PROCESSES, WHEN TO PERFORM ONE OR THE OTHER

The objectives of dossier and substance evaluation are, in some respects, different. Whilst the REACH Regulation contains no explicit requirement that dossier evaluation should precede substance evaluation, the Board of Appeal observes that there are a number of indications in the REACH Regulation which suggest that the normal course of action should be for the Agency to carry out a compliance check prior to the performance of a substance evaluation (Decision of 23 September 2015, Case A-005-2014, *Akzo Nobel Industrial Chemicals GmbH and Others*, paragraphs 52 to 73, para. 77).

Filling a standard information requirement for one of the registrants of a substance through substance evaluation could lead to significant costs for low tonnage and intermediate registrants who would not be exposed to such costs if the standard information had been provided through a registration by a higher volume registrant. The Agency should not therefore, without clear justification, in effect extend the standard information requirements to other registrants (Decision of 23 September 2015, *Akzo Nobel Industrial Chemicals GmbH and Others*, paragraphs 52 to 73, Case A-005-2014, para. 86).

# 4. The work on appeals: who, how and when

The BoA endeavours to deliver high quality decisions. In doing so, as any other public body, the BoA considers how to improve its efficiency in terms of time and effort spent in an appeal case without compromising the quality of its decisions. These goals need to be considered in light of BoA's resources: three BoA members, and the Registry team (Registrar, three legal advisors, one interim lawyer, two assistants and two secretaries).

Other elements that should also be mentioned in order to better understand how the BoA works:

• Working in a transparent manner: as required by the REACH Regulation and the Rules of Procedure all appeal cases are announced on ECHA's website. All final decisions are published as well as the procedural decisions on confidentiality and intervention. Summaries of all final decisions are published on-line in order to assist the wider interested audience to follow BoA decisions without necessarily reading the full decision. It has to be said however that the BoA encourages all interested parties to read its decisions in full. A new search application on BoA's section of ECHA's website is now operational. It enables a search of all BoA decisions (by dates, contents, subject, types of decisions etc.). As previously mentioned, reading of BoA decisions in their entirety is the best guidance for stakeholders as they can directly inform themselves of the approaches taken by the BoA in cases that it has examined thus far. This can help potential appellants to better understand the interpretation of REACH and BPR and its implementation by ECHA and help the Agency to amend its practices and processes if needed. The publication of procedural decisions regarding confidentiality claims and applications to intervene has also helped to refine or avoid unnecessary requests. Positive feedback was received from stakeholders as regards the on-line access to BoA decisions.

In this vein, it should be noted that the recently adopted Commission implementing Regulation (EC) 2016/823 amending the current Rules of Procedure of the BoA (RoP) will increase the transparency of the amicable agreements that are reached between the appellants and the Agency during the appeal proceedings. According to the RoP, a member of the BoA can be appointed to facilitate the possibility of an amicable agreement and, if an amicable solution is reached, a summary of it should be published on ECHA's website. In this way settlements between ECHA and appellants, which are reached in 31% of all the cases closed by the BoA, will serve also to other prospective appellants to inform them and give them the possibility to explore possible solution of the dispute, other than continuing with the appeal proceedings before the BoA.

- Learning from experience: systematic review of our practices and in particular taking lessons from how the issues present in appeal cases were dealt with has helped the BoA to refine its processes. Improved mid-term and long-term portfolio planning for oral hearings has been an important element in improving case management. Joining the hearings in similar cases has also been a measure for gaining efficiencies and to save time and resources. As regards the written part of the proceedings, the BoA has continued in its efforts to streamline case handling by framing at an earlier stage the most important issues in the case by posing specific written questions to the parties to help avoid, as much as possible, the collection of unnecessary documents and evidence. This reduces the effort and time spent with irrelevant information which also distracts the proper examination of the core elements of a case. However, in balancing between the need for celerity of the proceedings and the right of the parties to a proper defence of their respective interests, the BoA has conceded greater weight to the second and granted the numerous extensions of deadlines requested and justified by the parties, in particular the Agency. As a result and due also to the numerous stay decisions taken during the previous reporting period due to exceptional circumstances, when compared to the previous reporting exercise, the appeal cases take now on average longer.
- Focussing on the important issues: although all claims put forward by the parties should be considered, it is also true that the way to address them could be more or less expedited depending on the complexity and the link with the core issue at stake. Gaining efficiencies by focusing the attention on the core issues has been an objective of the BoA. In this respect the Commission implementing Regulation (EC) 2016/823 amending the current Rules of Procedure of the BoA will help to attain this objective. For example, the Chairman alone will decide on the closure of a case after a withdrawal of the appeal by the appellant. The collegiality, which invariably slows down the adoption of decisions, is reserved only for the substantial decisions.

