EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

DECISION OF THE CHAIRMAN OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

25 September 2015

(Biocidal Products – Active substance – Article 95 list – Admissibility)

Case number	A-020-2015
Language of the case	English
Appellants	Lysoform Dr. Hans Rosemann GmbH, Germany Bode Chemie GmbH, Germany B. Braun Melsungen AG, Germany Diversey Europa Operations By, The Netherlands Ecolab Deutschland GmbH, Germany Schülke & Mayr GmbH, Germany
Representative	Koen Van Maldegem FieldFisher LLP
Contested Decision	ACC-D-1128588-38-00/F of 16 July 2015 adopted by the European Chemicals Agency (hereinafter the 'Agency') in accordance with Article 95 of Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1) (hereinafter the 'BPR')

THE CHAIRMAN OF THE BOARD OF APPEAL

gives the following

Decision

Relevant legislation

The REACH Regulation

1. Article 92(1) of 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, p. 3; hereinafter 'the REACH Regulation') provides as follows:

   'Any natural or legal person may appeal against a decision addressed to that person, or against a decision which, although addressed to another person, is of direct and individual concern to the former.'

2. Article 93(2) of the REACH Regulation provides as follows:

   'In cases other than those referred to in paragraph 1 of this Article, the Chairman of the Board of Appeal shall examine whether the appeal is admissible within 30 days of the appeal being filed in accordance with Article 92(2). In the affirmative, the appeal shall be remitted to the Board of Appeal for examination of the grounds. Parties to the appeal proceedings shall be entitled to make an oral presentation during the procedure.'

3. Article 94(2) of the REACH Regulation provides as follows:

   'Should the Agency fail to take a decision, proceedings for failure to act may be brought before the Court of First Instance or the Court of Justice in accordance with Article 232 of the Treaty.'

The Rules of Procedure

4. Article 11(2) of Commission Regulation (EC) No 771/2008 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; hereinafter 'the Rules of Procedure') provides as follows:

   'If the Chairman does not decide on the admissibility of the appeal within the time limit laid down in Article 93(2) of Regulation (EC) No 1907/2006, the appeal shall be remitted to the Board of Appeal for examination of the grounds and the admissibility. The decision on admissibility shall form part of the final decision.'

The Biocidal Products Directive

5. Article 11(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 123, 24.4.1998, p. 1; hereinafter 'the BPD') provides as follows:

   'The receiving competent authority shall, within 12 months of accepting the dossiers, carry out an evaluation thereof. A copy of the evaluation shall be sent by the competent authority to the Commission, the other Member States and to the applicant, together with a recommendation for the inclusion, or otherwise, of the active substance in Annex I, IA or IB.

   If, when the dossiers are evaluated, it appears that further information is necessary for full evaluation to be made, the receiving competent authority shall ask that the applicant submit such information. The 12-month period shall be suspended from the date of issue of the competent authority's request until the date the information is

received. The competent authority shall inform the other Member States and the Commission of its action when it informs the applicant.'

6. Article 16(2) of that Directive provides as follows:

'Following the adoption of this Directive, the Commission shall commence a 10-year programme of work for the systematic examination of all active substances already on the market on the date referred to in Article 34(1) as active substances of a biocidal product for purposes other than those defined in Article 2(2)(c) and (d). A Regulation, adopted according to the procedure laid down in Article 28(3), will provide for all provisions necessary for the establishment and implementation of the programme including the setting of priorities for the evaluation of the different active substances and a timetable. No later than two years before completion of the work programme, the Commission shall forward to the European Parliament and the Council a report on the progress achieved with the programme.

During that 10-year period and from the date referred to in Article 34(1), it may be decided pursuant to the procedure laid down in Article 28(3) that an active substance shall be included in Annexes I, IA or IB and under which conditions, or, in cases where the requirements of Article 10 are not satisfied or the requisite information and data have not been submitted within the prescribed period, that such active substance shall not be included in Annex I, IA or IB.'

The 'First Phase' Regulation

7. Article 4(1) of Commission Regulation (EC) No 1896/2000 on the first phase of the programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council on biocidal products (OJ L 228, 8.9.2000, p. 6; hereinafter 'the FPR') provides as follows:

'Producers, formulators and associations wishing to apply for the inclusion in Annex I or Annex IA to the Directive of an existing active substance in one or more product types shall notify that active substance to the Commission by submitting the information referred to in Annex II to this Regulation to be received not later than 18 months after this Regulation enters into force.

Whenever a formulator or a producer is aware of another notifier's possible intention to notify the same active substance, they shall undertake all reasonable efforts to present a common notification, in whole or in part, in order to minimise animal testing.

