

# EU Renewal of Mesotrione and Implications of National Guidance on $PEC_{GW}$ Estimates for a pH Dependent Compound

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## Purpose

Mesotrione is currently being proposed EU review for inclusion on Annex I under Regulation (EC) No 1107/2009 with the UK assigned as RMS. The environmental fate and behaviour of mesotrione is defined by the pH dependence of sorption and degradation in soils as a consequence of the ionisation status of the compound. At an alkaline pH the compound is essentially fully ionised and therefore mesotrione is extremely mobile but consequently has an extremely short half-life (as a consequence of increased bioavailability). As the soils becomes increasingly acidic ( $pK_a = 3.2$ ), mesotrione becomes increasingly unavailable for degradation with resulting increases in both the values for sorption and  $DT_{50}$ .

This poster examines how pH dependent behavior is evaluated in the individual member states and the impact that this has on National GW exposure estimates versus core EU modelling.

## Methodology

$PEC_{GW}$  estimates were achieved by running FOCUS PELMO 5.5.3 using input definitions defined in the EFSA conclusion (EFSA Journal 2016; 14(3):4419). Derivation of National endpoints were derived for the purposes of modelling as outlined in the appropriate National Guidance document:

- Northern Zone Guidance Document
- German input decision tool v3.3

The core GAP of a single application of 150 g mesotrione/ha applied to maize early post-emergence as a broadcast spray annually was considered.

## Model Inputs

Compound	Mesotrione	Value in accordance with EU endpoint / Reference
Molar mass (g/mol)	339.3	Yes, EFSA (2016)
Water solubility (mg/L)	160* (20)	* Yes, EFSA (2016) ** Yes, RAR (2015)
Saturated vapour pressure (Pa)	0 (20)	Worst case assumption
$DT_{50}$ in soil (d)	EU 27.88/0.54 (acid/alk) DK 31.3 d DE 19.6 LT 31.3/11.4 (acid/alk)	Yes, EFSA (2016) NZ GD Input decision tool v3.3 NZ GD
$K_{FOC} / K_{FOM}$ (mL/g)	EU 156.7/17.4 (acid/alk) DK 48.0 DE 156.7 LT 48/16.4 (acid/alk)	Yes, EFSA (2016) NZ GD Input decision tool v3.3 NZ GD
1/n	0.94	Yes, EFSA (2016)
Plant uptake factor	0	Worst case assumption
Washoff factor (1/m)	not relevant	-
Foliar $DT_{50}$ (d)	not relevant	-

Scenario	Application dates (absolute)
Châteaudun	4-May
Hamburg	8-May
Kremsmünster	8-May
Okehampton	28-May
Piacenza	18-May
Porto	4-May
Sevilla	10-Mar
Thiva	23-Apr

