

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

10 February 2016

Application to intervene

(Interest in the result of the case – Organisation for the protection of the environment – Accredited Stakeholder Organisation)

Case number A-015-2015

Language of the case

English

Applicants ClientEarth, United Kingdom, and

Center for International Environmental Law, United States of America

Contested Decision

Decision of 11 March 2015 on the substance evaluation of silicon dioxide adopted by the European Chemicals Agency pursuant to Article 46(1), and in accordance with the procedure laid down in Articles 50 and 52, 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')

Appellants Evonik Degussa GmbH and Others

Representatives Ruxandra Cana, Indiana de Seze and Eléonore Mullier

Steptoe & Johnson LLP

THE BOARD OF APPEAL

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

Registrar: Alen Močilnikar

gives the following

Decision

Summary of the facts

- 1. On 10 June 2015, the Appellants filed an appeal at the Registry of the Board of Appeal against the Contested Decision of 11 March 2015 on the substance evaluation of silicon dioxide (hereinafter the 'Substance').
- 2. On 19 August 2015, an announcement of the Notice of Appeal was published on the website of the European Chemicals Agency (hereinafter the 'Agency') in accordance with Article 6(6) 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').
- 3. On 2 September 2015, the Applicants filed an application with the Registry of the Board of Appeal seeking leave to intervene in the proceedings in support of the Agency.
- 4. On 30 September 2015, the application to intervene was served on the Appellants and the Agency. On 9 and 20 October 2015 respectively, the Agency and the Appellants submitted their observations on the application to intervene.

Arguments

Applicants' arguments

- 5. ClientEarth, an environmental non-governmental organisation, claims an interest in the result of the case brought before the Board of Appeal for the following reasons:
 - (a) Since 2010 ClientEarth has involved lawyers working within its 'health and environment toxics programme' with the objective of using available legal tools to protect human health and the environment from the harmful effects of chemicals;
 - (b) ClientEarth is an accredited stakeholder at the Agency and is an observer at the Risk Assessment Committee, the Socio-Economic Analysis Committee and the Member State Committee (hereinafter the 'MSC'). It is also an observer in the meetings of the Competent Authorities for REACH and CLP ('CARACAL');
 - (c) ClientEarth has worked on the need for nanoforms of substances to be properly accounted for in registration dossiers submitted under the REACH Regulation, and for the Community Rolling Action Plan (hereinafter 'CoRAP') to include all identified substances in their nanoforms;
 - (d) In 2014, ClientEarth prepared, with other non-governmental organisations (hereinafter 'NGO' or 'NGOs'), a position paper on the regulation of nanoforms;
 - (e) In 2014, ClientEarth submitted a request for an internal review of the Commission Regulation approving synthetic amorphous silicon dioxide as an existing active substance for use in biocidal products. The internal review request was submitted because ClientEarth was concerned that a specific risk assessment was not performed separately for the nanoform of that substance, and that no justification had been provided to demonstrate the overall suitability of the tests used for the nanoforms of that substance;
 - (f) ClientEarth, together with other NGOs, issued a proposal for European Union legislation to address the risks of nanomaterials. It also responded to the European Commission's public consultations on the review of the Annexes to the REACH Regulation in relation to the information requirements for the registration of nanomaterials and the definition of nanomaterials;