In submitting the notification, the notifier shall use the special software package (IUCLID) made available free of charge by the Commission.

Member States may require notifiers established in their territory to submit simultaneously to their competent authorities the same information as is submitted to the Commission.'

The 'Second Phase' Regulation

8. Article 14(1) of Commission Regulation (EC) No 1451/2007 on the second phase of the 10-year work programme referred to in Article 16(2) of Directive 98/8/EC of the European Parliament and of the Council concerning the placing of biocidal products on the market (OJ L 325, 11.12.2007, p. 3; hereinafter 'the SPR') provides as follows:

'Where the Rapporteur Member State considers a dossier to be complete, it shall carry out the evaluation within twelve months of accepting the dossier in accordance with

Article 11(2) of Directive 98/8/EC and shall prepare a report on that evaluation, hereinafter 'the competent authority report'.

Without prejudice to Article 12 of Directive 98/8/EC, the Rapporteur Member State may take into account other relevant technical or scientific information regarding the properties of the active substance, metabolites or residues.'

The Biocidal Products Regulation

9. Article 62(2) of the BPR provides as follows:

'Any person intending to perform tests or studies ('the prospective applicant')

(a) shall, in the case of data involving tests on vertebrates; and

(b) may, in the case of data not involving tests on vertebrates,

submit a written request to the Agency to determine whether such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application under this Regulation or Directive 98/8/EC. The Agency shall verify whether such tests or studies have already been submitted.

Where such tests or studies have already been submitted to the Agency or to a competent authority in connection with a previous application, under this Regulation or Directive 98/8/EC, the Agency shall, without delay, communicate the name and contact details of the data submitter and data owner to the prospective applicant.

The data submitter shall, where relevant, facilitate contacts between the prospective applicant and the data owner.

Where the data acquired under those tests or studies are still protected under Article 60, the prospective applicant:

(a) shall, in the case of data involving tests on vertebrates; and

(b) may, in the case of data not involving tests on vertebrates,

request from the data owner all the scientific and technical data related to the tests and studies concerned as well as the right to refer to these data when submitting applications under this Regulation.'

10. Article 63(3) of the BPR provides as follows:

'*Where no agreement is reached with respect to data involving tests or studies on vertebrates, the prospective applicant shall inform the Agency and the data owner thereof, at the earliest one month after the prospective applicant receives the name and address of the data submitter from the Agency.*

Within 60 days of being informed, the Agency shall give the prospective applicant permission to refer to the requested tests or studies on vertebrates, provided that the prospective applicant demonstrates that every effort has been made to reach an agreement and that the prospective applicant has paid the data owner a share of the costs incurred. Where the prospective applicant and data owner cannot agree, national courts shall decide on the proportionate share of the cost that the prospective applicant is to pay to the data owner.

…'

11. Article 77(1) of the BPR provides as follows:

'1. Appeals against decisions of the Agency taken pursuant to Articles 7(2), 13(3), 43(2) and 45(3), Article 54(3), (4) and (5), and Articles 63(3) and 64(1) shall lie with the Board of Appeal set up in accordance with Regulation (EC) No 1907/2006.

Article 92(1) and (2) and Articles 93 and 94 of Regulation (EC) No 1907/2006 shall apply to appeal procedures lodged under this Regulation.

Fees may be payable, in accordance with Article 80(1) of this Regulation, by the person bringing an appeal.'

12. Article 95(1) , (2) and (3) of the BPR provide as follows:

'As of 1 September 2013, the Agency shall make publicly available and shall regularly update a list of all active substances, and all substances generating an active substance, for which a dossier complying with Annex II to this Regulation or with Annex IIA or IVA to Directive 98/8/EC and, where relevant, Annex IIIA to that Directive ('the complete substance dossier') has been submitted and accepted or validated by a Member State in a procedure provided for by this Regulation or that Directive ('the relevant substances'). For each relevant substance, the list shall also include all persons having made such a submission or a submission to the Agency in accordance with the second subparagraph of this paragraph, and indicate their role as specified in that subparagraph, and the product-type(s) for which they have made a submission, as well as the date of inclusion of the substance in the list.

A person established within the Union who manufactures or imports a relevant substance, on its own or in biocidal products ('the substance supplier') or who manufactures or makes available on the market a biocidal product consisting of, containing or generating that relevant substance ('the product supplier'), may at any time submit to the Agency either a complete substance dossier for that relevant substance, a letter of access to a complete substance dossier, or a reference to a complete substance dossier for which all data protection periods have expired. Following the renewal of the approval of an active substance, any substance supplier or product supplier may submit to the Agency a letter of access to all the data which was considered by the evaluating competent authority as relevant for the purpose of the renewal, and for which the protection period has not yet expired ('the relevant data').

