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Annual report from the Chairman of the Board of Appeal

50th Meeting of the Management Board 20-21 June 2018

Key messages

- BoA's decisions have helped clarify the interpretation of REACH[1] and the BPR[2] and helped ensure their effective implementation by ECHA. After the adoption of more than 100 decisions, it is clear that BoA's decisions are widely accepted by stakeholders, provide an effective legal remedy to appellants, and create a safety net to the Agency.

- BoA has raised the standards of good administration that ECHA has to observe as manager of REACH processes.

- BoA, its members and the Registry work independently, impartially and to a consistently high standard. There is however no slack in the BoA or its Registry to enable non-priority tasks to be undertaken or to cover any absences (planned or otherwise).

- BoA decisions are widely accepted by the parties to appeal proceedings. Three BoA decisions (from more than a hundred) have been challenged before the General Court of the EU: one by the appellant, one by a Member State, and one by an animal welfare NGO. The appeals process and the decisions of the BoA are a powerful filter for avoiding unnecessary litigation before the EU Courts.

- The outcome of BoA decisions is balanced. 24,5% of cases are decided in favour of appellants and 24,5 % of cases are dismissed. 51% of cases are closed following withdrawal of the appeal; in majority of these cases, either after the Executive Director has rectified the contested decision or the parties have settled the appeal.

- BoA has put in place open and accessible proceedings where all relevant interests can be heard before a decision is taken by BoA[3]. BoA has integrated the views of NGOs and animal welfare associations into many of its appeal proceedings, consistent with the stakeholder approach throughout the REACH system and the Aarhus Convention.

- When deciding on appeals, the BoA examines the pleas, arguments and evidence put forward by the parties. When BoA finds in favour of an appellant, it can either annul and remit the case back to the Agency or substitute the contested decision with its own decision. The standard of review applied by the BoA has been challenged before the General Court.[4] BoA expects that the forthcoming judgements of the General Court will provide clarity as to how the BoA performs its review of ECHA's contested decisions. The outcome in these Court cases could have major implications on the resources needed by the BoA, in particular in the Registry which supports its work[5].

- BoA performance, efficiency and effectiveness cannot be judged by the number of decisions taken or how long it takes to make these decisions. Such a view is too restricted as it misconstrues the purpose of the BoA. Whilst BoA decisions are case-specific, they often have a considerable impact on the implementation of REACH and the BPR and their application by ECHA.

- BoA has consistently made efforts to improve its efficiency. BoA has implemented its procedures[6] in a way that ensures that appeals are processed quickly, thoroughly and fairly (e.g. allowing a single appeal by different addresses of the same decision, joining appeal cases when appropriate, simplifying the processing of confidentiality requests and informing parties as early as possible of the likely date of a hearing).

- Feedback from industry on the operation of the BoA is positive overall.[7]

- The 2018 REACH Review report considered that '*Overall, the experience after 10 years of operation of REACH is that the BoA is a vulnerable body, depending on the solid performance of its members as well as their interpersonal relationships, as all BoA members have equal voting rights. Given that, according to REACH, there can only be one technically qualified member in the BoA, it has become clear that the assistance provided by the Registrar to the BoA should be strengthened to cover scientific aspects, and not be limited as it is today to legal research and drafting*'. The resources of the

BoA, in particular the scientific expertise should be therefore strengthened to support, in particular, the Chair and the legally qualified member.

- In next few years the current composition of the BoA will change[8]. The Chair's term of office runs until early in 2019 and the technically qualified member's until early 2021. As the responsible bodies for the selection of BoA members, the European Commission and Management Board should carefully plan the process, with a goal of ensuring the continuity of the BoA's work as well as a proper and timely handover of tasks.

Background

As part of ECHA's organisational structure, the BoA reports on its activities in the annual General Report of the Agency[9] and outlines its short and long-term activities within the planning and reporting cycle of the Agency. The Chairman of the BoA presents more comprehensive information at every June plenary session of the Management Board. Annex I contains the Report on the work of the BoA during the reporting period running from 10 June 2017 to 6 June 2018.

In addition, being this report the last one to be presented by the Chairman before the termination of her second and last term of office, an overview of 10 years of BoA work is included in Annex II. Annex III and IV contain information on members terms of mandate and statistics.

Finally, it should also be noted that the Chairman is in regular contact with the Management Board Working Group for the BoA (the 'MBWG-BoA')[10]; three of its members are also reporting officers for the BoA members. The MBWG-BoA reports to the plenary providing information on BoA developments from a different perspective.

Rationale

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

Drawbacks

N/A

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[1] Regulation (EC) No 1907/2006 of the European Parliament and of the Council concerning the Registration, Evaluation, Authorisation and Restriction of Chemicals (OJ L 396, 30.12.2006, p. 1; corrected by OJ L 136, 29.5.2007).
[2] Regulation (EU) No 528/2012 of the European Parliament and the Council regarding the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).
[3] Commission Staff Working Document accompanying the COM(2018) 116 Communication on Commission General Report on the operation of REACH and review of certain elements, SWD(2018) 58 final, 5 March 2018, pp. 19–21, available here.
[4] Action brought on 28 February 2017 in Case T-125/17 *BASF Grenzach* v *ECHA*; and action brought on 20 November 2017 in Case T-755/17 *Germany* v *ECHA*.
[5] Currently there are nine staff members working in the Registry; five of them are lawyers. Four are directly supporting BoA's activity in relation to appeal cases.
[6] Commission Regulation (EC) No 771/2001 laying down the rules of organisation and procedure of the Board of Appeal of the European Chemicals Agency (OJ L 206, 2.8.2008, p. 5), as amended by Commission Implementing Regulation (EU) 2016/823 (OJ L 137, 26.5.2016, p. 4).
[7] See footnote 3 above.
[8] Current BoA Chairman's term of office ends in April 2019, Technically qualified member recruitment will be required at the latest in 2020, and Legally qualified member first term of office ends in October 2020.
[9] Under Activity 9.
[10] MB WG-BoA is composed of: Mr Hans Meijer (Chair of the MBWG-BoA), Ms Luminiţa Tîrchilă, Ms Miroslava Bajaníková, Mr Kęstutis Sadauskas and Mr Oscar Gonzalez Sanchez.

Attachments:

- Annex I Report from the Chairman of the Board of Appeal
- Annex II Overview of 10 years of BoA work and its findings
- Annex III Table of BoA Members and their terms of office and numbers of staff in the Registry of the BoA
- Annex IV Appeals in graphics

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ANNEX I

Report from the Chairman of the Board of Appeal

1. Introductory remarks

The appeals system is the internal review mechanism set up by REACH to obtain a legal remedy for those adversely affected by certain ECHA decisions. The BoA is competent to review in an impartial and independent manner ECHA decisions regarding the main REACH processes, namely registration (including data sharing) and evaluation (including both dossier and substance evaluation). The BoA is also competent to review ECHA decisions taken under the BPR, including data sharing, technical equivalence, SME status and payable fees. The BoA is composed of three members appointed by the Management Board.

When deciding on a case, the BoA considers the pleas and arguments of the appellants and examines whether the contested decisions comply with REACH, BPR and associated implementing regulations and with EU law in general. An appeal before BoA has suspensive effect, meaning that the addressee of the contested decision does not have to comply with it until BoA decides on the appeal.

BoA decisions are decisions of the Agency. They can be challenged before the General Court of the European Union. So far, three BoA decisions have been challenged before the General Court; one case was dismissed as inadmissible and the other two cases are still pending. Their outcome may have a significant impact on the scope and extent of the BoA's review in substance evaluation cases, and in general under REACH.

This report contains information on how the BoA works and its results, in particular the main findings of the decisions, during the reporting period from June 2017 to June 2018.

2. Summary

During the reporting period, the BoA processed 35 appeals; 17 cases were closed with a final decision (7 after the appeal has been withdrawn) and 18 are ongoing. 11 oral hearings were held in this period. In addition to the final decisions, many procedural decisions were adopted in the course of the proceedings (12 decisions on intervention, 2 on confidentiality, 11 on stay of proceedings decision and 1 decision joining the cases). The number of procedural measures (consisting of e.g. questions to parties, inviting them to make submissions) prescribed by the BoA was around 600. The number of documents registered (incoming and outgoing documents) in the Register of appeals during the reporting period is close to 900. The average duration of an appeal is close to 15 months.

During the reporting period the BoA was called to decide upon several new issues. For example, the BoA decided upon consolidation of a single registration into the joint submission; information requirements on nanomaterials; interaction between REACH and the Cosmetics Regulation; whether the Agency can request 'standard information' during substance evaluation; and the conditions under which the Agency can request further information to clarify persistency properties. In that regard, it should be noted that, almost all appeal cases that the BoA handles are legally and scientifically complex and relate to grey areas of REACH and the BPR. The BoA has to make high quality decisions, in a timely

fashion for these appeal cases.

The performance objective set for the BoA for processing appeals 'at a satisfactory rate'[11] is that 80% of final decisions will be made within 90-working days of the closure of the written procedure (or after the hearing); and that the average time to process an appeal should not exceed 15 months. In the reporting period, the BoA processed an appeal in 14 months on average, while the final decisions were completed in 90 days in 60% of cases. The 90 days indicator was exceeded in some cases because of the complex, mainly technical issues, that required in-depth examination of circumstances of the given case and possible effects of the BoA decision on implementation and application of the REACH Regulation. It should also be remembered that decisions cannot be agreed and finalised in the absence of a BoA member.

The trend observed is the increase in the number of appeals concerning dossier evaluation, including both compliance check and testing proposals[12] cases, and a slight decrease in the number of substance evaluation appeals, which probably corresponds with the lower number of appealable decisions of that kind taken by the Agency over the same period.

