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-015-2015

(*Substance evaluation – Nanomaterials – Potential risk – 'Forms' of a nanomaterial - Proportionality – Error of assessment – Article 25 – Legal certainty)*

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 (35 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 claimed firstly that the Agency's decision to include silicon dioxide on the Community Rolling Action Plan ('CoRAP') is illegal and that as a result the Contested Decision is based on an unlawful decision and must be annulled. The Board of Appeal found however that it was not competent to decide on appeals against decisions to include substances on the CoRAP. The Appellants' claim was therefore dismissed as inadmissible.

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 contested the Agency's reliance on the Reuzel *et al.* publication as grounds for considering that SAS constituted a potential risk to human health. In particular, the Appellants alleged a failure to apply a weight-of-evidence approach and an error of assessment in interpreting the results of the Reuzel *et al.* publication.

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.

The Appellants claimed that the Agency exceeded its competence by requesting information on *'forms'.* The Board of Appeal found that under substance evaluation the Agency can request information on *'forms'* of a substance as long as it can, inter alia, demonstrate that this information would assist in the clarification of the potential concern identified. Consequently, the Appellants' claims in this respect were dismissed as unfounded.

The Board of Appeal found however that the request for information on physicochemical properties for pyrogenic SAS breached the principle of proportionality as the Agency had not demonstrated how the information would clarify the potential concern identified. The information request was therefore annulled.

In relation to the request for inhalation toxicity studies on four '*forms'* of pyrogenic SAS the Appellants argued inter alia 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.

Regarding the Appellants' plea that the request for inhalation toxicity testing the alleged breach of the principle of legal certainty, the Board of Appeal found that the *'forms'* of pyrogenic SAS to be tested were clearly defined by reference to surface area and the degree of hydroxylation. Consequently, the Appellants were able to clearly and precisely know which *'forms'* should be tested with regards to this particular information requirement. The Appellants' plea was therefore dismissed as unfounded.

However, in relation to the request to provide information on the uses of each individual '*form*' of pyrogenic SAS, the Board of Appeal found that the term '*SAS form*' was not clearly defined in the Contested Decision. The lack of clarity meant that the Appellants could not be certain what constituted a '*form*' and therefore what information they were required to provide. As a result, it was not possible for the Appellants to identify uses per *'form'*. The Board of Appeal also observed that in the absence of information about the inhalation toxicity of pyrogenic SAS, the request for further information on uses was premature. The Appellants' plea that the request breached the principle of legal certainty was therefore 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.

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.
