Could a spatially distributed modelling approach enhance post approval considerations for veterinary medicines?

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CEA

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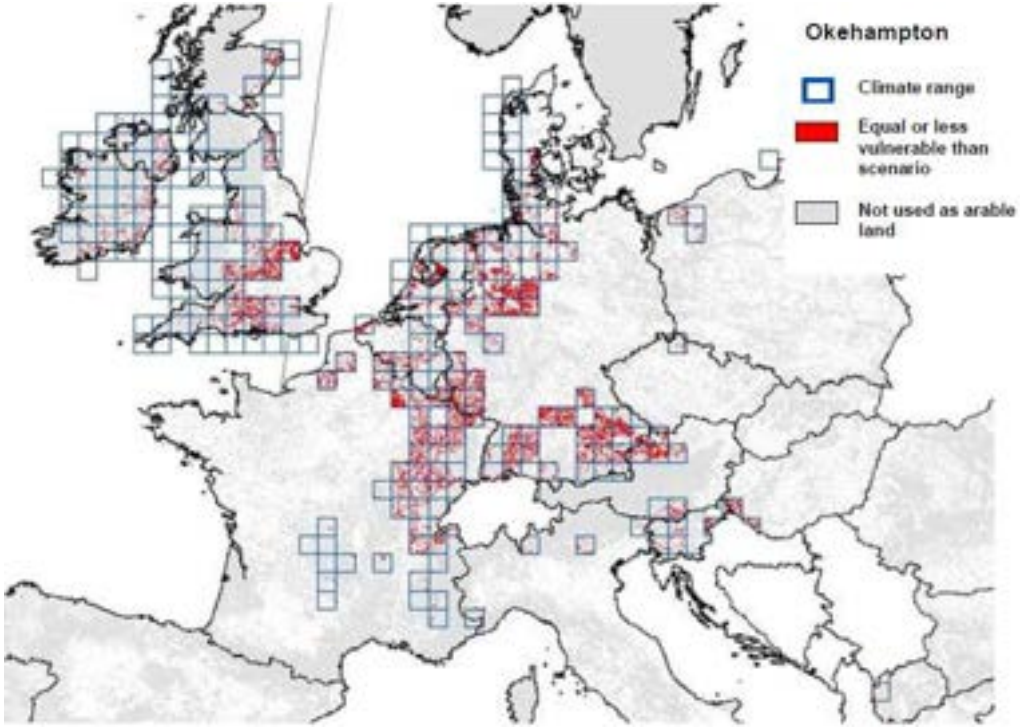
Background

- Veterinary medicines follow tiered ERA approach
- FOCUS SW and GW modelling considered a higher tier option
- Standardised scenarios defined

GW standard scenario

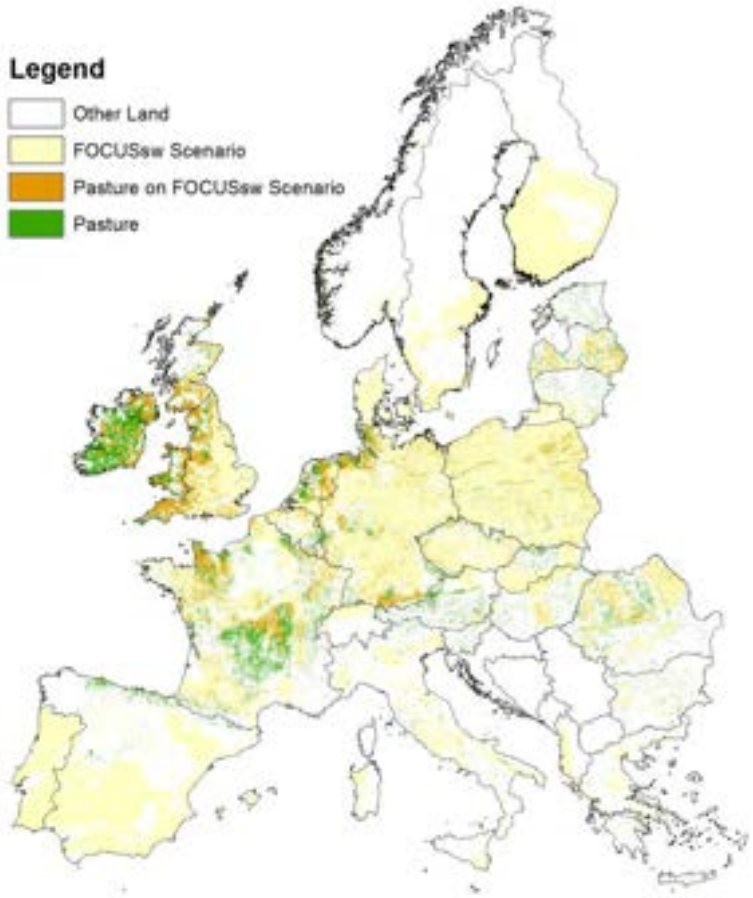
- PEARL 4.4.4
- Okehampton
- Application is early autumn, arable, before crop emergence



