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Minority position of the German CA on “pyrogenic, synthetic amorphous silicon dioxide, nano, surface treated” (PT 18) discussed at BPC-17

The German Competent Authority (CA) does not agree with the conclusion of the BPC Opinion for this biocidal active substance because of the approach that was taken in deriving the toxicological reference values for human health. In fact, the German CA is of the opinion that there are no adequate data available to derive reference values for inhalation toxicity. Without reliable reference values, the risk to human health cannot be evaluated.

Since no study with the active substance was available for the purpose of deriving reference values, the eCA used a study with a test substance similar to the active substance, i.e. a read-across approach. However, this study is of low quality. Basic requirements of the relevant OECD test guideline 413, such as the use of a sufficient number of dose groups, were not met: only one dose group was investigated. Therefore, no adequate data for the derivation of reference values could be obtained from this study, a fact that the eCA itself acknowledges in the Assessment Report.

Furthermore, although the test substance is chemically similar to the active substance, it has not been shown whether it is also toxicologically equivalent. For example, the test substance and the active substance differ with regard to their surface coating, a difference which could influence biodegradation and/or interaction with human tissues. Basic requirements for a read-across according to the relevant guidance (ECHA Read-Across Assessment Framework) were therefore not met.

The applicant had proposed a different approach using a study of better quality, but conducted with a test substance of limited similarity to the active substance. This study would have resulted in a lower, and therefore more critical, reference value.

In summary, the applied approach is based on a study of low quality, conducted with a test substance similar, but possibly not toxicologically equivalent to the active substance. The approach suggested by the applicant, on the other hand, is based on a valid study that was however conducted with a test compound of limited similarity to the active substance. The German CA supports neither approach. Since no adequate data are available to derive reference values, the risk to human health cannot be evaluated. In consequence, for this active substance the approval proposal of the BPC is not supported by the German CA.