- (g) ClientEarth has long held the position that nanoforms of substances present different risks for human health and the environment from the substances themselves, and that registration dossiers do not provide adequate information for assessing those risks; and
- (h) Given ClientEarth's involvement in advocating for the registration, assessment, and evaluation of the nanoforms of substances, the annulment of the Contested Decision would directly affect ClientEarth as the Contested Decision involves an issue of principle liable to affect ClientEarth's interests to an appreciable extent.
- 6. The Center for International Environmental Law (hereinafter 'CIEL'), an environmental non-governmental organisation, claims an interest in the result of the case brought before the Board of Appeal for the following reasons:
 - (a) Since the REACH Regulation entered into force in 2008 the focus of CIEL's 'environmental health programme' has been on ensuring that nanomaterials are adequately addressed by the REACH Regulation. CIEL has, in particular, focused on ensuring that nanomaterials are adequately registered under the REACH Regulation, and that sufficient information is provided to the Agency to guarantee an adequate risk assessment of all nanomaterials entering the European Union market;
 - (b) CIEL is one of two NGOs representing civil society in the meetings of the REACH Competent Authority sub-group on nanomaterials, focusing on adapting the REACH framework to the specificities of nanomaterials;
 - (c) CIEL has published, individually and jointly, studies on the application of the REACH Regulation to nanomaterials and is involved in civil societies' engagement in this issue; and
 - (d) Given CIEL's involvement in advocating for the registration, assessment, and evaluation of the nanoforms of substances, the annulment of the Contested Decision would directly affect CIEL as the Contested Decision involves an issue of principle liable to affect CIEL's interests to an appreciable extent.

Arguments of the Agency and the Appellants

- 7. The Agency states that it leaves the Board of Appeal to decide whether the conditions set out in Article 8(1) of the Rules of Procedure have been met in the present case. The Agency adds however that neither of the Applicants took part in the discussion leading to the adoption of the Contested Decision. The Agency states that, according to the minutes of the MSC meeting at which the Contested Decision was adopted, neither of the Applicants observed the deliberations of the Committee.
- 8. The Agency also makes reference to the observations it has made in other cases regarding its interpretation of the case-law of the European Courts on the notion of interest in the result of a case as regards NGOs.
- 9. The Agency states that ClientEarth is an Accredited Stakeholder Organisation with the Agency whilst CIEL is not.
- 10. The Appellants claim that neither of the Applicants has established an interest in the outcome of the present case and therefore neither meets the criteria for being granted leave to intervene.
- 11. The Appellants claim that the Applicants' interest concerns nanomaterials in general and that neither of the Applicants has established an interest in the outcome of this specific case.

- 12. The Appellants claim in particular that the Applicants have not satisfied the criteria for applications to intervene by organisations committed to the protection of the environment as set out by the General Court. In support of their arguments the Appellants refer to the Order of the First Chamber of the General Court of 20 October 2014 in Case T-451/13, Syngenta Crop Protection AG v Commission, and the Order of the First Chamber of the General Court of 21 October 2014 in Case T-429/13, Bayer CropScience AG v Commission, EU:T:2014:920, in which applications by ClientEarth, amongst others, were considered. In particular, the Appellants claim, based on that case-law, that the activities described in the present application to intervene are much wider than, and unconnected to, the registration of the substance which is the focus of the Contested Decision and are even wider than the REACH Regulation itself.
- 13. The Appellants add that the intervention, if granted, is limited to supporting the remedy sought by the Agency, which is the dismissal of the appeal. The Appellants claim that such a remedy is not liable to affect the Applicants to an appreciable extent.
- 14. The Appellants also state that CIEL has no legal establishment in the European Union.
- 15. The Appellants argue that none of the evidence presented by the Applicants to demonstrate an interest in the present case refers to the Substance. According to the Appellants, the evidence presented by the Applicants refers only to the REACH Regulation as a whole or nanomaterials in general. According to the Appellants, the only reference to the Substance was made in the context of Regulation (EU) No 528/2012 of the European Parliament and the Council concerning the making available on the market and use of biocidal products (OJ L 167, 27.6.2012, p. 1).