Another change brought by the amended RoP, in substance evaluation cases, the evaluating Member State Competent Authority will be considered to be the 'privileged applicant' that as a result will not have to establish an interest to intervene in an appeal case and no reasoned collegial decisions from the BoA will be needed anymore.

- <u>Investing time and efforts in quality</u>: a sound, clear and well-reasoned BoA decision is the best tool for ensuring efficiency. A sound and rigorous BoA decision can persuade appellants not to challenge it before the General Court and in return avoiding additional efforts and expenses that the Agency would need to commit in defending the case before the EU Courts. To date no BoA decisions have been challenged before the General Court by unsuccessful appellants. Likewise, BoA decisions also enable ECHA to reconsider and, if necessary, change its administrative practices and processes so that future appeals may be avoided in the first place.
- <u>Transmitting confidence and trustfulness</u>: through its decisions, the BoA has always proven its independence from the Agency, the registrants and other stakeholders. However, to reinforce this idea the revised Rules of Procedure introduce an important organisational element which is the swop of managerial powers over the Registrar, and the Registry staff from the Executive Director of ECHA to the Chairman of the BoA. In this way, all the individuals working for the BoA in relation to appeal proceedings are moved away from the managerial powers of one of the parties in the proceedings.
- Team-working with the alternate members of the BoA the Registry: During the reporting period, as well as during the previous periods, the Alternate Members of the BoA have proven to be essential in guaranteeing the operability of the BoA. This shows how important it is for the appeals system to have a team of skilled and motivated alternate and additional members available to it. In this context the Chairman updates the AAMs on a quarterly basis about the activities of the BoA and in particular about the decisions taken. The annual workshop with alternate members, BoA and the Registry team will be held in autumn. It provides the opportunity to discuss key issues arising from the processing of appeal cases and additionally to share experience, with those members who did not yet participate in cases. It will assist in preparing them for their possible future involvement in cases. In the pending appeal cases submitted prior to the appointment of the new Legally Qualified Member, the BoA is working in a composition that includes an alternate legally qualified member. With the support of the Registry staff, that collaboration runs efficiently and the appeals are processed effectively, although this necessary approach puts a considerable extra demand on the full-time BoA members which would not be sustainable with a high number of active cases. Also, a documented system for conflict of interest checking regarding each appeal, according to the Court of Auditors recommendation is always done before allocating any case to the BoA members and Registry staff.
- Working in timely fashion: there is no legal deadline for deciding on appeals; however the BoA has set as a performance indicator<sup>8</sup> to adopt 90% of the decisions within 90 working days from the moment the case is ready for decision (this starts from the conclusion of the oral hearing or, if no hearing is held, 14 days after the closure of the written procedure). During the reporting period, whilst there was only one case who took longer than the 90 days deadline, the indicator was observed was observed.

During the previous reporting period and due to reasons beyond the control of the BoA, in 12 cases the BoA, after consulting the parties, stayed the proceedings for three months in 2015. In this reporting period, after the stay expired, the 'stayed' cases resumed after a well and carefully studied planning, avoiding any prejudice for the parties. In the reported period, the longest time spent in the processing of an appeal has been 27 months<sup>9</sup>. The average duration appeal cases in which the BoA adopted final decisions going into the substance of the case was 15 months.