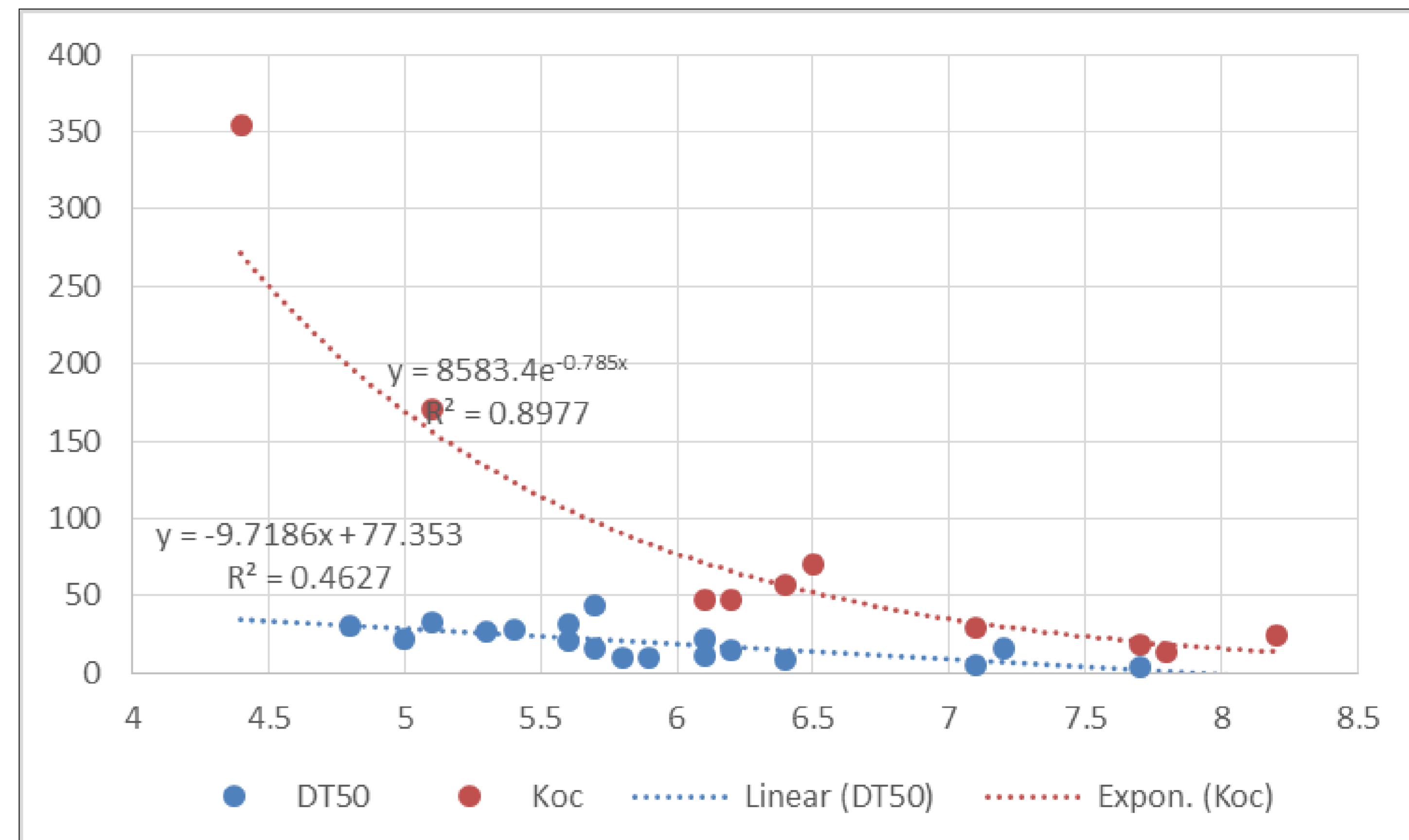


Fig. 1: pH dependent behaviour of mesotrione in standard soil test systems

From Figure 1, it is evident that as pH changes, both  $DT_{50}$  and  $K_{FOC}$  change concurrently and cancel each other out in the model. As such, National Guidance input parameters that break the pH dependence (i.e. decouple the relationship between sorption and degradation) exaggerate the leaching potential of mesotrione resulting in unrealistic model outputs.

FOCUS zone	EU	DK	DE	LT
Châteaudun	<0.001	-	-	-
Hamburg	0.006	1.73	0.001	0.889
Kremsmünster	0.003	-	-	-
Piacenza	0.008	-	-	-
Thiva	<0.001	-	-	-
Okehampton	0.007	-	-	-
Sevilla	<0.001	-	-	-
Porto	0.002	-	-	-

Table 1: Comparison of Modelled Outputs for Mesotrione and the Impact of National Guidance on  $PEC_{GW}$  Estimates

## Conclusion

At the "core" EU level, analysis of leaching potential via PELMO for representative acidic and alkaline scenarios showed that mesotrione did not leach to any significant extent, whilst at the national level, regulatory mandated approaches for assessing leaching of pH dependent compounds (e.g. Guidance Document on Work Sharing in the Northern Zone in the Authorisation of PPPs, 2016), resulted in a ~X1000 increase in predicted leaching of mesotrione as a consequence of uncoupling the degradation and sorption input parameters.

In particular, regulatory guidance on combining worst case endpoints irrespective of the potential for these to occur in the environment was rejected during the mesotrione AIR review as providing overly conservative estimates of the leaching potential of pH dependent compounds (EU Commission, Volume 3 B.8 (PPP) Callisto 100SC Renewal Assessment Report).

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