

## Report from the Chairman of the Board of Appeal

38<sup>th</sup> meeting of the Management Board 17-18 June 2015

<b>Item</b>	10.4
<b>Action</b>	For information
<b>Status</b>	Final - public

### Key messages

1. The Management Board (hereinafter the 'MB') is invited to note the activities of the ECHA Board of Appeal (hereinafter the 'BoA') since the last Report to the Management Board in June 2014.
2. The MB is invited to note, and if appropriate comment on, the content of this report.

### Background

As part of ECHA's organisation, the BoA reports its activities in the Annual Report of the Agency<sup>1</sup> and plans its short term and long term activities within the annual and multiannual work programme of the Agency (available on ECHA's website). The Chairman of the BoA gives more detailed information at the every June plenary session of the Management Board as part of the MB rolling plan. Annex I to this report contains a more detailed report on the work of the BoA during the reporting period covering June 2014 to June 2015.

In addition, the BoA has also been in regular contact with the Management Board Working Group for the BoA (the 'MBWG-BoA'), whose members<sup>2</sup> also carry out the tasks of reporting officers for the BoA members. The MBWG-BoA also presents its report to the plenary providing comprehensive information on BoA developments from a different perspective.

### Matters for consideration

1. The BoA is now a mature adjudicatory body within ECHA, whose aim is to provide legal redress by deciding upon appeals taken against decisions taken by ECHA pursuant to REACH and the Biocidal Product Regulation (the 'BPR'). The issues raised in these appeals are often legally and scientifically complex and the aim of the BoA is to deliver high quality decisions after appeals have been brought against a decision of the Agency. The trend observed during the past two years is that the BoA is dealing with an increasing number of appeals and has consolidated some of its case handling practices<sup>3</sup>. Since the last report to the MB in June 2014, 24 new appeals have been lodged and 11 cases were closed with a final decision. 10 intervention decisions, 3 confidentiality decisions and 17 decisions on stay of proceedings were issued. The number of communications from the Registry to the parties was 525. All final decisions have been taken within the 90 working days deadline set as performance indicator in the annual Work Programme<sup>4</sup>. The appeals related, in particular, to dossier evaluation and data sharing proved to be legally and scientifically complex. The pending appeals on substance

<sup>1</sup> Activity 9

<sup>2</sup> Mrs Ana Fresno, Catherine Mir, Luminita Tîrchilă, Messrs Alexander Nies and Kestutis Sadauskas.

<sup>3</sup> Oral hearings, written submissions, evidence, etc.

<sup>4</sup> 90 w/d from the day the case is ready for decision, i.e. when oral hearing is concluded or if no oral hearing is requested, 14 days after the closure of written procedure.

evaluation that are currently being examined by the BoA also present scientific complexities and legal questions of principle related to the aim and nature of the substance evaluation process. During the reporting period the first appeals contesting ECHA decisions on biocides have also been brought<sup>5</sup>.

2. The appeal system established by REACH works well and serves the foreseen aims. It provides an effective access to legal redress to stakeholders with many having their interests met through a combination of decisions being annulled, rectified, and withdrawn. In some cases both parties to the appeal process (ECHA Secretariat and appellants) have their interests met if there is a mutually acceptable solution leading to withdrawal of the appeal. Many BoA decisions are however important not only to the parties involved in appeal proceedings but also to stakeholders generally (including ECHA) in clarifying the interpretation and implementation of REACH<sup>6</sup>. BoA decisions contribute to the continuous improvement of the operation of REACH.

## Efficiency

3. The Board of Appeal strives, as the rest of ECHA, to be as efficient as possible i.e. doing the same or more with less. In this regard the Board of Appeal has taken certain steps to increase the efficiency of the appeals process. Most notably the Board of Appeal has allowed, even encouraged, joint appeals by multiple registrants. This however reduces the number of appeals by over 20; this of course does not help the Board of Appeal in terms of demonstrating that it has dealt with more appeals but is efficient in terms of the workload and expense of the stakeholders involved. By publishing procedural decisions as well as final decisions the Board of Appeal has also helped avoid unnecessary applications for information to be kept confidential and informed potential interveners what they need in order to justify an application to intervene. Again this does not help the Board of Appeal in terms of the number of applications made and decisions taken but does help with the efficiency of the appeals system as a whole.

4. However, the Board of Appeal does not consider that a quantification of the outputs of the Board of Appeal is an appropriate measure for the Board of Appeal's work anyway. The test of the Board of Appeal is the effectiveness of its decisions and of the appeals process as a whole. For example, a few decisions that are effective in clarifying the interpretation and implementation of REACH is more efficient and effective than taking many decisions that do not; i.e. more decisions with less staff would not be more efficient if those decisions had little or no impact. The Board of Appeal has to ensure the continued effectiveness of its decisions and the appeals process whilst looking, at the same time, for ways to be more efficient. This is a very relevant issue looking forward as the Board of Appeal has a back log of pending appeals as a result of events totally outside its control.

5. In this regard there are several indications that the Board of Appeal is being effective:

- An increase in the number of appeals as an indicator of the trust of stakeholders in the appeal system.
- More or less every Board of Appeal decision so far has helpfully clarified aspects of the interpretation and implementation of REACH.
- The Board of Appeal's decisions are widely recognised as being very thorough and highly competent reviews of complex legal and scientific issues.
- The decrease in the number of appeals on SME related issues demonstrates the impact of a number of thoughtful and carefully worded decisions in clarifying certain issues.
- The European Commission is using the Board of Appeals decisions on data and cost sharing to inform the drafting of a Commission Regulation on data and cost sharing.