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<sup>&</sup>lt;sup>8</sup> ECHA Annual work programme

<sup>&</sup>lt;sup>9</sup> The extended duration of this case A-022-2013 'Charcoal case' is in particular down to the fact that during the case parties were considering whether to try and settle a case and the fact that the language of the case was German and that required organisation of the interpreting services for the hearing and the translation of the final decision took more time than in normal cases.

## 5. Efficiency and Effectiveness

As the rest of ECHA and any other public body, the BoA strives to be as efficient and effective as possible, that is doing the same or more with less. In this regard, in addition to what is explained in the previous part of this report, the BoA has continued to implement measures with a view of increasing the efficiency of the appeals process. For example, the BoA has allowed that multiple addressees of the same ECHA decision submit a joint appeal. During the reporting period, this measure reduced the number of appeals by eighty-five<sup>10</sup>. This approach simplifies considerably the case handling and reduces the costs for the appellants, as well as the use of resources by the ECHA Secretariat.

In regard of the particular point of timing and workload, it should be noticed that the BoA has also managed to clear the backlog created by the events totally out of its control in an exceptionally short time after the composition was finalised. The BoA was able to clarify any delays and all cases are on track.

It is submitted that the efficiency test of the BoA's activity should not be based so much on the ratio of the number of decisions and the time or resources spent on them but rather on the impact that its decisions have. This is to say, the impact on the REACH processes that the BoA indirectly reviews when deciding on an appeal; or in other words, on its effectiveness stemming out of well-reasoned, clear and helpful decisions. For example, a few ground-breaking well-reasoned decisions on substance evaluation assisted not only the appellants but also ECHA Secretariat in clarifying important aspects of this process<sup>11</sup>; this meant in practice that ECHA Secretariat improved its decisions by aligning them with the BoA findings and ultimately with the objectives of the REACH. This led ECHA towards sounder decisions that are potentially less prone to being challenged before the BoA. This will result in fewer appeals in the future. The BoA has to ensure the continued effectiveness of its decisions and the appeals process whilst, at the same time, looking to the most efficient manner to use its resources.

With regard to the above, there are several indications demonstrating the BoA's effectiveness:

- Thus far, more or less every BoA decision has constructively clarified certain aspects of the interpretation and implementation of REACH;
- ECHA Secretariat is using BoA decisions for improving management of its processes as mentioned in several official publications<sup>12</sup>;
- Stakeholders are improving their understanding of REACH processes through BoA decisions, as mentioned in several articles published in specialised publications and media<sup>13</sup>. The BoA's decisions are widely recognised as being very thorough and highly competent reviews of complex legal and scientific issues;
- No appeals on SME related issues since that last BoA decision on this matter demonstrates
  the impact of a number of thoughtful and meticulously worded decisions in clarifying
  certain issues;
- The European Commission's roadmap REFIT evaluation in view of the obligation stemming from Article 117(4) to report by 1 June 2017 on REACH implementation is using the relevant findings stemming out of the BoA decisions in order to assess how the REACH legislation is being applied and implemented;

<sup>&</sup>lt;sup>10</sup> It has to be noted that in one of the pending appeal cases, the appeal was submitted jointly by 35 appellants.

<sup>&</sup>lt;sup>11</sup> 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..."

<sup>&</sup>lt;sup>12</sup> See ECHA Report on the Operation of REACH and CLP 2006 (page 66-67, 69, etc.)

<sup>&</sup>lt;sup>13</sup> See ChemicalWatch, issue 81, October 2015, extended article on "New phase for Echa Board of Appeal"; see BNA Bloomberg article on "Lessons learned and prospects on the European Chemicals Agency's Board of Appeal, 7 January 2016.

- No legal actions brought against BoA decisions to the EU Courts (N.B. it should be however noted that it is not BoA's aim to have no actions against its decisions as there will be issues where a definitive opinion of the EU Courts is desirable);
- Appeals being made to the BoA are proving to be less costly and time consuming, when compared with the court proceedings before the EU Courts; and
- The BoA notices that majority of the appellants gain a certain satisfaction through the
  appeals process. For example, through ECHA decisions, contested in appeal proceedings,
  being annulled or being rectified, or appeals being withdrawn, and even when losing cases
  through the clarification of important issues and having an opportunity to request and
  later present its views in a hearing.