Extension of the 'Okehampton' GW scenario. FOCUS (2009) "Assessing Potential for Movement of Active Substances and their Metabolites to Ground Water in the EU" Report of the FOCUS Ground Water Work Group, EC Document Reference Sanco/13144/2010 version 1, 604 pp.

Drawbacks?

- FOCUS intended for arable agriculture
- Doesn't inform post approval or regional considerations
- Would spatially distributed modelling help?



FOCUS Surface Water Scenarios in the EU Evaluation Process under 91/414/EEC, Report of the FOCUS Working Group on Surface Water Scenarios, SANCO/4802/2001-rev.2. 245 pp.,

MetaPEARL model

- Metamodel proposed by Tiktak et al. (2006):

$$lnC_L = \alpha_0 - \alpha_1 X_1 - \alpha_2 X_2$$

Where:

$$X_1 = \frac{\mu \theta_{LT} L}{q}$$

μ = Degradation rate coefficient (d^{-1})

ϑ_{LT} = Soil water content (m^3/m^3)

L = Depth (1 m)

q = Volume flux of water at 1 m (m/day) (q100)

Tiktak, A., Boesten, J.J.T.I., van der Linden, A.M.A. Vanclooster, M., 2006. Mapping Ground Water Vulnerability to Pesticide Leaching with a Process-Based Metamodel of EuroPEARL. Journal of Environmental Quality, 35 (4): 1213-1226

MetaPEARL model

$$X_2 = \frac{\mu \rho f_{OM} K_{OM} L}{q}$$

ρ = Dry bulk density of soil (kg/m^3), f_{OM} = Organic matter content (kg/kg), K_{OM} = Sorption coefficient (dm^3/kg)

Climate zone	Mean Annual Precipitation (m)	Mean Annual Temperature (°C)	α_0[1]	α_1[1]	α_2[1]
Temperate, dry	<0.8	<12.5	5.30	0.16	0.46
Temperate, wet	>0.8	<12.5	4.95	0.16	0.60
Warm, dry	<0.8	>12.5	5.20	0.07	0.37
Warm, wet	>0.8	>12.5	5.02	0.23	0.57

[1]Tiktak, A., Boesten, J.J.T.I., van der Linden, A.M.A. Vanclooster, M., 2006. Mapping Ground Water Vulnerability to Pesticide Leaching with a Process-Based Metamodel of EuroPEARL. Journal of Environmental Quality, 35 (4): 1213-1226

