Guest Column: Looking back on ten years of Echa's Board of Appeal

With more than 100 Echa BoA decisions under his belt as the technically qualified member, Andrew Fasey is nearing the end of his second and final term. He shares his favourite decisions – and other insights from a decade in the role

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Chemical Watch: What has your role as a technically qualified member of the Echa Board of Appeal involved?

Andrew Fasey: The role of the technically qualified member (TQM) is exactly the same as that of the chair of the Board of Appeal (BoA) and its legally qualified member. We decide independently of each other what we think the outcome of every appeal should be. I have exactly the same voice and vote as the other two members. I have to assess the legal aspects of a case as well as the scientific in order to arrive at my opinion on an appeal. Of course, it is possible that I will look at an appeal and the issues raised from a different perspective to my legal colleagues, but the job is the same. I can also say from the experience of over 100 appeals under the REACH Regulation that I am just as likely to agree or disagree with one of my legal colleagues as they are with each other.

What the role of TQM does not entail is being the final arbiter on all things scientific. It is not my, or BoA's, job to decide what is right or wrong scientifically. I look at the facts and circumstances of an appeal to make sure, in light of the pleas and arguments of the appellant, the legislation and relevant case law, that Echa has done its job correctly. It is not for me to say whether Echa or a registrant is correct scientifically. A difference of scientific opinion cannot be a reason to overturn a decision. However, a failure to take into account all the information pertinent to the case in question might be.

When the idea of a BoA was first included in the Commission's proposal for REACH, it was thought that it would receive many hundreds of appeals and each would be addressed quickly. This has not proven to be the case. If you make an appeal you can be guaranteed that the appeals process is rigorous. There are many steps and I think that I can safely say that the parties to every appeal, regardless of the outcome, feel that they have been genuinely heard.

CW: What have been the high points in the past ten years?

AF: Working as a member of the BoA is one of the hardest jobs I have done. You have to put your name to decisions that are legally, and scientifically, sound and which can have a major impact on the interpretation of REACH (and the biocidal products Regulation) and its implementation by Echa. They can have a major impact on the level of protection of human health and the environment, animal testing and welfare, innovation and costs to business. Stakeholders value the opportunity to 'have their day in court'. The Echa Secretariat benefits from the BoA

being able to spend perhaps more time than they do on considering some very complex and multi-faceted challenges and problems.

Almost without exception, every full BoA decision has had to address new issues. This keeps the job interesting and motivating. But it is never far from your thoughts that our decisions can have a significant impact.

I am very pleased that some of our most important decisions on substance evaluation have been challenged before the General Court in Luxembourg, and the substance and content found to be correct in almost every respect. There are a number of appeals against BoA decisions pending before the courts. I welcome this. Even if the courts find that we are wrong in certain respects, this at least brings further clarity and certainty. We do our best but to expect us to be right in everything we do is probably unrealistic.

Of course, any discussion of my 'high points' has to mention my colleagues. I have worked with some exceptional people in BoA and its registry, Echa and external stakeholders. I have to give particular thanks to Mercedes Ortuño, the first chair of the Board of Appeal, who turned a legal idea into reality and carried BoA through many challenges in its first ten years. She has been succeeded by Antoine Buchet who is continuing the high standard set by Mercedes Ortuño and is, I am sure, a very safe pair of hands.

CW: Among the more than 100 cases you have worked on, which stand out most to you?

AF: My 'favourite' decisions, based on importance and how interesting they were to work on, include the following. [For links to the decisions on Echa's website, see 'Further Information below']

Honeywell (compliance check and animal welfare) (A-005-2011)

BoA's decision set out, for the first time, the powers and duties of the agency under compliance check (and more generally). In particular, BoA examined the agency's discretion as well as its responsibilities (eg under Article 25 and with regards to cooperation with registrants). It also set out for the first time how the principle of proportionality is applied in such cases.

BoA confirmed that the agency was entitled to require further information on the substance at issue because of concerns arising from the results of a prenatal 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 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.

Solutia Europe – the follow-up procedure under Article 42 (A-019-2013)

This decision related to a follow-up evaluation case and a statement of non-compliance (Sonc) letter. BoA clarified the duties of the agency in following up a dossier evaluation decision. Under 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.

Note that the General Court's 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.

The General's Court decision was appealed in C-471/18 P. A judgment is expected on 21 January. On the follow-up procedure, see also BoA's decisions in cases A-012-2019, A-013-2019 and A-001-2019.

Akzo Nobel Industrial Chemicals GmbH and others – substance evaluation (A-005-2014)

One of the early substance evaluation (SEv) cases. BoA developed the criteria that Echa must satisfy to demonstrate that information requested is necessary. (These criteria have been confirmed by the General Court in T-125/17, BASF Grenzach v Echa and T-755/17, Germany v Echa.) This decision also sets out in detail the reasons behind the criteria.

