

**SUMMARY OF DECISION OF 2 APRIL 2014
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

Case number: A-008-2012

(Compliance check of a registration – Substance identity)

Factual background

Following a compliance check, under the dossier evaluation procedure, of the registration submitted by Przedsiębiorstwo Produkcyjno - Handlowe UTEX Sp. z.o.o. (hereinafter the 'Appellant'), the European Chemicals Agency (hereinafter the 'Agency') adopted a decision in which it requested the Appellant to submit certain information related to the substance identity of the registered substance.

The Agency explained in its decision that the registration dossier of the Appellant contained information on two different substances, namely 'pure SDA' and 'mixture SDA Product and ash', which would require separate registrations. On this basis, the Agency requested the Appellant to remove from the dossier any information that does not refer to the registered substance, which the Agency identified as being 'pure SDA'.

The Appellant lodged an appeal before the Board of Appeal seeking for an amendment of the Agency's decision to the extent that it required the Appellant to submit separate registrations for 'pure SDA' and 'mixture SDA Product and ash'.

Main findings of the Board of Appeal

In its Decision of 2 April 2014, the Board of Appeal firstly examined what registrants may be required to register pursuant to the REACH Regulation¹ and specifically clarified the interpretation of 'substance' and 'mixture' within this context. In the light of that clarification, the Board of Appeal concluded that the Appellant's registration dossier may have contained information on more than one substance which is subject to the registration obligations under the REACH Regulation.

The Board of Appeal also confirmed that each registration dossier must relate to only one substance. Consequently, two different substances cannot be registered in the same registration dossier regardless of whether they have the same hazard properties.

The Board of Appeal also clarified the roles of the various actors in the registration process. The Board of Appeal firstly observed that it is the duty of every registrant to identify the substances they need to register to comply with the REACH Regulation, and that the decision regarding which substance or substances to register lies with the manufacturer or importer concerned.

¹ 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 Board of Appeal then recalled that it is the responsibility of the Member State enforcement authorities to take action if they consider that a manufacturer or importer has failed to register a substance in accordance with the REACH Regulation.

The Board of Appeal further explained that, following the registration of a substance, the compliance check conducted by the Agency under the dossier evaluation procedure is intended to verify the registration dossier's compliance with the information requirements specified in the REACH Regulation for registration purposes. The Board of Appeal considered that the Agency is not competent however to instruct a particular company to register a particular substance or substances. Furthermore, the Agency is not competent to check whether a particular company is complying with the REACH Regulation with regard to registering all the substances that it is required to register.

In light of the above, the Board of Appeal recalled that where a dossier potentially contains information on more than one substance, the Agency cannot unilaterally dictate, based on assumptions, no matter how persuasive, which of those substances should be the subject of the registration dossier in question. The Board of Appeal considered that, in doing so, the Agency would be encroaching on the Appellant's right to decide which substances to register. In other words, the Agency would be acting outside the powers accorded to it by the REACH Regulation.

Meanwhile, the Board of Appeal encouraged the Agency to help registrants, especially when examining the dossiers of small and medium sized enterprises ('SMEs'), to understand their duties with regard to the registration of substances and the content thereof, in situations where it is not clear which substance is intended to be covered by a particular registration dossier. According to the Board of Appeal, the Agency should provide advice to help companies to comply with their registration responsibilities, including helping them to identify their registration strategy as well as the information required to meet registration requirements.

In light of the above, the Board of Appeal observed that, in the present case, the Agency exceeded its powers by selecting which of the substances contained in the registration dossier should be the focus of that dossier. The Board of Appeal noted that, instead of explicitly indicating to the Appellant that its dossier should only cover 'pure SDA', the Agency could have, consistent with its legal powers, stated in the Contested Decision that the registration dossier appears to contain information on more than one substance. To this the Agency could have added that, since registration dossiers may only cover one substance, the Appellant should remove all information which does not relate to the substance which the Appellant intended to register in a particular dossier. The Board of Appeal added that this would have avoided the Agency exceeding its powers by unilaterally selecting which substance is covered by a specific registration dossier.

The Board of Appeal therefore annulled the Contested Decision and remitted the case to the Agency for re-evaluation of the Appellant's registration dossier. The Board of Appeal also observed that, based on the Board of Appeal's findings in the case, the Appellant should re-examine its registration strategy with regard to which substances it is obliged to register pursuant to the REACH Regulation.

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.

Unofficial document, not binding on the Board of Appeal

The [full text](#) of the decision of the Board of Appeal is published on the ECHA website on the day of delivery