…'

'For the purposes of making a submission in accordance with the second subparagraph of paragraph 1 of this article, Article 63(3) of this Regulation shall apply to all toxicological, ecotoxicological and environmental fate and behaviour studies relating to substances listed in Annex II to Regulation (EC) No 1451/2007, including any such studies not involving tests on vertebrates.'

Summary of the facts

13. On 28 August 2015, the Appellants filed an appeal at the Registry of the Board of Appeal against the Contested Decision. The Appellants became aware of the Contested Decision, taken in accordance with Article 95(1) of the BPR, through a list of suppliers of active substances and biocidal products that the European Chemicals Agency (hereinafter the 'Agency') publishes on its website on a monthly basis pursuant to Article 95(2) of the same Regulation (hereinafter the 'Article 95 list'). By the Contested Decision, the Agency approved the inclusion of a company (hereinafter 'the other company') in the Article 95 list. The inclusion of the other company is apparent from the printout of the Article 95 list from the Agency's website dated 31 July 2015 and attached by the Appellants to the Notice of Appeal.

14. In the Notice of Appeal the Appellants request the Board of Appeal to declare the appeal admissible and well-founded, annul the Contested Decision and order the Agency to pay the costs of the proceedings.

Background to the dispute

15. Under Article 16(2) of the BPD, read in conjunction with Article 4(1) of the FPR, producers or formulators of biocidal active substances that were on the EU market prior to 14 May 2000 (hereinafter 'existing substances'), were required to notify these existing substances to the Commission before 28 March 2002 for their review under a ten year work programme. A programme of work was established to identify all existing substances and determine those to be evaluated under a review programme (hereinafter 'the review programme') with a view to their possible inclusion in Annex I, IA or IB to the BPD. The SPR established detailed rules for the implementation of the programme of work for the systematic examination of all existing substances.

16. Under the review programme, the compliance check of notifications with the requirements of Article 4(1) of the FPR was carried out by the Commission in cooperation with the Member States. On 1 September 2013 and in accordance with Article 96 of the BPR, the BPD was repealed and producers and formulators of existing substances who had submitted a dossier that was accepted or validated by a Member State under the review programme were added to the Article 95 list.

17. The Appellants are members of a task force created in 2001 (hereinafter 'the task force') to share the cost of submitting a dossier for the review of several existing substances. The Appellants made a nofitication to the Commission for one of these existing substances (hereinafter the 'active substance') pursuant to Article 4(1) of the FPR before 28 May 2002 and submitted a dossier to the German competent authorities who acted as the Rapporteur Member State (hereinafter 'the RMS') for the purposes of Article 11 of the BPD. During the process of the review of the active substance, the RMS requested the Appellants on several occasions and pursuant to Article 11(2) of the BPD, read in conjunction with Article 14(1) of the SPR, to generate information on the *in vivo* mutagenicity of the active substance through a Comet Assay on rat liver, stomach and blood cells (hereinafter the 'Comet Assay'). The RMS justified the request based on its assessment of the properties and use of the substance and the application of Annex IIA, Section VI, Subsection 6.6.4 of the BPD. The task force subsequently generated and submitted the results of the Comet Assay to the RMS.

18. After the repeal of the BPD on 1 September 2013 and in accordance with Article 95(1) of the BPR, the Appellants were eligible to be automatically included in the Article 95 list with reference to the active substance and were subsequently included on the list on 24 September 2014.

19. The Appellants indicate that the other company made a request to the task force for access to an inhalation toxicity study in September 2013. The Appellants further indicate that the other company did not request access to the Comet Assay.

20. On 05 March 2015, the other company submitted a Letter of Access to a complete substance dossier to the Agency for the active substance in accordance with the second subparagraph of Article 95(1) of the BPR. On 16 July 2015, the Agency informed the other company through the Contested Decision that '*the application for inclusion in the Article 95 list is approved.*' In the Contested Decision, the Agency informed the other company that '*[i]n accordance with Article 263 of the Treaty on the Functioning of the European Union, you may lodge an application for the annulment of this decision with the General Court of the European Union.*'

21. On 28 July 2015, the Appellants wrote a letter to the Agency in which it '*informed [the Agency] that [the other company] applied for inclusion on the Article 95 list but did not submit or have access to [the Comet Assay].*' The Appellants further indicated in the letter that '*[d]espite this situation, [the Agency] still included [the other company] in the Article 95 list published on 26 June 2015.*' The Appellants requested in the letter