<sup>5</sup> See Table of all appeals since 2009 in Annex III and graphics in Annex IV

<sup>6</sup> Regulation (EU) 528/2012

- The overwhelmingly positive response from stakeholders on the quality of BoA decisions.
- The limited number of appeals to BoA decisions to the EU Courts (N.B. it should not be an aim to have no appeals to BoA decisions as there will be issues where a definitive opinion is desirable. The Board of Appeal would in fact welcome review by the EU Courts of some decisions.).
- Appeals being made to the Board of Appeal rather than having to be made to the EU Courts.
- The majority of Appellants are gaining a measure of satisfaction through the appeals process. For example, through ECHA decisions being annulled, ECHA decisions being rectified, appeals being withdrawn, and even when losing cases through the clarification of important issues.

## Next Steps

During the next reporting period the BoA will deal with:

- the adoption of the first substance evaluation decisions which are likely to shed some light on areas of REACH where there appears to be differences of interpretation between registrants and the Agency;
- the first decisions under the BPR;
- adapting to revised rules of organisation and procedure of the BoA<sup>7</sup> (RoP);
- introducing new administrative arrangements BoA Chairman/Executive Director adapted to the revised RoP; and
- catching up with the back log of cases caused by events outside the control of the Board of Appeal.

## Attachments:

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

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<sup>7</sup> Commission Regulation (EC) No 771/2008

## Report from the Chairman of the Board of Appeal

- 1. Summary
- 2. Findings from BoA decisions to date
- 3. The appeals work: improving efficiency
- 4. Looking forward

### 1. Summary

Since being established in 2009, the BoA has dealt with 69 appeals. The BoA has had an increase in the number of appeals in recent reporting periods: there were 24 appeals during the current reporting period, during June 2013 to June 2014 26 appeals; whereas during June 2012 to June 2013 had 8 appeals and June 2011 to June 2012 had only 5 appeals. Over the reference period of this report, the BoA adopted 11 final decisions. In 3 cases the appeal was dismissed, in 1 case the BoA decided in favour of the appellant, and 7 cases were closed after the appellants withdrew their appeals (in three cases because the Executive Director rectified the contested decision and in four cases because the parties settled the case during the appeal proceedings). There are currently 26 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 this regard it is interesting to note that in two recent data sharing decisions, whilst the appellant lost its appeals, it also found that the BoA decision contained useful information and convincing reasons for correcting its practices as regards cost-sharing in a non-discriminatory manner. The appellant consequently accepted the BoA decision, confirming that of the Agency, without challenging it before the competent EU court. The numbers of appeals contesting SME status decisions have been significantly reduced compared with the previous reporting period and no new cases related to revocation of registration have been received. The BoA believes that this is in large part due to the major impact of decisions taken by the BoA which helped to clarify certain issues for registrants and the Agency. The appellants withdrew some of these appeals after a settlement between them and the Agency during the appeal process. The BoA also received its first appeals challenging decisions related to Biocidal Regulation No 528/2012 on technical equivalence and data sharing.

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 issues included staying proceedings if 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 because of organisational reasons (i.e. the need to give priority to some older cases over the more recent ones as a result of organisational problems outside the control of the Board of Appeal), and joining several cases together to handle them more efficiently. Five oral hearings were held as a result of the request of the Parties which enabled Appellants to express their arguments directly and the BoA to ask questions directly to the parties and interveners involved.

During the handling of each case, the BoA adopted a considerable number of procedural decisions (e.g. addressing applications to intervene, addressing requests for time extensions, summons to hearings, decisions staying the proceedings, joining similar cases). The Chairman considered some other requests for information to be kept confidential. In line with the transparency values of ECHA, the BoA publishes all appeals announcements, final decisions and the most relevant procedural decisions from closed cases, namely on 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, two Legally Qualified Alternate Members of the BoA were called to participate in eight (8) appeal cases due to the vacancy of the permanent Legally Qualified Member position (the new LQM was appointed in December 2014) thereby ensuring the continuous operability of the BoA. The MBWG-BoA was duly informed of those designations and the Chairman of the BoA reported in detail to that Working Group on this issue.

Finally, REACH 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. ECHA must be a 'learning organisation' and the BoA's decisions contribute to this end.

## 2. Findings from Decisions on Appeal Cases to Date <sup>8</sup>

The next section of this report summarises some of the key findings from BoA decisions taken over the reporting period.

### 2.1. Confirming the Agency's Position:

#### PERMISSION TO STAY ON THE MARKET

The responsibility to verify whether companies have complied with the provisions of the REACH Regulation regarding the registration of the substances they manufacture or import falls within the competence of the Member States. As a result, the BoA considers that neither the Agency nor the BoA is competent to decide whether a registrant, which has submitted a registration dossier for a phase-in substance by the deadline set in Article 23, has failed the TCC under the third subparagraph of Article 20(2), and has not yet received a registration number pursuant to Article 20(3), is permitted to continue manufacturing or importing a particular substance until a registration number is assigned by the Agency. (Decision of 03.12.2014, Case A-005-2013, *Vanadium (I)*, para. 63)

#### ADMISSIBILITY OF NEW EVIDENCE [ART. 12(1) RoP]

During the hearing in Case A-005-2013, *Vanadium (I)*, the Appellant claimed that the Agency's oral responses regarding the BRC (Business Rules) constitute new evidence. The Board of Appeal observed however that the claims related to the BRC were raised for the first time by the Appellant in its final submission prior to the closure of the written procedure and that the Agency was not given the opportunity prior to the hearing to respond to those arguments. In view of this fact, the BoA considered that the Agency's delay in offering the evidence related to the BRC is justified pursuant to Article 12(1) of the Rules of Procedure. (Decision of 03.12.2014, Case A-005-2013, *Vanadium (I)*, para. 48)

#### CONSEQUENCES OF PROCEDURAL IRREGULARITIES

According to settled case-law, a procedural irregularity leads to annulment of all or part of a decision only if it is established that the content of that decision could have differed if that irregularity had not occurred. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 104)

#### DUTIES OF A DILIGENT AND PRUDENT REGISTRANT

Every registrant has the duty to act in a diligent and prudent manner in fulfilling its obligations pursuant to the REACH Regulation (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 28).

<sup>8</sup> See Table on Annex III; in addition, all BoA decisions and the case announcements are available on line on ECHA web site

While the principle of respect for the rights of defence imposes on the [EU administration] a number of procedural obligations, it also implies a certain amount of diligence on the part of the party concerned. Accordingly, if the party concerned considers that its rights of defence have not been respected, or have not been adequately respected, in the administrative procedure, it is for the party to take the measures necessary to ensure that they are respected or, at the very least, to inform the competent administrative authority of that situation in good time (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 28).

#### **EXCUSABLE ERROR**

Human errors cannot be regarded as exceptional and unforeseeable events and therefore such errors constitute a failure to comply with the obligation to exercise due care (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 32).

The concept of excusable error, which must be strictly construed, can concern only exceptional circumstances in which, in particular, the conduct of the institution concerned has been, either alone or to a decisive extent, such as to give rise to a pardonable confusion in the mind of a party acting in good faith and exercising all the diligence required of a normally experienced trader (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 34).

#### **PROTECTION OF LEGITIMATE EXPECTATIONS**

Where the Agency has published guidelines on its administrative procedure, its discretion can be limited by such guidelines. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 82)

#### **DATA SHARING AND SHARE INFORMATION IN A NON-DISCRIMINATORY WAY**

The obligation for the Data Claimant to submit its registration dossier is not subject to any prior authorisation from the Agency regardless of whether a data sharing dispute is pending. The obligation to submit a registration dossier stems directly from the REACH Regulation. (Decision of 03.12.2014, Case A-005-2013, *Vanadium (I)*, para. 46)

It is within the Agency's discretion to carry out the Technical Completeness Check at any point within the three months granted to it under the second subparagraph of Article 20(2), regardless of whether there is a pending data sharing dispute. (Decision of 03.12.2014, Case A-005-2013, *Vanadium (I)*, para. 60)

The Agency should not, during its assessment of a data sharing dispute, examine whether the actual and precise cost of a letter of access is reasonable or justified. The BoA considers that the Agency is entitled however to make an assessment of whether each of the parties to the data sharing dispute made, pursuant to Article 30(1), '... every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way'. Furthermore, the BoA observes that this requirement should be read as a whole. In other words, the test for the Agency to apply is whether every effort was made bearing in mind the need for the cost sharing to be determined in a fair, transparent and non-discriminatory way. The BoA also highlights that the Agency's analysis of a data sharing dispute is case-specific and context driven. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 41-43)

A system whereby the costs borne by each registrant of a particular substance are subsequently adjusted to take into account the eventual number and level of registrations may, in certain circumstances, be considered to be an important point in assessing whether every effort had been made. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 53)

In its assessment of whether every effort had been made, the Agency cannot take into consideration arguments or justifications that were not made during those negotiations. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 56)

Before permission to refer is actually granted it is the duty of the Agency to clarify the individual relevant studies to which access is sought. In particular, a definitive list of the studies requested is necessary to ensure that access, if granted, is only given to the data required to cover a claimant's registration requirements. In this respect, it is also important to note that, pursuant to Article 30(3), permission to refer can only be granted to studies involving vertebrate animals and not other data that may have been part of the initial negotiations. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 74)

The task of the Agency in a data sharing dispute is to examine the efforts made by the parties to reach an agreement during data sharing negotiations. This entails examining the records of the negotiations, and the arguments presented therein, as provided by the parties to that dispute. The Agency's assessment of whether every effort is made is wholly based on the exchanges of information between the two parties. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 99)

The time at which a data sharing dispute should be lodged with the Agency and the amount of time that parties should invest in negotiating the sharing of data is entirely dependent on the facts in the particular case. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 113)

Regardless of what is in a SIEF agreement, the parties still have to make every effort and it is this that must be assessed by the Agency in a data sharing dispute. The BoA finds that, for the assessment of a data sharing dispute under Article 30(3), the actions taken from the moment the data sharing negotiations commence are the most relevant. Whilst the early circulation of a SIEF agreement is good practice, the lack of a response to this cannot be taken as agreement to the terms therein. (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 130)

## 2.2. Areas for Improvement

### **GOOD ADMINISTRATION: NOTIFICATION OF INVOICES FOLLOWING AN SME DECISION**

Questions falling within the scope of essential procedural requirements can be raised by the [BoA] of its own motion. The BoA may exercise any power of the Agency. Consequently, it is competent to examine the means used for the notification of SME verification decisions (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 23).

An invoice for the payment of a supplementary registration fee following an SME verification decision is inherently linked to the SME verification decision. It is not a merely ancillary document which does not produce legal effects (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 25).

Such an invoice should, in principle, be notified by the same means used for the notification of the SME verification decision, and in particular not only by RECH-IT but also by registered mail. There is no legal basis for the notification only via REACH-IT of acts having potentially serious adverse effects for their addressee (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, paras. 25-26).

However, an error such as the notification at issue via REACH-IT only cannot by itself lead to the annulment of the contested decision (Decision of 13.11.2014, Case A-020-2013, *Ullrich Biodiesel*, para. 27).

### **POOR ADMINISTRATIVE PRACTICES**

The BoA considers that it is poor administrative practice to attribute the same reference number to two separate letters with the same date, on the same issue, with different content, to two parties (Decision of 03.12.2014, Case A-005-2013, *Vanadium (I)*, para. 56).

**RIGHT TO BE HEARD**

The procedure for the Agency's examination of a data sharing dispute, in particular the opportunity for the parties to such a dispute to receive copies of the respective submissions, is not specifically foreseen in the REACH Regulation. Nonetheless, pursuant to Article 41(2)(a) of the Charter of Fundamental Rights of the European Union, the right to good administration includes 'the right of every person to be heard, before any individual measure which would affect him or her adversely is taken'. The BoA considers however that this does not mean that there is an automatic requirement for submissions to be cross-notified to the parties to a data sharing dispute for their observations or comments. The absence of such a step does not therefore automatically mean that there has been a breach of this right to be heard. The Agency must consider, on a case-by-case basis, what measures need to be taken in order to comply with the fundamental right to be heard (Decision of 17.12.2014, Case A-017-2013, *Vanadium (II)*, para. 98).

**ANIMAL TESTING AS A LAST RESORT: PUBLIC CONSULTATION ON TESTING PROPOSALS**

The BoA considers however that, whilst it is NOT legally obliged to do so, the Agency should consider, in certain cases, making third party consultations more explanatory so that all possibly relevant data is made available to the Agency to help it in deciding whether to approve, modify or reject testing proposals. In certain circumstances this could entail publishing in the third party consultation the actual test proposed, as well as the hazard endpoint in question. This could also contribute to fulfilling the Agency's obligations under Article 25(1) to ensure that testing on vertebrate animals is only undertaken as a last resort. In the present case it is possible that the inclusion of the hazard endpoint only could mean that some information, in relation to the EOGRTS proposed was not provided that might have been useful to the Agency in its deliberations (Decision of 09.06.2015, Case A-001-2014, *CINIC Chemicals Europe Sárl*, para. 48).

**BREACH OF THE AGENCY'S OBLIGATION TO TAKE ALL INFORMATION AVAILABLE TO IT INTO ACCOUNT, INCLUDING INFORMATION SUBMITTED TO IT AS PART OF ANOTHER DOSSIER ON THE SUBSTANCE**

The fact that the Agency has a wide margin of discretion does not, however, prevent the BoA from examining whether the Agency, when exercising its discretion, took into consideration all the relevant factors and circumstances of the situation the act was intended to regulate (see, by analogy, Case T-96/10, *Rütgers Germany GmbH and Others v ECHA*, ECLI:EU:T:2013:109, paragraph 100). In exercising its discretion the Agency is required to take into account and balance a number of, sometimes competing, considerations. For the purposes of the present case, those considerations included the need, pursuant to Article 25(1), to ensure that testing on vertebrate animals is undertaken only as a last resort, and the need for administrative efficiency (Decision of 09.06.2015, Case A-001-2014, *CINIC Chemicals Europe Sárl*, para. 74).

**BALANCE ADMINISTRATIVE WITH THE AGENCY OBLIGATIONS PURSUANT ART. 25 OF REACH**

In the specific factual circumstances of the present case (Decision of 09.06.2015, Case A-001-2014, *CINIC Chemicals Europe Sárl*) involving a testing proposal, the Agency was at fault because it does not have in place a mechanism for dealing with substantial new information submitted to it before the Contested Decision was adopted but after its cut-off point, which was unknown to the Appellant prior to the cut-off point, and that might have led to a different decision being taken. The Agency's procedures in this respect were too rigid and lead to the situation where the Contested Decision was adopted without taking into account substantial new information available prior to its adoption, and this failure could have resulted in the unnecessary use of a substantial number of animals and associated costs.

The BoA therefore finds that, in the present case, the Agency should have taken into account in the decision-making process leading to the adoption of the Contested Decision the other registrant's OECD 421 screening study. In the particular circumstances of this case, the Agency's strict application of the cut-off point, on the grounds of administrative efficiency, was



too inflexible. The Agency did not, in this particular case, take account of all the relevant facts and circumstances in balancing the need for administrative efficiency with the obligations placed on the Agency pursuant to Article 25(1). As a result, the BoA finds that the Agency's decision was in breach of Article 25(1) insofar as it did not take account of all the relevant circumstances in applying that Article. The Contested Decision should therefore be annulled and the case remitted to the Agency for further action (Decision of 09.06.2015, Case A-001-2014, CINIC Chemicals Europe Sárl, paras. 103 and 104).

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

The BoA endeavours to deliver high quality decisions. In doing so, the BoA, as any other public body, considers how to improve its efficiency in terms of time and effort without compromising the quality of its decisions. These goals must be considered in light of BoA's resources: three BoA members (during the reporting period the circumstances required that alternate legally qualified members joined the BoA), and the Registry (Registrar, four legal advisors, 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 REACH and the Rules of Procedure all cases are announced and published on ECHA's website. All final decisions are also published as well as the procedural decisions on confidentiality and on the requests for intervention. Summaries of all final decisions are published on line to help a wider audience to understand the basis of BoA decisions without necessarily having to read a long decision. A new search application on BoA's section of ECHA's website is now in operation to enable a search of all BoA decisions. Reading BoA decisions in their entirety is the best guidance for stakeholders as they can inform themselves of the approaches taken by the BoA in cases that it considered thus far. This can help potential appellants to better understand the BoA interpretation of REACH processes and help the Agency to amend its practices and processes if needed. The publication of confidentiality decisions has also helped to refine or avoid unnecessary requests (i.e. appellants know that it is not necessary to request confidential treatment for personal data because the Chairman of the BoA has already stated that personal data is not disclosed to third parties by application of Article 8 of Regulation 45/2001). That practice has therefore also significantly reduced the number of requests and allowed the BoA to focus on more substantial aspects of the appeal process.
- Learning from experience: systematic review of our practices and specially taking lessons from how things were dealt with in previous cases has helped the BoA to refine its processes. For example, preparation for oral hearings have been standardised and simplified, reducing time, costs and effort (e.g. better preparation based on previous experience, reduction in time spent for oral statements and questions, etc.). The written part of the proceedings has been also streamlined by framing at an earlier stage the information and issues likely to be relevant for the final decision and avoiding, as far as possible, the collection of unnecessary documents and evidence. This importantly reduces the effort and time spent with unnecessary and irrelevant information which also distracts attention from the core elements of a case.
- Maintaining high quality standards for each decision: a well-reasoned, sound and rigorous decision can persuade appellants not to challenge the decisions before the General Court and in that way avoid additional efforts and expenses that the Agency would need to commit in defending the case before the EU Courts. A sound, clear and well-argued BoA decision is the best tool for ensuring efficiency. To date no BoA decisions have been taken before the General Court by unsuccessful appellants.
- Good BoA decisions also enable ECHA to change its administrative practices and processes, if necessary, so that future appeals may be avoided in the first place. This for example seems to

be the case with the various BoA decisions on SME related issues and the ECHA actions taken as a result of the appeals and the BoA decisions.

- Improve interaction between BoA members, AAMs and the Registry: During the reporting period 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 trained 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 AAMs, BoA and the Registry will be held in the 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 as well as the new two Legally Qualified Members appointed in 2014, on the AAMs' interactions with the rest of the case team. 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 has been implemented with all BoA members and alternates, including for the relevant staff members of the Registry.

With regard to the duration of appeals, whilst there is no legal deadline for deciding on appeals, the BoA has set a performance indicator<sup>9</sup> to adopt the decision in an appeal case within 90 working days (this starts from the conclusion of the oral hearing or, if no hearing is held, 14 days after the closure of the written procedure). In the reporting period all cases have been decided within this time. During the reporting period the longest time spent in the processing of an appeal has been 17 months.

## 4. Looking forward

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

### 4.1. First decisions on Substance Evaluation (SEv)

At the time of drafting this report five SEv related appeals have been lodged. The first oral hearing on substance evaluation has already been held and the final decision will be ready for adoption soon. In deciding on specific cases, the BoA will have the opportunity to provide its view on essential issues under dispute such as the scope of the SEv process (based on hazard; based on risk; suspected risks; standard information etc.), the proportionality test applied to the measures imposed, and the relationship between SEv and dossier evaluation (DEv).

### 4.2. First decisions related to biocides

The first decisions against ECHA decisions taken under the BPR will be adopted during the course of 2016, in particular, on appeals against data sharing decisions. The Registry of the BoA has recruited a new legal advisor that previously worked in the field of biocides. The BoA will, as resources allow, continue to raise awareness among stakeholders on the scope of appeals and the appeals process under the BPR.

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

At the 32nd meeting of the Management Board, the MBWG-BoA presented its opinion on the need to review the Rules of organisation and procedure of the BoA (the 'Rules of Procedure' or

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<sup>9</sup> Annual work programme

'RoPs'). The Commission has undertaken the review in cooperation with BoA, ECHA Secretariat and the Management Board through the MBWG-BoA. The review will include procedural changes in appeals' handling and organisational aspects for the BoA. The representative of the Commission within the MBWG-BoA will report to the plenary after the Chairman's June report on this matter.

As regards possible changes affecting the appeals procedure, the BoA has provided its inputs to the Commission (for example, deadlines for submitting the defence, simplify the handling of confidentiality issues, amicable solutions procedures, etc.) based on its experience acquired in appeal proceedings so far.

#### **4.4. Prolongation of mandates of TQM and certain alternates<sup>10</sup>**

The term of office of the technically qualified member (Mr Andrew Fasey) expires on 14 March 2016. Following the ECHA practice on prolongation of staff members' contracts notices the MB shall decide at the June meeting on the prolongation of the term of office of the current TQM. In this plenary session the MB should decide as well on the prolongation of the terms of office of three alternate-Chairmen: Messrs Ioannis Dimitrakopoulos, Christopher Hughes and Christoph Bartos.

Finally, it should also be recalled that Mr Andreas Bartosh, who was appointed as alternate chairman until November 2014 informed the BoA Chairman and the MB secretariat that he was not interested in a prolongation of his mandate and his term of office was not prolonged.

As regards the alternate and additional members, the terms of office of the two technically qualified alternate members (Ms Jonna Sunell-Huett and Mr Arnold van der Wielen), two legally qualified members (Messrs Rafael López Parada and Barry Doherty) and the Chairman of the BoA were prolonged for a second and last mandate of 5 years, until 2019.

To conclude, I would like to share with the management Board my reflection that what the BoA needs now more than anything is a period of stability with the full support of the MB and the ECHA Secretariat where it can concentrate on making important decisions without other distractions such as possible changes to its structure and composition. Once the new RoPs are agreed and implemented the BoA needs to be allowed to focus on its primary objective, that is making high quality decisions, with the full support of the MB and the ECHA Secretariat.

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

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<sup>10</sup> See table with all members and their respective term of office in Annex II

**ANNEX II****Table of BoA members: full time and alternate members  
(June/2015)**

Name	Role	Term started	Term ends
Mercedes <b>ORTUÑO</b>	Chair	15 Apr 2009	14 April 2019**
Andrew <b>FASEY</b>	TQM	15 March 2011	14 March 2016*
Dimitrina <b>PETROVA</b>	LQM	1 December 2014	P/P 31 August 2015***
Christoph <b>BARTOS</b>	Alt Chair	15 Oct 2010	14 October 2015*
Ioannis <b>DIMITRAKOPOULOS</b>	Alt Chair	15 Oct 2010	14 October 2015*
Cristopher <b>HUGHES</b>	Alt Chair	15 Oct 2010	14 October 2015*
Harry <b>SPAAS</b>	TQAAM	01 Dec 2010	30 November 2015*
Jonna <b>SUNELL-HUET</b>	TQAAM	16 May 2009	15 May 2019**
Arnold <b>VAN DER WIELEN</b>	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. <b>Moreno Molina</b>	LQAAM	1 December 2014	30 November 2019*
Sakari <b>Vuorensola</b>	LQAAM	1 December 2014	30 November 2019*

\*-First mandate

\*\* - Second and last mandate

\*\*\*-Expiry of probationary period

**Registry Unit supporting BoA's work**

- 1 Registrar: Sari **HAUKKA**
- 4 legal advisors
- 2 legal assistants
- 2 secretaries

## ANNEX III

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
69	<u>A-013-2015</u> OPEN	23/04/2015	Evonik Degussa GmbH	Compliance check	
68	<u>A-012-2015</u> OPEN	18/03/2015	SHARDA EUROPE B.V.B.A.	Data Sharing BPR	
67	<u>A-011-2015</u> 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	<u>A-008-2015</u> OPEN	16/03/2015	Evonik Degussa GmbH	Compliance check	
63	<u>A-007-2015</u> OPEN	12/03/2015	Celanese Chemicals Europe GmbH	Compliance check	
62	<u>A-006-2015</u> 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	<u>A-002-2015</u> CLOSED	17/02/2015	Lubrizol SAS	Compliance check	Final Decision 04/05/2015 Rectified by ED
57	<u>A-001-2015</u> 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	Stay of proceedings
55	<u>A-017-2014</u> OPEN	17/12/2014	BASF SE	Compliance check	Stay of proceedings
54	<u>A-016-2014</u> 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	Stay of proceedings
52	<u>A-014-2014</u> OPEN	11/12/2014	BASF Pigment GmbH	Compliance check	
51	<u>A-013-2014</u> OPEN	10/12/2014	BASF SE	Substance Evaluation	Stay of proceedings

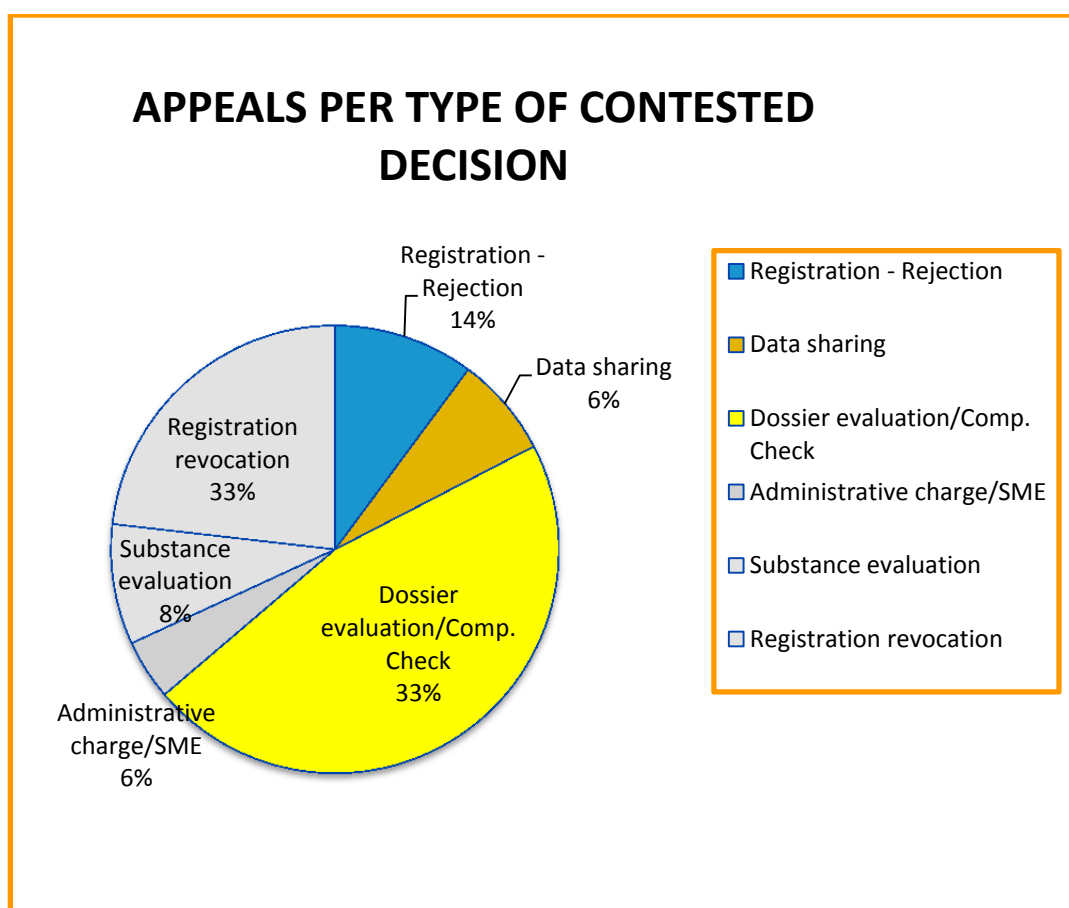
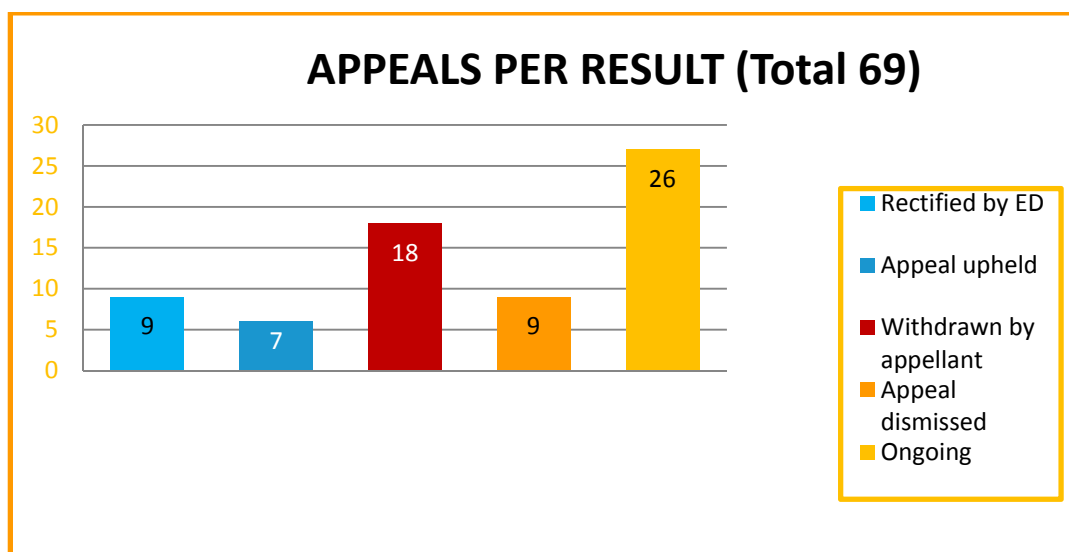
No.	Case No.	File Date	Appellant	Keywords	Result/decision date
50	<a href="#"><u>A-012-2014</u></a> OPEN	21/11/2014	HUNTSMAN HOLLAND BV	Compliance check	Stay of proceedings
49	<a href="#"><u>A-011-2014</u></a> OPEN	16/09/2014	Tioxide Europe Ltd and others	Compliance check	Stay of proceedings
48	<a href="#"><u>A-010-2014</u></a> OPEN	28/08/2014	Nordenhamer Zinkhütte GmbH	Compliance check Intermediate	Stay of proceedings
47	<a href="#"><u>A-009-2014</u></a> OPEN	22/08/2014	Albemarle Europe SPRL and others	Substance evaluation	
46	<a href="#"><u>A-008-2014</u></a> OPEN	14/08/2014	CROSFIELD ITALIA S.r.l.	SME status	Stay of proceedings
45	<a href="#"><u>A-007-2014</u></a> CLOSED	27/05/2014	SA Azko Nobel Chemicals NV	Testing proposal	Final Decision 11/07/2014 Withdrawal by Appellant
44	<a href="#"><u>A-006-2014</u></a> OPEN	26/05/2014	International Flavours & Fragrances B.V.	Substance evaluation	
43	<a href="#"><u>A-005-2014</u></a> OPEN	26/05/2014	Collective appeal representing several Appellants	Substance evaluation	
42	<a href="#"><u>A-004-2014</u></a> OPEN	16/05/2014	Collective appeal representing several Appellants	Substance evaluation	
41	<a href="#"><u>A-003-2014</u></a> CLOSED	17/04/2014	Aluwerk Hettstedt GmbH	SME status	Final Decision 16/12/2014 Withdrawal by Appellant
40	<a href="#"><u>A-002-2014</u></a> CLOSED	17/04/2014	Richard Anton KG	SME status	Final Decision 15/12/2014 Withdrawal by Appellant
39	<a href="#"><u>A-001-2014</u></a> OPEN	15/01/2014	CINIC CHEMICALS EUROPE SARL	Testing proposal Information in other dossiers	
38	<a href="#"><u>A-022-2013</u></a> OPEN	12/12/2013	REACheck Solutions GmbH	Registration Completeness check Absence of data sharing	
37	<a href="#"><u>A-021-2013</u></a> CLOSED	20/11/2013	Zementwerk Hatschek GmbH	Revocation of registration number	Final Decision 5/11/2014 Withdrawal by appellant
36	<a href="#"><u>A-020-2013</u></a> CLOSED	11/11/2013	Ullrich Biodiesel GmbH	Rejection of registration	Final Decision 13/11/2014 Appeal dismissed
35	<a href="#"><u>A-019-2013</u></a> OPEN	25/10/2013	Solutia Europe sprl/bvba	Statement of compliance	
34	<a href="#"><u>A-018-2013</u></a> CLOSED	23/10/2013	BASF SE	Compliance check	Final Decision 05/12/2013 Rectified by ED
33	<a href="#"><u>A-017-2013</u></a> 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 href="#"><u>A-016-2013</u></a> OPEN	15/10/2013	Marchi Industriale SpA	SME status 'Linked enterprises'	Stay of proceedings

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
31 30 29 28 27	<u><a href="#">A-015-2013</a></u> <u><a href="#">A-014-2013</a></u> <u><a href="#">A-013-2013</a></u> <u><a href="#">A-012-2013</a></u> <u><a href="#">A-011-2013</a></u> CLOSED	09/09/2013	Confidential	Revocation of registration number	Final Decision 01/04/2014 Withdrawal by Appellant
26	<u><a href="#">A-010-2013</a></u> CLOSED	29/08/2013	Tecosol GmbH	Revocation of registration number SME status	Final Decision 22/01/2014 Withdrawal by Appellant
25 24 23	<u><a href="#">A-009-2013</a></u> <u><a href="#">A-008-2013</a></u> <u><a href="#">A-007-2013</a></u> CLOSED	15/08/2013	Hermann Trolius GmbH	Revocation of registration number SME status	Final Decision 08/01/2014 Withdrawal by Appellant
22	<u><a href="#">A-006-2013</a></u> CLOSED	15/08/2013	Hermann Trolius GmbH	SME status Language of communication	Final Decision 08/01/2014 Withdrawal by Appellant
21	<u><a href="#">A-005-2013</a></u> CLOSED	07/08/2013	Vanadium R.E.A.C.H. Forschungs- und Entwicklungsverein	Data sharing Permission to refer	Final Decision 03/12/2010 Appeal dismissed
20	<u><a href="#">A-004-2013</a></u> CLOSED	01/08/2013	Cromochim SpA	Revocation of registration number SME status	Final Decision 05/12/2013 Withdrawal by Appellant
19	<u><a href="#">A-003-2013</a></u> CLOSED	08/05/2013	Poudres Hermillon Sarl	Revocation of registration number SME status	Final Decision 14/01/2014 Withdrawal by Appellant
18	<u><a href="#">A-002-2013</a></u> CLOSED	19/04/2013	Distillerie DE LA TOUR.	Revocation of registration number SME status Administrative charge	Final Decision 21/05/2014 Appeal upheld
17	<u><a href="#">A-001-2013</a></u> CLOSED	08/02/2013	Infineum UK Ltd	Compliance check Substance identity	Final Decision 09/04/2014 Appeal dismissed
16	<u><a href="#">A-008-2012</a></u> 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	<u><a href="#">A-007-2012</a></u> 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	<u><a href="#">A-006-2012</a></u> CLOSED	20/09/2012	Momentive Specialty Chemicals B.V.	Compliance check Use of read-across data	Final Decision 13/02/2014 Appeal dismissed
13	<u><a href="#">A-005-2012</a></u> CLOSED	01/08/2012	SEI EPC ITALIA SpA	Administrative charge SME status	Final Decision 27/02/2013 Appeal dismissed
12	<u><a href="#">A-004-2012</a></u> CLOSED	05/07/2012	Lanxess Deutschland GmbH	Compliance check Testing involving animals	Final Decision 10/10/2013 Appeal dismissed
11	<u><a href="#">A-003-2012</a></u> CLOSED	25/05/2012	THOR GmbH	Compliance check Updated dossier	Final Decision 01/08/2013 Appeal upheld
10	<u><a href="#">A-002-2012</a></u> CLOSED	30/04/2012	BASF SE	Testing proposal Updated dossier	Final Decision 21/06/2012 Rectified by ED
9	<u><a href="#">A-001-2012</a></u> CLOSED	24/01/2012	Dow Benelux B.V.	Compliance check Rejection of suggested read-across	Final Decision 19/06/2013 Appeal dismissed
8	<u><a href="#">A-006-2011</a></u> CLOSED	03/08/2011	5N PV GmbH	Administrative charge SME status	Final Decision 30/11/2011 Withdrawal by

No.	Case No.	File Date	Appellant	Keywords	Result/decision date
					Appellant
7	<u><b>A-005-2011</b></u> CLOSED	21/06/2011	Honeywell Belgium N.V.	Compliance check Testing involving animals	Final Decision 29/04/2013 Appeal upheld
6	<u><b>A-004-2011</b></u> CLOSED	11/04/2011	Kronochem GmbH	Rejection of registration Registration fee	Final Decision 07/10/2011 Appeal dismissed
5	<u><b>A-003-2011</b></u> CLOSED	21/02/2011	BASF SE	Data-sharing Permission to refer	Final Decision 27/05/2011 Withdrawal by Appellant
4	<u><b>A-002-2011</b></u> CLOSED	11/02/2011	Feralco (UK) Ltd	Rejection of registration Incomplete dossier	Final Decision 31/03/2011 Rectified by ED
3	<u><b>A-001-2011</b></u> CLOSED	11/02/2011	Feralco Deutschland GmbH	Rejection of registration Incomplete dossier	Final Decision 31/03/2011 Rectified by ED
2	<u><b>A-001-2010</b></u> CLOSED	21/12/2010	N.V. Electriciteits – Produktiemaatschappij Zuid-Nederland EPZ	Rejection of registration Registration fee	Final Decision 10/10/2011 Appeal upheld
1	<u><b>A-001-2009</b></u> CLOSED	16/09/2009	Specialty Chemicals Coordination Center sa/nv	Rejection of registration Incomplete dossier	Final Decision 30/10/2009 Rectified by ED



## Graphics



# Graphics

