

**SUMMARY OF DECISION OF 23 MARCH 2018  
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

**Case number: A-011-2017**

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

*Background*

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

Another registrant of the same substance (the 'other registrant'), who had previously registered charcoal entirely separately from the joint registration, wanted to make its separate registration part of the joint registration.

According to the Agency's procedures, in order to do so the other registrant needed an alphanumeric passcode (the 'token'). This token could be obtained either from the lead registrant or, failing that, in certain circumstances from the Agency. By analogy to the data-sharing procedure (Article 30 of the REACH Regulation), the Agency would issue the token only if it found, following an assessment, that the other registrant had made every effort in its negotiations with the lead registrant to reach an agreement on the terms on which the token would be issued by the lead registrant.

In the present case, following a request from the other registrant, the Agency examined the efforts made by the other registrant and the Appellant in their negotiations. The Agency found that the other registrant had made every effort to reach an agreement and consequently gave it the token.

*Main findings of the Board of Appeal*

The Contested Decision was adopted, according to the Agency, on the basis of Article 11 of the REACH Regulation and Article 3 of Implementing Regulation 2016/9,<sup>1</sup> applying the procedure laid down in Article 30 of the REACH Regulation by analogy.

In order to determine whether the Contested Decision was among the decisions that can be appealed the Board of Appeal had to determine the correct legal basis for the Contested Decision.

In order to do so, the Board of Appeal examined the system established by the REACH Regulation for the use of opt-outs in the registration of substances.

First, the Board of Appeal examined the requirements of the requirement for '*one substance, one registration (OSOR)*' (Articles 11(1) and (2) and Articles 26 to 30 of the REACH Regulation; see paragraphs 31 to 35 of the Board of Appeal Decision). All registrants of the same substance must, amongst other things, communicate with other registrants, share information derived from testing on vertebrate animals, and submit certain information jointly as part of the registration of the same substance.

Second, the Board of Appeal examined the conditions for a registrant to submit all the information required for its registration separately, i.e. rely on a complete opt-out (Article 11(3) of the REACH Regulation; see paragraphs 36 to 44 of the Board of Appeal Decision).

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<sup>1</sup> 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).

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 registration part of the joint registration.

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). The Agency has no discretion in this regard.

Third, the Board of Appeal examined how the REACH Regulation allows the Agency to ensure that registrants do not abuse the use of complete opt-outs (see paragraphs 45 to 58 of the Board of Appeal Decision).

The Board of Appeal found 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. The Agency should ensure that the use of a complete opt-out is not abused by applying the completeness and compliance check procedures (according to Articles 20 and 41 of the REACH Regulation).

On the basis of this examination, the Board of Appeal concluded that the Agency does not have any margin of discretion on whether or not to give a token to a registrant who relies on a complete opt-out. Pursuant to Article 11, the Agency must give a registrant who relies on a complete opt-out a token if one is requested. The REACH Regulation however contains procedures which help ensure that the use of a complete opt out for registration purposes is not abused (see paragraphs 59 to 66 of the Board of Appeal Decision).

The Board of Appeal therefore held that the legal basis of the Contested Decision, which was a decision giving a token to a registrant who intended to rely on a complete opt-out, was Article 11.

As decisions based on Article 11 are not included in the closed list of decisions that can be challenged before the Board of Appeal (Article 91 of the REACH Regulation) the appeal was found to be inadmissible.

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**NOTE:** The Board of Appeal of ECHA is responsible for deciding on appeals lodged against certain ECHA decisions. The ECHA decisions that can be appealed to the Board of Appeal are listed in Article 91(1) of the REACH Regulation. Although the Board of Appeal is part of ECHA, it makes its decisions independently and impartially. Decisions taken by the Board of Appeal may be contested before the General Court of the European Union.

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*Unofficial document, not binding on the Board of Appeal*

*The full text of the decision is available on the Board of Appeal's section of ECHA's website:*

<http://echa.europa.eu/about-us/who-we-are/board-of-appeal>