

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

31 January 2017

# **Application to intervene**

(Interest in the result of the case)

Case number	A-007-2016
Language of the case	English
Appellant	Sharda Europe B.V.B.A., Belgium
Representative	Claudio Mereu Fieldfisher LLP, Brussels
Contested Decision	[CONFIDENTIAL] adopted by the European Chemicals Agency (hereinafter the 'Agency') pursuant to 63(3) of Regulation (EC) 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, 27.06.2012, p. 1; hereinafter the 'BPR')
Applicant to intervene	BASF Agro B.V. Arnhem (NL) – Zürich Branch, Switzerland

### THE BOARD OF APPEAL

composed of Mercedes Ortuño (Chairman and Rapporteur), Andrew Fasey (Technically Qualified Member) and Sari Haukka (Legally Qualified Member)

Registrar: Alen Močilnikar

gives the following

#### Decision

#### Summary of the facts

- 1. On 18 May 2016, the European Chemicals Agency (hereinafter the 'Agency') adopted the Contested Decision decision in accordance with Article 63(3) of the BPR by which it decided not to grant the Appellant permission to refer to certain studies it had requested from BASF SE.
- 2. The data-sharing dispute concerns the Appellant's request for access to certain studies for the purposes of an application to be included on the list of suppliers of active substances and biocidal products maintained by the Agency pursuant to Article 95 of the BPR (hereinafter the 'Article 95 list').
- 3. On 11 August 2016, the Appellant filed an appeal at the Registry of the Board of Appeal against the Contested Decision requesting its annulment. A copy of the Contested Decision was also sent to BASF SE.
- 4. On 29 September 2016, in accordance with Article 6(5) of Commission Regulation (EC) No 771/2008 of 1 August 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, as amended by Commission Implementing Regulation (EU) 2016/823, OJ L 137, 26.05.2016, p. 4, hereinafter the 'Rules of Procedure'), the Registrar of the Board of Appeal informed BASF SE of the lodgement of the appeal.
- 5. On 27 October 2016, an announcement of the Notice of Appeal was published on the website of the Agency in accordance with Article 6(6) of the Rules of Procedure.
- 6. On 9 November 2016, the Applicant to intervene (hereinafter the 'Applicant') filed an application with the Registry of the Board of Appeal seeking leave to intervene in the proceedings in support of the Agency.
- 7. On 18 November 2016, the application to intervene was served on the Appellant and the Agency for their observations. On 25 and 30 November 2016 respectively, the Agency informed the Board of Appeal that it raises no objections to the application to intervene, while the Appellant objected to the Applicant's intervention.

### Arguments

### Applicant's arguments

- 8. The Applicant claims an interest in the result of the case brought before the Board of Appeal for the following reasons:
  - (a) The Applicant manufactures and supplies alpha-cypermethrin, the active substance which is the subject of the Contested Decision (hereinafter the 'active substance'), and is the owner of the studies to which the Appellant seeks data access pursuant to Article 63 of the BPR. The Applicant claims that the Board of Appeal's decision under the present appeal could, if it found in favour of the Appellant, '*directly affect its right of ownership [to its] studies*' on the active substance. The Applicant adds that this right of ownership 'guarantees that [it] may unilaterally decide whether and to what extent it grants access rights to [its] property [and that] the right to property is a fundamental right of citizens and legal entities.'
  - (b) The Applicant adds that, following the Appellant's request for access to certain data, it has tried to reach an agreement on the sharing of the studies on the active substance and in particular on the associated cost. The Applicant adds that, pursuant to Article 63 of the BPR, it is entitled to the payment of a proportionate share of the costs incurred. The Applicant explains that its estimate of the cost compensation and that of the Appellant differed considerably. The Applicant submits that it 'proposed to agree on an independent

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third party laboratory to evaluate the baseline study cost, [meaning] the replacement value of the studies, and to define a compensation formula to establish the compensation required within a defined financial range.' The Applicant stresses that this proposal was rejected by the Appellant.

- (c) The Applicant claims that, should the Board of Appeal find in favour of the Appellant, a decision to grant permission to the Appellant to refer to the Applicant's data would necessarily require a decision on compensation, based on a proportionate share of the cost for the studies owned by the Applicant, to be decided by a national court in accordance with Article 63(3) of the BPR. The Applicant claims that the payment of such compensation 'qualifies as a direct, existing interest in the result of the present case.'
- (d) As an applicant for approval of the active substance, the Applicant claims that it has made investments and borne 'the risk to support [the active substance] as a biocide under the BPR.' The Applicant explains that it will start benefiting from this investment now that the active substance has been approved and that products containing the active substance are about to be authorised. If the Appellant becomes an approved supplier of the active substance, enjoying the same rights as the Applicant, the Applicant claims that the Appellant 'has to contribute to the cost of generation of the requested studies and offer a fair compensation to the Applicant.' The Applicant adds further that it 'continues to make every effort to reach an agreement in good faith with the Appellant.'

# Appellant's arguments

- 9. The Appellant objects to the application to intervene for the following reasons:
  - (a) The Appellant claims that the Applicant was not directly and individually concerned by the Contested Decision. The Appellant submits that BASF SE was in copy of the Contested Decision and not the Applicant, BASF Agro B.V. Arnhem (NL) Zürich Branch. The Appellant further submits that this is confirmed by the letter of the Registry of the Board of Appeal to the Appellant referred in paragraph 4 above. The Appellant concludes that the Applicant, which seeks to intervene, is a different legal entity from the one involved in the Contested Decision and, *a fortiori*, in the appeal proceedings lodged before the Board of Appeal.
  - (b) The Appellant claims that the Applicant was neither directly nor individually concerned with the data sharing proceedings which are the subject of the Contested Decision as it was never involved in the negotiations. The Appellant submits that BASF SE and another entity, BASF France S.A.S, were the entities with whom the data sharing negotiations took place.
  - (c) The Appellant claims that the Applicant does not have a direct and existing interest in the result of the case. The Appellant submits that, as BASF SE and BASF France S.A.S were the legal entities with whom the data sharing negotiations took place, it follows that the Applicant does not have any direct interest in the payment by the Appellant of compensation in exchange for access to the studies. The Appellant claims that the Applicant will not be affected by the form of order sought by the Appellant in the current appeal proceedings, such as one allowing the Appellant to refer to the requested studies.