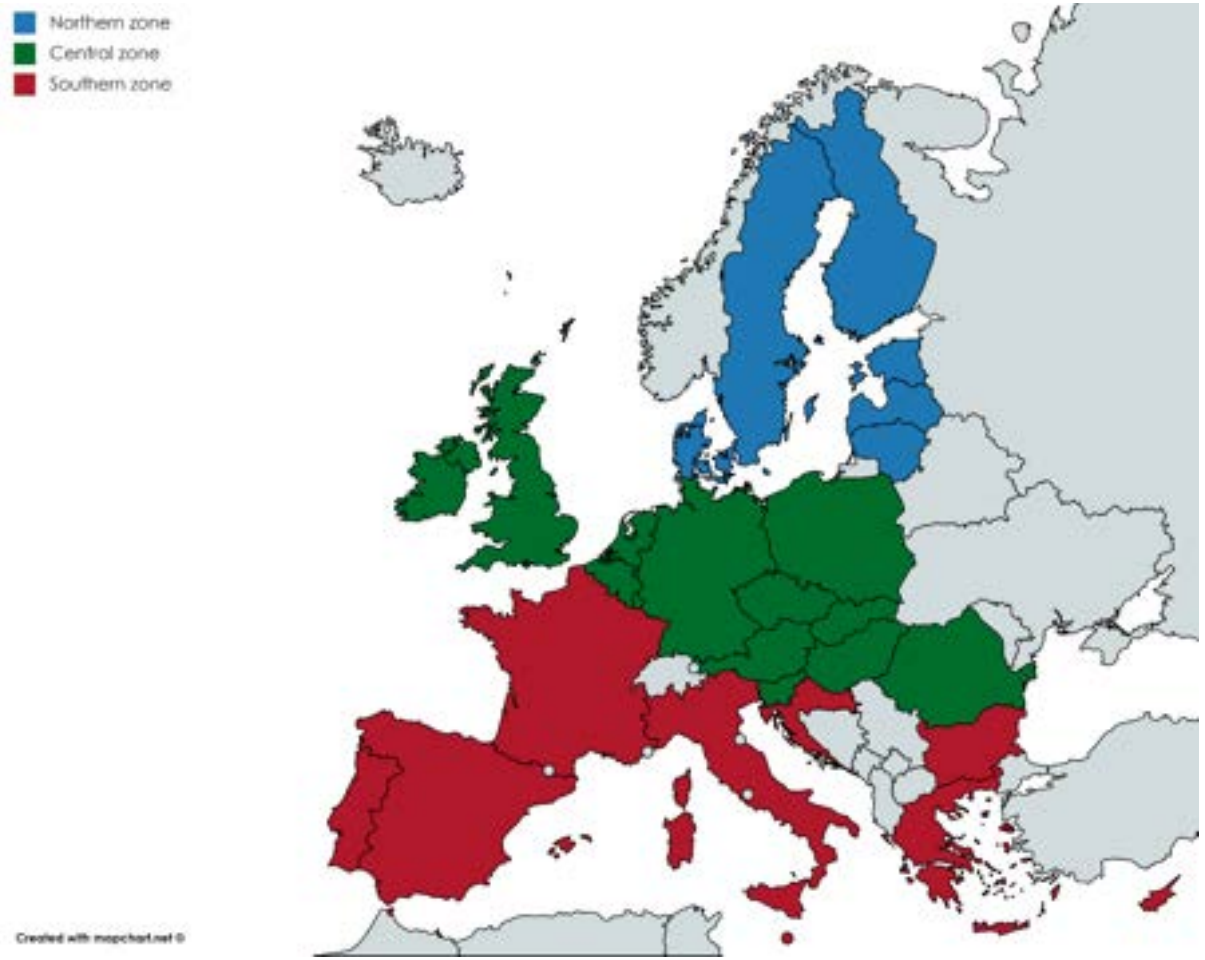
MetaPEARL model

- FOCUS Substance B (K_{OM} = 10, DT_{50} = 20)
- Applied for every 1 km^2 arable land in 26 MS

