

Industry perspective: scientific risk assessment is possible for pesticides and mixtures thereof

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INTRODUCTION

The question of how to address risk from environmental exposure to mixtures of chemicals has recently gained more traction. A number of regulatory agencies share the viewpoint that current risk assessment methods do not adequately take combined environmental exposure to chemical mixtures and the risks from those mixtures into consideration. This has led to a proposal in accordance with REACH under which a generic mixture assessment factor should be applied to counteract the risk from unintentional mixtures.

METHODOLOGY

The toxicity and risk assessment of chemical mixtures has previously been directly addressed under the Plant Protection Product (PPP) legislation in the EU. Plant protection products are chemical mixtures that contain one or more active substances together with other chemical components and the combined product toxicity is evaluated under Regulation (EC) No 1107/2009, for both human health and for the environment.

The risk for individual PPPs that contain multiple active substances is based on scenarios. For example, for a consumer risk assessment, it is based on worst-case assumptions concerning diet and residue levels and the use of additivity of common assessment groups (CAGs) based on common adverse outcomes.

Environmental Risk Assessments (ERA) consider the risk from active substances and other formulation components through testing of the effects and/or calculation of mixture effects based on scenarios that assume worst-case exposure levels. The chemical mixtures currently assessed are those that are most likely to occur, i.e. when chemicals are applied together as a formulated product.

RESULTS

This looks at the scenarios in which exposure levels will be highest – considering in-field exposure for terrestrial organisms and edge of field exposure for aquatic organisms.

While approaches to address combined risk exist, these assume the additivity of effects and worst-case exposures. Unlike other aspects of the ERA for PPPs, there is currently limited opportunity for a tiered refinement. In effect, only a screening level assessment is carried out, assuming additive toxicity of active substances and maximum exposure values, or simple addition of worst-case risk quotients. A screening approach is appropriate, but a mixture assessment that combines worst-case assumptions will be overly conservative and a scientific, tiered approach to refinement should be adopted. Refinement could consider whether additivity is always appropriate or whether certain groupings should be used, using common adverse outcomes, as in the Human Health Assessment. Data are available for refinement through consideration of more realistic time variable exposures to combinations of chemicals, combining exposure and effects modelling, rather than peak exposures for each component of the mixture.

DISCUSSION

Combined exposure to pesticides beyond combination products, e.g. for multiple exposures at landscape level, may be addressed further. However, data could be gathered to investigate the extent to which this aspect is covered by the worst-case assumptions in the existing risk assessment procedures. The potential impact from different spray series has been evaluated in several experimental and theoretical modelling approaches. These will be evaluated, looking at the evidence as to whether we may be underestimating risk and whether any major uncertainties exist, and, if so, where. It is important again to follow a scientific, tiered assessment approach and this will likely require the development of new scenarios to allow for changes in the scale of the assessment and to deal with the exposure and varying temporal and topographical effects.

In this contribution we will consider:

- current approaches to mixture assessments for PPPs, their scope, and potential options for refinement,
- assessment of tank mixes and spray programmes, using scenario-based approaches,
- implications for aligning mixture toxicity/risk considerations for PPP in REACH.