# **6. Looking forward**

The next reporting period will most likely see the BoA dealing with the following matters:

### **6.1. Decide upon new and complex matters: Nanoforms (SEv)**

At the time of drafting this report, seven 'nanos' related appeals have been lodged. The first oral hearing for four of these cases was held earlier in June and the final decision will be ready in autumn. In deciding on these specific cases, the BoA will have the opportunity to provide its view on essential issues under dispute such as the applicability of REACH to nanoforms related information, proportionality of the measures imposed etc. and provide clarity on certain aspects which are new for both the appellants and the Agency.

#### 6.2. First substantive decisions related to biocides

So far the decisions taken by the BoA on biocides were limited to the admissibility aspects of the case and the two cases decided upon were found inadmissible. The forthcoming decisions on biocides will be considering the essential aspects of the biocidal legislative framework such as the data sharing disputes and the technical equivalence between active substances.

# 6.3. Implementing the Rules of Organization and Procedure of the Board of Appeal (Commission Regulation (EC) No. 771/2008)

As anticipated along the lines of this report, the BoA Rules of Procedure were revised and amended by the implementing Regulation 2016/823. They contain important aspects that will contribute towards more efficient processing of appeals and to enhance the external perception of BoA independence vis-à-vis ECHA Secretariat and to the transparency of the appeal system.

As a result of the amended RoP, the Board of Appeal will review its Practice Directions to the parties which is a document available on line in all languages and provides guidance to potential appellants or interveners.

Also, the administrative arrangements signed in 2009 by the ED and the BoA Chairman have been revised and will be approved soon after the endorsement of the MB. These arrangements contain the practicalities to guarantee the change in the Registry's organic dependency, now from the BoA, and the explicit delegation of managerial powers from the ED on the Chairman of the BoA.

# 6.4. Keep on working with high quality standards and improving with more stability in the organization and composition of the BoA

As mentioned in my previous report for 2015, the BoA is called to examine and decide on very complex matters and ultimately plays one of the key roles in the implementation of REACH in line with all of its objectives. To perform these important tasks the stability regarding its

organisation and its composition is crucial factor in which the Management Board decisions are of paramount importance. The stability of its structure and organisation was finally decided last year by the MB by concluding that it is a permanent body within ECHA. The stable composition of the permanent formation with highly qualified and professional members is the second element which will be finally decided in the fourth coming reporting period. These elements will help the BoA, supported by a motivated team of highly skilled Registry members, to maintain its cruising speed and to continue to produce high quality decisions. This is the way in which the BoA wants to contribute to the successful implementation of REACH.

- Annex II Table of BoA members and their terms of office
- Annex III Table of Appeals
- Annex IV Statistics

#### **ANNEX II**

# Table of BoA members: 'regular' and alternate and additional members (June 2016)

Name	Role	Term started	Term ends
Mercedes ORTUÑO	Chairman	15 Apr 2009	14 April 2019**
Andrew <b>FASEY</b>	TQM	15 March 2011	14 March 2021**
Sari <b>HAUKKA</b>	LQM	1 December 2015	30 November 2020*
Christoph BARTOS	Alt Chair	15 Oct 2010	14 October 2020**
Ioannis <b>DIMITRAKOPOULOS</b>	Alt Chair	15 Oct 2010	14 October 2020**
Cristopher <b>HUGHES</b>	Alt Chair	15 Oct 2010	14 October 2020**
Harry <b>SPAAS</b>	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 <b>DOHERTY</b>	LQAAM	15 Apr 2009	14 April 2019**
Rafael <b>LÓPEZ PARADA</b>	LQAAM	15 Apr 2009	14 April 2019**
Angel M. MORENO MOLINA	LQAAM	1 December 2014	30 November 2019*
Sakari <b>VUORENSOLA</b>	LQAAM	1 December 2014	30 November 2019*