Reasons

- 16. 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 that case.
- 17. Article 8(2) of the Rules of Procedure provides that an application to intervene must state the circumstances establishing the right to intervene and must be submitted within two weeks of publication of the announcement of the notice of appeal on the website of the Agency. Furthermore, pursuant to Article 8(3), the application must be limited to supporting or opposing the remedy sought by one of the parties. In addition, Article 8(4) lists the information the application shall contain.
- 18. Since the application complies with Article 8(2), (3) and (4) of the Rules of Procedure, the Board of Appeal will examine whether the application also complies with Article 8(1) of the Rules of Procedure, in other words whether the Applicants have established an interest in the result of the present case. In this regard, the Board of Appeal will firstly examine ClientEarth's interest in the result of the present case.
- 19. The Board of Appeal observes that in its observations on the application to intervene the Agency refers to the fact that it considers that the Board of Appeal has previously made a broad interpretation of the case-law of the European Courts and that in its observations on applications to intervene made in other cases the Agency has presented a different and narrower interpretation of that case-law. The Board of Appeal observes, however, that only arguments specifically made in a submission for the case at issue can be considered by the Board of Appeal for the purposes of that case. References to arguments made in other cases, unless reiterated in full, cannot be accepted. Consequently, the Agency's references to observations it has made in previous cases cannot be taken into account by the Board of Appeal for the purposes of the present application.

- 20. In its application to intervene ClientEarth states that it is an Accredited Stakeholder Organisation with the Agency and that it has a particular interest in areas of the Agency's work related to nanomaterials.
- 21. The Board of Appeal underlines that Article 8(1) of the Rules of Procedure should be interpreted with due regard to the REACH Regulation and the administrative nature of these proceedings.
- 22. The Board of Appeal also observes that the REACH Regulation foresees the involvement of stakeholders in the Agency's work through consultations and in the workings of the committees that are established within the Agency (see, for instance, Article 108 of the REACH Regulation). This involvement aims to help ensure that various interests are taken into account in the Agency's decision-making.
- 23. The document endorsed by the Management Board of the Agency on 16 December 2011 on the Agency's approach to engagement with its Accredited Stakeholder Organisations (Doc.: MB/69/2011 final) states that the Agency's values of transparency, trustworthiness, efficiency, independence and commitment to well-being encourage it to extend its engagement beyond what is specifically stated in the REACH Regulation. According to that document, the engagement is based on 'cooperation models providing maximum mutual benefit, and is proactive'. Moreover, Accredited Stakeholder Organisations represent a variety of different areas of interest and allow the Agency to engage in a dialogue with key actors having an interest in the REACH Regulation. In addition, the document endorsed by the Management Board states that one of the main objectives for the Agency's stakeholder engagement policy is working together with them through 'meaningful activities'.
- 24. Consequently, when assessing the present application to intervene, the Board of Appeal must have regard to the role given to stakeholders in the REACH Regulation and in the documents endorsed by the Agency's governing body. With this in mind, the Board of Appeal finds that, contrary to the arguments of the Appellants, it is not appropriate for the Board of Appeal to apply strictly the Court's test for environmental NGOs (see, for example, Order of the First Chamber of the General Court of 21 October 2014 in Case T-429/13, Bayer CropScience AG v Commission, EU:T:2014:920).
- 25. The Board of Appeal will examine whether ClientEarth has established an interest in the result of the present case in light of the above considerations.
- As indicated in the announcement of the present appeal, the Appellants raise a number of issues related to the requirements pertaining to nanomaterials under the Regulation. For example, the Appellants claim that characterisation/nanoparticles, toxicity of different forms of the substance' cannot constitute grounds of concern for inclusion of a substance on the CoRAP. The Appellants claim that the Agency included the Substance on the CoRAP merely because it was a nanomaterial. As a result, the Appellants claim that the decision to include the Substance on CoRAP should be annulled. The Appellants also challenge the application to the REACH Regulation of the definition of 'nanomaterials' set out in the Commission Recommendation 2011/696/EU (OJ L 275, 20.10.2011, p. 38). The Appellants claim that the mere fact that the substance meets the non-legally binding definition of 'nanomaterials' in Recommendation 2011/696/EU is not sufficient to justify the requests for information in the Contested Decision. According to the Appellants, by requesting information on the substance on the grounds that the substance meets the non-legally binding definition of 'nanomaterials' in the Commission Recommendation, the Agency failed to identify a valid concern that needs to be addressed through the substance evaluation procedure.
- 27. The Board of Appeal observes that ClientEarth is an Accredited Stakeholder Organisation with the Agency. As such, ClientEarth must, by implication, fulfil the five eligibility criteria set out in the Revised Eligibility Criteria for ECHA's Accredited