- 10. In accordance with Article 8(1) of the Rules of Procedure, any person establishing an interest in the result of a case submitted to the Board of Appeal may intervene in the proceedings before the Board of Appeal.
- 11. Article 8(2) of the Rules of Procedure provides further that an application to intervene must state the circumstances establishing the right to intervene and must be submitted within three weeks of publication of the announcement of the notice of appeal on the website of the Agency. Furthermore, pursuant to Article 8(3) of the Rules of Procedure the application must be limited to supporting or opposing, in whole or in part, the remedy sought by one of the parties. In addition, Article 8(4) of the Rules of Procedure lists the information the application shall contain.
- 12. Since the application complies with Articles 8(2), 8(3) and 8(4) of the Rules of Procedure, the Board of Appeal shall examine whether the application complies with Article 8(1) of the Rules of Procedure, in other words whether the Applicant has established an interest in the result of the present case.
- 13. The Board of Appeal observes that, as cited above, when examinining an application to intervene pursuant to 8(1) of the Rules of Procedure, it needs to consider whether an applicant has established an interest in the result of a case. Contrary to the Appelant's claim it is not necessary for the Board of Appeal to examine whether the Applicant is directly and individually concerned by the Contested Decision but only if the Applicant can show an interest in the result of the appeal.
- 14. The Appellant also argues against the application to intervene as the Contested Decision was not addressed to the Applicant. The Board of Appeal notes in this regard that there is no requirement in the Rules of Procedure for an intervener to be the addressee of a contested decision. The Board of Appeal further observes that the issue as to whether the Contested Decision was or was not addressed to the Applicant is not decisive when examining the requirement for the Applicant to have established an interest in the result of the case. For example, the Board of Appeal previously granted leave to intervene to a non-governmental association that was not the addressee of the contested decision as the case raised questions of principle liable to affect their members (see Case A-001-2014, *Cinic Chemicals Europe Sàrl*, Decision of the Board of Appeal of 2 June 2014 on the application to intervene by the European Coalition to End Animal Experiments). The argument that the application has to be rejected because the Applicant was not the addressee of the Contested Decision is therefore irrelevant for the purpose of the present decision.
- 15. As to the Appellant's argument that the Applicant was not involved in the data sharing negotiations which are the subject of the Contested Decision, the Board of Appeal finds that this is not the case. The Board of Appeal observes that, on 29 October 2014, following an inquiry from the Appellant according to Article 62(2) of the BPR, the Agency identified the Applicant and BASF SE as the data submitters for the active substance and provided the Appellant with the contact details of both BASF entities. The Board of Appeal notes that the Appellant signed a confidentiality agreement with the Applicant on 10 February 2015 (hereinafter the 'confidentiality agreement') preventing the disclosure of confidential information contained in the requested studies being shared. The Board of Appeal also notes from the submissions in the case that when negotiating access to data on the active substance prior to the adoption of the Contested Decision with the representatives of BASF SE and BASF France S.A.S, the Appellant did not raise any objections to the Applicant being the other party to the confidentiality agreement.
- 16. Furthermore, the Appellant has been involved in negotiations for data access on the basis of a draft '*Data Access Agreement*' (hereinafter the 'draft letter of access') sent by BASF SE on 14 August 2015 which explicitly indicates that the Applicant is the owner of the data concerned. On 26 August 2015 the Appellant sent back to BASF SE a marked-up version of the draft letter of access without objecting to, or questioning, the mention of the Applicant as the data owner. Finally, the Board of Appeal notes that

the printout of the Article 95 list as published on the Agency's website on 27 July 2016 includes the Applicant as the only active substance supplier.

- 17. In view of the above, the Board of Appeal finds that although the Applicant was not directly involved in the data sharing negotiations it is clear from the documents mentioned above that the negotiations were conducted on its behalf.
- 18. Moreover, the Board of Appeal notes that the Appellant's submissions, in particular the confidentiality agreement and the draft letter of access, show that the Applicant holds ownership rights to the studies subject to the Contested Decision. This has not been disputed by the Appellant.
- 19. The Board of Appeal considers therefore that the outcome of the present appeal may affect the Applicant's ownership rights. The result of the present appeal may mean that the Applicant has to share some of its data with the Appellant, and this may mean that they are then entitled to financial compensation for such data potentially after the ruling of a national court according to Article 63(3) of the BPR.
- 20. The Board of Appeal concludes therefore that the Applicant has established an interest in the result of a case as provided in Article 8(1) of the Rules of Procedure.
- 21. In those circumstances, the application to intervene submitted by the Applicant must be granted.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to intervene by BASF Agro B.V. Arnhem (NL) Zürich Branch in Case A-007-2016 in support of the Agency.
- 2. Instructs the Registrar to arrange for copies of the non-confidential versions of the Notice of Appeal and the Defence to be served on the Intervener.
- 3. Allows the Intervener a period of four weeks, following the serving of the Notice of Appeal and the Defence to lodge a statement in intervention.

Mercedes Ortuño Chairman of the Board of Appeal

Alen Močilnikar Registrar of the Board of Appeal