ECHA
EUROPEAN CHEMICALS AGENCY
BOARD OF APPEAL

SUMMARY OF DECISION OF 30 JUNE 2017 OF THE BOARD OF APPEAL OF THE EUROPEAN CHEMICALS AGENCY

Case number: A-014-2015

(*Substance evaluation – Nanomaterials – Potential risk – Proportionality – Error of assessment – Article 25*)

Factual background

Following the substance evaluation of silicon dioxide by the Netherlands, the European Chemicals Agency (hereinafter the 'Agency') adopted a decision requesting the Appellants (two registrants of synthetic amorphous silica - hereinafter 'SAS' - who jointly lodged the appeal) to provide information on physicochemical properties of each individual '*form'* of the four types of SAS (excluding surface-treated '*forms'*), inhalation toxicity studies on different '*forms'* of one type of SAS, information on the uses of each individual '*form*' of SAS (excluding surface-treated forms), information on the physicochemical properties of each individual surface-treated SAS *'form'* and all available toxicological information on surface-treated SAS. The four types of SAS addressed in the Contested Decision were pyrogenic SAS, precipitated SAS, colloidal SAS and silica gel.

The Appellants requested the Board of Appeal to annul the Contested Decision.

Main findings of the Board of Appeal

The Appellants alleged that the Agency failed to establish a potential risk justifying the requests for information as it based its conclusions on its finding that SAS is a nanomaterial. The Board of Appeal found that being a nanomaterial was insufficient on its own to justify a potential risk. The Board of Appeal found, however, that the Contested Decision was justified primarily by reference to the results of a study, the Reuzel *et al.* publication. The Appellants' claim that the Agency's requests for information were based on its finding that SAS is a nanomaterial was therefore dismissed as unfounded.

The Appellants claimed that the Contested Decision should be annulled on the grounds that the Agency committed an error of assessment in interpreting the findings in the Reuzel *et al.* publication as supporting the requests for information on all four types of SAS. The Board of Appeal found that the Agency had not demonstrated a potential risk with regards to precipitated SAS, silica gel and colloidal SAS. As a result, all the information requests regarding precipitated SAS, silica gel and colloidal SAS were annulled. The Board of Appeal found that a potential concern was only identified for one type of SAS, pyrogenic SAS. Consequently, the Board of Appeal continued examining the appeal solely as regards the pyrogenic type of SAS.

The Board of Appeal found that the Agency had demonstrated a potential risk with regards to inhalation toxicity for pyrogenic SAS. The evidence of a potential inhalation toxicity concern, taken in conjunction with the widespread exposure potential, meant that the Agency did not make an error of assessment in concluding that there is a potential risk for inhalation toxicity with regards to pyrogenic SAS. The Appellants' arguments that, with regards to pyrogenic SAS, the Agency failed to apply a weight-of-evidence approach and committed an error of assessment in interpreting the results of the Reuzel *et al*. publication were therefore dismissed as unfounded.

In relation to the request for information on physicochemical properties of all '*forms'* of pyrogenic SAS the Appellants alleged that the request was disproportionate. Whilst the primary objective of substance evaluation is to clarify potential risks, it must be clearly

explained how information requests will do so in a scientifically rigorous as well as proportionate way. The Board of Appeal found that, in this case, the Agency had not explained how the requested information would be used to clarify the potential risk identified. The Appellants' claim was therefore upheld.

In relation to the request for inhalation toxicity studies on four '*forms'* of pyrogenic SAS the Appellants argued that the request was disproportionate. The Board of Appeal found that in light of the objective legitimately pursued, clarifying the inhalation toxicity of pyrogenic SAS, and evidence from the Reuzel *et al.* publication it was appropriate and necessary to require a 90-day sub-chronic toxicity study in rats via the inhalation route on four pyrogenic SAS '*forms'*. The Appellants' claim that the request for inhalation toxicity testing on four *'forms'* of pyrogenic SAS was disproportionate was therefore dismissed.

The Board of Appeal also found that the request for inhalation toxicity studies on pyrogenic SAS did not breach Article 25(1) which provides that '*in order to avoid animal testing, testing on vertebrate animals for the purposes of [the REACH] Regulation shall be undertaken only as a last resort*.' Shorter tests would not clarify the concern arising from repeated exposure nor clarify whether the effects seen in the Reuzel *et al.* publication are reversible and whether the effects are due to particle overload or the toxicity of pyrogenic SAS. The Board of Appeal also noted that there is currently no alternative to testing on vertebrate animals that would allow the assessment of sub-chronic inhalation toxicity.

With regards to the Appellants' pleas related to the request for further information on the uses of pyrogenic SAS and the proportionality of that request the Board of Appeal found that, in the absence of information about the inhalation toxicity of pyrogenic SAS, the request for further information on uses was premature. The Board of Appeal also stated that the Contested Decision had not explained how information on uses would be used to clarify the concern, particularly with regards to improved risk management measures. The Appellants' plea that the request for further information on the uses of pyrogenic SAS breached the principle of proportionality was upheld.

The Board of Appeal also found that the Agency could not rely on a general concern regarding surface-treated substances that were also nanomaterials. The Agency had to be able to demonstrate a potential risk in relation to the substance at issue. With regards to surface-treated SAS the Board of Appeal found that the Agency had failed to demonstrate a potential risk. The information requests regarding surface-treated SAS were therefore annulled in their entirety.

In conclusion, the Board of Appeal maintained the request in the Contested Decision for inhalation toxicity testing on pyrogenic SAS. It annulled the Contested Decision in so far as it requested information on: precipitated SAS, colloidal SAS and silica gel; surface-treated SAS; and physicochemical properties and uses of '*forms'* of pyrogenic SAS.

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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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