EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

– ENGLISH VERSION –

DECISION OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

23 March 2018

(Registration – Article 11 – Principle of one substance, one registration – Complete opt-out – Admissibility – Competence of the Board of Appeal)

Case number	A-011-2017
Language of the case	German
Appellant	REACheck Solutions GmbH, Germany
Representative	Andreas Krellmann Rechtsanwälte Bach|Dr. Krebs|Zahn|Valdfogl, Germany
Contested Decision	DSH-30-3-D-0075-2017 of 29 May 2017, adopted by the European Chemicals Agency (the 'Agency') pursuant to Article 11 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; the 'REACH Regulation') and Article 3 of Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with the REACH Regulation (OJ L 3, 6.1.2016, p. 41).

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

Background to the dispute

1. The Appellant is the lead registrant for the joint registration of the substance charcoal (EC No 240-383-3, CAS No 16291-96-6).

2. In 2013, PPH 'WEGAS' Waldemar Demski ('WEGAS') registered charcoal entirely separately from the joint registration.

3. On 26 January 2016, Commission Implementing Regulation (EU) 2016/9 on joint submission of data and data-sharing in accordance with the REACH Regulation (OJ L 3, 6.1.2016, p. 41; 'Implementing Regulation 2016/9') entered into force.

4. On 15 March 2016, the Board of Appeal issued its decision in Case A-022-2013, *REACheck Solutions*, in which it found that a registration is incomplete if it is entirely separate from the joint registration for the same substance.

5. On 21 June 2016, according to the Agency's Defence in the present case, the Agency changed its registration procedures and the information technology system used to manage them ('REACH-IT'). A registrant must now be in possession of an alphanumerical passcode or '*token*' in order to submit a registration dossier for a substance that has already been registered. This '*token*', which is normally issued by the lead registrant, allows the registrant to identify the joint registration for its substance and makes its submission part of that joint registration.

6. According to the Agency, a '*token*' is required even if the registrant intends to share no data with other registrants of the substance and to submit all the relevant information separately in accordance with Article 11(3) of the REACH Regulation (a 'complete opt-out'; all references to Articles or Recitals hereinafter concern the REACH Regulation unless stated otherwise).

7. If a registrant relying on a complete opt-out and a lead registrant fail to agree on the terms on which the '*token*' is to be issued by the lead registrant, according to the Agency's procedures, the registrant relying on a complete opt-out may submit a '*joint submission dispute*' to the Agency. The Agency then examines the efforts made by the parties and, if it finds that the registrant relying on a complete opt-out has made '*every effort*' to reach an agreement with the lead registrant, issues the registrant relying on a complete opt-out with the '*token*' (see the Agency's Guidance on Data-Sharing, version 3.1, January 2017, p. 159).

8. Starting on 21 June 2016, the Agency also took action to ensure that registrants who had already registered a substance entirely separately from a joint registration would make their submissions part of the joint registration for that substance. To this end, the Agency sent a communication to WEGAS, requesting it to make its separate submission part of the joint registration for charcoal by 15 May 2017.

9. On 12 December 2016, WEGAS wrote to the Appellant indicating that it intended to rely on a complete opt-out. It consequently requested no data from the Appellant but only the '*token*' required to make its submission part of the joint registration for charcoal.

10. On 19 December 2016, the Appellant replied to WEGAS that it would issue it with a '*token*' on the basis of an '*appropriate contract*' and in return for the payment of a '*fee*' of 1200 EUR.

11. To this communication, the Appellant attached a draft contract. Article 2(1) of this draft contract stated:

    '*Following timely receipt of payment of [1200 EUR], [the Appellant] shall furnish [WEGAS] with the following data for the granted usage rights:*

- *Name of the Joint Submission*
- *Token for the submission of the Dossier*

No further obligation on the part of [the Appellant] shall ensue herefrom. In particular, [WEGAS] shall perform the registration himself and autonomously comply with the required guidelines therefor.'

