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COMMENT ON THE PROPOSAL FOR T-CLASSIFICATION TO AZOXYSTROBIN

Comment on use of weight of evidence approach in the T-criterion assessment to Azoxystrobin

According to ECHA guidance[1] (2014) a substance with an acute aquatic Ecotoxicity endpoint between 0.1 and 0.01 mg/L would qualify for a *potential* "T" criterion. A substance could only be assigned the T criterion based on acute aquatic Ecotoxicity endpoints if one or more acute endpoint(s) were below the trigger of 0.01 mg/L. This is not the case for Azoxystrobin and therefore, the assessment of the T criterion must rely on available chronic Ecotoxicity data.

For Azoxystrobin, a large robust aquatic database from regulatory laboratory studies exists, including several acute (LC/EC_{50}) and chronic (NOEC) endpoints reviewed by EFSA and listed in their conclusions with which to inform and facilitate the T-assessment. According to ECHA guidance[1] (2014), the assessment should take into account all relevant and available information, in other words a "weight of evidence" approach may also be applied. Therefore, due to the large dataset for Azoxystrobin a weight of evidence approach would be more appropriate, than to just simply compare the most chronic toxic endpoint, from the available regulatory laboratory studies, with the "cut-off" values, as further detailed below.

Chronic Ecotoxicity data

A number of chronic Ecotoxicity endpoints are available for Azoxystrobin from regulatory laboratory studies in fish, Crustacea and algae. If you apply the T-assessment criteria in its simplest form, using the lowest toxicity endpoint from these regulatory studies, the chronic *A. bahia* study has the mean measured NOEC = 0.00954 mg/L. This endpoint is only just slightly more toxic than the "cut-off" value of 0.01 mg/L, for T-classification. Indeed, all mean measured concentrations in this study were within ± 20% of nominal. Therefore, according to the USEPA test guideline (USEPA 74-2) endpoints could have been reported as nominal (0.00954 mg/L mean measured, or 0.01 mg/L nominal). In this laboratory study, the true NOEC is also very likely to be >0.01 mg/L, as the LOEC was 0.016 mg/L. All other NOEC endpoints from the regulatory laboratory studies for fish, *Daphnia* and algal species do not demonstrate any effects at ≤0.01 mg/L. Therefore, using a weight of evidence approach the laboratory data demonstrates NOECs of >0.01 mg/L and that Azoxystrobin should not be assessed as "T".

Conclusion

Using the available endpoints from the chronic regulatory laboratory studies for Azoxystrobin, a weight of evidence approach should be applied when assessing the relevance of the T-classification. This approach considers all available chronic regulatory laboratory data for Azoxystrobin in determining the T-classification, rather than the more limited approach of only comparing the lowest endpoint to the "cut-off" value. It can be estimated that there would be no effects in chronic regulatory laboratory studies at concentrations less than 0.01 mg/L. Therefore, sufficient evidence has been provided to suggest that Azoxystrobin should not be classified as "toxic" in a PBT assessment and should be considered as "non-toxic."

[1] ECHA (2014). Guidance on Information Requirements and Chemical Safety Assessment. Chapter R.11: PBT/vPvB assessment. Version 2.0, November 2014. European Chemicals Agency, Helsinki.