Modelling and monitoring of pesticides fate and exposure in a regulatory context

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Introduction

The use of generic default values in current regulatory modelling frameworks describing pesticide loss pathways and possible exposure mitigations , especially at the field scale, may result in difficulties in demonstrating regulatory compliance for specific pesticide uses and compounds that do not fit the standardised exposure assessment approach. In these cases, higher tier field studies may be a preferred option to demonstrate safety directly through environmental monitoring or generate use or compound specific model parameter or mitigation effectiveness values. However, the current lack of guidelines available for the conduct of many such studies has meant that acceptability of the experimentally derived data might be variable across the regulatory processes and EU Member States.

This poster illustrates experiences in designing and carrying out a range of higher tier field studies for a variety of exposure sources and pathways aimed at providing application/use or compound specific data that should be considered suitable to be used directly in the risk assessment process in place of generic model parameter or effectiveness values or even simulated exposure.

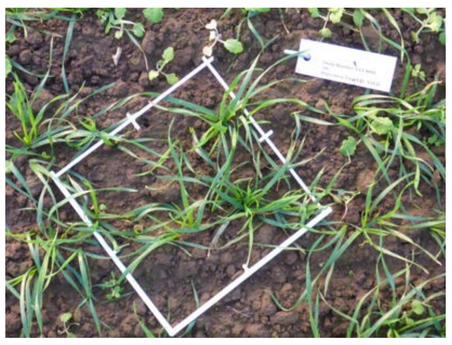
Materials & Methods

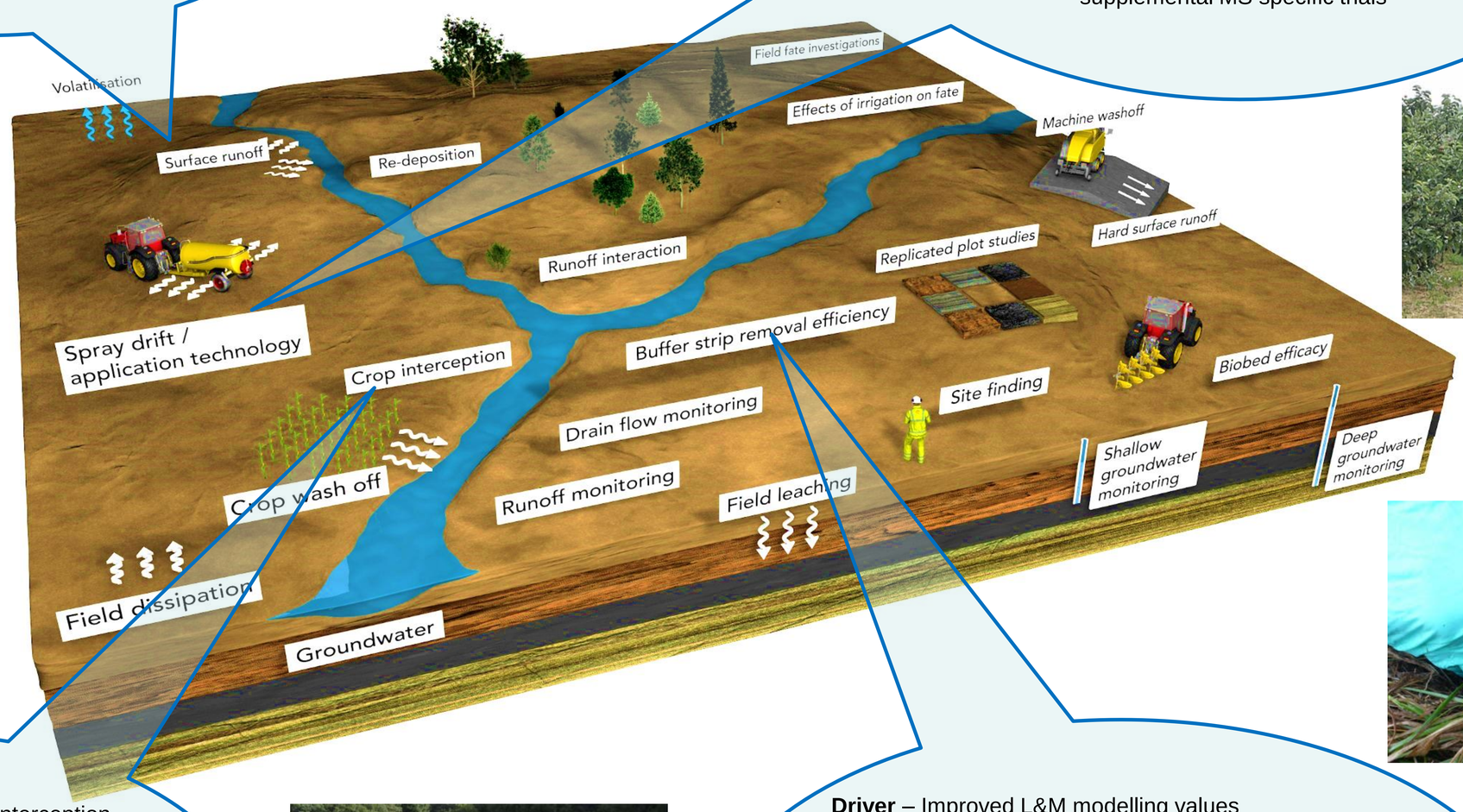
Driver – Refinement of runoff losses including novel mitigation strategies - eg. Soil compaction/irrigation
Exposure pathway – Soil/runoff (PECsoil/PECsw)
Product properties – Volatile
Registration stage – Pre-registration
Guideline – Not available
- CEA protocol developed for specific usage profiles

Effectiveness – Effective
Acceptability – Annex 1, not readily accepted
- Annex 3, MS dependent, improved by pre-submission meeting

Driver – More relevant drift curve (than standard boom sprayer)
Exposure pathway – Spray drift refinement (PECsw)
Product properties – All, and optional use of dye tracers to provide generic data
Registration stage – Pre-registration
Guideline – ISO 22401 – methods for field measurement of spray drift
- CEA protocols developed over 15 years of conducting studies

Effectiveness – Highly effective
Acceptability – Annex 1, not readily accepted
- Annex 3, MS dependent, improved by pre-submission meeting and supplemental MS specific trials





Driver – Improved FOCUS crop interception values
Exposure pathway – Soil/groundwater
Product properties – All, and use of dye tracer to provide generic data
Registration stage – Pre-registration
Guideline – Not currently available
- CEA developed protocol available

Effectiveness – Highly effective for spring applications
Acceptability – Pending evaluation

Driver – Improved L&M modelling values
Exposure pathway – Runoff refinement (PECsw)
Product properties – Low Koc soluble compounds
Registration stage – Pre-registration
Guideline – Not currently available
- CEA protocol developed over 5 studies, evaluated at Annex 1 and 3

Effectiveness – Highly effective
Acceptability – Annex 1, not readily accepted
- Annex 3, MS dependent, improved by pre-submission meeting and accompanied by VFSMod simulations

Discussion & Conclusions

In an increasingly challenging regulatory process, Higher Tier modelling, drawing on or supported by Higher Tier field studies is more frequently required to demonstrate safety, and to accommodate compounds that may not fit the standard approach. Although there are few guidance documents currently available to support this approach, experience has shown that regulatory acceptance is possible by providing robust methodologies and building in regulatory context when designing field based programmes.