12. On 20 December 2016, WEGAS replied to the Appellant: '*We consider [1200 EUR] an excessively high charge and propose a more reasonable token administration fee of [200 EUR].*'

13. Between 25 January and 8 February 2017, WEGAS and the Appellant had further exchanges regarding the '*fee*' for the '*token*'. The Appellant repeatedly stated in its communications with WEGAS that the '*fee*' of 1200 EUR was not negotiable.

14. On 3 March 2017, WEGAS submitted a '*joint submission dispute*' to the Agency following the procedure described in paragraph 7 above.

15. On 29 May 2017, the Agency adopted the Contested Decision.

Contested Decision

16. The Contested Decision examines the efforts made by WEGAS and the Appellant to agree the terms on which the Appellant would issue WEGAS with the '*token'.* It concludes that WEGAS '*exhausted every effort to reach an agreement with [the Appellant] on the access to the joint [registration] and filed the dispute as a measure of last resort, while in turn the [Appellant] did not comply with [its] obligation to reach a fair transparent and non-discriminatory agreement on the provision of the token*'.

17. As a consequence, the Contested Decision grants WEGAS '*access to the joint [registration]*' named '*js-charcoal*' and provides a '*token*' to enable WEGAS to make its submission part of the joint registration.

18. The relevant part of the Contested Decision states:

'*Based on Article 11 of [the REACH Regulation] and Article 3 of [Implementing Regulation 2016/9], and applying the procedure laid down in Article 30 of the REACH Regulation by analogy,*

ECHA grants [WEGAS] access to the joint [registration]' (emphasis added).

Procedure before the Board of Appeal

19. On 24 August 2017, the Appellant filed this appeal.

20. On 30 October 2017, the Agency submitted its Defence. On 21 November 2017, the Board of Appeal closed the written part of the appeal procedure.

21. On 2 February 2018, a hearing was held at the Appellant's request. At the hearing, the Parties made oral submissions and responded to questions from the Board of Appeal.

Form of order sought

22. The Appellant requests the Board of Appeal to annul the Contested Decision.

23. The Agency requests the Board of Appeal to dismiss the appeal as unfounded.

Reasons

24. The Contested Decision allows WEGAS, who relied on a complete opt-out and informed the Agency and the lead registrant accordingly, to make its submission part of the joint registration for charcoal by giving it a '*token*'.

25. The Contested Decision cites primarily Article 11 of the REACH Regulation and Article 3 of Implementing Regulation 2016/9 as its legal basis (see paragraph 18 above).

26. The Appellant claims, amongst other things, that this is incorrect and that there is no legal basis in the REACH Regulation or in Implementing Regulation 2016/9 for the Contested Decision.

27. Article 91(1) sets out the Agency decisions that may be appealed before the Board of Appeal. According to that provision, '*[a]n appeal may be brought against decisions of the Agency taken pursuant to Article 9, Article 20, Article 27(6), Article 30(2) and (3) and Article 51*'.

28. In light of the circumstances set out in paragraphs 25 to 27 above, the Board of Appeal will examine, of its own motion, whether the Contested Decision falls within its competence and whether the appeal is therefore admissible.

29. At the hearing, the Parties were invited to comment on whether the Board of Appeal is competent to decide on this case. The Appellant argued that this case is admissible because there must be an effective remedy allowing it to contest any decision of the Agency. The Agency argued that this case is admissible because the Contested Decision was adopted pursuant to '*the procedure*' set out in Article 30, applied by analogy to a '*joint submission dispute*'.

30. In order to determine what the legal basis of the Contested Decision was or ought to have been, the Board of Appeal will examine (I) the requirements of the principle of one substance, one registration, (II) the conditions for a registrant to rely on a complete opt-out, and (III) the role of the Agency and the measures it can take when a registrant relies on a complete opt-out.

I. The requirements of the principle of one substance, one registration

31. Articles 6 and 7 provide a general obligation for manufacturers or importers of substances on their own, in mixtures or in articles in quantities above one tonne *per annum* to register their substances with the Agency.

32. Articles 26 to 30 set out the data-sharing rules that must be followed, in different circumstances, if more than one manufacturer and/or importer registers the same substance, in particular with regard to information derived from testing on vertebrate animals.