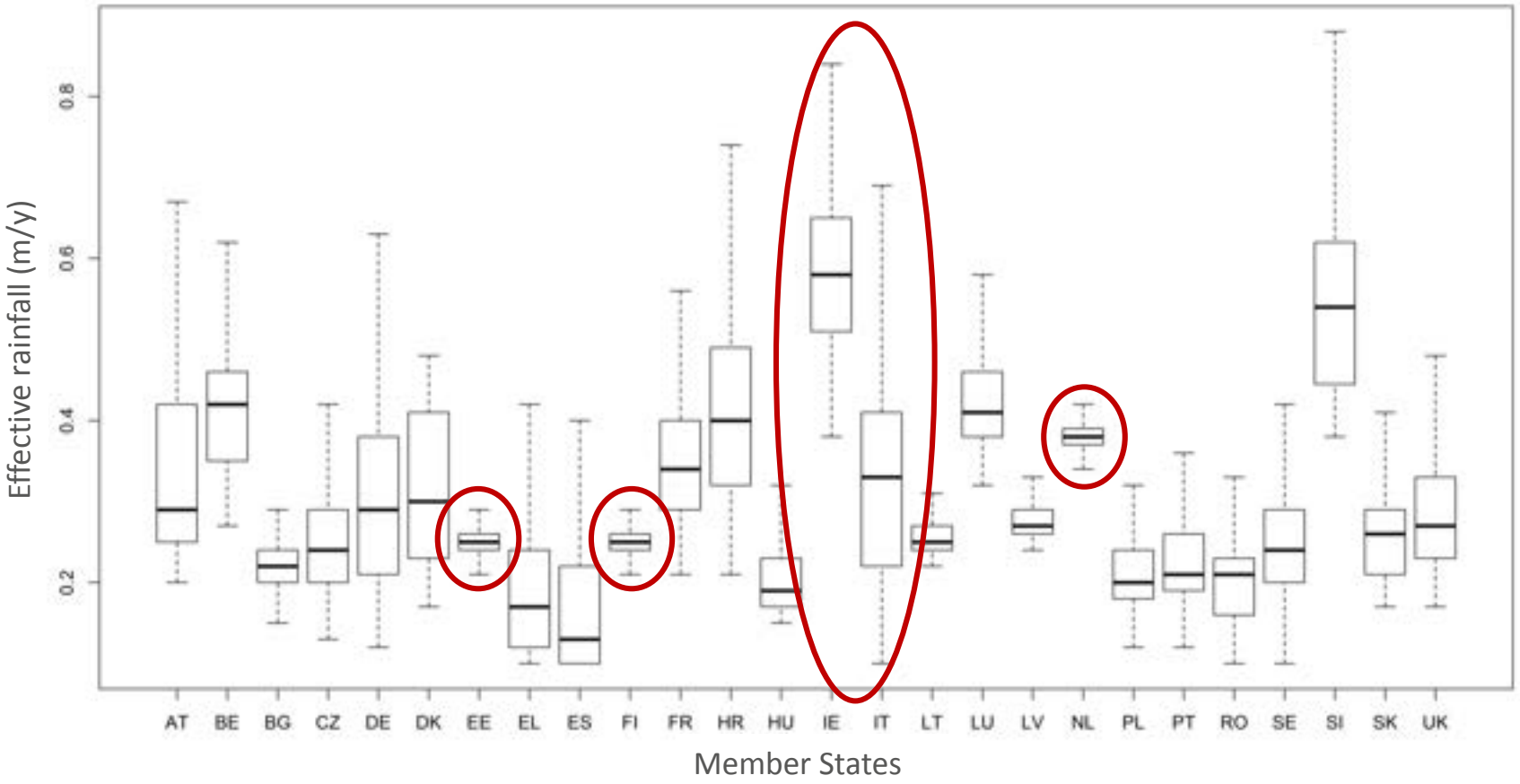
Variable	Description	Dataset, source
Soil Organic Matter	Topsoil	OCTOP, Jones et al., 2005. Eur J of Soil Sci, 56(5): 655-671
	Subsoil	European Soil Database Derived Data, European soil data centre
Soil Texture	Topsoil	
	Subsoil	
Soil Water Content	Field capacity	Calculated from soil texture
Rainfall	Mean annual rainfall	Worldclim, Hijmans et al., 2005 Int J Climatol, 25: 1965-1978
Temperature	Mean annual temperature	
Land Cover; Use	Arable; wheat	Corine land cover 2012, European Environment Agency; NUTS2 statistics (EUROSTATS) CAPRI2000 (EFSA, 2012)

Spatial scale

- Results reported on MS and PPP zonal level



Results – variation in effective rainfall (q100)



