

How can we reduce compounded conservatism for a more relevant non-dietary risk assessment of pesticides?

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INTRODUCTION

The European non-dietary risk assessment of pesticides uses either generic prediction models or scenario-specific default values to estimate exposure for various populations. Worker re-entry exposure became a key reason to refine risk assessments after the implementation of the EFSA guidance document in 2014. Hence, a CropLife Europe team recently reviewed the factors that impact European worker re-entry risk assessment (Kluxen et al., 2021, Regulatory Toxicology and Pharmacology, 121, 104864).

The risk parameters and drivers in the current European Union (EU) worker risk assessment for pesticides were considered, i.e. crop maintenance, crop inspection and harvesting activities. Overall, the current approach is very conservative due to multiple worst-case default assumptions, for example the use of high percentile default values which are multiplied together.

METHODOLOGY

Data from 16 good laboratory practice (GLP)-compliant worker exposure studies for six crops were evaluated with a total number of 184 workers. For those, measured exposure data was compared with generic exposure model predictions using EFSA (2014).

RESULTS

It is shown that external cumulative dermal exposure is overpredicted about 50-fold on average as compared to the current model. Using average default values, which can be derived based on the underlying datasets, still results in an overprediction but reduces its extent to 9-fold on average.

DISCUSSION

In the current deterministic non-dietary exposure assessment, the use of high percentile default values seems to result in a substantial misalignment between predicted and actual dermal exposures.

One reason is that default values are derived independently from each other, without considering the overall impact on the exposure estimation. Hence, overestimation can be reduced by considering the individual contribution of a default value to the intended conservatism or by simply using averages, which is also protective.

Alternatively, probabilistic methods could be developed for more realistic risk estimation, since the current model assumes daily high exposures in the same scenario, corresponding to the reference values' underlying study duration, which is unrealistic based on agricultural practice.

Overall, the EU risk assessment includes several numerically unaccounted 'hidden safety factors', for example in relation to worker re-entry exposure. Hence, workers are well protected but risk assessments are also biased towards failing due to compounded conservatism.