BoA also addressed for the first time the issue of the agency requesting standard information under SEv rather than compliance check (CCH). The position has been clarified in other SEv decisions (see for example A-023-2015, SA Akzo Nobel Chemicals NV).

Huntsman Holland – compliance check, titanium dioxide (A-011-2014)

The BoA decision held that the REACH Annexes, at the time, did not permit Echa to ask for the information in its appealed decision on nanoforms for the purposes of registration. As a result of this BoA decision the registration Annexes were changed. The decision also found that if a registrant chooses to define its substance broadly, it then needs to show that the registration information it provides covers the entire breadth of the definition.

Evonik Degussa GmbH and others – substance evaluation (A-015-2015)

BoA addressed issues regarding requests for information on nanomaterials under SEv.

The contested decision requested information on four types of synthetic amorphous silica ('SAS'). BoA upheld a request for inhalation toxicity testing on four 'forms' of one type of SAS, pyrogenic SAS. However, BoA annulled the contested decision in so far as it requested information on: precipitated SAS, colloidal SAS and silica gel; surface treated SAS; and physico-chemical properties and uses of 'forms' of pyrogenic SAS.

BoA found that the agency had not demonstrated a potential risk for three types of SAS. In particular, it 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 concern for inhalation toxicity related to pyrogenic SAS. The evidence of this, 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 pyrogenic SAS.

BoA found that the request in the contested decision for information on the physico-chemical properties of each individual 'form' of pyrogenic SAS breached the principle of proportionality because the agency had not demonstrated how that information would clarify the potential concern identified. The request was therefore annulled.

SI Group UK – substance evaluation of a polymer (A-006-2016)

The BoA decision held that it is in principle possible to require the registrants of a monomer to provide information on polymers, namely information on the content of monomers in the polymer as an impurity after polymerisation, or as break-down products of the polymer. It pulled together several strands of BoA precedent, resulting from appeals against Echa substance evaluation decisions.

BASF Grenzach – substance evaluation of triclosan (A-018-2014)

A crucial BoA decision because it led to an important judgment by the General Court (T-125/17), following an appeal, confirming the approaches BoA was taking to substance evaluation.

Clariant Plastics & Coatings – compliance check, long-term aquatic toxicity testing (A-011-2018)

The BoA decision pulled together a number of strands of BoA precedent, resulting from appeals against Echa compliance check decisions eg the role of Echa in compliance checks, the requirements for weight-of-evidence adaptations, the burden of proof, the relevant time for assessing the compliance of a study with test guidelines. It also provided the BoA interpretation of Col 2 of section 9.1. of Annex IX (long-term aquatic toxicity testing (fish)).

Symrise – cosmetics (A-010-2018)

The BoA decision addresses the complex and challenging relationship between the cosmetics Regulation and REACH. It is currently being challenged before the General Court. The BoA decision contains a clear explanation of why BoA came to the conclusion it did. Even if the courts disagree with the BoA decision, it should at least bring about long needed clarity to the area.

Arkema France – first BoA decision on technical equivalence under the biocidal products Regulation (A-004-2019)

BoA clarified the duties of the agency in the technical equivalence (BPR) decision-making procedure.

Under Article 54(5) of the BPR, if the agency considers that the information provided in an application for technical equivalence is insufficient, it must request that the applicant submit the necessary additional information.

BoA found that the agency must ensure that its additional information request is sufficiently clear and comprehensive to allow the applicant to gather and submit the information needed for the technical equivalence assessment.

BoA held that the agency breached the appellant's right to good administration in two respects. First, it failed to specify clearly and comprehensively the additional information that the appellant was supposed to submit. Second, the agency breached the appellant's right to be heard by rejecting its application, partly based on considerations on which the appellant did not have an opportunity to effectively make known its views.

3V Sigma – UVASORB HEB (A-004-2017)

BoA confirmed its previous finding that PBT (persistence, bioaccumulation, toxicity) assessment of a substance must be based on data obtained under relevant conditions that allow for an objective assessment of the PBT/vPvB (very persistent/very bioaccumulative) properties instead of under particular environmental or realistic conditions.

It clarified the role of transformation and/or degradation products in the PBT assessment of a parent substance, the use of the Qsar models in predicting the properties of substances and the relevance of different indicators for bioaccumulative properties. In particular, BoA found that the agency had, by use of the results from Qsar models, established that the substance UVASORB HEB may form transformation and/or degradation products in the environment and that some of those may be PBT and pose a potential risk to the environment. It was therefore necessary to clarify this uncertainty, by requesting a study aiming at identifying the transformation and/or degradation products that are actually formed.

The appellant contested the decision before the General Court in case T 176/19, 3V Sigma v Echa. By its judgment of 16 December 2020, the General Court confirmed the findings of BoA in particular with regard to the relevant testing temperature for simulation studies, aiming at identifying the transformation and/or degradation products of a substance.

CW: What have the challenges been?

AF: BoA is a vulnerable body. It is very small and housed at Echa, supported by its staff and services. I would urge the Echa management board to maintain its vigilance to protect the integrity and independence of BoA. In some respects, a BoA may be considered a luxury but I think it has, during its just over ten years' existence, shown its worth.

BoA's relationship with the Echa Secretariat has generally been rather fraught. Perhaps this is the way it should be? After all, Echa is one of the parties to every dispute that comes before BoA. While this makes life hard sometimes on a day-to-day basis, perhaps it is a very clear sign that the BoA is genuinely independent. Its independence was questioned by many in its early days. But this concern seems to have completely disappeared as stakeholders see our decisions and that, while they may not agree with all of them (and nor do I), they do demonstrate genuine independence.

Sometimes certain stakeholders have been critical of aspects of our decisions. Some of the criticism misrepresents what BoA is there to do. We don't make policy or legislation. We interpret legislation and as it has been written. This often requires looking at multiple language versions, records of the negotiations leading to the legislation, adopting a teleological approach and, of course, the case law of the EU courts. Our decisions do not reflect our personal wishes, rather our understanding of the legislation. We have to remember that every piece of EU legislation has been adopted by the EU Council and the European Parliament, our elected representatives, often representing many interests and positions, and often striking a balance between competing objectives. I certainly don't agree with every aspect of REACH but this is irrelevant. Our job is to apply the legislation as written and as intended, so far as we can judge, not to make policy.

CW: Looking forward, how do you see the future for Echa?

AF: The future for Echa is bright. There is increasing recognition that a holistic approach to the management of chemicals is needed. And who better than an established agency to take this forward? Echa is looking forward, it is looking strategically at the role it can play in implementing the European Commission's new chemicals strategy for sustainability, the European Green Deal, the circular economy, managing climate change, as well as work on endocrine disruptors, combination effects and very persistent chemicals, and other initiatives too numerous to mention here.

While REACH is a huge step forward in generating the information we need on chemicals, there is a far too piecemeal approach to how we then manage them; many actors and stakeholders, and many pieces of legislation often with fundamentally different approaches. I am a great believer in the idea of 'one substance, one assessment', at least to the extent possible. Let's assess the risks posed by substances (and yes, of course, mixtures and products in due course) and take a holistic approach to their management rather than depending on

an ad hoc approach under different pieces of legislation, and by many different bodies, actors, committees etc. And, of course, the more international we make the acceptance of such an assessment and its outcomes the better.

CW: And what does the future hold for you?

AF: I am as keen as ever to improve the management of chemicals, in the EU and internationally. Not only to ensure the protection of human health and the environment but also to help ensure that the capacity of chemicals to improve our lives is fulfilled. Chemicals are everything. They are everywhere, sometimes in places they shouldn't be! But we need them. They do amazing things. But they also of course cause many problems. I should like to help bring chemicals to the top of the agenda at an individual level, locally, nationally, EU-wide and globally. Developing, using and managing chemicals can be the key to (yes, I know this sounds rather grand) a better world and if I can be part of promoting this for the rest of my career I will be very happy. As a Brit I am extremely disappointed that I won't be at the centre of the EU's activities. But I hope that, despite my nationality, I can continue to make a contribution to national, EU and international developments.

For a more detailed look at BoA's decisions, please see three articles from Andrew Fasey and Luca Bolzonello which explain their impact on, first, the substance evaluation process, second, dossier evaluation, and, third, registration and cost and data sharing.

Andrew Fasey was one of the lead EU negotiators in the development of the Globally Harmonized System for the classification and labelling of chemicals (GHS). He represented the UK on the UN sub-committee of experts on the GHS. He was a key member of the team at the European Commission that drafted its proposal for the REACH Regulation. And he was special adviser on REACH to the Government of Finland when the Regulation was finally adopted. These are his personal views and do not necessarily represent the views of BoA or Echa.

FURTHER INFORMATION

Decision of the BoA: A-005-2011, Honeywell (compliance check and animal welfare)

Decision of the BoA: A-019-2013, Solutia Europe (the follow-up procedure under Article 42)

Decision of the BoA: Case A-005-2014, Akzo Nobel Industrial Chemicals GmbH and Others (substance evaluation)

Decision of the BoA: A-011-2014, Huntsman Holland (Compliance check, titanium dioxide)

Decision of the BoA: A-015-2015, Evonik Degussa GmbH and Others (substance evaluation)

Decision of the BoA: A-006-2016, SI Group UK (Substance evaluation of a polymer)

Decision of the BoA: A-018-2014, BASF Grenzach (Substance evaluation of triclosan)

Decision of the BoA: A-011-2018, Clariant Plastics & Coatings (Compliance check, long term aquatic toxicity testing (fish))

Decision of the BoA: Symrise – cosmetics (A-010-2018)

Decision of the BoA: Arkema France – first BoA decision on technical equivalence under the biocidal products Regulation (A-004-2019)

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