Helsinki, 21.06.2012

Report from the Chairman of the Board of Appeal

Meeting of the Management Board 20-21 June 2012

Item	15
Action	For information
Status	Final - Internal

Outline

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1. Summary

The ECHA Board of Appeal (BoA) is now receiving a steady stream of appeals, albeit at a slower rate than was envisaged. Over the reference period of this report -June 2011 up to now- decisions were taken by the BoA on 2 appeals that went through the entire appeals process; 1 decision was taken supporting the appeal and 1 decision was taken supporting the original ECHA decision. In addition, 1 appeal was withdrawn by the Appellant. A further 4 appeals are on going.

The experience of the BoA to date is that the appeal cases prove to be more complicated than they appear at first sight from a legal and/or scientific perspective. In addition appeal cases have proved to be procedurally challenging when there are (multiple) claims for confidentiality and applications to intervene in a case. A large number of procedural decisions (for example, addressing requests for information to be kept confidential, applications to intervene, a request to rectify a BoA decision, requests for observations from the parties and/or interveners, specific questions posed to the parties) have been taken by the BoA (and Chairman in the case of requests for confidentiality) on the closed cases and those still pending. The attached table sets-out the state of play on all the appeals received by the BoA to date.

The members of the BoA and the staff of the supporting Registry are gaining experience, many for the first time, with the procedures and content of a case. This experience will lead to the refinement of procedures (already the case with regard to the processing of confidentiality claims) and greater efficiency in the consideration and processing of cases.

In recognition of the fact that the number of appeals was significantly lower than expected, Registry staff are being deployed on a part-time basis to other parts of ECHA to work on projects that are not appeal related. If the number of cases increases (either REACH or, in the future, biocides related) consideration will need to be given to these staff returning to work for the Registry full-time, the increased use of the Alternate and Additional Members (AAMs), and, eventually, additional legal advisors being appointed to the Registry.

It is important for the BoA to be familiar with the 'stakeholder environment' and to raise awareness on the appeal system as a way of legal redress. To this end the members of the BoA and Registry participate in various stakeholder events (e.g. conferences, workshops). The BoA would welcome invitations from the Member States to participate in events to increase its awareness of the stakeholder environment in the member States.

2. Introduction

The aim of this document is to provide to the members of the Management Board (MB) additional and supporting information and to complement the presentation of the Chairman of the Board of Appeal (BoA) at the meeting on 20 June 2012.

As part of ECHA, the BoA reports on its activities as a part of the Annual Report of the Agency (Activity 9) and plans its short term and long term activities within the annual and multiannual work programme of the Agency (available on ECHA website).

This report provides a detailed update on the progress of the work of the BoA since the last update given to the Management Board in the meeting of June 2011.

3. Processing of Appeals

3.1. BoA Team & Management Board Working Group for the BoA

As a brief reminder, last year a new member of the Board of Appeal was appointed (Andrew Fasey, Technically Qualified Member) who joined the existing members (Mercedes Ortuño, Chairman of the Board of Appeal; and Mia Pakarinen, Legally Qualified Member).

The BoA is supported by the Registry composing the Registrar (Sari Haukka) and a team of three legal advisors and two legal assistants.

The BoA has been in regular contact with the Management Board Working Group for the BoA. Its members (Ana Fresno, Gustaaf Borchardt, and Jan Karel Kwisthout) act as reporting officers for the BoA members and carried out the 2011 appraisal exercise of BoA members in March and agreed on the 2012 objectives to be met by the BoA members.

3.2. Number & Type of Decisions; Case Allocation[1]

In 2011, three (3) cases were closed with a final decision. In addition, a higher number of procedural decisions were also taken by the BoA related to these and other appeal cases: six (6) decisions on confidentiality claims, (3) intervention requests; and forty-seven (47) decisions were adopted to resolve other questions as requesting further submissions from the parties or interveners, request to use another language, rectification applications, requests for extensions of time limits etc. The appeals contested different types of ECHA decisions including the rejection of registrations and the dossier evaluation (compliance checks). The appeals submitted have generally been very different and, without exception, have proven to be more complicated than anticipated, both in terms of the legal and scientific issues raised and the procedural measures to be taken.