The activity of the BoA is made as transparent as possible. All appeal announcements and final decisions are published on line. After an appeal case is concluded, the BoA also publishes a summary of the final decision and the main procedural decisions adopted.

During the reporting period, an alternate Technically Qualified Member (TQM) participated in one case. This was due to a potential conflict of interest. In order to ensure that appeals are processed without unnecessary delay, the appointment of an alternate TQM helped to ensure the continuous operability of the BoA. The MBWG-BoA was duly informed of those appointments.

3. Main BoA findings during the reporting period[13]

This section summarises some main findings and conclusions in decisions that the BoA adopted during the reporting period. The findings are presented under relevant REACH process or under BPR matters.

3.1. REACH Regulation

3.1.1 Registration

- **Consolidation of a single registration into the joint submission**

The BoA dismissed as inadmissible the appeal of an Agency 'joint submission dispute' decision. The registrant was relying on Article 11 to opt-out completely from the joint registration of a substance. Under the Agency's registration procedures, the registrant, in order to finalise its registration, had to negotiate access to an alphanumerical token in possession of the appellant, who was a lead registrant. As the registrant and the appellant did not manage to find an agreement, the registrant as the claimant filed, as per the Agency's procedure, a 'joint submission dispute'. Following that procedure, the Agency granted the claimant access to the joint submission lead by the appellant. The appellant appealed that decision. The BoA found that 'joint submission disputes' were not necessary under the REACH Regulation and that the Agency, as it had implemented itself the use of 'tokens' under registration, must, when requested, give the 'token' to any registrant who informs it of its decision to rely on a complete opt-out in accordance with Article 11(3). The BoA observed that the completeness and compliance check provisions of REACH Regulation require the Agency to assess that registrants relying on complete opt-outs do not submit incomplete dossiers or duplicate vertebrate animal tests (Decision of 23 March

[11] Key Performance indicators (KPI) which are set on the ECHA's Annual Working Programme
[12] 18 on compliance check vs 6 in previous reporting period. The number of testing proposals cases remained stable, at 2 for this reporting exercise and the previous one.
[13] All BoA decisions and the case announcements are available on-line on ECHA website.

2018, Case A-011-2017, *REACheck Solutions GmbH*).

3.1.2 Dossier evaluation (compliance check and testing proposal)

- **Testing proposal and the Cosmetics Regulation**

The BoA annulled a decision rejecting a testing proposal for a substance used exclusively in cosmetic products. The BoA explained that, as the registered substance was used exclusively as an ingredient in cosmetic products and, depending on how one interprets Article 18(1)(b) of the Cosmetics Regulation, testing the substance on vertebrate animals could or could not lead to a marketing ban. Because of legal certainty, the Agency should have explained in the Contested Decision how it interpreted the relationship between the REACH Regulation and Article 18(1)(b) of the Cosmetics Regulation (Decision of 12 December 2017, Case A-013-2016, *BASF Personal Care and Nutrition GmbH*).

- **Testing proposal and the legal basis for it**

The BoA held that an Agency testing proposal decision requiring the Appellant to provide information on a sub-chronicity toxicity study and a pre-natal developmental toxicity study was adopted on the wrong legal basis. As the Appellant clearly intended to submit a read-across adaptation rather than a testing proposal, the Contested Decision should have been adopted under the compliance check procedure (Article 41 of the REACH Regulation) rather than the testing proposal procedure (Article 40 of the REACH Regulation). However, this wrong choice of legal basis was not sufficient to lead to the annulment of the Contested Decision. The choice of legal basis did not deprive the Appellant of the procedural guarantees set out in Articles 50 and 51. In addition, the Agency's reliance on the testing proposal procedure rather than the compliance check procedure did not lead to a different assessment of the Appellant's registration dossier for the endpoints in question and would not have led to a different decision. The BoA also held that the Agency had not breached the REACH Regulation by rejecting the Appellant's read-across adaption. Although the Appellant had established that the two substances concerned are structurally similar it had failed to demonstrate that they had similar toxicological properties as required by Section 1.5 of Annex XI (Decision of 30 January 2018, Case A-005-2016, *Cheminova A/S*).

3.1.3 Substance evaluation

- **CoRAP**

The BoA is not competent to decide on appeals against decisions to include substances on the CoRAP (Decision of 30 June 2017, Case A-015-2015, *Evonik Degussa GmbH and Others*).

- **Nanomaterials**

In relation to two appeals against the same substance evaluation decision requesting information on four types of synthetic amorphous silica ('SAS') the BoA upheld a request for inhalation toxicity testing on four '*forms*' of one form of SAS, pyrogenic SAS. However, the BoA annulled the Contested Decision in so far as it requested information on: precipitated SAS, colloidal SAS and silica gel; surface treated SAS; and physicochemical properties and uses of '*forms'* of pyrogenic SAS (Decisions of 30 June 2017, Case A-014-2015, *Grace GmbH & Co. KG and Advanced Refining Technologies GmbH* and Case A-015-2015, *Evonik Degussa GmbH and Others*).

The BoA found that the Agency had not demonstrated a potential risk as regards precipitated SAS, silica gel and colloidal SAS. In particular, the BoA held that being a nanomaterial is insufficient on its own to justify a potential risk for the purposes of requesting information under substance evaluation. However, based on results of a study, the Agency had demonstrated a potential risk with regard to inhalation toxicity related to pyrogenic SAS. The evidence of a potential inhalation toxicity concern, taken in conjunction with the widespread exposure potential, meant that the Agency did not make an error of assessment in concluding that there is a potential risk for inhalation toxicity with regard

to pyrogenic SAS.

The BoA also held that the Agency can request information on '*forms*' of a substance as long as it can demonstrate that this information would assist in the clarification of a potential risk. The BoA found however that the request in the Contested Decision for information on the physicochemical properties of each individual '*form*' of pyrogenic SAS breached the principle of proportionality as the Agency had not demonstrated how that information would clarify the potential concern identified. The request was therefore annulled.

The BoA also found that the Agency could not rely on a general concern regarding surface-treated substances that were also nanomaterials. The Agency had to be able to demonstrate a potential risk in relation to the substance at issue. With regard to surface-treated SAS, the BoA found that the Agency had failed to demonstrate a potential risk.

- **Persistence criteria in Annex XIII**

The BoA held that registrants cannot be subjected to obligations that may turn out to be impossible to perform. It therefore annulled an obligation to achieve the aim of identifying all the metabolites of the registered substance. In addition, the Agency, supported by the eMSCA, had not established that the required TG 308 study (simulation testing in aquatic sediment system) was appropriate to measure the adsorption of the degradation of the registered substance. The BoA held that the Agency failed to establish that all the metabolites formed in the OECD TG 309 test could be identified at the low concentrations in which they would be present. It therefore annulled the obligation to identify all the metabolites of the registered substance. In addition, the Agency, supported by the eMSCA, had not established that the OECD TG 308 study on simulation testing in aquatic sediment system was appropriate to measure the adsorption of the degradation of the registered substance and how the study would clarify the identity and properties of non-extractable residues.
The persistence criteria set out in Annex XIII to the REACH Regulation concern the intrinsic hazardous properties of a substance and not the risk that a particular use or uses may pose in practice. Under substance evaluation, once the Agency has established that a substance poses a potential risk to the environment because of its persistence it may require testing in any environmental compartment to clarify the persistence of the substance. It is not obliged to choose, from several compartments, the one that mirrors most closely the distribution patterns of a substance in the environment from one particular use or user.
(Decision of 8 September 2017, Case A-026-2015, *Envigo Consulting Ltd*; challenged before the General Court in Case T-755/17 *Germany* v *ECHA*).

- **Pre-natal developmental toxicity ('PNDT') study**

The BoA rejected the Appellants' claim that the Agency had failed to demonstrate a concern related to developmental toxicity to justify the request for a PNDT study in the second species. The BoA found that in this case the results of a first species PNDT study using the substance were sufficient to justify the request for a second species study and that the Agency had not misinterpreted the results of the first species study. In addition, the BoA held that, although the second species PNDT study should ordinarily have been requested under dossier evaluation, the Agency was able to follow the substance evaluation procedure. This is due to the fact that the Agency had demonstrated a potential risk to human health and the Appellants' rights had not been prejudiced by the Agency's use of the substance evaluation procedure rather than the dossier evaluation procedure. The BoA also rejected the Appellants' argument that the Agency had exceeded its competence by making proposals for amendment during the decision-making procedure (Decision of 13 December 2017, Case A-023-2015, *SA Akzo Nobel Chemicals NV*).

- **Substance evaluation of monomers**

The BoA found that when a monomer is evaluated under substance evaluation a request for further information may extend to information on the presence of that monomer in

polymers as an unreacted impurity after polymerisation or as a degradation product of those polymers. The BoA held that registrants cannot be obliged to obtain information on polymers that they do not manufacture or import themselves (Decision of 6 June 2018, Case A-006-2016, *SI Group-UK Ltd and Others*).

3.2. BPR regulation

3.2.1 Data sharing

The BoA held that a data owner had not failed to make every effort in the negotiations on data access of an active substance by requiring chemical similarity to be established between its source of the active substance and the prospective applicant's source. This was because the data owner and the prospective applicant had contractually agreed to establish chemical similarity between their sources of the active substance. The Agency had not assessed the efforts of both parties to the data sharing dispute in a balanced manner because it focussed primarily on the prospective applicant's efforts and had not considered the terms of the mutually agreed contract. In addition, the Agency had not taken into account that irrespective of the contractual agreement on chemical similarity, the data owner was still open to resolving the chemical similarity issue and to finding an agreement (Decision of 7 March 2018, Case A-014-2016, *Solvay Solutions UK Ltd*).

