

**SUMMARY OF THE DECISION OF 3 DECEMBER 2014
OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY**

Case number: A-005-2013

(Permission to proceed with registration – Registration deadline for phase-in substances – Data sharing dispute – Admissibility – Business rules check – Technical completeness check)

Factual background

A company (hereinafter the 'Data Claimant') submitted a request for permission to refer to data on vertebrate animal testing contained in a joint registration dossier following an alleged failure between the Appellant and the Data Claimant to agree on the costs of sharing such data in accordance with Article 30 of the REACH Regulation¹.

The Agency sent a letter to the Appellant (hereinafter the 'Contested Decision') requesting it to provide information regarding the efforts made to reach an agreement on the costs of sharing the data. In that letter the Agency also stated that, due to the approaching registration deadline, the Agency could allow the Data Claimant '... to proceed with the registration without the full data set, while the data sharing dispute is being processed ... this permission is only temporary...'.

The Agency also sent a letter to the Data Claimant on the same day informing the latter inter alia of what the Agency termed a 'contingency procedure' whereby the Agency could 'allow' the Data Claimant 'to proceed with the registration dossier without a full data set, while the data sharing dispute is being processed'. The letter also described the legal consequences of the contingency procedure and gave instructions on how to complete the fields in the registration dossier for the endpoints subject to the data sharing dispute.

The Appellant lodged an appeal seeking the partial annulment of the Contested Decision in so far as it allowed the Data Claimant to temporarily proceed with its registration without a full data set.

Main findings of the Board of Appeal

The Appellant claimed that there was no legal basis for the Contested Decision and that the Agency had exceeded its competence by adopting a decision granting the Data Claimant permission to proceed with its registration on a temporary basis without access to the vertebrate animal data contained in the joint submission.

The Board of Appeal observed that the obligation to submit a registration dossier stems directly from the REACH Regulation and is not subject to any prior authorisation from the Agency regardless of whether a data sharing dispute is pending. The Board of Appeal found therefore that the Data Claimant's right to submit the registration dossier was not affected by the Contested Decision.

The Appellant claimed that, through the Agency's contingency procedure, the Agency had instructed the Data Claimant how to pass the business rules check despite the fact that its registration dossier was essentially empty, in order to allow it to proceed to the technical completeness check.

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). All references to Articles hereinafter concern the REACH Regulation.

The Board of Appeal found that the absence or otherwise from a dossier of the information subject to the data sharing dispute in this case is not verified during a business rules check. The Board of Appeal found that only at the technical completeness check, performed pursuant to Article 20(2), does the Agency verify whether the information that is subject to a data sharing dispute is provided. As a consequence, in this particular case, whatever the Data Claimant had included in the fields concerning the information subject to the data sharing dispute, even if they had been left empty, the registration dossier would not have failed the business rules check on this basis. The Board of Appeal therefore concluded that the instructions contained in the Agency's contingency procedure did not assist the Data Claimant to circumvent the business rules check.

The Board of Appeal also observed that certain of the language used in the Contested Decision could have contributed to the Appellant's impression that the Agency had taken a decision and granted specific rights to the Data Claimant. Nonetheless, the Board of Appeal considered that an examination of the facts and the applicable legislation demonstrated that the submission of the Data Claimant's registration dossier and the Agency's treatment thereof were in accordance with the REACH Regulation, as well as the Agency's own rules on the business rules check. The potentially misleading nature of the Agency's communications in the present case did not therefore alter the Board of Appeal's finding that no decision had been taken permitting the Data Claimant to proceed with registration on a temporary basis.

The Appellant claimed that the Data Claimant should have ceased manufacturing from the date of the failure of the technical completeness check until the time the Agency decides that its registration dossier is complete and grants the Data Claimant a registration number pursuant to Article 20(3).

The Board of Appeal found that the responsibility to verify whether companies have complied with the REACH Regulation regarding the registration of the substances they manufacture or import falls within the competence of the Member States. As a result, the Board of Appeal considered that neither the Agency nor the Board of Appeal is competent to decide whether a registrant, which has submitted a registration dossier for a phase-in substance by the deadline set in Article 23, has failed the technical completeness check under the third subparagraph of Article 20(2), and has not yet received a registration number pursuant to Article 20(3), is permitted to continue manufacturing or importing a particular substance until a registration number is assigned by the Agency. The Board of Appeal also considered that it is clear from the facts of the case that the Agency did not take any decision to that effect.

In light of the above, the Appellant's claim that the Agency acted illegally in granting a temporary right to proceed with registration without a full data set was dismissed as unfounded. Since the Board of Appeal found that no decision of the sort alleged by the Appellant was taken by the Agency, the appeal was dismissed as inadmissible.

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