

**SUMMARY OF DECISION OF 2 MARCH 2017 OF THE BOARD OF APPEAL OF THE
EUROPEAN CHEMICALS AGENCY**

Case number: A-011-2014

*(Dossier evaluation – Compliance check –
Substance identity – Nanoforms – Nanomaterials)*

Background

Titanium dioxide (the ‘Substance’) exists in many forms differing in crystal phase, particle size and surface treatment. Some of these forms are nanoforms.

The Contested Decision, issued following a compliance check, required one of the nine Appellants, namely the lead registrant (the ‘first Appellant’), to provide detailed substance identity information on the crystal phases, nanoforms and surface treatment of nanoforms covered by its registration.

The Appellants claimed that ECHA does not have the power to request information on crystal phases, nanoforms and surface treatment of nanoforms as substance identity information.

The Agency acknowledged that Section 2 of Annex VI, which lists the substance identity information that must be provided for a registration, contains no explicit provision for the information at issue. However, it argued that this provision must be interpreted in light of its purpose, namely to achieve a high level of protection of human health and the environment. According to the Agency, knowledge of the precise crystal phases and/or nanoforms covered by a registration is an implicit ‘*prerequisite*’ for assessing the hazards and risks posed by a substance. A strictly literal interpretation of Section 2 of Annex VI would defeat the purpose of that provision, leading to the unacceptable consequence that manufacturers and importers of nanoforms of substances would not be required to assess the relevant hazards and risks posed by those nanoforms.

Main findings of the Board of Appeal

The Board of Appeal’s decision reflects the case-law of the EU Courts according to which if the wording of a provision of EU law is clear and precise, its contextual or teleological interpretation cannot call into question the literal meaning of that provision (*interpretatio cessat in claris*).

The Board of Appeal found that each relevant information requirement in Section 2 of Annex VI is worded in a technically precise, clear and unambiguous way. Section 2 of Annex VI must therefore be applied according to its wording as enacted by the legislature and cannot be interpreted to require detailed substance identity information on crystal phases, nanoforms and surface treatment of nanoforms.

In addition, the Board of Appeal dismissed ECHA’s argument that a strictly literal interpretation of Section 2 of Annex VI would defeat the purpose of that provision. In this regard, the Board of Appeal examined the information requirements for a registration as set out in the REACH Regulation. It found that a registrant is at liberty to give a broad definition

of the substance which it intends to register, for example by including both the bulk forms and the nanoforms of the substance in question. If a registrant gives a broad definition of its substance, however, the hazards posed by all possible forms of the substance covered by the substance definition must be addressed by, inter alia, the toxicological and ecotoxicological information provided in the registration dossier.

ECHA could therefore have performed a compliance check verifying if the registration dossier included toxicological and ecotoxicological information addressing all possible forms of the substance as defined by the registrant. In this case, the primary objective of the REACH Regulation, namely to achieve a high level of protection of human health and the environment, could have been met. Consequently, the Board of Appeal found that the alleged contradiction between the purpose and the wording of Section 2 of Annex VI, did not stem from the wording of that provision but from the fact that the compliance check in the present case was limited only to the substance identity information.

Finally, the Board of Appeal noted that it is not for the Agency or the Board of Appeal to interpret the REACH Regulation in such a way as to amend or to extend it. The power to establish information requirements, in this case for the registration of substances, is reserved exclusively to the legislature of the European Union. The Annexes to the REACH Regulation may be amended in accordance with Article 131. If the legislature sees a need for further information on the nanoforms of substances subject to registration then it would need to amend the Annexes to the REACH Regulation accordingly.

The Board of Appeal therefore concluded that the Contested Decision exceeded ECHA's powers under Section 2 of Annex VI. The Contested Decision was annulled in so far as it requested information on crystal phases, nanoforms and the surface treatment of nanoforms.

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 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>*