33. Article 11 gives effect to one of the fundamental pillars of the REACH Regulation, namely the principle of one substance, one registration. This means that, if there is more than one registrant for a phase-in substance, the registrants should form a joint registration and submit data jointly. Equally, if a subsequent registrant intends to register a substance for which there is already a joint registration, that registrant is required to join the existing joint registration (see Case A-022-2013, *REACheck Solutions*, Decision of the Board of Appeal of 15 March 2016, paragraph 73).

34. Article 11(1) and (2), in particular, set out how the information required for registration purposes is to be submitted to the Agency if more than one manufacturer and/or importer registers the same substance:

'*1. When a substance is intended to be manufactured in the Community by one or more manufacturers and/or imported by one or more importers, and/or is subject to registration under Article 7, the following shall apply.*

Subject to paragraph 3, the information specified in Article 10(a)(iv), (vi), (vii) and (ix), and any relevant indication under Article 10(a)(viii) shall first be submitted by the one registrant acting with the agreement of the other assenting registrant(s) (hereinafter referred to as the lead registrant).

Each registrant shall subsequently submit separately the information specified in Article 10(a)(i), (ii), (iii) and (x), and any relevant indication under Article 10(a)(viii).

The registrants may decide themselves whether to submit the information specified in Article 10(a)(v) and (b) and any relevant indication under Article 10(a)(viii) separately or whether one registrant is to submit this information on behalf of the others.

2. Each registrant need only comply with paragraph 1 for items of information specified in Article 10(a)(iv), (vi), (vii) and (ix) that are required for the purposes of registration within his tonnage band in accordance with Article 12.'

35. It follows from Article 11(1) and (2) and Articles 26 to 30 that, pursuant to the principle of one substance, one registration, all registrants of the same substance must communicate with other registrants, share at least all information derived from testing on vertebrate animals that may be required for the registration of that substance, and submit certain information jointly as part of the same registration.

II. The conditions for a registrant to rely on a complete opt-out

36. Whilst the principle of one substance, one registration applies whenever two or more registrants register the same substance, Article 11(3) constitutes an exception to the obligation, set out in Article 11(1) and (2), to submit information jointly:

'*A registrant may submit the information referred to in Article 10(a)(iv), (vi), (vii) or (ix) separately if:*

(a) it would be disproportionately costly for him to submit this information jointly; or

(b) submitting the information jointly would lead to disclosure of information which he considers to be commercially sensitive and is likely to cause him substantial commercial detriment; or

(c) he disagrees with the lead registrant on the selection of this information.

If points (a), (b) or (c) apply, the registrant shall submit, along with the dossier, an explanation as to why the costs would be disproportionate, why disclosure of information was likely to lead to substantial commercial detriment or the nature of the disagreement, as the case may be.'

37. Article 11(3) allows a registrant to submit the information required for its registration separately if any of the exceptions in Article 11(3)(a) to (c) apply. If a registrant wishes to submit information separately it must submit an explanation of how one or more of the conditions of the first subparagraph of Article 11(3) are fulfilled.

38. It is apparent from its wording, however, that Article 11(3) constitutes an exception only to Article 11(1) and (2), and not to Articles 26 to 30.

39. In particular, Article 11(3) does not alter the fact that a registrant who relies on a complete opt-out must make its submission as part of a joint registration. Nor does it excuse it from communicating with other registrants of the substance and from sharing at least all information derived from testing on vertebrate animals that may be required for the registration of that substance.

40. It also follows from the wording and structure of Article 11 that it falls exclusively to a registrant to decide whether it intends to rely on a complete opt-out. Neither the Agency nor the lead registrant of a substance can prevent a registrant who has decided to rely on a complete opt-out from making its submission part of the joint registration.

41. This is expressly confirmed by Article 3(3) of Implementing Regulation 2016/9, which provides:

'*Where a potential registrant has complied with his obligations under Articles 26 or 29 of [the REACH Regulation] and has ascertained that he is not required to share tests on vertebrate animals for the purposes of his registration, he may decide to invoke Articles 11(3) or 19(2) in order to submit separately all or part of the relevant information in Article 10(a) of that Regulation*.