In another case, the BoA held that the Agency, in data sharing disputes under the BPR, must take into account the balance of both parties' efforts with regard to the entirety of the negotiations and not just as regards the last step in a long negotiation process. The Agency's decision refusing a data claimant access to certain studies was therefore annulled (Decision of 29 May 2018, Case A-007-2016, *Sharda BVBA*).

4. Maintaining high standards of quality, transparency and efficiency

The BoA continues making efforts to maintain high quality for its decisions and working methods. Working transparently is particularly important for an appellate body in REACH regulatory context, where BoA decisions can greatly impact ECHA processes and all stakeholders affected by ECHA's activities. At the same time, improving efficiency without diminishing quality is an important challenge.

4.1. Quality

The quality of BoA decisions and their utility for both, stakeholders and the Agency's secretariat are widely recognised. An important test for the quality of BoA decisions is the high level of acceptance by stakeholders. A robust and well sound decision is also part of the legal remedy sought and expected by appellants.

As regards industry in general and appellants, according to the 2017 Stakeholder Survey, the BoA is perceived across industry as independent and impartial and the appeals procedure allows decisions of the Agency to be challenged in a fair and reasonable way. A great majority of respondents to the survey knew that they could appeal the Agency's decision before BoA and also considered that information contained in adopted and published BoA decisions was useful to them.

The over 100 decisions taken by the BoA since 2009 form a robust and consistent body of work. They are all available on line and can be searched on the BoA database within the ECHA website.[14]

4.2. Working in a transparent manner

According to the Commission General Report on the operation of REACH of 2018, the BoA has put in place open and accessible proceedings where all relevant interests of

[14] https://echa.europa.eu/about-us/who-we-are/board-of-appeal/decisions

'stakeholder' organisations are heard before a decision is made by BoA.

The BoA continues to be committed to maintaining high levels of transparency in its work and promoting the participation of interested REACH stakeholders, including NGOs and animal welfare associations, in accordance with the applicable rules. BoA manages administrative proceedings and not judicial proceedings. The participation of interested third parties in administrative recourses affecting public interests can contribute to better serve the REACH aims, protection of public health and environment and it is in line with the Aarhus Convention[15].

All appeals received by the BoA are announced on ECHA's website; oral hearings are announced on the website one month before they are due to take place; final decisions and summaries thereof are published, and when a case is closed, any related procedural decisions are normally published. Members of the public can also attend oral hearings. All these measures help ensure that stakeholders can learn from the publicly available information and potentially refine and improve registration dossiers as well as future submissions in appeals.

The revised Rules of Procedure provide for an 'amicable agreement' procedure which aims to facilitate the settlement of disputes between appellants and ECHA. This procedure aims to enhance the transparency of appeal proceedings that would be closed after an appellant and the Agency have settled the case and the appellant withdrew the appeal. So far the amicable agreement procedure has been requested only once by an appellant, and ECHA did not want to proceed with this option.[16]

4.3. Efficiency

Resources

The main test of the BoA's efficiency is the impact that its decisions have on ECHA's processes, clarifying the requirements placed on all actors under REACH and the BPR, and the impact on appellants' confidence in the interpretation and implementation of REACH and the BPR. The BoA consists of the three regular, full-time members who can be substituted by alternates (see Annex III). The BoA is supported by the Registry, composed of the Registrar, four legal advisers, two legal assistants and two administrative assistants.

Whilst the impact of its decisions on ECHA processes is considerable, the BoA is the smallest unit in ECHA. Due to the quasi-judicial nature of its work, BoA's tasks cannot be outsourced. Furthermore, the use of the AAMs can be limited by their availability (e.g. depending on their academic or professional occupations). However, the BoA is making the best use of the resources currently at its disposal. It should be added that, in light of demanding scientific and technical issues present in appeal cases, the BoA intends to request that a scientific advisor is provided to the Registry to fulfil an analogous role to that currently undertaken by the legal advisers.[17]

The appeals (around 35 simultaneously during this reporting period) are being processed in 14 months on average in cases that are concluded by a 'full' final decision. As mentioned above, the time taken to finalise a decision may vary considerably due to the complexity of cases and the nature of the decision made by the BoA. For example, some substance evaluation cases are highly technical and may raise complicated and novel legal questions which involve a high degree of preparation and thorough discussions, also considering possible wider implications for the implementation of the REACH Regulation. Data sharing cases are in comparison relatively more straightforward from a legal and technical standpoint, but, involve a careful analysis of their factual backgrounds because they

[15] Convention on access to information, public participation in decision-making and access to justice in environmental matters, signed at Aarhus on 25 June 1998 and approved on behalf of the European Community by Council Decision 2005/370/EC of 17 February 2005 (OJ 2005 L 124, p. 1).
[16] In appeal case A-022-2015 *Manufacture Française des Pneumatiques Michelin.*
[17] See to that effect also in REACH Review 2018, footnote 3 above.

include the assessment of the whole negotiations between companies on access to data on substances.

The KPI is a useful indicator to measure the average time taken to process and decide appeal cases across the board. However, it is not a useful indicator of performance on a case-by-case basis. The average time taken to adopt final decisions can be interesting but, even then, it must be used carefully as the time taken is often dependent on the particular cases considered and the decision taken. For example, the time to process appeal cases can be also affected by procedural decisions on matters such as applications to intervene, confidentiality claims, requests for extensions, and requests for stays of proceedings, amongst other things. The BoA is always looking for opportunities to improve its efficiency by reviewing regularly its internal processes and by communicating with parties proactively. It must also be taken into account that in the absence of BoA members for any reason (e.g. unexpected leaves, sickness) decisions cannot be progressed at the same rate or final decisions adopted.

Improving planning

Active case management: After the new appeal arrives, the Registry prepares a case calendar for the upcoming 15 months, outlining all of the main, usual steps in the proceedings and attempting to anticipate the timeline of the case in relation to other pending cases. This planning approach complements other existing tools used by the BoA. One of the main aims of this longer projection is to enable the BoA to better understand and estimate how, which and when the next steps in pending appeals need to be dealt with and what will be the required efforts and resources. This planning minimises the risk of lengthy proceedings and backlogs. However, it must be mentioned that appeal cases rarely follow the anticipated plan and planning, as there may be unforeseen complications that arise in any appeal case. These complications range from the need for the BoA to take decisions on, for example, confidentiality requests, stays of proceedings and applications to intervene, to the absence of key staff (as such a small unit the ability to cover absences is limited, and for the BoA members it is impossible unless the BoA member is actually replaced). The reality is that even with good planning there are frequently periods of prolonged, intense pressure when many cases need to be processed simultaneously. When this happens it may be necessary to prioritise certain cases at the expense of others and this may also have an impact on the time taken to finalise a BoA decision. Recently, a considerable amount of the BoA's time that would be otherwise dedicated exclusively to dealing with the appeals, went to the preparation of ECHA submissions in cases before the General Court.

Caseload priority management: the BoA and its Registry staff meet once a week to go through the case load and to identify the current priorities. Priorities are defined with regard to the required phase and step in appeal case. This method enables the focusing of efforts where they are needed the most. This ensures more efficient and predictable processing of appeals cases.

Planning of hearings: possible hearing dates are now planned by looking six months ahead. For example, the BoA plans that hearings in five cases could take place from September to December 2018. This planning also helps the parties to make their arrangements as early as possible. The parties also have the possibility to attend the hearing using remote access (e.g. by WebEx).[18] This alternative is most often used by Member States' Competent Authorities when intervening in an appeal case.

[18] The possibility to attend a hearing from another location, without being present in Helsinki, by video-conferencing or by WebEx was used by several Member State Competent Authorities as interveners in various cases.

5. Looking forward

5.1. As regards REACH cases

New appeals may come in relation to:

- ECHA's new approach towards the verification of dossier completeness, and stricter implementation of the 'one substance, one registration' (OSOR) principle. Such checks may culminate in the rejection or revocation of registrations. Those decisions, as well as possible resulting data sharing disputes under REACH may then be contested before the BoA.

- For the 2018 registration deadline, 33 363 registrations were submitted to ECHA which cover 11 114 substances. ECHA carries out enhanced completeness checks and rigorous verification of the full opt out registration are already in place; these processes, if resulting in new decisions, may bring about related appeals.

- Forthcoming and recent changes in REACH annexes regarding respectively nanomaterials related information requests and regarding the extended one-generation reproductive toxicity study (EOGRTS), could result in new appeals[19].

5.2. As regards BPR cases

Most appeals brought under the BPR concerned data-sharing disputes. However two appeals were lodged in 2017 that concern decisions taken under the Review Programme Regulation. These two appeals are still pending. The inclusion of companies on the 'Article 95' list of suppliers of biocidal active substances remains the main issue, and the appellants are concerned about gaining the market access. The question of whether and to what extent the Agency can define objective criteria on the 'every effort' condition will be interesting to follow up.

There have been no appeals to date on decisions on technical equivalence although the concept appeared in case A-014-2016 because companies often draft clauses in their data sharing agreement regarding the chemical similarity or technical equivalence of their active substance. The Agency also provides a chemical similarity check service that companies sharing data under the BPR have been using. The issue of similarity of active substances in the context of data sharing remains a distinct feature of BPR data sharing appeals and it will also be interesting to see how it evolves.

5.3. Changes in BoA composition

The second term in office of the Chairman will expire in April 2019. In addition, the terms in office of two alternate legally qualified members (see Annex II) and two alternate technically qualified members are coming to an end. The planning of the selection process for replacements should take into account the need to guarantee the continuous smooth functioning of the BoA.