Stakeholders, adopted by the Management Board on 21 June 2011 (MB/34/2011; hereinafter the 'Revised Eligibility Criteria'). The five criteria that an organisation must satisfy to become an Accredited Stakeholder Organisation are as follows:

- (i) They are legally established within the EU/EEA and have activities at the EU level;
- (ii) They have a legitimate interest in the work of the Agency;
- (iii) They are representative in the field of their competence;
- (iv) They are non-profit making and do not exclusively represent individual companies; and
- (v) They are registered in the Register of Interest Representatives maintained by the European Commission. This last criterion only applies if they wish to participate as observers in the Committee and Forum meetings of the Agency.
- 28. Furthermore, with regards to the legitimate interest of an organisation in the work of the Agency, the Revised Eligibility Criteria sets out the following supporting definition:

'The organisation represents a sector affected by the EU chemicals legislation (such as the REACH, CLP, Biocides or PIC Regulation) falling within the scope of the tasks of ECHA. An organisation is also considered to have a legitimate interest in the areas of work of ECHA if it represents a sector indirectly affected by the legislation. This also includes [NGOs] engaged in issues affected by the mentioned legislation.

ECHA's Accredited Stakeholders are accordingly typically active in industry, human health, animal welfare, environmental protection, scientific research and development, and consumer protection'.

- 29. And with regards to whether an organisation is representative in the field of its competence, the Revised Eligibility Criteria sets out the following supporting definition:
 - 'The organisation must represent the interests of a substantial part of the actors in its field of competence. ECHA's Accredited Stakeholders should be representative of actors in their sector or field of competence. The necessary number of member organisations and their size depends on the structure of the relevant sector. Also, the sector need not have a particular size, but must be distinguishable from other sectors with different fields of interest'.
- 30. The Board of Appeal observes that in the annexes to the application to intervene ClientEarth attached extracts from its annual reports of 2011, 2012, 2013 and 2014 which refer inter alia to its activities in relation to the Agency. ClientEarth also attached to its application a paper it published in 2012 with another NGO entitled 'Identifying the bottlenecks in REACH implementation' in which it inter alia offers its assessment of the implementation of the REACH Regulation and in particular the role of the Agency.
- 31. Having regard in particular to its status as an Accredited Stakeholder Organisation the Board of Appeal finds that ClientEarth has established an interest in the field of the REACH Regulation and the work of the Agency in general.
- 32. The Board of Appeal observes that ClientEarth's objective is set out in its bylaws as follows 'to promote and encourage the enhancement, restoration, conservation and protection of the environment, including the protection of human health, for the public benefit'. Specifically in relation to the present case, ClientEarth states that its work 'includes a significant focus on the need for the nanoforms of substances to be properly accounted for in registration dossiers submitted under the REACH Regulation, and for the [CoRAP] to include all identified substances in their nanoforms'.
- 33. More specifically, ClientEarth attached a number of documents to its application to intervene to demonstrate its interest in the regulation of nanomaterials under the REACH Regulation. For example, ClientEarth attached a document it had jointly published in November 2012 with two other NGOs entitled 'High Time to Act on