In such cases, the potential registrant shall inform any previous registrants of that substance of his decision. He shall also inform the Agency which shall ensure that this separate submission, made in accordance with Article 11(3) or 19(2), remains part of the existing registration for that substance in accordance with paragraph 1' (emphasis added).

42. Article 11 therefore clearly covers the situation whereby a registrant relies on a complete opt-out for registration purposes. Article 3(3) of Implementing Regulation 2016/9 clarifies that it is the responsibility of the Agency, in such cases, to ensure that '*this separate submission […] remains part of the existing [joint] registration for that substance*'. The Agency does not have any margin of discretion in this regard. Therefore, giving the '*token*' to a registrant cannot depend, by analogy to Article 30, on whether the registrant has '*exhausted every effort to reach an agreement with [the lead registrant] on the access to the joint [registration]*'.

43. It is therefore clear that there is no need for a '*joint submission dispute*' and consequently no need to put in place a procedure to resolve differences between the lead registrant and another registrant over the provision of a '*token'* if the other registrant relies on a complete opt-out for registration purposes. There is also no such provision in the REACH Regulation.

44. In practice, since the Agency has implemented Article 11 by means of an information technology system requiring the use of a '*token*', the Agency 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).

III. The role of the Agency and the measures it can take when a registrant relies on a complete opt-out

45. The REACH Regulation establishes a coherent administrative system for the registration, evaluation, authorisation and restriction of chemicals. The possibility for registrants to rely on a complete opt-out is specifically included in the REACH Regulation (see paragraphs 36 and 37 above). The implications of registrants relying on complete opt-outs are anticipated in the checks and balances of the system.

46. First, in accordance with Article 20, the Agency undertakes a completeness check of each submitted registration in order to ascertain that all the information required for a registration has been provided.

47. According to Article 20(2), '*the completeness check shall not include an assessment of the quality or the adequacy of any data or justifications submitted*'. However, the Agency must verify, at a minimum, that the information submitted is meaningful (see, to this effect, Case A-022-2013, *REACheck Solutions*, Decision of the Board of Appeal of 15 March 2016, paragraph 107).

48. Article 20, therefore allows the Agency to ensure that Article 11(3) is not abused by the submission of dossiers devoid of meaningful information. If the Agency finds the registration dossier submitted by a registrant who relies on a complete opt-out to be incomplete, that registrant will have to rectify the shortcomings of its dossier. This may require it to share data, and therefore costs, with the existing registrants of the substance in accordance with Article 27 or 30.

49. Second, Article 41(5)(a) provides that if a registrant has invoked Article 11(3) the Agency '*shall give priority*' to its registration dossier for a compliance check.

50. In accordance with Article 41(1), when performing a compliance check '*the Agency may examine any of the following:*

    (a) that the information in the technical dossier(s) submitted pursuant to Article 10 complies with the requirements of Articles 10, 12 and 13 and with Annexes III and VI to X;

    (b) that the adaptations of the standard information requirements and the related justifications submitted in the technical dossier(s) comply with the rules governing such adaptations set out in Annexes VII to X and with the general rules set out in Annex XI;

    (c) that any required chemical safety assessment and chemical safety report comply with the requirements of Annex I and that the proposed risk management measures are adequate;

    (d) that any explanation(s) submitted in accordance with Article 11(3) or Article 19(2) have an objective basis.'

51. If a registrant relies on a complete opt-out, the Agency should therefore verify that there is an objective basis for the opt-out (Article 41(1)(d)). Moreover, if any information required for the registration of the substance is missing or insufficient, the Agency must require the registrant to submit it following a compliance check decision (Article 41(1)(a) and (b)).

52. Under Article 41, the Agency therefore ensures that Article 11(3) is not invoked without an objective basis, and that the registration is compliant. If the Agency finds that a registrant has no objective reason to rely on Article 11(3), or that its registration is incompliant, that registrant may have to share data, and costs, in accordance with Article 27 or 30.