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

5.4. Changes in BoA competences

When deciding on a case, the BoA examines the pleas, arguments and evidence put forward by the parties. It takes also into account facts and evidence which has been brought to the appeal proceedings. The BoA examines all these elements and the scientific issues under dispute. When BoA finds in favour of an appellant, it can either annul the contested decision and remit the case back to the Agency; or substitute the contested decision with its own decision. The standard of review applied by the BoA has recently been challenged before the General Court. As a result the BoA may need to reconsider its standard of review and the intensity of its own scientific assessment of the cases. The outcome in these Court cases could have further implications on the resources needed by the BoA, in particular in the Registry which supports its work.

5.5. Other

New Code of Conduct of the Board of Appeal: The BoA adopted new Code of Conduct on 1 February 2018. Changes were made to align the Code of Conduct to the measures adopted by the Agency since 2010 on the management of conflicts of interest. The ethical standards in the revised Code of Conduct apply to alternate and additional members of the BoA, as full-time members of the BoA are subject to the ethical standards of the Staff Regulations of the European Union.

Relations between ECHA secretariat and BoA: BoA welcomes the appointment of the new Executive Director and is hopeful that a new spirit of cooperation will characterise the relations between BoA and the ECHA secretariat. In particular, BoA and its Registry's staff should in future be involved in all horizontal training activities within the Agency; likewise BoA should be provided with the necessary resources for fulfilling its tasks. Without prejudice to the independence of the BoA, exchanges of the latest information on technical and legal aspects of the implementation of REACH and the BPR should in the future take place on a regular basis between BoA and different units in ECHA.

ANNEX II

Overview of 10 years of BoA work and its findings

This Annex of the Chairman's Report presents a compilation of the main findings contained in BoA's decisions adopted over 10 years of the existence of the REACH Regulation. This information is the Chairman's selection of the most relevant findings and conclusions. It is not an exhaustive list of BoA conclusions in its decisions. The most comprehensive information on all appeals can be gained by reading the BoA decisions that are available on BoA section of the Agency website[20].

Before presenting those findings of the BoA in its decisions on appeals, some figures should be given. The BoA was set up in April 2009, since then it has received 120 appeals by 221 appellants. It has adopted 102 final decisions, 163 procedural decisions (e.g. interventions, confidentiality, stays), over thousand procedural measures (e.g. written questions to the parties, requests for comments), held 40 public oral hearings, and had 5300 communications registered in the Register of appeals. The average duration of an appeal is close to 15 months. On average, a notice of appeal with all the annexes submitted alongside it has over 500 pages. The appeals process is both heavy and rigorous.

Registration

➢ Good administration – clear decisions

The registration process under REACH Regulation is an administrative procedure which must satisfy the criteria for good administration as laid down in EU law, particularly including the general principles of law and Article 41 of the Charter of Fundamental Rights of the EU. In that case, the BoA found that ECHA's actions and acts did not meet the requirements of good administration, particularly as regards the requirement for clarity in communicated information.
Lacking clarity, accuracy and precision in Agency's communications which induce a reasonably prudent registrant using due care to make a mistake in his obligations is a breach of the principle of good administration.
(Decision of 10 October 2011, Case A-001-2010, *N.V. Elektriciteits – Produktiemaatschappij Zuid-Nederland EPZ*)

➢ Good administration - language of communications

Communications notified during the completeness check procedure, must be sent to a registrant in the official language of his Member State of establishment unless the registrant explicitly agreed to the contrary based on a genuine choice. A reply to a communication sent in a language other than that of the Member State of establishment does not fulfil these requirements (Decision of 21 May 2014, Case A-002-2013, Distillerie de la Tour).

➢ Good administration – clear notifications

In order to prove the date on which the time limit for lodging an appeal starts to run, the Agency must request registrants to confirm the receipt of emails or request a receipt from the REACH-IT system (Decision of 27 February 2013, Case A-005-2012, *SEI EPC Italia*).

Invoices should be notified by the same means used for the notification of SME verification decisions, and in particular not only by REACH-IT but also by registered mail.

[20] BoA decisions in appeal cases are available here.

It is the responsibility of each REACH-IT account holder to update information concerning its user account details, and to ensure that communications are addressed to the proper person (Decision of 13 November 2014, Case A-020-2013, *Ullrich Biodiesel GmbH*).

The BoA found that the Agency had not fulfilled all the requirements of good administration because the Appellant was not notified in a clear and accurate manner of the second deadline of the registration fee (Decision of 10 October 2011, Case A-001-2010, *N.V. Elektriciteits – Produktiemaatschappij Zuid-Nederland EPZ*).

- **Good administration – Clarity of ECHA instructions for registrants**

In the context of dossier updates occurring during the final stage of decision procedures on compliance, every measure adopted by the Agency about the obligations applicable to registrants must be clear and precise, and also must be clearly brought to the notice of persons concerned. Persons concerned must be (i) individually and specifically informed in due time, and (ii) information made available to the registrants about rules applicable to them must be clear and precise. Shortcomings of such may cause a prudent and diligent registrant to be mistaken (Decision of 23 August 2016, Case A-005-2015, *Thor GmbH*).

➢ OSOR principle and joint submission

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. If a registration breaches the OSOR principle, the Agency 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*).

Each registration dossier must relate to a single substance and, consequently, two different substances cannot be registered in the same dossier regardless of whether they present the same hazard properties (Decision of 2 April 2014, Case A-008-2012, *PPH Utex Sp. Z o.o.*).

The decision on which substance or substances to register lies with the manufacturer or importer concerned. Where a dossier contains more than one substance, the Agency cannot unilaterally dictate which of those substances should be the subject of registration. (Decision of 2 April 2014, Case A-008-2012, *PPH Utex*; Decision of 2 March 2017, Case A-011-2014, *Huntsman P&A UK*).

➢ Consolidation of single registrations into the joint submission

The BoA found that 'joint submission disputes' were not necessary under REACH Regulation and that the Agency, as it had implemented itself the use of 'tokens' under registration, must, when requested, give the 'token' to any registrant who informs it of its decision to rely on a complete opt-out in accordance with Article 11(3). The BoA observed that the completeness and compliance check provisions of REACH Regulation require the Agency to assess that registrants relying on complete opt-outs do not submit incomplete dossiers or duplicate vertebrate animal tests.
Under Article 20, the BoA observes that registrants should be prevented from submitting registrations which are not part of an existing joint submission for the same substance. The Agency must verify whether an individual registrant has submitted information about the lead registrant for a joint submission on the relevant substance, and whether it has provided the necessary information required by Section 1.2 of Annex VI (Decision of 23

March 2018, Case A-011-2017, *REACheck Solutions GmbH*).

➢ Duties of a prudent and diligent registrant

Every registrant has the duty to act in a diligent and prudent manner in fulfilling its obligations pursuant to REACH Regulation.
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 (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.
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. 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 November 2014, Case A-020-2013, *Ullrich Biodiesel GmbH*)

➢ Intermediates

The BoA clarified the two criteria for a substance to qualify as intermediate:
(i) the substance must be manufactured for, and consumed in, a chemical process, and;
(ii) there must be an intentional transformation of the substance into another substance in that chemical process.

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, this is irrelevant for the consideration of an intermediate. The Board of Appeal notes that Article 3(15) does not differentiate between main aim of a plant or production process and the other aims of a plant or process.
The relevant process to be taken into account is not the entire production process but the chemical reaction of the substance with the raw materials. It is irrelevant whether the resulting substance is the only substance produced in a plant, the main substance of the plant in terms of revenue or quantity, a by-product or just one of the many substances produced in the plant.
The BoA considered a literal interpretation of the phrase 'in order to be transformed into another substance'; therefore an unintentional transformation from one substance into another, is not sufficient for a substance to qualify as an intermediate.
(Decision of 25 May 2016, Case A-010-2014, *Nordenhamer Zinkhütte GmbH*)

Data Sharing under REACH

➢ Assessment of every effort

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. However, the Agency is entitled to make an assessment of whether each of the parties to the data sharing dispute made, 'every effort to ensure that the costs of sharing the information are determined in a fair, transparent and non-discriminatory way'.
The Agency's analysis of a data sharing dispute is case-specific and context driven.
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.

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 no other data that may have been part of the initial negotiations.
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.
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 of a particular case.
(Decision of 17 December 2014, Case A-017-2013, *Vanadium (II)*)

Dossier evaluation

Compliance check

➢ Follow-up dossier evaluation – Statement of Non-Compliance (SONC)

In an important decision related to a follow up evaluation case and a statement of non-compliance letter (SONC), 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.
Pursuant to Article 42(1) of the REACH Regulation, where the Agency adopts a new decision following the evaluation of substantial new information provided by a registrant in response to a previous Agency 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*)

The General Court's recent judgment in Case T–283/15, *Esso Raffinage* v *ECHA*, also examined the Agency's policy on SONCs. The Court's judgment was broadly similar to the position taken by the BoA in *Solutia Europe*. However, the General Court adopted an even stricter interpretation regarding the situations in which the Agency must undertake a new decision-making procedure in follow-up to information submitted in response to a previous Agency decision.

➢ Requesting information involving testing on vertebrate animals

The BoA confirmed that the Agency was entitled to require further information on the substance because of concerns arising from the results of a pre-natal developmental toxicity study on rabbits. The BoA decision also recognised a broad margin of discretion by the Agency to require the conduct of further studies according to Section 8.6.4 of Annex X, and subsequently examined how this discretion was exercised, as well as the legality of the measure imposed.
The BoA decision was taken on the basis that in this particular case, a request for information under Section 8.6.4 of Annex X to the REACH Regulation, the contested decision breached the principle of proportionality because the Agency did not take all necessary steps to ensure that testing on vertebrate animals was only taken as a last resort, and it failed to ensure that a test using the minimum number of vertebrate animals would be used.
(Decision of 29 April 2013, Case A-005-2011, *Honeywell Belgium NV*)

The fact that the Agency has a wide margin of discretion does not 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. 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 case at hand, those considerations included, pursuant to Article 25(1), the need to ensure that testing on vertebrate animals is undertaken only as a last resort, and the need for administrative efficiency (Decision of 10 June 2015, Case A-001-2014, *CINIC Chemicals Europe Sárl*).

➢ Animal welfare

Considering Article 13 of the Treaty on the Functioning of the European Union and Article 25(1) of REACH Regulation, the protection of animal welfare is an important consideration in the framework of EU legislation and REACH Regulation in particular. The BoA noted that, under REACH Regulation, the Agency has a legal obligation to consider animal welfare in its decision-making. Where the Agency requires additional testing pursuant to a substance evaluation, it must ensure that vertebrate animals are used only as a last resort and its actions should demonstrably not run counter to the principles of Directive 2010/63 (first in Decision of 29 April 2013, Case A-005-2011, *Honeywell Belgium NV* and other later cases).

➢ Right to be heard

In certain circumstances it is possible that the addressees of a decision should be given the opportunity to comment beyond the opportunities foreseen in Article 51(2) to (8).
The BoA also assessed the argument from the Appellant that the revised draft decision contained '*significant and key new elements and raised new concerns*' (Decision of 19 October 2016, Case A-004-2015, *Polynt SpA*).

Observance of the right to be heard is, in all proceedings initiated against a person which are liable to culminate in a measure adversely affecting that person, a fundamental principle of Community law which must be guaranteed even in the absence of any rules governing the proceedings in question. That principle requires that the addressee of a decision which significantly affects its interests should be given the opportunity to effectively make known its views on the correctness and relevance of the facts, objections and circumstances put forward by the institution (Decision of 29 July 2015, Case A-019-2013, *Solutia Europe sprl/bvba*).

The right to be heard does not extend to the final position which the Authority intends to adopt, however, it extends to all the factual and legal material on which a decision is based (Decision of 19 June 2013, Case A-001-2012, *Dow Benelux BV*).

➢ Information requirements

Substance identification and nanoforms

A registrant is at liberty to give a broad definition of the substance which it intends to register, for example by including both the bulk forms and the nanoforms of various crystal phases of the substance in question. If a registrant gives a broad definition of its substance, however, the hazards posed by all possible forms of the substance covered by the substance definition must be addressed by the toxicological and ecotoxicological information provided in the registration dossier. If the Agency were then to find, for example, that different nanoforms of a substance have different toxicological properties that have not been adequately addressed, it could request further information through the appropriate regulatory procedure under REACH Regulation. However, REACH Regulation as it stood at the time of the appeal proceedings did not provide for the precise identification of the substance identity of nanoforms (Decision of 2 March 2017, Case A-

011-2014, *Huntsman P&A UK Ltd and Others*).

Revealing the identity of the substance and of the Appellant exposes a combination of information that allows competitors to find out the trade name of the substance. Substance identification can be regarded as confidential if the disclosure of such could result in commercial harm to an appellant (Decision of 1 August 2016, Case A-003-2015, *BASF Pigment GmbH*).

Nanoforms and legal certainty

The BoA considered that the contested decision failed to clearly identify the terms 'grade' and 'forms'. As a result, a diligent registrant could not know with any degree of certainty what information it was required to provide to ensure compliance with the contested decision. The contested decision therefore breached the principle of legal certainty (Decisions of 12 October 2015 in Cases: A-008-2015, *Evonik Degussa GmbH*, A-009-2015, *Iqesil SA*, A-010-2015, *Rhodia Operations SAS* and A-011-2015, *JM Huber Finland Oy*).

The Agency confirms the BoA's consideration that the term 'nanoforms' is not defined in the REACH regulation or in the Commission Recommendation 2011/696/EU (Decision of 12 October 2015, Case A-008-2015, *Evonik Degussa GmbH*).

UVCB substances

For UVCB substances registrants must identify any constituent present in the substance at 10% or more. Any constituents below this 10% threshold should also be identified as long as it is possible and reasonable to do so. According to the Agency's Guidance; any constituents that are relevant for classification must be identified (Decision of 9 April 2014, Case A-001-2013, *Infineum UK Ltd*).

The Agency can identify the appropriate method for the identification of PBT/vPvB properties as per Annex XIII on a case-by-case basis, in light of the objectives of the REACH Regulation, and after examining, carefully and impartially, and taking into consideration, all the relevant facts and circumstances of the individual case (Decision of 9 September 2015, Case A-004-2014, *Altair Chimica SpA and Others,* '*MCCP Registrants*').

Developmental toxicity study on first or second species

The information requirements set out in Column 1 of Annexes VII to X are cumulative and, under Section 8.7.2 of Annex X, registrants are required to perform a developmental toxicity study on a species other than the species used for a pre-natal developmental toxicity study under Column 1 of Section 8.7.2 of Annex IX, unless the adaptations in Section 8.7 of Annex X or Annex XI apply (Decision of 10 October 2013, Case A-004-2012, *Lanxess Deutschland GmbH*).

Pre-Natal Developmental Toxicity

Column 2, Section 8.7 of Annex IX (specific rules for adaptation from standard information required) and Weight of Evidence adaptations serve different purposes. As regards the three cumulative conditions of the Column 2 adaptation, the BoA observes that the Column 2 adaptation in question is used to show that information on the PNDT endpoint is not necessary as it would not provide further useful information on that endpoint, whilst a weight of evidence adaptation means that the information on the PNDT endpoint already exists. Thus, the evidence to justify one adaptation is unlikely to support the other (Decision of 1 August 2016, Case A-014-2014, *BASF Pigment GmbH*; Decision 1 August 2016, Case A-003-2015, *BASF Pigment GmbH*).

Mere evidence of low bioavailability does not satisfy the 'no absorption' condition in the

wording of the Column 2 adaptation to the PNDT endpoint (Decision of 1 August 2016, Case A-003-2015, *BASF Pigment GmbH*).

Column 2 adaptation does not make a provision for waiving the requirement to conduct studies on reproductive toxicity on the basis that a substance has been identified as a SVHC due to its respiratory sensitising properties (Decision of 19 October 2016, Case A-004-2015, *Polynt SpA*).

➢ Adaptations of the standard testing regime

Read-across

The Agency is not obliged to compile arguments on behalf of the registrants when assessing read-across adaptations or waiving statements. The burden of proof is on registrants.
It is within the Agency's margin of discretion to assess and decide whether the uncertainty inherent to a read-across proposal is acceptable or not.
(Decision of 19 June 2013, Case A-001-2012, *Dow Benelux BV*)

The registrant must clearly set out the reasons for its decision not to provide certain information to allow the Agency to assess the applicability of the relevant adaptation. The Agency is not required to compile adaptation arguments on behalf of the registrant from the information set out in other parts of the registration dossier (Decision of 10 October 2013, Case A-004-2012, *Lanxess Deutschland GmbH*; Decision of 13 February 2014, Case A-006-2012, *Momentive Specialty Chemicals BV*).

The BoA considers that the test for establishing structural similarity, for the purposes of identifying grounds for concern under substance evaluation, is not the same as the test for use of read-across pursuant to Section 1.5 of Annex XI. Registrants must explain the premise for a read-across adaptation proposed and then show that the evidence supports that premise within the legal requirements outlined in the REACH Regulation. Then, it is the Agency's job to decide whether registrants have satisfactorily done so. When deciding, the Agency must balance the objectives of the read-across provisions with the uncertainty in any read-across adaptation and the need for predictive (eco)toxicology to be alert to the unexpected (Decision of 13 February 2014, Case A-006-2012, *Momentive Specialty Chemicals BV*).

The Agency is allowed to check whether registrations comply with the information requirements set out in the REACH Regulation due to the dossier evaluation provisions. Thus, the discretionary powers of the Agency are limited to examining whether a read-across adaptation submitted in a registration dossier complies with rules governing the adaptations listed in Annex XI. If the Agency decides a read-across adaptation does not satisfactorily comply with these rules, the Agency must require the performance of the relevant test or tests in order to satisfy the information requirements of the REACH Regulation (Decision of 19 October 2016, Case A-004-2015, *Polynt SpA*).

Read across using testing proposals for other substance

The BoA held that an Agency testing proposal decision requiring the Appellant to provide information on a sub-chronicity toxicity study and a pre-natal developmental toxicity study was adopted on the wrong legal basis. As the Appellant clearly intended to submit a read-across adaptation rather than a testing proposal, the Contested Decision should have been adopted under the compliance check procedure, (Article 41 of the REACH Regulation) rather than the testing proposal procedure (Article 40 of the REACH Regulation). However, this wrong choice of legal basis was not sufficient to lead to the annulment of the Contested Decision. The choice of legal basis did not deprive the Appellant of the procedural guarantees set out in Articles 50 and 51. In addition, the Agency's reliance on the testing

proposal procedure rather than the compliance check procedure did not lead to a different assessment of the Appellant's registration dossier for the endpoints in question and would not have led to a different decision. The BoA also held that the Agency had not breached the REACH Regulation by rejecting the Appellant's read-across adaption. Although the Appellant had established that the two substances concerned are structurally similar it had failed to demonstrate that they had similar toxicological properties as required by Section 1.5 of Annex XI (Decision of 30 January 2018, Case A-005-2016, Cheminova A/S).