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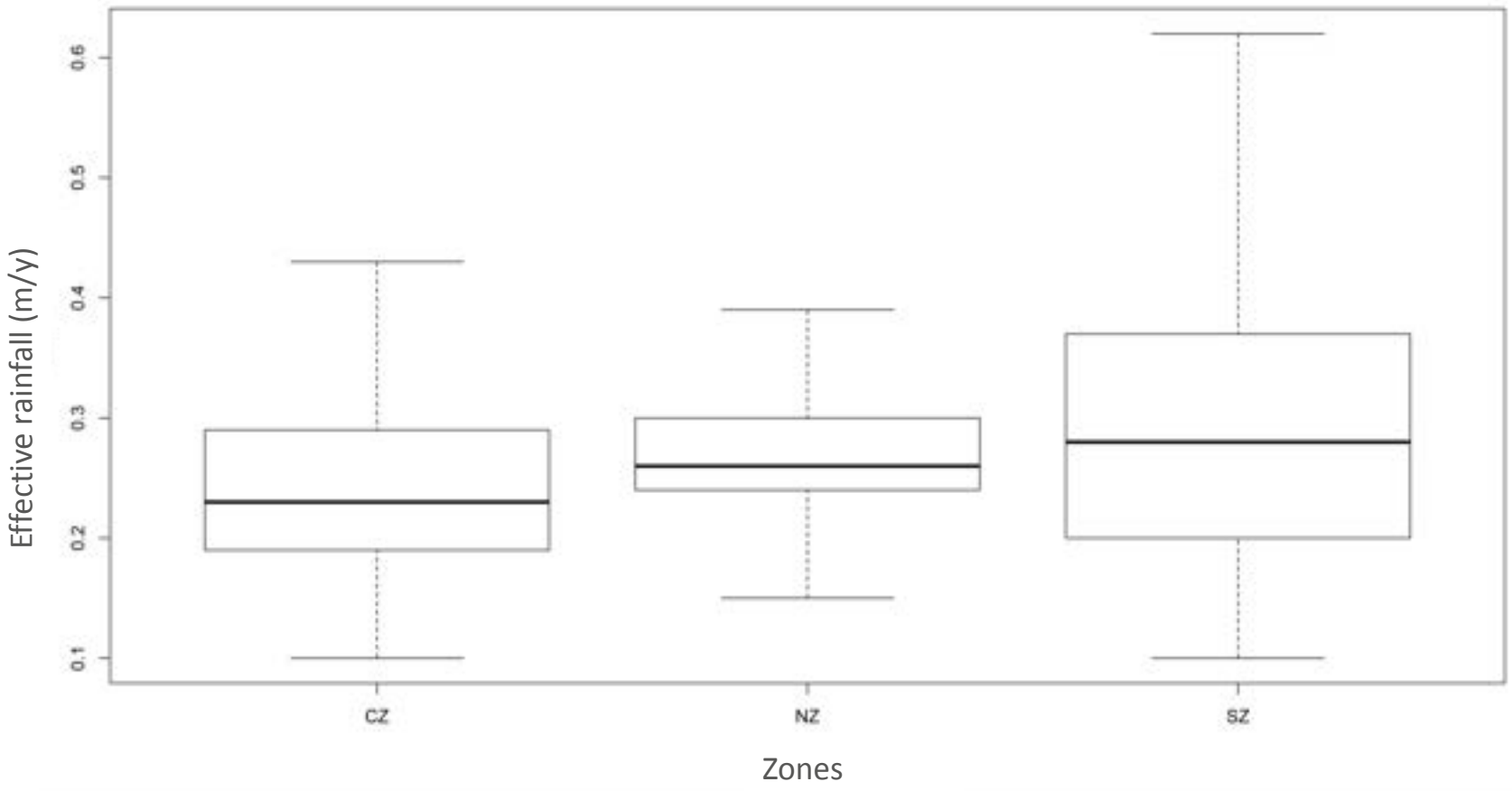