53. Third, if a registrant who relies on a complete opt-out fails to provide the information required following a compliance check under Article 41, or repeats animal tests unnecessarily contrary to Articles 13 and 25, the Agency should inform the enforcement authorities of the Member States (see Recital 120), which may take action accordingly.

54. It follows that, in the coherent administrative system established by the REACH Regulation, reliance on a complete opt-out is a narrow exception that requires careful scrutiny by the Agency and, potentially, action by the enforcement authorities of the Member States.

55. By implementing Article 20 (completeness check) and Article 41 (compliance check) with regard to complete opt-outs, and informing the enforcement authorities of the Member States of any potential breaches of Articles 13, 25, 27 or 30, the Agency can ensure that the use of complete opt-outs is not abused.

56. By applying the REACH Regulation as established, the Agency can therefore ensure that the following two important aims of the registration system are achieved.

57. First, the Agency can ensure that reliance on a complete opt-out does not mean that a registration dossier is devoid of the information required for registration purposes. Application of the completeness check and compliance check procedures, and adopting as necessary decisions pursuant to Articles 20 and 41, shall ensure that the information in registration dossiers is meaningful and meets the detailed registration requirements. This contributes to the achievement of a high level of protection of human health and the environment, which is the main purpose of the obligation to register substances (judgment of 7 July 2009, *S.P.C.M. and Others*, C-558/07, EU:C:2009:430, paragraph 45).

58. Second, the Agency can ensure that data-sharing takes place as required. This helps ensure that animals are not sacrificed unnecessarily. This also ensures the protection of the legitimate interest of joint registrants in gaining compensation for test data, in particular for tests on vertebrate animals.

IV. Conclusion

59. Article 11(3) allows a registrant of a substance for which there is an existing joint registration to rely on a complete opt-out (see paragraphs 36 to 40 above). Once a registrant has informed the Agency and any previous registrants of its decision to rely on a complete opt-out, under Article 11, as clarified by Article 3 of Implementing Regulation 2016/9, the Agency must give the '*token*' to that registrant (see paragraphs 42 to 44 above).

60. The legal basis for the Contested Decision, which allowed WEGAS to make its submission part of the joint registration for charcoal by giving it a '*token*', is therefore Article 11.

61. Article 11 is not listed in Article 91(1) among the decisions that can be challenged before the Board of Appeal.

62. This case consequently falls outside the competence of the Board of Appeal. It is therefore inadmissible.

63. This conclusion is not called into question by the Parties' arguments on the admissibility of this case (see paragraph 29 above).

64. First, contrary to the Agency's argument, the Board of Appeal is not competent to decide on this case on the grounds that '*the procedure*' in Article 30 applies by analogy. Even assuming that Article 30 prescribes a '*procedure*', this '*procedure*' would not apply by analogy because under Article 11 the Agency has no margin of discretion as to whether to grant the '*token*' to a registrant who informs it of its decision to rely on a complete opt-out (see paragraph 42 above).

65. Second, the Board of Appeal rejects the Appellant's argument that this case is admissible because there must be an effective remedy allowing it to contest any decision of the Agency (see paragraph 29 above). In accordance with Article 94(1), an action may be brought before the General Court '*in cases where no right of appeal lies before the Board [of Appeal]*'.

66. Finally, when considering the admissibility of a case it is irrelevant that the Contested Decision states that it can be appealed before the Board of Appeal. The competence of the Board of Appeal, as set out in the REACH Regulation, cannot be altered by an incorrect statement of remedy in a decision of the Agency.

Refund of the appeal fee

67. In accordance with Article 10(3) of Commission Regulation (EC) No 340/2008 on the fees and charges payable to the European Chemicals Agency pursuant to the REACH Regulation (OJ L 107, 17.4.2008, p. 6), if an appeal is inadmissible, the appeal fee is not refunded.

On those grounds,

THE BOARD OF APPEAL

hereby:

1. **Dismisses the appeal as inadmissible.**
2. **Decides that the appeal fee shall not be refunded.**

Mercedes ORTUÑO
Chairman of the Board of Appeal

Alen MOČILNIKAR
Registrar of the Board of Appeal