Weight of evidence

The inclusion in the dossier of adequate and reliable documentation of the applied adaptation method is essential to allow the Agency to carry out its role, set out in Article 41(1)(b) of the REACH Regulation, of evaluating whether the 'adaptations of standard information requirements and the related justifications comply with the rules governing such adaptations set out in Annexes VII to X and the general rules set out in Annex XI (Decision of the Board of Appeal of 13 February 2013, Case A-006-2012, Momentive Specialty Chemicals B.V.).

It is not the task of ECHA to develop, justify or improve, a weight of evidence adaptation on a registrant's behalf. In this case, a weight of evidence could not have been assessed by ECHA as it was not explicitly claimed by the Appellant.
In order for a weight of evidence adaptation to succeed 'the focus has to be meeting the information requirements for the respective endpoint, e.g. the key parameters need to be covered'.
(Decision of 1 August 2016, Case A-014-2014, *BASF Pigment*; and Decision of 1 August 2016, Case A-003-2015, *BASF Pigment*)

Testing Proposals

- **Public consultation**

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 (Decision of 10 June 2015, Case A-001-2014, *CINIC Chemicals Europe Sárl*).

- **Testing proposals for substances used in cosmetics**

Annulling ECHA's decision rejecting a testing proposal for a substance used exclusively in cosmetic products, the BoA explained that, as the registered substance was used exclusively as an ingredient in cosmetic products and, depending on how one interprets Article 18(1)(b) of the Cosmetics Regulation, testing the substance on vertebrate animals could or could not lead to a marketing ban. The Agency should therefore have explained in the Contested Decision how it interpreted the relationship between the REACH Regulation and Article 18(1)(b) of the Cosmetics Regulation (Decision of 12 December 2017, Case A-013-2016, *BASF Personal Care and Nutrition*).

Substance evaluation

- **Relationship between dossier and substance evaluation**

The objectives of dossier and substance evaluation are, in some respects, different. The REACH Regulation contains no explicit requirement that dossier evaluation should precede

substance evaluation. However, 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.

Although dossier evaluation should normally precede substance evaluation, the standard information requirements set out in Annexes VII to X may, in certain circumstances, also be requested under substance evaluation. In order to be able to use the substance evaluation procedure rather than the dossier evaluation procedure, amongst other things:

(a) the Agency must be able to demonstrate that the substance concerned presents a potential risk to human health or the environment; and
(b) the rights of all current registrants of the substance concerned must not be prejudiced by the Agency's decision to follow the substance evaluation rather than the dossier evaluation procedure.

(Decision of 13 December 2017, Case A-023-2015, *Akzo Nobel Chemicals GmbH and Others*)

The standard information requirements set out in Annexes VII to X may, in certain circumstances, be requested under substance evaluation. For example, the Agency could potentially request information that is standard at the highest tonnage band for a substance that has not been registered at that tonnage band or, for a substance that has been registered at the highest tonnage band but the relevant test results were not included as the information requirement was successfully waived in a registration dossier.

If data gaps in registration dossiers could be filled through substance evaluation and directed at several registrants of a substance, regardless of the tonnage registered and the type of registration made, with the associated consequences for cost sharing, this could undermine the balance achieved in the legislation, for example between cost and information. Filling a standard information requirement 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.
(Decision of 23 September 2015, Case A-005-2014, *Akzo Nobel Industrial Chemicals GmbH and Others*)

➢ Right to be heard

In certain circumstances, for example where a decision can significantly affect its addressee's interests and the latter adequately justifies it, the addressee of such decision may be given the opportunity to comment beyond the opportunities foreseen in Article 52 of the REACH Regulation (Decision of 12 July 2016, Case A-009-2014, *Albemarle Europe Sprl*).

In all proceedings initiated against a person which are liable to result in a measure that adversely affects that person, observance of the right to be heard is a fundamental principle of Community law which must be guaranteed, even absent rules governing the proceedings. This principle requires that the addressee of a decision, that significantly affects its interests, should have the opportunity to effectively articulate its views on the correctness and relevance of the facts, circumstances, and objections put forward by the institution (Decision of 29 July 2015, Case A-019-2013, *Solutia Europe sprl/bvba*).

➢ Addressees of a decision – Concerned registrants

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

Article 50(1) of REACH does not oblige the Agency to request comments from concerned registrants on all amended drafts following the first draft of a compliance check decision. Article 51(5) also only gives the registrant the opportunity to comment once on proposals for amendment and not repeatedly. The Agency is not compelled, in principle, to take into account the registrant's comments after the referral of a draft to the member states' competent authorities (Decision of 7 October 2016, Case A-017-2014, BASF SE; and Decision of 19 October 2016, Case A-004-2015, *Polynt SpA*).

However, the BoA considered that, in certain circumstances, registrants should be given the opportunity to comment in addition to the ones foreseen in Articles 50 and 51. For example, if a decision is based on new elements of fact or law on which the Appellant had not had a prior possibility to make its views known (Decision of 19 October 2016, A-004-2015, *Polynt SpA*).

➢ Admissibility of the appeal by downstream user

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

➢ Different scientific opinion does not amount to an error of assessment

The Agency does not act illegally when choosing the testing material and the tests to be performed, when appellant's arguments demonstrate solely a difference of scientific opinion without demonstrating an error of assessment on the part of the Agency (Decision of 9 September 2015, Case A-004-2014, *MCCP Registrants*).

The fact that the appellant does not share the Agency's view on a scientific point is not sufficient to demonstrate that the Agency's exercise of its administrative discretion was flawed. On its own, a difference of scientific opinion is not capable of calling into question the legality of a contested decision (Decision of 19 December 2016, Case A-018-2014, *BASF Grenzach GmbH*).

➢ Standard of review of scientific conclusions in contested decision

Where a ground for concern has been identified there is an uncertainty that may need to be addressed. Under substance evaluation it falls to the Agency to resolve that uncertainty through the exercise of its broad administrative discretion by the adoption of a decision. In the event of an appeal against that decision, the BoA subsequently verifies whether

that discretion was exercised properly (Decision of 19 December 2016, Case A-018-2014*, BASF Grenzach GmbH*).

This decision is currently challenged before the General Court (Case T-125/17).[21] The applicants before the Court claim that the BoA was not correct in limiting its role to a review of legality instead of conducting a 'full administrative review'. This is the first time that a BoA decision is challenged by an appellant. The judgment of the Court will be of crucial importance in defining the BoA's role.

➢ Conditions for requesting further information

Under substance evaluation, in order to request additional information consistent with the proportionality principle, the Agency must 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*'; 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 27 October 2015, Case A-006-2014, *International Flavors & Fragrances BV*; Decision of 12 July 2016, Case A-009-2014, *Albemarle Europe Sprl*).

Substance evaluation is intended to assess risks that may occur in reality and not purely theoretical risks. Under substance evaluation, 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 12 July 2016, Case A-009-2014, *Albemarle Europe Sprl*).

The BoA observes that the compliance check procedure set out in Article 41 has been put in place to evaluate whether registration dossiers comply with the relevant information requirements. If, when carrying out the compliance check of a registration dossier under Article 41, the Agency considers that there is a data gap and as a result the registration dossier does not comply with the standard information requirements, the registrant will be requested to provide the information that is considered to be missing (Decision of 13 December 2017, Case A-023-2015, SA *Akzo Nobel Chemicals NV*).

➢ Link between CoRAP identification and substance evaluation

The priority setting exercise for substances to be included in CoRAP must identify those substances that potentially pose a risk to human health and the environment. The subsequent assessment of substances in CoRAP is not limited to the concern(s) that led the Agency to include that substance in CoRAP in the first place (Decision of 27 October 2015, Case A-006-2014, *International Flavors & Fragrances BV*).

➢ Endocrine disruptors - Applicability of test results to humans

The appellant argued that an enhanced developmental neurotoxicity study in rats was not appropriate to clarify a potential concern because the results cannot be extrapolated to humans. The BoA found that the contested decision carefully considered the species differences between rats and humans, and that the appellant did not establish that the Agency had made an error in this regard. The BoA also acknowledged that extrapolating the results from one species to another is complex. However, in the case at issue the test methods requested were 'state of the art' at that point in time. The existence of species'

[21] Application from Official Journal, brought on 28 February 2017, is available here.

differences was found not to be sufficient to demonstrate that the requested study would not provide useful information on the effects of the substance on exposed humans (Decision of 19 December 2016, Case A-018-2014, *BASF Grenzach GmbH*).

➢ Testing on vertebrate animals

The fact that the Agency has a wide margin of discretion does not 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. 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 to ensure that testing on vertebrate animals is undertaken only as a last resort, pursuant to Article 25(1), and the need for administrative efficiency (Decision of 10 June 2015, Case A-001-2014, *CINIC Chemicals Europe Sárl*).

The protection of animal welfare is an important consideration in the framework of EU legislation and the REACH Regulation in particular. The BoA noted that, under the REACH Regulation, the Agency has a legal obligation to consider animal welfare in its decision-making. Where the Agency requires additional testing pursuant to a substance evaluation, it must ensure that vertebrate animals are used only as a last resort and its actions should not demonstrably run counter to the principles of Directive 2010/63 (Decision of 9 September 2015, Case A-004-2014, *Altair Chimica SpA and Others* [`MCCP Registrants']).

The two components of the heading of Title III of the REACH Regulation (data sharing and avoidance of unnecessary testing) are not, in principle, indissolubly linked. The requirement to avoid unnecessary testing goes beyond the data sharing requirements. Where the Agency requires additional testing, it must ensure that vertebrate animals are used only as a last resort. Its actions should demonstrably not run counter to the principles of Directive 2010/63/EU (Decision of 29 April 2013, Case A-005-2011, *Honeywell Belgium NV*).