- Nanomaterials: A proposal for a 'Nano Patch' for EU Regulation' in which proposals are made for the regulation of nanomaterials in the European Union.
- 34. In addition, ClientEarth attached to its application a paper it had published in April 2014, together with other NGOs, entitled 'European NGOs' position paper on the regulation of nanomaterials' in which it sets out, for example, how it considers that nanomaterials are different from other substances and why the risk from nanomaterials must be assessed and evaluated. That document also states that the CoRAP should include all identified substances in their nanoform and evaluations should be carried out without delay.
- 35. ClientEarth's application also contained its response to the public consultation on the draft European Commission recommendation on the definition of the term 'nanomaterial' and its response from September 2012 to the European Commission's public consultation relating to the Annexes to the REACH Regulation with regards to nanomaterials.
- 36. The Board of Appeal finds that the documents attached to the application to intervene clearly demonstrate ClientEarth's long-standing interest in the regulation of nanomaterials under the REACH Regulation.
- 37. The Board of Appeal considers that, having regard to the Agency's commitment to involve certain stakeholders in its work (see paragraphs 22 and 23 above), it would be an unnecessarily restrictive interpretation of Article 8(1) of the Rules of Procedure in relation to Accredited Stakeholder Organisations to require that an applicant's activities would have to be specifically focused on the actual substance within the context of the REACH Regulation. The Board of Appeal observes that it is rarely in the remit of an environmental NGO to work solely on a specific substance.
- 38. Nonetheless, the Board of Appeal notes that ClientEarth has shown an interest in a form of silicon dioxide albeit in relation to the legislation on biocidal products. In this respect ClientEarth attached to its application to intervene a request for internal review it sent to the European Commission regarding Commission Implementing Regulation (EU) No 408/2014 approving synthetic amorphous silicon dioxide as an existing active substance for use in biocidal products for product-type 18 (OJ L 121, 24.4.2014, p. 17). In particular, in that document ClientEarth sets out its concerns in relation to the nanoforms of synthetic amorphous silicon dioxide. The Board of Appeal considers that even though this was not in relation to the REACH Regulation this document demonstrates ClientEarth's interest in the nanoforms of silicon dioxide.
- 39. The Board of Appeal therefore finds that ClientEarth has established an interest in the result of the present case in particular regarding the need for information on the properties of nanomaterials and their accurate identification.
- 40. The Board of Appeal also observes that the discussions on nanomaterials in the context of the REACH Regulation are still at an early stage with a number of important issues surrounding nanomaterials remaining uncertain and under discussion. ClientEarth therefore has a particular interest at the present time in influencing the debate on nanomaterials.
- 41. For the above reasons, the Board of Appeal finds that the ClientEarth has established an interest in intervening in the present proceedings in support of the Agency. The application to intervene submitted by ClientEarth must therefore be granted.
- 42. Having established that ClientEarth has an interest to intervene in the present proceedings the Board of Appeal considers that it is not necessary to examine whether CIEL has also established an interest in the result of the present case. In particular, it must be observed that the Applicants have submitted one and the same application. In this case, even if a separate examination of the admissibility of CIEL's application were to reveal that CIEL has not established an interest in the result of the present case, the Board of Appeal has nonetheless already granted the application to

intervene. There are also no grounds of procedural economy that would justify examining CIEL's application individually. The Board of Appeal observes that the General Court has adopted a similar approach according to which if the same decision is challenged by several applicants and it is established that one of them has *locus standi* the Court considers that there is no need to examine the other applicants' standing to bring proceedings (see, for example, Case T-135/13, *Hitachi Chemical Europe GmbH* v *ECHA*, EU:T:2015:253, paragraph 39). The Board of Appeal considers that this approach is equally applicable to applications to intervene in cases before it.

43. Finally, the Board of Appeal observes that in their application to intervene the Applicants request the Board of Appeal to order the Appellants to bear the costs of the proceedings, including the costs of the Applicants. In this respect, the Board of Appeal highlights that according to Article 8(6) of the Rules of Procedure interveners shall bear their own costs.

On those grounds,

THE BOARD OF APPEAL

hereby:

- 1. Admits the application to jointly intervene by ClientEarth and the Center for International Environmental Law in Case A-015-2015 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 one month, following the serving of the procedural documents, to lodge observations on the Notice of Appeal and the Defence.

Mercedes ORTUÑO Chairman of the Board of Appeal

Alen MOČILNIKAR Registrar of the Board of Appeal