Results – Temperature and OM

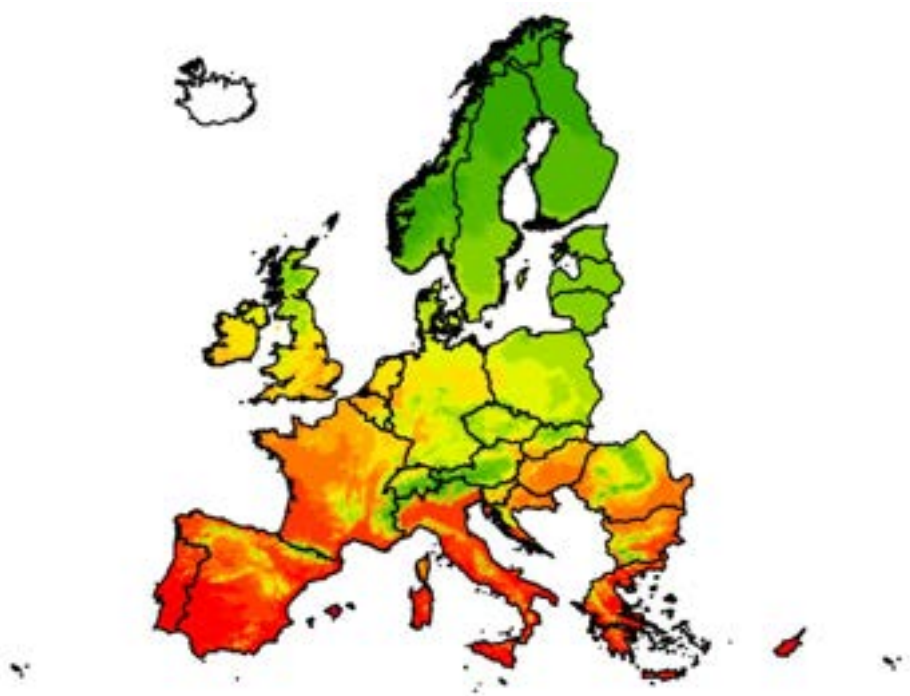
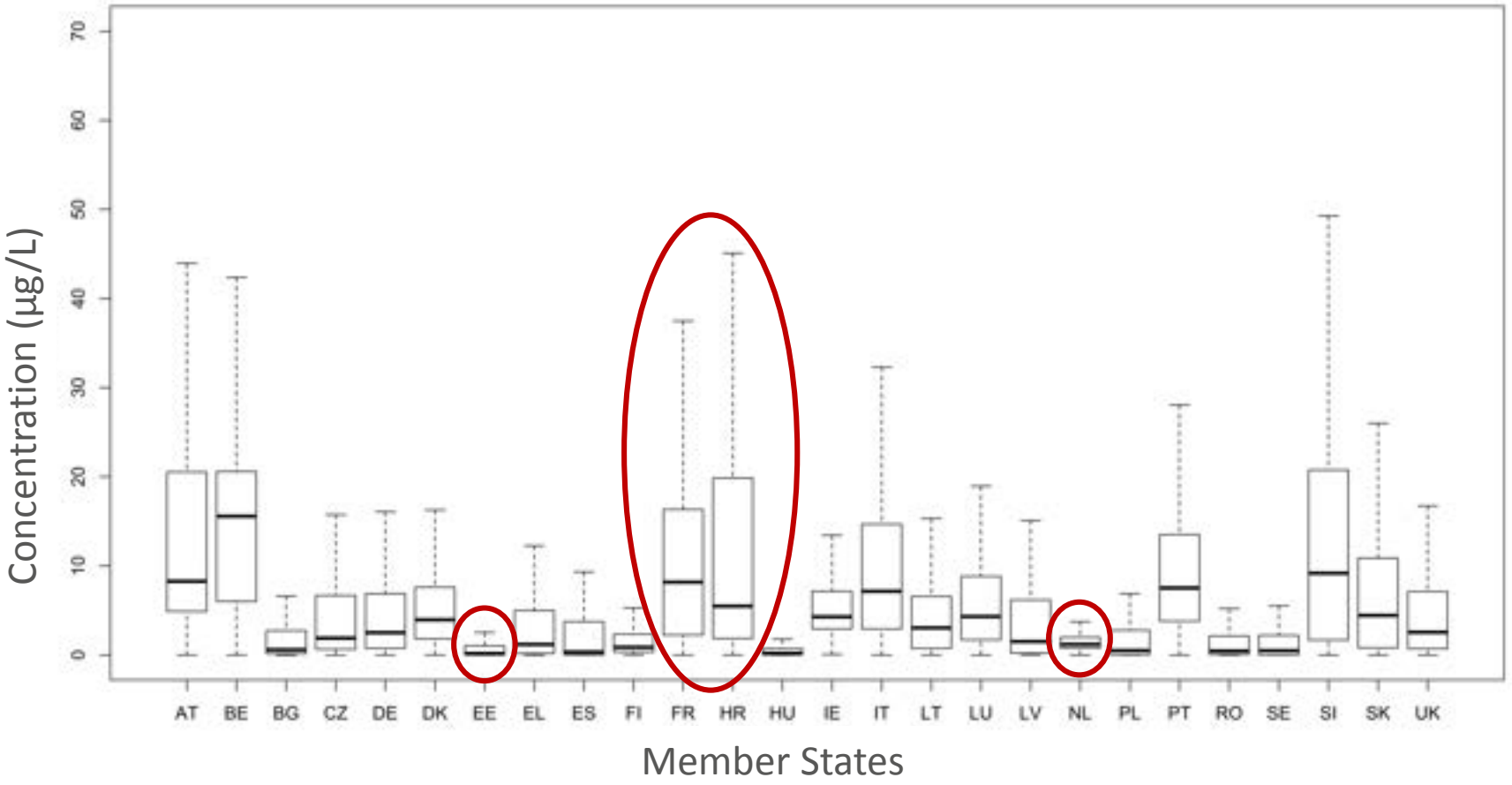