One of the main purposes of the provisions of the REACH Regulation related to read-across is to ensure that testing on vertebrate animals is undertaken only as a last resort. In the present case, which concerned a standard information requirement, Article 13(1) of the REACH Regulation requires the use of read-across if the conditions of Section 1.5 of Annex XI are met. The Agency's role in this respect is to verify whether a registrant's proposed use of read-across satisfies the requirements of Section 1.5 of Annex XI. The BoA considers that Article 13 TFEU and Article 25(1) of the REACH Regulation do not impose any additional duties on the Agency in this respect. If a registrant's proposed use of read-across does not comply with the requirements of Section 1.5 of Annex XI the Agency is entitled to reject the proposal (Decision of 13 February 2014, Case A-006-2012, *Momentive Specialty Chemicals BV*).

➢ Assessment on Persistency

The BoA has held that registrants cannot be subjected to obligations that may be impossible to perform. Thus, it annulled an obligation to achieve the aim of identifying all the metabolites of the registered substance. In addition, the Agency, supported by the eMSCA, had not established that the required TG 308 study (simulation testing in aquatic sediment system) was appropriate to measure the adsorption of the degradation of the registered substance.

The BoA also held that the Agency failed to establish that all of the metabolites formed in the OECD TG 309 test could be identified at the low concentrations in which they would be present. Thus, it annulled the obligation to identify all the metabolites of the registered substance. In addition, the Agency, supported by the eMSCA, had not established that the OECD TG 308 study on simulation testing in an aquatic sediment system was appropriate

to measure the adsorption of the degradation of the registered substance and how the study would clarify the identity and properties of non-extractable residues.
(Decision of 8 September 2017, Case A-026-2015, *Envigo Consulting Ltd*)

➢ Substance evaluation of monomers

The BoA found that when a monomer is evaluated under substance evaluation a request for further information may extend to information on the presence of that monomer in polymers as an unreacted impurity after polymerisation or as a degradation product of those polymers. The BoA held that registrants cannot be obliged to obtain information on polymers that they do not manufacture or import themselves (Decision of 6 June 2018, Case A-006-2016, *SI Group-UK Ltd and Others*).

➢ Precautionary principle

Interpretation of Article 2(9) according to which the Agency may require information on the presence of a monomer in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers, is fully consistent with the precautionary principle. There may be grounds to suspect that a monomer may pose a potential risk to human health or the environment because of its presence in polymers as an unreacted impurity after polymerisation, or as a degradation product of those polymers. In this case, the Agency must be able to clarify that potential risk so that protective measures can eventually be adopted with regard to that monomer or its uses in the manufacture of polymers (Decision of 6 June 2018, Case A-006-2016, *SI Group-UK Ltd and Others*).

Data sharing under BPR

➢ Assessment of every effort

The BoA found that the Agency committed an error of assessment by failing to assess the efforts of both parties to reach an agreement in a balanced manner, as required by Article 63(3) of the BPR. This is because the Agency did not take into account the various instances in which the parties agreed to the performance of the technical equivalence assessment and let its own legal opinion that there was no need to perform such an assessment influence the outcome of the Contested Decision. It also failed to take into account that the prospective applicant had also failed to make every effort in not advancing the data sharing negotiations for three months prior to submitting the data sharing dispute to the Agency (Decision of 23 August 2016, Case A-005-2015, *Thor GmbH*).

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

When assessing whether the parties to a data sharing dispute have made 'every effort', the Agency must examine the efforts of both parties in a balanced manner. Also, considering the parties' contractual freedom, the Agency needs to take into account a mutually agreed condition for the data-sharing (Decision of 23 August 2016, Case A-005-2015, *Thor GmbH*).

In another case, the BoA held that the Agency, in data sharing disputes under the BPR,

must take into account the data owner’s efforts regarding the entirety of the negotiations (Decision of 29 May 2018, Case A-007-2016, Sharda BVBA).

ANNEX III

Table of BoA members: 'full-time' and alternate and additional members (June 2018)

Name	Role	Term started	Term ends
Mercedes **ORTUÑO**	Chairman	16 Apr 2009	15 April 2019**
Andrew **FASEY**	TQM	1 March 2011	28 February 2021**
Sari **HAUKKA**	LQM	1 November 2015	30 October 2020*
Christoph **BARTOS**	Alt Chair	15 Oct 2010	14 October 2020**
Ioannis **DIMITRAKOPOULOS**	Alt Chair	15 Oct 2010	14 October 2020**
Cristopher **HUGHES**	Alt Chair	15 Oct 2010	14 October 2020**
Harry **SPAAS**	TQAAM	1 Dec 2010	30 December 2018 **
Jonna **SUNELL-HUET**	TQAAM	16 May 2009	15 May 2019**
Arnold **VAN DER WIELEN**	TQAAM	16 May 2009	15 May 2019**
Barry **DOHERTY**	LQAAM	15 Oct 2008	14 Oct 2018**
Rafael **LÓPEZ PARADA**	LQAAM	15 Oct 2008	14 Oct 2018**
Angel M. **MORENO MOLINA**	LQAAM	15 December 2014	14 December 2019*
Sakari **VUORENSOLA**	LQAAM	15 December 2014	14 December 2019*

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

Registry Unit supporting BoA's work during the reporting period

- 1 Registrar: Alen Močilnikar
- 4 Legal Advisors
- 2 Legal Assistants
- 2 Administrative Assistants

Appeals in graphics

Figure 1: Number of lodged appeals against decision related to different processes (REACH and BPR)