<sup>\*-</sup> First mandate

# Registry Unit supporting BoA's work in the reporting period

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

<sup>\*\*-</sup> Second and last mandate

# **ANNEX III**

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
86	A-004-2016 OPEN	28/04/2016	Huntsman P&A UK Limited	Substance Evaluation	
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
83	A-001-2016 OPEN	13/01/2016	Troy Chemical Company	Data Sharing, BPR	
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	<u>A-024-2015</u> OPEN	15/12/2015	Elkem AS	Registration Decision appealed by a non-addressee	
79	<u>A-023-2015</u> OPEN	13/11/2015	Akzo Nobel Chemicals N.V. and others	Substance Evaluation Tert-butyl perbenzoate (TBPB)	
78	A-022-2015 OPEN	10/11/2015	Manufacture Française des Pneumatiques Michelin	Substance Evaluation	
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

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
67	A-011-2015 OPEN	16/03/2015	J.M. HUBER FINLAND OY	Compliance check	
66	<u>A-010-2015</u> OPEN	16/03/2015	RHODIA OPERATIONS SAS	Compliance check	
65	<u>A-009-2015</u> OPEN	16/03/2015	IQESIL SA	Compliance check	
64	A-008-2015 OPEN	16/03/2015	Evonik Degussa GmbH	Compliance check	
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	<u>A-005-2015</u> OPEN	03/03/2015	THOR GmbH	Data sharing BPR	
60	<u>A-004-2015</u> OPEN	27/02/2015	Polynt S.P.A.	Compliance check	
59	<u>A-003-2015</u> OPEN	24/02/2015	BASF Pigment GmbH	Compliance check	
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	<u>A-018-2014</u> OPEN	17/12/2014	BASF Grenzach GmbH	Substance Evaluation	
55	<u>A-017-2014</u> OPEN	17/12/2014	BASF SE	Compliance check	
54	A-016-2014 CLOSED	17/12/2014	Oxiteno Europe SPRL	Compliance check	Final Decision 11/02/2015 Withdrawal by Appellant
53	<u>A-015-2014</u> OPEN	15/12/2014	BASF SE	Compliance check	
52	A-014-2014 OPEN	11/12/2014	BASF Pigment GmbH	Compliance check	
51	<u>A-013-2014</u> OPEN	10/12/2014	BASF SE	Substance Evaluation	
50	<u>A-012-2014</u> OPEN	21/11/2014	HUNTSMAN HOLLAND BV	Compliance check	
49	<u>A-011-2014</u> OPEN	16/09/2014	Tioxide Europe Ltd and others	Compliance check	
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 OPEN	22/08/2014	Albemarle Europe SPRL and others	Substance evaluation	

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
46	<u>A-008-2014</u> OPEN	14/08/2014	CROSFIELD ITALIA S.r.I.	SME status	Stay of proceedings Litis Pendentia
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	<u>A-016-2013</u> OPEN	15/10/2013	Marchi Industriale SpA	SME status 'Linked enterprises'	Stay of proceedings Litis Pendentia
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
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

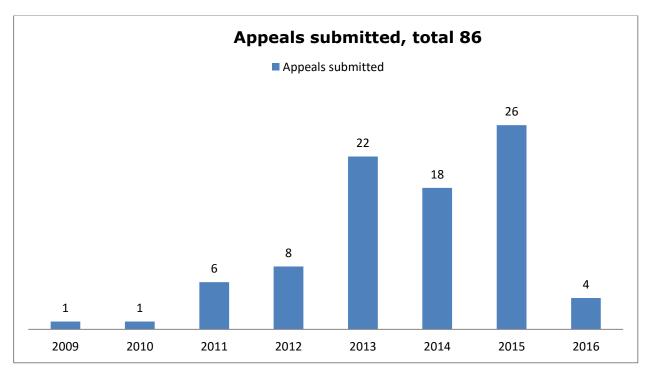
No.	Case No.	File Date	Appellant Keywords		Result/decision date
22	A-006-2013 CLOSED	15/08/2013	Hermann Trollius GmbH	SME status Language of communication	Final Decision 08/01/2014 Withdrawal by Appellant
21	A-005-2013 CLOSED	07/08/2013	Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein	Data sharing 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 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