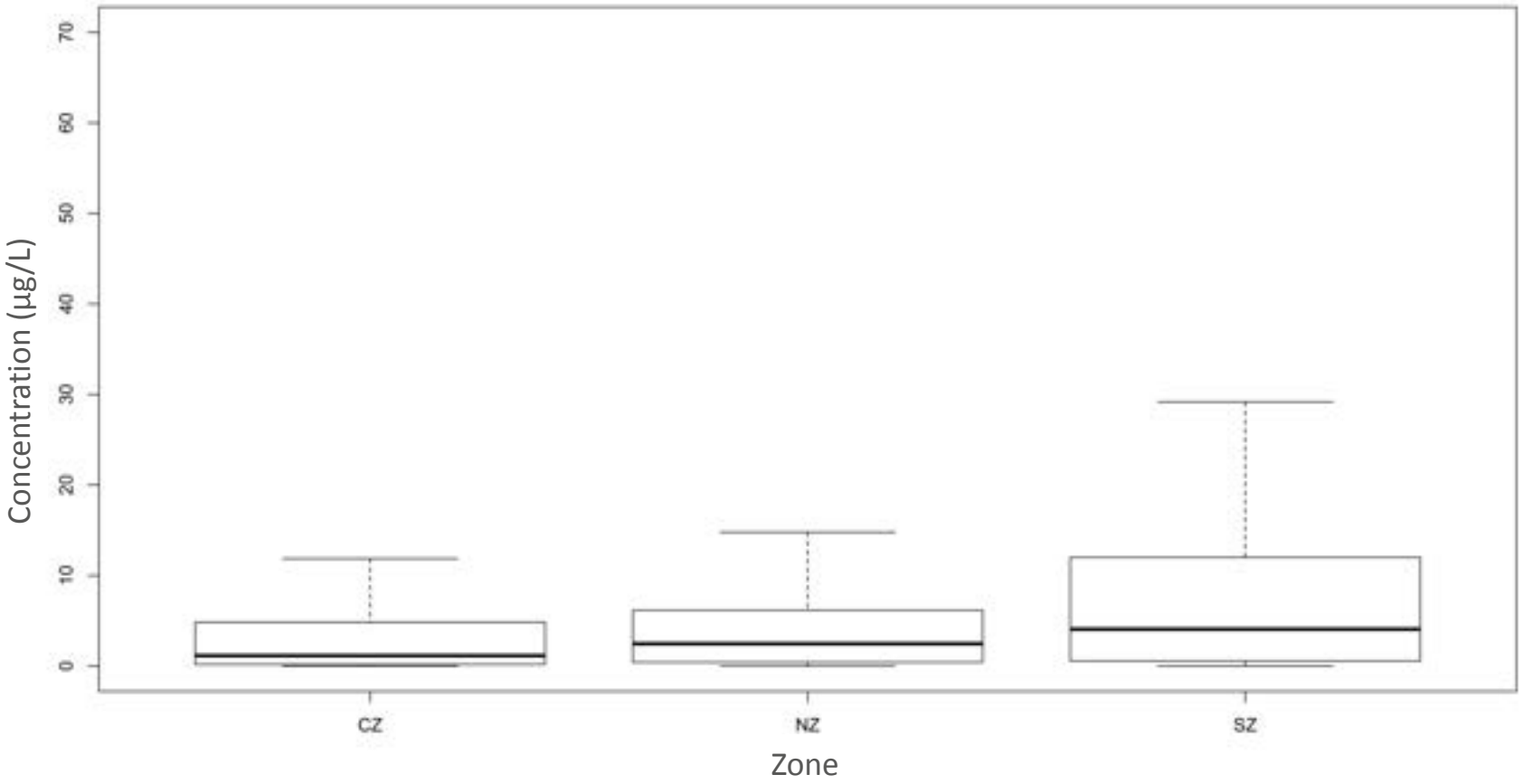
Figure 1 - Mean Annual Temperature

Figure 2 – Organic matter

Results – Member States

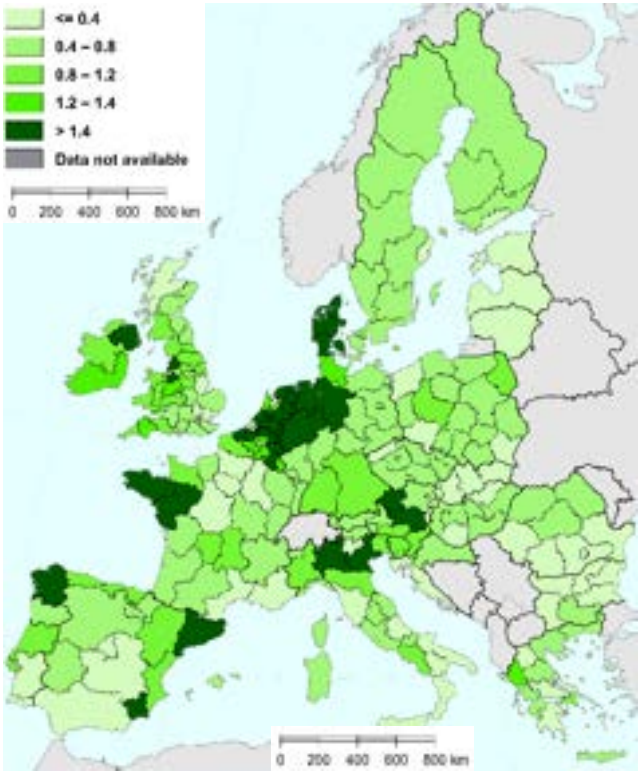


Results - Zonal



Other considerations

- VMP doesn't always enter the environment where it's applied
- Manure processing and transport common
- Economically viable:
  - SE/FI[1] – up to 10 km
  - UK[2] – 16-80 km
  - NL[3] – 150-300 km



EU Livestock density by NUTS 2 regions in 2013 (LSU/ha) (EUROSTAT)