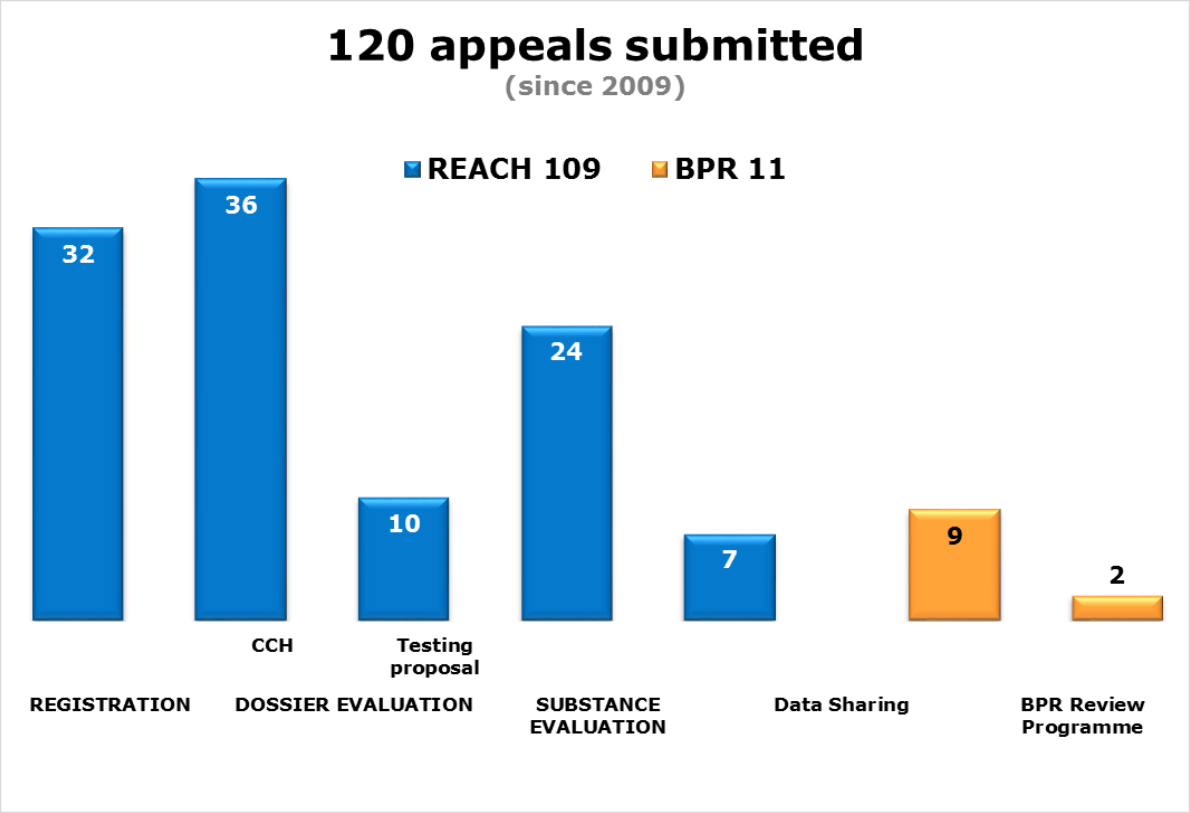

Figure 2: Number of appeals per calendar year

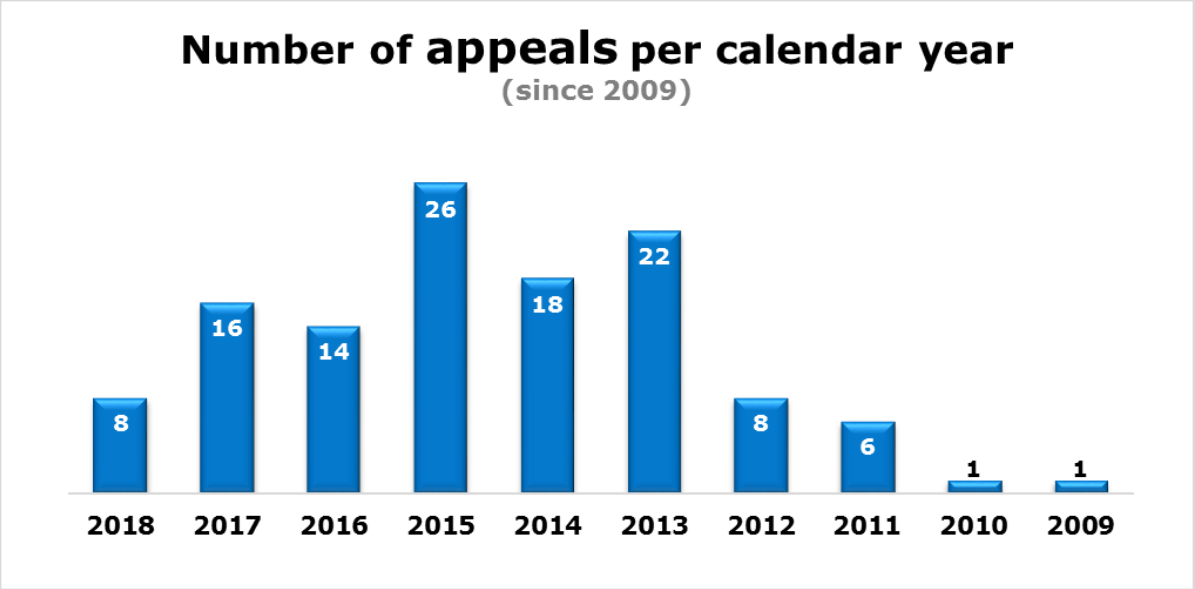

Figure 3: Appeal outcomes since 2009 (until 6 June 2018)

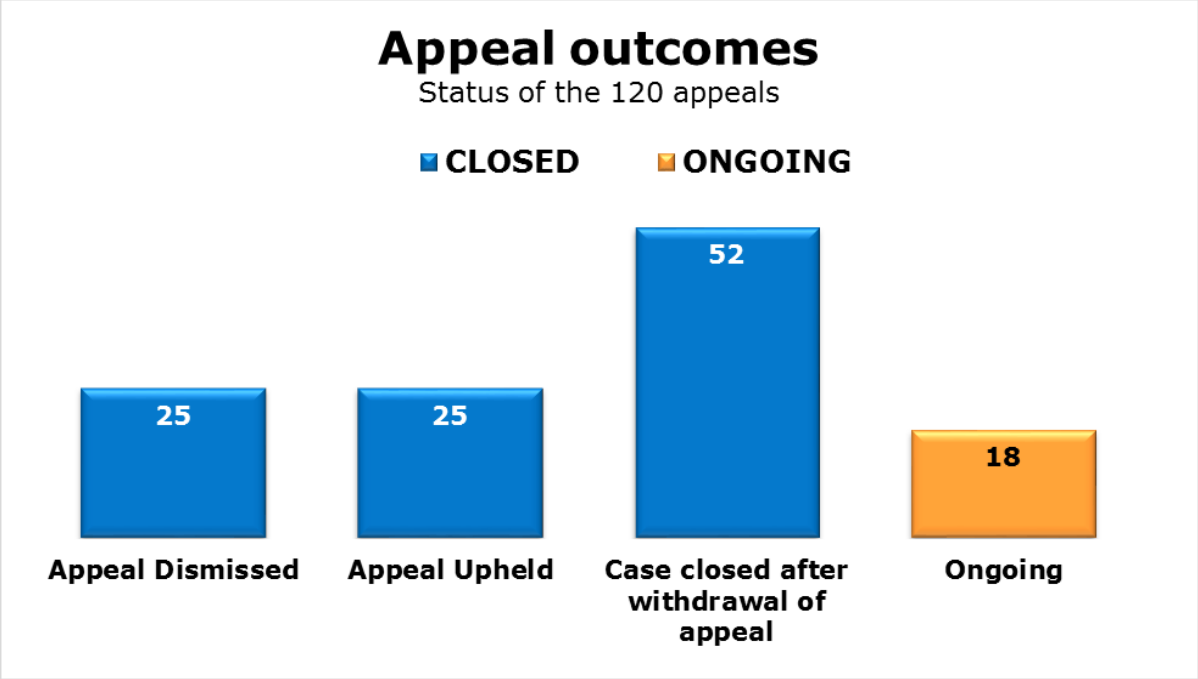

Figure 4a Proportion of submitted cases based on legislation since 2009

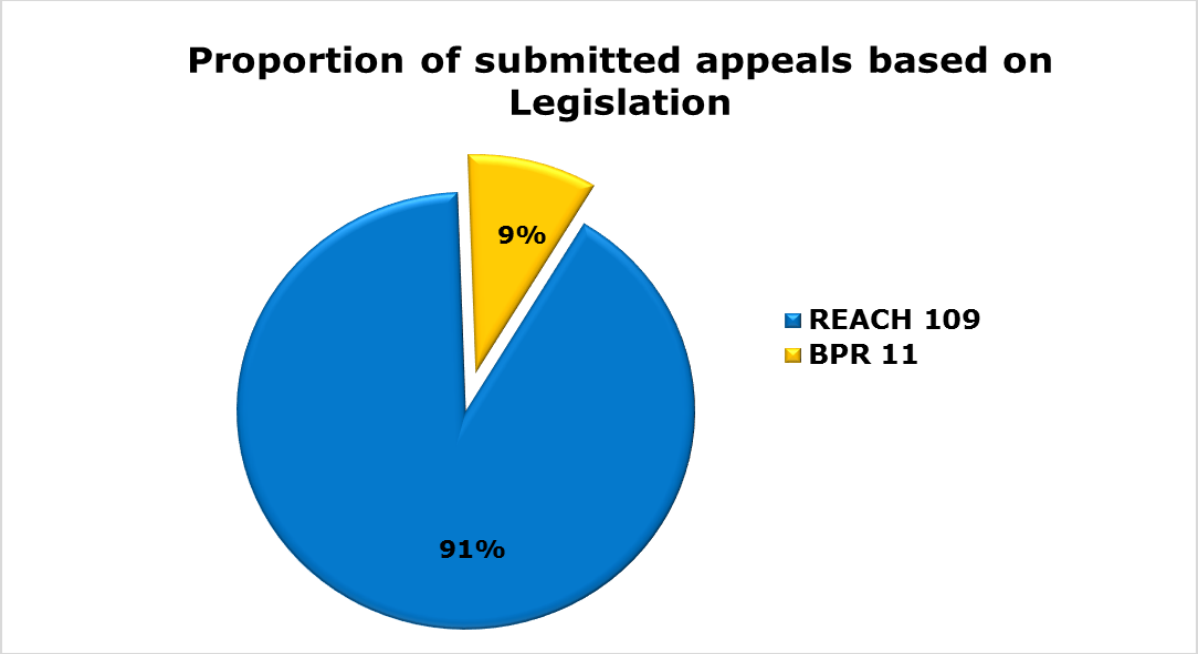
Proportion of submitted appeals based on Legislation
9%
91%
REACH 109
BPR 11

Figure 4b Ongoing cases as a proportion of all cases based on legislation since 2009

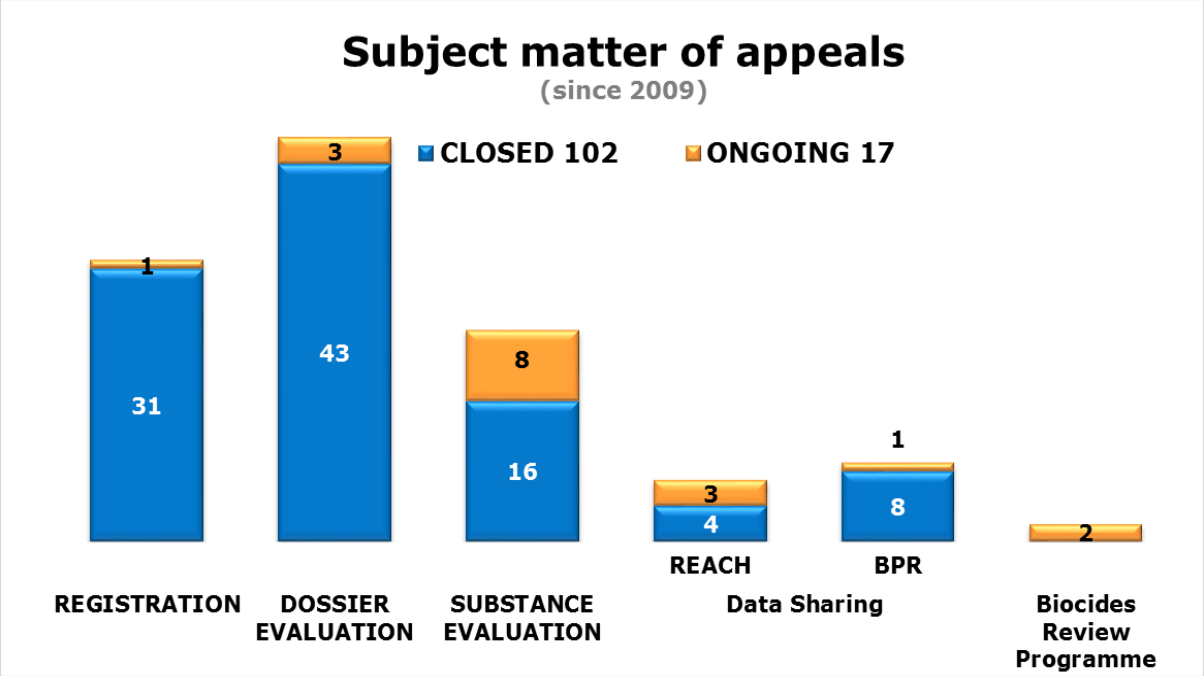

Figure 5 Origin of appeals (until 6 June 2018)