Shortly after being received, the appeal cases are allocated to the BoA members by the Chairman after checking for any conflicts of interest. Members of the BoA and the alternate and additional members as well, prepare an annual declaration of interests. In addition, the BoA has a rigorous system to check for any conflicts of interest on a case-by-case basis. There have been no conflicts of interest identified or declared in the last year. Once the composition of the BoA is determined, the Chairman also designates a case rapporteur which is in charged of drafting the final decision.

3.3. Appeal process: Who, What, When

The main elements of the appeal proceedings are contained in Commission Regulation 771/2008, laying down the Rules of Organization and Procedure of the Board of Appeal (the 'Rules of Procedure'). In accordance with Recital 10 of the Rules of Procedure, in the last year, the EU Commission, in consultation with ECHA, the BoA and other affected actors, has considered whether a review of the 'Rules of Procedure' was needed on the basis of the experience gained to date. The conclusion was that whilst some changes could be considered, the limited experience with the 'Rules of Procedure' to date meant that such a review was premature.

Based on the Rules of Procedure, the Board of Appeal adopted a document explaining the basic steps of the procedure and associated timing. This document is available for the public on ECHA website[2]. Additionally, some internal organizational aspects have been identified as needed of further clarification. These aspects will be addressed in an internal procedural document (Appeal-PRO) in line with ECHA quality management policy.

The PRO out lines who is responsible to carry out tasks related to processing of an appeal and when they should be done; and in general, serves as a guide for the actors carrying out those tasks in the appeals proceedings. The PRO should also be seen as a manual providing alternate and additional members (AAMs) information on stages and tasks involved in processing of an appeal by the BoA.

3.4. Reflections on the processing of appeals up to now

[1] See table in attachment (Annex I)

[2] http://echa.europa.eu/documents/10162/13607/procedure_appeal_proceedings_before_the_boa_v01_new_coverpage_en.pdf

- Considering that the issues being raised in appeal proceedings before the Board of Appeal are new, dealing with them is time consuming. However, time spent on them now should result in their quicker resolution in the future (for example, legal research that is carried out for the first time will not have to be repeated).
- Interveners participating in appeal cases in 2011 add complexity to the appeal's proceedings, especially with regard to confidentiality issues.
- The appeal cases are procedurally more onerous than anticipated; e.g. case A-005-2011 with 120 separate communications between the BoA, the parties and the interveners and many procedural decisions required.
- BoA members and the Registry are reviewing processes and practices in light of the experience being gained; a wealth of knowledge and experience is being accumulated by individuals and the team as a whole.
- First decisions may be longer and more detailed than will be the case in the future as issues are being considered and points are being made for the first time; as more BoA decisions are published, it may not be necessary to repeat certain elements at least to the same extent.
- Decisions will be taken quicker in the future as experience is gained, processes are refined and understood, and similar issues are considered for the 2nd, 3rd, nth time.

4. Update on Appeal Cases[3]

4.1. Appeal A-001-2010: Rejection of Registration

-State of Play: On 10 October 2011, the BoA annulled the contested decision and ordered the Agency to refund the registration fee to the Appellant.

-Summary: The appeal was lodged in December 2010. The contested decision rejected a registration because of the late payment of the registration fee. As a result, the Appellant had to re-register and pay the registration fee for a second time. The contested decision also stated that the initial fee as paid would not be reimbursed.

The Appellant argued that the late payment was due to the lack of clarity of the on-line information provided by ECHA. As a consequence, the Agency received the fee twice for only one registration. The Agency's decision not to reimburse the first registration fee paid was considered by the Appellant to be unfair.

The Agency's defence was that that it took all reasonable measures to put the Appellant in a position to pay the fee on time, that the Appellant had disregarded the Agency's communications and the information provided on-line, and that the Appellant did not contact the Agency's Helpdesk for assistance

In the course of the proceedings, the BoA considered it necessary to adopt procedural measures posing questions to the parties and requesting documents. Confidentiality of certain pieces of information was requested and decided upon.

-Main conclusions of the BoA: The registration procedure under the REACH Regulation is an administrative procedure which must satisfy the criteria for good administration as laid

[3] See http://echa.europa.eu/appeals_en.asp ; see also the table and statistics in attachments

down in EU law, including in particular the general principles of law and Article 41 of the Charter of Fundamental Rights of the European Union. The Board of Appeal found that the Agency's actions and acts, in this case, did not meet the requirements of good administration, particularly as regards the requirement for clarity in communicated information.

In this case, an alternate member was called upon to work on the case because the interim vacancy of the technically qualified member. The mechanisms for working together with a non-regular BoA member worked successfully (e.g. exchange of documents, remote conferencing, confidentiality, timing and coordination).

4.2. A-004-2011: Rejection of Registration

-State of Play: on 7 October 2011 the appeal was dismissed.

-Summary: In April 2011, an appeal was filed against a decision of the Agency rejecting the appellant's registration on the grounds that the fee payment had not been received by the deadline set.

The appellant claimed that it had made its submission successfully and had fulfilled all the relevant obligations. However, due to an internal error, the necessary fee was paid 26 days after the deadline. The rejection of the registration, together and the consequent obligation to submit a new registration and to pay the registration fee again was considered disproportionate and "out of scale".

The Agency argued that it had taken all reasonable measures to put the Appellant in a position to pay the fee on time and that the failure to pay could not be attributed to the Agency. Furthermore, the Agency was obliged to reject the registration following the late payment of the registration fee and could not have adopted any other measure. The Agency had not therefore violated the principle of proportionality by adopting the contested decision.

A confidentiality request was made by the appellant which the Chairman accepted in part.

-Main conclusions of the BoA: the Appellant did not provide any grounds which could justify the Agency not applying the relevant legislation (for example, the existence of force majeure or failure by the Agency to fulfill its obligations towards it).
An error by the Appellant cannot constitute sufficient grounds for the Agency not to apply the clear provisions of the REACH Regulation and the Fee Regulation. In addition, the Appellant did not attempt in its submissions to attribute its error to the actions of the Agency. In fact, it explicitly accepted that the fault was its own.

Furthermore, the Board of Appeal did not identify from the facts presented in this case any reasons why the Agency should not have applied the provisions of the applicable legislation regarding the rejection of the registration.

4.3. A-005-2011: Dossier Evaluation (Additional information required)

-State of play: The written phase of the proceedings is on-going. The BoA is awaiting further submissions from both parties following a procedural decision of the BoA.

-Summary: In June 2011, an appeal was filed against a decision taken by the Agency in the course of a compliance check. In that decision the appellant was requested to submit

additional information following conduct of the 90-day repeated dose toxicity study by inhalation in the rabbit.

Several confidentiality requests were made by the parties and decided upon by the Chairman.

Two applications to intervene in the case were made. The applications were accepted in separate BoA decisions (a NGO and a manufacturer of the same substance). ECHA submitted a request for rectification of one of the intervention decisions; this request was rejected by a decision of the BoA.

4.4. A-006-2011: Registration Related: (SME Status)

-State of Play: on 30 November 2011 the case was closed. The appellant withdrew the appeal.

-Summary: In August 2011, an appeal was filed against a decision imposing an administrative charge following a review by the Agency of the conditions under which the appellant claimed to be eligible for the SME reduction. It was concluded that the Appellant could no longer qualify as an SME (as it was at the time of the pre-registration).

4.5. A-001-2012: Dossier Evaluation (Read Across)

-State of play: the written phase of the proceedings is on-going and further submissions have been requested by the BoA.

-Summary: In January 2012 an appeal was filed contesting a decision on a dossier evaluation of the substance dipropylene glycol methyl ether acetate (DPMA). In that decision the Agency requested the Appellant to submit additional information (studies) and did not accept a proposal for *read across* of information.

One application to intervene in the case was made (a NGO). The application was accepted in a BoA decision.

4.6. A-002-2012: Dossier Evaluation (requesting a test)

State of Play: The contested decision has been rectified by the Executive Director. The case shall be closed soon

Summary: In April 2012, an appeal was filed against a decision on a dossier evaluation for the substance Aziridine, CAS No 151-56-4 (EC No 205- 793-9) obliging the Appellant to carry out a long term fish toxicity test.

The Appellant had submitted in their registration dossier a testing proposal for a short-term fish toxicity test in order to fulfil the information requirements set out in Annex IX to the REACH Regulation. Subsequently, and based on the written comments of one of the Member State competent authorities during the evaluation process, the Appellant realised that, in their view, the test was in fact not necessary and withdrew their testing proposal.

One application to intervene in the case was made (a NGO).

4.7. A-003-2012: Dossier Evaluation (requesting a test)

-State of Play: the written phase of the proceedings is on going.

-Summary: In May 2012, an appeal was filed against a decision on a dossier evaluation. By the challenged decision, the Agency requests the Appellant to perform three additional studies. According to the appellant, in making the decision the Agency has not taken into consideration the appellant's last update to its registration dossier and the waiving concept contained in it.

4.8. Decisions taken on confidentiality requests:

In the course of an appeal procedure, procedural decisions have to be taken by the BoA, for example, responding to confidentiality claims submitted by the parties, applications to intervene in a case, requests for observations or information from the parties. Most of these decisions are taken by the BoA as a whole but decisions on confidentiality requests are taken by the Chairman. Decisions on confidentiality requests have to be properly reasoned (in accordance with the principle of sound administration) and have consequences regarding the information that is contained and available to the public (potentially in both the announcement and final decision) and, if applicable, is also provided to interveners.

In the last year, 6 confidentiality related decisions were adopted, (4 requests made by the appellant and 2 by the Agency). Typically the appellant requests several pieces of information to be treated as confidential: appellant's identity (1 instance: not granted); name of the substance (1 instance: 1 granted); business information in research works (1 instance: granted); tonnage of the substance (1 instance: dismissed as irrelevant); uses of the substance (1 result: not granted); studies (1 instance: not granted); personal data (2 instances: granted); blanket requests, without specification or justification (1 instance: rejected except for information confidential by its nature e.g. bank account numbers etc). The Agency has so far requested, in particular, confidentiality for the personal data included in its submissions; these requests have all been granted to date.
In making these decisions the Chairman consults repporteur of the respective case. Dealing with multiple confidentiality claims in the same case has proven to be particularly challenging; not only because of the number of such claims and requests but also because of the complexity of the issues arising and their implications for making information available to interveners. The approach to managing such claims has already changed in light of experience and further improvements in working methods with regard to confidentiality claims can be expected in the future.

4.9. Decisions taken on applications to intervene

As mentioned above, procedural decisions on applications to intervene have been taken in two cases. The decisions of the BoA have required substantial legal research and a consistent approach to the issue.

5. Maintaining and improving Board of Appeal's expertise

5.1. In-depth understanding on ECHA's Processes

It is the responsibility of the BoA to make timely and well reasoned decisions from the legal and technical/scientific point of view. It is therefore essential for the BoA to have an in-depth understanding of REACH processes and ECHA working methods.

Since June 2011, the training received from the ECHA operational units to date has been helpful in this regard. The BoA, and in particular the Technically Qualified Member, has designed a program coordinated with ECHA operational units, covering some of the training needs of the BoA team. Training has been received on: Substance Identity, Evaluation, Data Sharing, 'Working in SIEFs' and the work of the ECHA Committees. Recently, in the interests of maximising the effectiveness of this training to ECHA as a whole, the sessions have been open to other units. This initiative has been highly appreciated by others in ECHA, and the training sessions have been oversubscribed.

The quarterly BoA/ Executive Director meetings are also very important to ensure that the BoA is regularly updated on ECHA's main developments and on operational news. Access to ECHA's decisions, as relevant to the work of the BoA, has been implemented and facilitates the preparatory work of the BoA.