'*confirmation that [their] understanding is correct: i.e. that you do not consider that this study is necessary for the inclusion of [the other company] on the Article 95 list.*'

22. On 18 August 2015, the Agency replied to the Appellants' letter in the following terms: '*The assessment of the Article 95 applications is done in line with the provisions of the BPR. Please be aware that the data requirements for some endpoints are dependent on the outcome of other endpoints. Thus the data requirements may differ between dossiers for the same substance.*' The Agency further observed that '*with regard to your question about the Article 95 submissions from [the other company], we confirm that the in vivo study owned by [the task force], referred to in your letters of 28 July 2015 and 28 May 2015, is not required for the inclusion of [the other company] in the Article 95 list.*'

Arguments of the Appellants as regards the admissibility of the appeal

23. The Appellants submit that '*while the Contested Act is not expressly adopted on the basis of Article 63(3) of the BPR, […] this appeal can be brought under Article 77(1) [of the BPR] as if it had been.*'

24. In the Notice of Appeal, the Appellants formulate the premise that '*the Comet Assay test is necessary for any dossier on [the active substance supplied by the Appellants] to be considered complete.'* The Appellants add that '*another core premise is that the new regime of mandatory data sharing under the BPR would apply to the Comet Assay test meaning that the other company would have to negotiate access to the study in order to complete its dossier.*' The Appellants further submit that they expected the Agency to '*insist that [the other company] negotiates access to the Appellants' Comet Assay test under Article 62 and 63 of the BPR.*'

25. The Appellants explain their premise on the basis that the Appellants were requested by the RMS to submit a Comet Assay in order for their dossier for the active substance to be complete and by the fact that data sharing rules are mandatory under the BPR.

26. The Appellants further claim that *'had the proper rules and regimes been followed, [the Agency] would potentially have adopted a decision under Article 63(3) of the BPR*' and that such a decision would therefore have been appealable in accordance with Article 77(1). The Appellants therefore indicate that '*the Appeal is brought as if a decision had been taken by [the Agency] to grant access to [the other company] to the Comet Assay test in order for [the other company] to complete its dossier for Article 95 list inclusion purposes, which is, it is submitted, the course of procedure that should have been followed.*'

27. The Appellants further claim that '*no failure to act action under Article 265 of the Treaty on the Functioning of the European Union ("TFEU") can be brought by it against [the Agency] before the General Court for failure to issue an appealable decision under Article 63 of the BPR because no dispute procedure has been lodged under Article 62 of the BPR.*'

28. The Appellants further submit that '*if it can show that it is directly and individually concerned by the Contested Act, its appeal will be admissible in terms of a joint reading of Article 77(1) second paragraph of the BPR and Article 92(2) of REACH.*'

29. The Appellants submit that the Contested Decision is of direct concern to the Appellants as it granted an unfair competitive advantage to the other company which did not have to share a proportion of the costs borne by the Appellants during the review programme. The Appellants add that the other company can as a result sell its products at a cheaper price to its customers.

30. The Appellants also consider that they are individually concerned as they are participants in the review programme for the active substance under the BPD and the

BPR, and as they are listed in the Article 95 list and are owners of the Comet Assay '*which is lacking from [the other company's] dossier and which should have been included in that dossier for it to be included on the Article 95 List.*' The Appellants further add that '*the Appellants' data and dossier have been used by [the Agency] for the review of [the active substance]*' and that the Contested Decision had an influence on the competitive relationship between the Appellants and the other company as the other company can continue to place the active substance on the EU market after 1 September 2015.

Reasons

31. The Chairman of the Board of Appeal (hereinafter 'the Chairman') observes that the Appellants dispute the inclusion of the other company in the Article 95 list with reference to the active substance and consider that a decision should have been taken by the Agency under Article 63(3) of the BPR concerning the sharing of the costs of the Comet Assay between the other company and the Appellants.

32. The Chairman further observes that Article 63(3) of the BPR is triggered when no agreement is reached between a prospective applicant under the BPR and a data owner after a request to the Agency has been made by a prospective applicant in accordance with Article 62(2) of the same Regulation, in order for the prospective applicant to be given the name and contact details of a data owner when tests and studies have already been submitted in connection with a previous application under the BPD or the BPR. The Appellants do not claim that the other company made such a request. The Chairman observes that Article 63(3) of the BPR could not therefore have been triggered to enable the Agency to take a decision under that Article.

