# Assessing Environmental Risk of Co-formulants Used in Plant Protection Products Under REACH – A case study of when a chemical use doesn't fit the standard assessment framework

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## Introduction

Part of the REACH approach to assessing environmental exposure for wide dispersive use of general chemicals involves conducting both a local and regional scale assessment. Both scales assume release of the chemical to an urbanised area: waste water releases at the local scale are modelled via a municipal STP supporting a standard town of 10,000 inhabitants, and the regional scale is assumed to be to a densely populated area of 20 million inhabitants (200 x 200 km) with 80% of waste water treated by a STP. Direct release to air and soil from wide dispersive uses is not assessed at the local scale, only at the regional scale. This standard REACH assessment framework is poorly suited to the wide dispersive use assessment of co-formulants used in plant protection products. Instead, exposure to co-formulants is potentially via release to an edge of field water body via spray drift, drainage and runoff as well as direct release to soil. A summary of the approach developed by ECPA (http://www.ecpa.eu/information-page/regulatory-affairs/reach) to address these differences is presented below, along with an investigation into one specific area: model sensitivity to regional scale releases to water.

## Summary of ECPA approach

Regional scale: ECPA SpERC 8d.1.v2 and ECPA SpERC 8d.2.v2

- Tonnage based assessment in EUSES/ECETOC TRA/Chesar
- Regional background concentrations arising from all uses of the substance (PEC Regional)
- Spray formulations: release to soil and air dependent on vapour pressure; Granule formulations: 100% release to soil

Local scale: ECPA Local Environment Tool (LET) v3.0

- Imports PEC Regional from tonnage based assessment
- Conducts FOCUS based ERA for default worst-case scenario assuming:
  - 1 ha agricultural field with adjacent water body
  - Spray drift to waterbody of 15.7%
  - Runoff/drainage input to waterbody of 5%
  - No crop interception
  - Release to soil dependent on vapour pressure for sprays, 100% release to soil for granules (based on USES 4.0 approach)
- Reports PECs, RCRs and safe application rate for a given RCR (e.g. RCR=0.90)

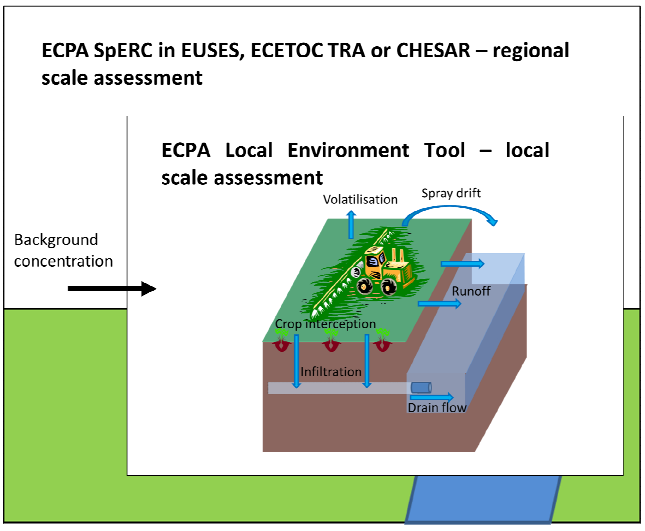


**Figure 1. Summary of environmental assessment approach for co-formulants used in PPPs**

## Investigation

The above approach considers potential direct release to water from co-formulant uses (via spray drift) in the local scale model. The regional scale models consider release to surface water indirectly (via runoff from soil). By default these models assume a densely populated area with 80% of release to water (defined by the tonnage used and the related emission fraction) going via a STP, rather than an agricultural region with direct release to surface water.

An investigation was conducted of the sensitivity of the local scale PEC to the regional scale tonnage based models, varying the two relevant regional scale parameters: emission fraction and STP connectivity.

PECLocal = Clocal + PEC Regional

32 hypothetical substances with systematically varied properties (vapour pressure, water solubility, logPow, biodegradability, QSAR class) were run in ECETOC TRAv3.1, with release to soil and air dependent on vapour pressure. For each substance 1000 tonnes was assumed at the European scale, of which 10% was directed to co-formulant use at the regional scale. Various 'release to water' scenarios were examined for the applied substance tonnage: emission fraction = 0% (default); emission fraction = 0.3% (unrealistic worst-case), 80% STP connectivity; emission fraction = 0.3%, 0% STP connectivity. Regional PECs for each substance were imported into the ECPA LETv3.0 and run in a 'Default' assessment for sprayed co-formulants, to calculate Clocal and PECLocal.

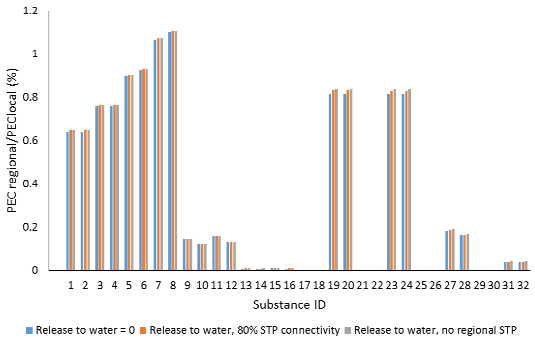


**Figure 2. Contribution of freshwater PEC Regional to PECLocal where emission fraction to water and STP connectivity are varied**

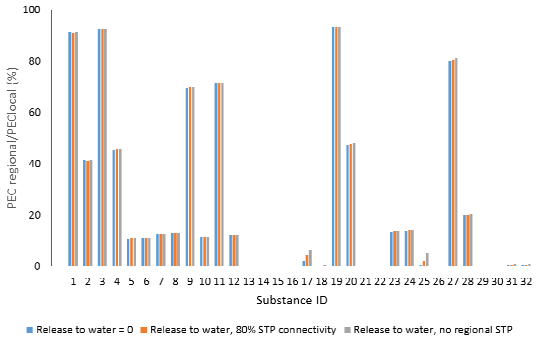


**Figure 3. Contribution of freshwater sediment PEC Regional to PECLocal where emission fraction to water and STP connectivity are varied**

## Conclusions

- Slight absolute increases in the PEC Regional observed for freshwater and sediment with non-zero emission to water.
- Largest relative increase in PECLocal observed for the sediment compartment.
- Slight increases in PEC Regional were too small to effect the safe application rate calculated in ECPA LETv3.0.
- Small increase in PECLocal when no regional STP was assumed. The default 80% STP connectivity appears to have a negligible impact on the overall exposure assessment for the substances.

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