5.2. BoA involvement in ECHA's Committees and Forum

Since December 2011, the BoA has been able to participate in the meetings of the Committees' and the Forum (except in those agenda items where case related issues may be discussed). This participation provides the BoA with a better understanding of the working methods of the Committees and gives direct information on relevant matters which could be useful for producing quality decisions. In this respect the training received from the Committees' Secretariat on the functioning of these bodies was invaluable.

5.3. Contact with Stakeholders

It is also necessary for the BoA to be in contact with stakeholders and to understand the 'stakeholder environment'. In this respect the BoA members have participated in selected workshops and conferences, such as a conference on European Chemicals Policy, CEFIC workshops, National Competent Authorities, University forums etc. It is important that contacts are made with a range of stakeholders and steps are being taken to try to ensure that this is the case. Invitations from Member States to the BoA to both deliver presentations on the possibility to appeal and to hear the experiences of Member State stakeholders would be very welcome.

5.4. Networking

Lines of communication have been established with other similar bodies with more extensive experience, for example, Office for Harmonization in the Internal Market's (OHIM) BoA, Community Plant variety Office's (CPVO) BoA, and the BoA of the US Environmental Protection Agency. The BoA is both learning from the experience of others and exchanging information on relevant developments and best practice.

6. BoA Resources & Operability

6.1. BoA Resources, some Reflections

The three BoA members are supported by the Registry team (the Registrar, 3 legal advisors, 2 assistants and 2 secretaries; currently most of the Registry team also do some work for other parts of ECHA). According to the staff planning made in conjunction with the Registrar and based on the experience gained with cases to date, this staff situation would allow the BoA to deal with 12 appeals per year. If more appeals than this are submitted, the BoA will need to see whether an increased workload can be dealt with through even more efficient working, involving alternate and additional members to work on certain cases, and/or whether additional legal advisor resource should be put in place.

As the number of appeals has been lower than anticipated, and in order to maximize the potentialities of all ECHA staff, it has been agreed that if the level of workload allows it (lower than 5 pending appeals) the Registry staff shall work on a part-time basis with other ECHA Units on tasks that are not related to the subject of possible appeals, for example, Staff Regulations, procurement, CLP, access to information requests. This reallocation of resources started in May 2012.

The uncertainty related to the numbers, the type and the complexity of appeal cases makes planning of BoA/Registry resources very difficult. This leads to certain further reflections:

- At a certain point, the work of additional members could be important for processing appeals at a satisfactory rate. The regular update and training of the AAMs is therefore important
- Whilst every case is equally important, the first cases are a pioneer experience both for the individuals involved and to examine the systems and processes already put in place
- Some BoA members and the Registry staff have not yet been through a complex case from start to finish; a steep and long learning curve linked to such involvement will bring huge benefits in the future

6.2. Interaction with Alternate/ Additional Members

Since the last Progress Report presented at the Management Board in June 2011, no new Additional and Alternate Members (AAMs) have been used in appeal cases.

Thus far, only in one case an alternate member has been used. Carlo Lupi was called upon to work as the Technically Qualified Member in appeal case A-001-2010. There were no significant problems with remote communication (via conference call or CIRCABC) that worked well. It should however be mentioned that the AAM in question was not the rapporteur in the case and neither the case involved scientific issues. The effective use of AAMs will be tested in a more significant way in the future.

Once a year, a meeting is held with all the AAMs for training and information sharing purposes. In addition, an interest group within the environment of the Commission tool CIRCABC (ex-CIRCA) has been set-up for the secure exchange of information among the members. This interest group serves not only for the secure exchange of case related documents but also as a means of regularly updating AAMs on relevant issues relevant to the BoA (via quarterly letters from the Chairman to the AAMs, and a monthly legal updates). It is also possible to hold discussions on issues of relevance to the BoA and AAMs through interactive Newsgroups hosted by CIRCABC. Currently there a Newsgroup on legal matters is open.

7. Challenges

7.1. To continuously improve efficiency

Appeal cases received to date have already revealed some challenges that the BoA needs to respond to. Other challenges are more theoretical for the time being but need to be also dealt with.

The processing of appeals at a satisfactory rate is an aspiration established by REACH regulation. At the same time, the need/obligation of the BoA to have enough information on the case, in particular of the scientific matters involved and the rights of the parties to be heard requires a careful assessment in order to strike the right balance between costs, time and thoroughness.

The BoA is committed to improving its efficiency year-on-year. To this effect the BoA has for the first time introduced in its objectives a requirement to adopt final decisions within 90 working days from the close of the written or oral procedure (whichever is the latter) in 90% of cases. This objective will be reviewed in light of experience.

7.2. Staff planing with unpredictable workload

The BoA's future workload is hard to predict. To date, far fewer appeals have been received than expected but it is still too soon to know whether this trend will continue or whether, as the number of decisions on evaluation rises significantly as a consequence of the targeted approach recently announced, the number of appeals will rise.

The number and timing of appeals will also in part be linked to the various deadlines (e.g. registration, time limits for appeals, evaluation progress within ECHA) and the number and importance of ECHA's decisions. The registration related appeals could be linked to the number of negative decisions from ECHA; but appeals against decisions related to evaluation are less predictable as they may only require the dissenting opinions of the addressee of the decision (case owner) and the Agency (for example, about scientific matters or about the interpretation of technical requirements).

The Registry team supporting the BoA's activities needs to be put in place despite the lack of certainty on the base line figures (numbers of appeals). Resources have to be estimated on the basis of theoretical calculations and tentative figures provided by the Agency. Different workload scenarios have to be foreseen and flexible solutions have to be found. For example, the partial redeployment of staff as is currently being trialled.

7.3. New competences under Biocidal Products Regulation

The prospective Regulation on Biocidal Products, already adopted by the Council and the European Parliament, attributes competences to the BoA on certain decisions, such as technical equivalence of products, data sharing and authorisations. The number of potential appeals remains of course uncertain but the BoA has to be prepared to process and consider any such appeals as and when they arrive.

7.4. Implications of 2013 Registration deadline of 2013

A known challenge is the next registration deadline. Many smaller companies will be preparing for the 2013 registration deadline. These companies may have fewer resources,

less experience of regulatory chemicals issues and REACH in particular and there may be more data gaps for the substances subject to registration. This may well result in more data-sharing disputes as well as a greater number of questions on the compliance of registration dossiers, generating appeal cases in the future.

7.5. Keeping high level of knowledge on legal/scientific developments

It is likely that the evaluation related cases which come to the Board of Appeal are those ones which entail particular difficulties of interpretation as one would assume that most straightforward disputes are solved in the course of the operational process.

It is therefore essential to maintain a high level of technical expertise which allows understanding of the intricate aspects of those cases. This is not easy if the regular Technically Qualified Member is not considered as part of the scientific community of the Agency, whilst at the same time maintaining his impartiality. Partial solutions to this problem have already been identified but more needs to be done (regular contacts with ECHA experts to discuss technical and scientific issues which do not concern a particular case, participation in scientific platforms, colleagues to use as 'sounding boards' (e.g. from the authorisation side of the house etc).

8. Action requested

The Management Board in invited to take note of the information provided in this report.

Attachment:

Annex I Appeals' table

Annex II Statistics

Helsinki, 21.06.2012

Annex I

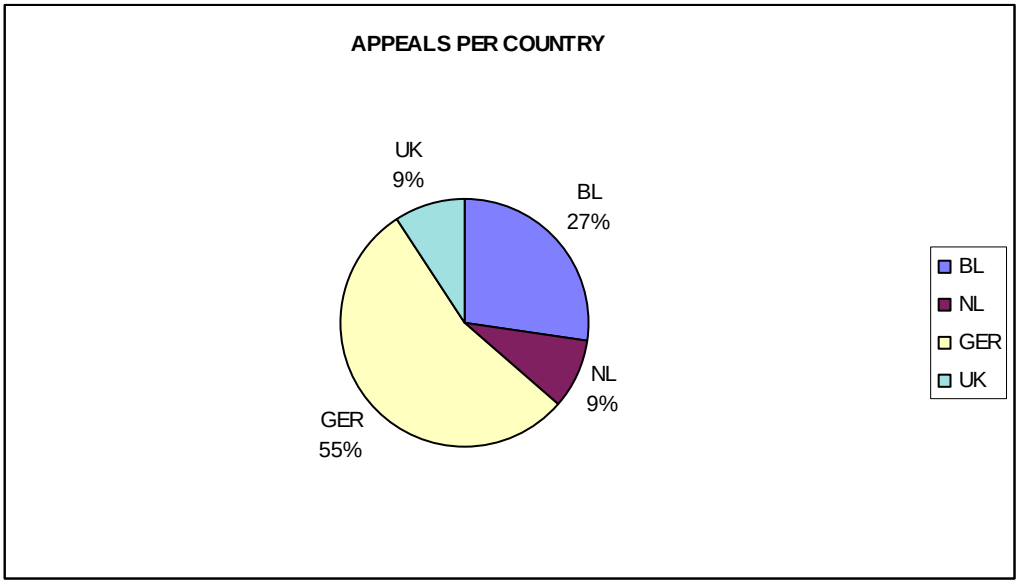
APPEALS' TABLE

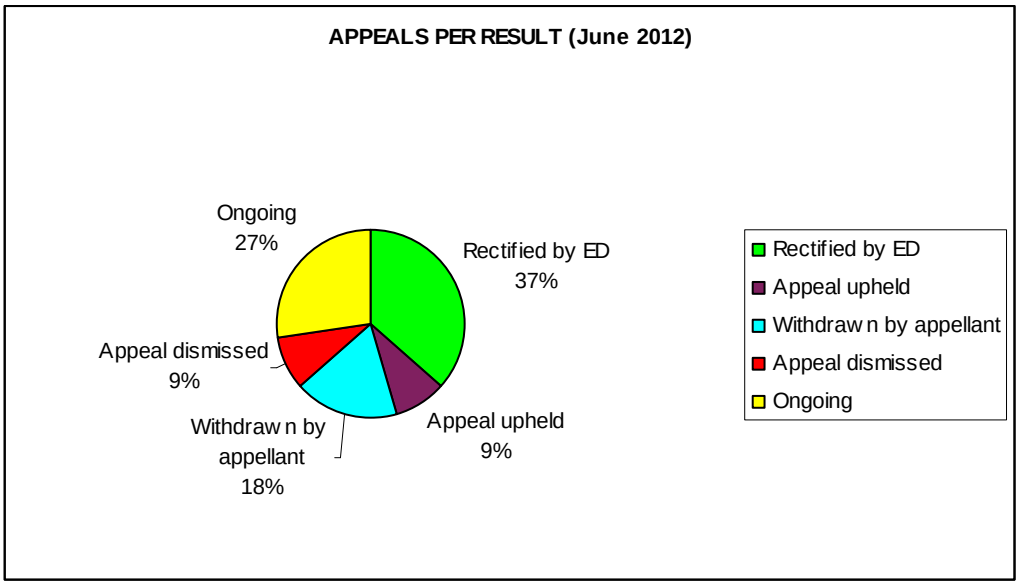
Order of Reception at BoA	Appeal Case number	Appellant	Country	Decision Being Appealed	Confidentiality Claims	Days from filing to Closure of Written Procedure	Days from CWP to final decision§	Days from filing to final decision	Case status	Results
1	A-001-2009	Specialty Chemicals Coordination Center sa/nv	BL	Registration - Rejection (incomplete dossier)	YES	N/A	N/A	44	Closed 30/10/2009	Rectified by ED
2	A-001-2010	Appellant: N.V. Elektriciteits – Produktiemaatschappij Zuid-	NL	Registration - Rejection (Late payment)	YES	259	34	293	Closed 10/10/2011	Appeal Upheld
3	A-001-2011	Feralco Deutschland GmbH, Germany	GER	Registration - Rejection (incomplete dossier, missing: production volumes	NO	N/A	N/A	48	Closed 31/03/2011	Rectified by ED
4	A-002-2011	Feralco (UK) Ltd	UK	Registration - Rejection (incomplete dossier, production volumes missing)	NO	N/A	N/A	48	Closed 31/03/2011	Rectified by ED
5	A-003-2011	BASF SE	GER	Data Sharing (Failure to make all efforts "every effort" to ensure that test costs were shared in a fair, transparent and nondiscriminatory way)	YES	N/A	N/A	95	Closed 27/05/2011	Withdrawn by Appellant
6	A-004-2011	Kronochem GmbH	GER	Registration - Rejection (Late payment)	NO	119	60	179	Closed 07/10/2011	Appeal dismissed
7	A-005-2011	Honeywell	BL	Dossier evaluation (requiring additional testing)	YES	_	_	_	Ongoing	Ongoing
8	A-006-2011	5N PV GmbH	GER	Administrative Charge Change of fee from SME to large and administrative charge	NO	N/A	N/A	119	Closed 30/11/2011	Withdrawn by Appellant
9	A-001-2012	Dow Benelux	BL	Dossier evaluation (read across of information)	NO	_	_	_	Ongoing	Ongoing