33. The Chairman considers that the Agency cannot take a decision of its own motion pursuant to Article 63(3) of the BPR. The Agency can only take a decision under that provison where it has been informed of a data sharing dispute by a prospective applicant. In essence, the argument of the Appellants amounts to requesting the Board of Appeal to consider whether the Agency should, notwithstanding the absence of a legal basis to do so, take decisions of its own motion in accordance with the data sharing obligations of the BPR to ensure the fair treatment between a participant to the review programme and a prospective applicant under Article 95(1) of the BPR.

34. In claiming that the Agency should have taken a decision to grant access to the other company to the Comet Assay when no Article of the BPR places such an obligation on the Agency, the Appellants implicitly contest the legality of the BPR. The Board of Appeal is not, however, competent to decide on this issue as only the Court of Justice of the European Union can rule on the legality of the BPR (see by analogy Case A-004-2011, *Kronochem GmbH*, Decision of the Board of Appeal of 7 October 2011, paragraph 66).

35. The Chairman observes that the Appellants claim that the Agency should have taken a decision in accordance with Article 63(3) of the BPR. The Chairman considers that if the Agency had a legal basis to take such a decision, which it did not, the Appellants' assertion would entail that the Agency had potentially failed to act under the BPR. The Chairman observes that the Board of Appeal does not have competence to examine claims of the Agency's failure to act. The Chairman notes that in accordance with Article 94(2) of the REACH Regulation, should the Agency fail to take a decision, proceedings for failure to act may be brought before the General Court. The Chairman further observes that it is not for the Board of Appeal to consider whether the requirements of an action for failure to act before the General Court are fulfilled.

36. The Chairman observes that the Contested Decision was adopted pursuant to Article 95(1) of the BPR. The Chairman further notes that the Board of Appeal cannot

examine an appeal against a decision that is not explicitly listed in Article 77(1) of the BPR and its implementing legislation or Article 91(1) of the REACH Regulation. In this respect, the Chairman notes that none of these provisions list decisions taken pursuant to Article 95(1) as appealable decisions.

37. The Appellants also rely on Article 92(1) of the REACH Regulation, which pursuant to Article 77(1) of the BPR is also applicable to appeals under the BPR, to justify that the Contested Decision, although not addressed to the Appellants, '*is of direct and individual concern to [the Appellants]*.' In particular, the Appellants consider that the inclusion of the other company on the Article 95 list had an influence on the competitive relationship between the Appellants and the other company.

38. The Chairman notes that, even if Article 92(1) of the REACH Regulation does open the possibility for potential appellants to appeal decisions not addressed to them, it does not open the possibility to appeal against decisions that are not under the competence of the Board of Appeal. As the Contested Decision is not listed as an appealable decision in the applicable legislation (see paragraph 36 above), it would thus not be appealable before the Board of Appeal even by the addressee(s) of the Contested Decision. It cannot therefore be contested by persons claiming to be individually and directly concerned.

39. For the reasons listed above the Chairman finds that the appeal does not comply with Article 77(1) of the BPR read in conjunction with Article 92(1) of the REACH Regulation. It is therefore inadmissible.

40. Consequently, the Chairman considers, in accordance with Article 93(2) of the REACH Regulation, that it is not necessary to examine the grounds raised by the Appellants in support of their request to annul the Contested Decision.

Claim for reimbursement of appeal costs

41. In their Notice of Appeal, the Appellants request the Board of Appeal to order the Agency to pay the Appellants' costs arising from the appeal proceedings.

42. The Board of Appeal observes that there is no legal basis in the Rules of Procedure for the reimbursement of costs that are not, as provided in Articles 17 and 21(1)(h) thereof, related to taking of evidence in appeal proceedings.

43. Consequently, and as in the present case no costs arose in relation to taking of evidence, the Board of Appeal rejects the Appellants' request for reimbursement of costs that it incurred in the appeal proceedings.

Refund of the Appeal fee

44. In accordance with Article 4(3) of Commission Implementing Regulation (EU) No 564/2013 on the fees and charges payable to the European Chemicals Agency pursuant to Regulation (EU) No 528/2012 of the European Parliament and of the Council concerning the making available on the market and use of biocidal products (OJ L 167, 19.6.2013, p. 17), if the appeal is considered inadmissible by the Chairman, the fee shall not be refunded.

On those grounds,

THE CHAIRMAN OF THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal.**
2. **Rejects the claim for the reimbursement of costs incurred by the Appellants in the appeal proceedings.**
3. **Decides that the appeal fee shall not be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal