

How can aggregate exposure scenarios of agrochemicals be mapped?

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INTRODUCTION

Cumulative assessment groups (CAGs) have been established for the thyroid and the nervous system and probabilistic cumulative dietary risk- and uncertainty assessments have been conducted. Refinements were necessary to show that the thresholds for regulatory consideration were not reached. Reference values as well as exposure data relevant for the dietary situation are available. Non-dietary exposure is more difficult to estimate, as model estimates are over-predictive and measured data are only rarely available. Furthermore, non-dietary sub-populations may need to be combined (operators are also residents and may additionally be re-entry workers) and the exposure duration profile of the non-dietary exposure population is unlike the profile of the dietary exposure population. EFSA/DG SANTE plans to integrate non-dietary exposure into cumulative risk assessments (CRA). A more scientifically stringent generation of CAGs and a more realistic exposure assessment is needed, as well as prioritisation criteria in order to conduct relevant cumulative and aggregate risk assessments in the future.

METHODOLOGY

The thyroid CAG was selected as the first representative. The compounds were (re-)assigned to the CAG following the methodology described by Colnot et al., 2020. Further target (organ) toxicities were selected to apply prioritisation criteria for CAG establishment, e.g. reproduction & development. Only agrochemicals registered in Europe and/or currently present in the European diet were considered. Processing factors as well as market share data were applied to the occurrence/concentration data to accurately reflect expected human dietary exposure. The level of non-dietary exposure estimates was assessed in various ways: (a) similar to the Tier II GAP scenario (van Klaveren et al., 2021; i.e. non-dietary exposure as the actual scenario (focal exposure) and dietary exposures for compounds from the same CAG providing the 'background' exposure) and (b) by mapping combined spraying scenarios linked to the chemicals' CAG assignment.

RESULTS

The hypothyroidism group was reduced to approximately 50 % when the criteria for a weight of evidence for grouping was applied with more scientific stringency. Applying further prioritisation criteria to the establishment and population of the CAGs focused efforts, thereby leading to fewer and more relevant risk assessments. The results of the exposure and risk calculations are presented, including the integration of non-dietary exposures with dietary CRAs.

DISCUSSION

In the last ten years, methodologies have been developed to conduct cumulative dietary risk assessments and safe uses have been shown, using a high degree of expert judgment. At the same time, the regulatory consequences of excessive cumulative risk are still unclear. In future, the critical and relevant exposure and use scenarios have to be prioritised, including non-dietary exposure. Different approaches need to be taken, as realistic application data are not sufficiently mapped and monitoring data are not readily available. From a risk management perspective, clear regulatory consequences for exceeding the cumulative risk cup need to be developed and applied in a transparent manner to ensure trust and predictable assessments. The current approach may block future innovation, with dietary exposure accounting for a significant proportion of the full risk cup with the larger exposure contributors in an aggregate assessment yet to come.