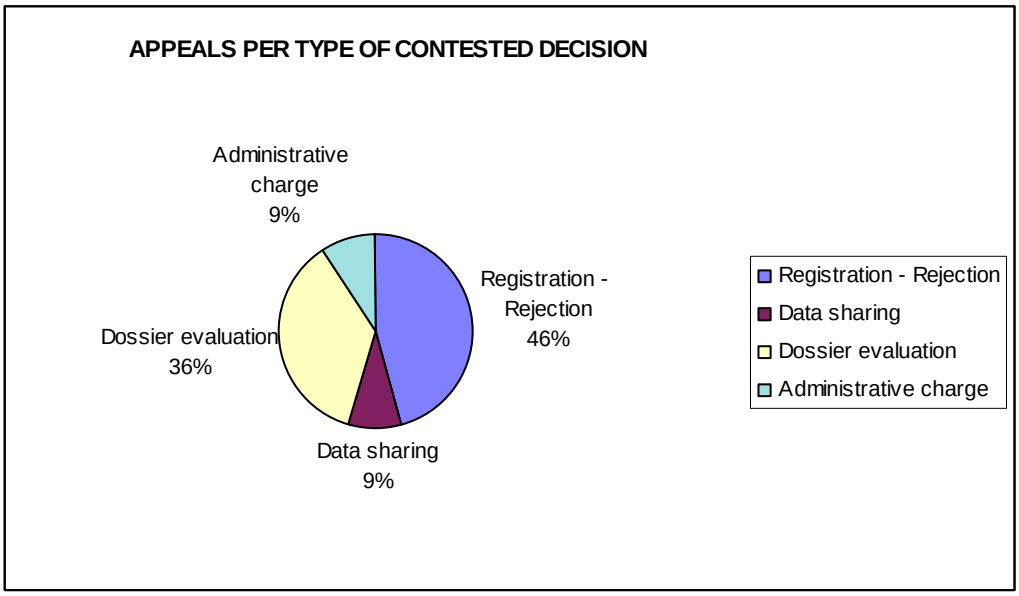
§ The objective of the BoA is to take the final decision within the 90 working days following the closure of the written procedure (ECHA Work Programme 2013, Activity 9)

10	A-002-2012	BASF SE	GER	Dossier evaluation (update of dossier; waiving of testing proposals)	YES	_	_	_	Ongoing	Rectified by ED
11	A-003-2012	THOR GmbH	GER	Dossier evaluation (late update of dossier; Evaluation of waiving arguments)	YES	_	_	_	Ongoing	Ongoing

STATISTICS **Annex II**






APPEALS PER TYPE OF CONTESTED DECISION
Administrative charge 9%
Registration - Rejection 46%
Dossier evaluation 36%
Data sharing 9%
Registration - Rejection
Data sharing
Dossier evaluation
Administrative charge