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
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

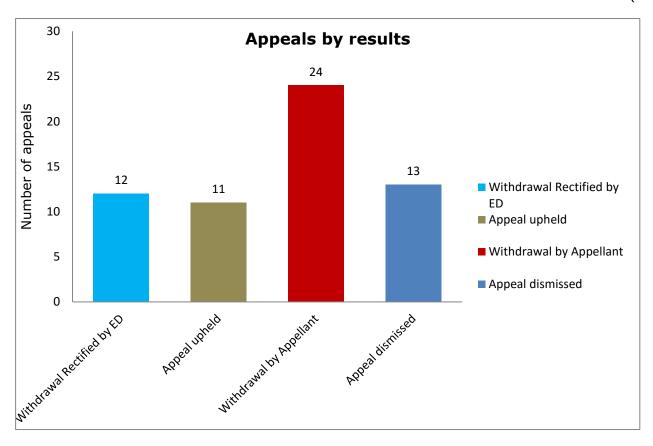
#### **ANNEX IV**

# **Graphics**

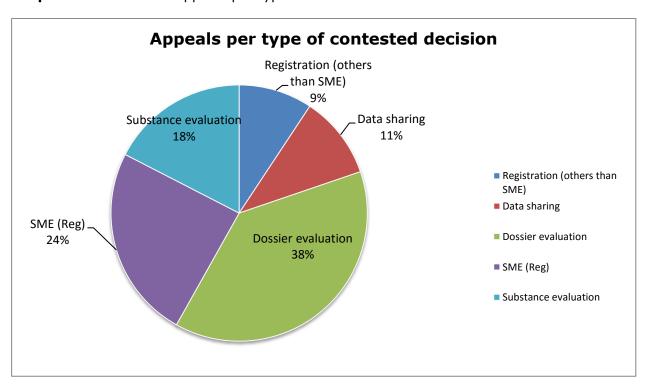
**Graphics 1:** Number of appeals per year



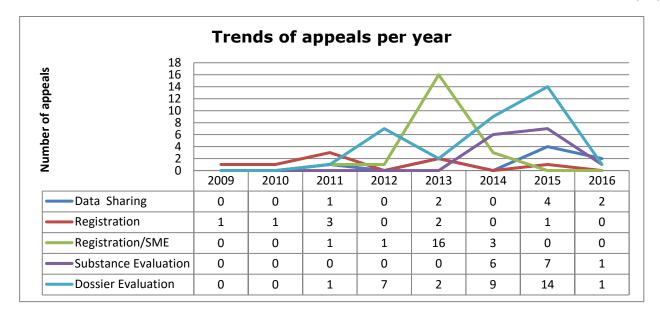
**Graphics 2:** Number of concluded appeals by the result



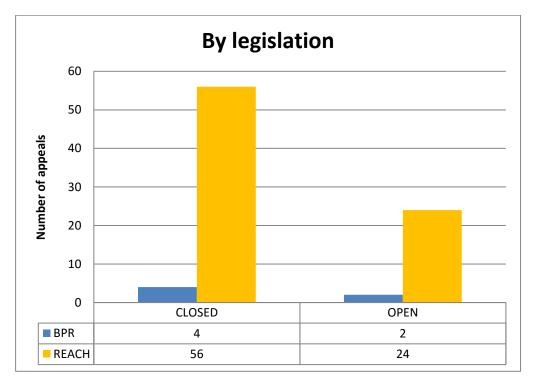
**Graphics 3**: Submitted appeals per type of contested decision



Graphics 4: Trends of appeals submitted per year



**Graphics 5**: Number of appeals by legislation 2009–2016



**Graphics 7**: Appeals per member state