[1]Pellervo, K. et al., 2013, Knowledge Report, Economics of manure logistics, separation and land application, Baltic Forum for Innovative Technologies for Sustainable Manure Management, [2]ADAS personal communication, 2018, [3]Manure, A valuable resource, Wageningen UR Livestock Research

Conclusions

- Standard GW scenario masks variation in climate, agriculture and leaching potential across Europe
- Spatially distributed modelling used in other regulatory areas (e.g. PPP)
- Potential to inform risk assessment decisions

Thanks!

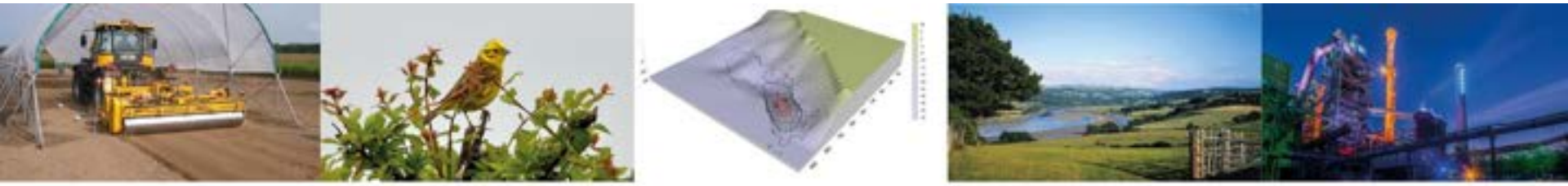
Thank you to colleagues Greg Hughes and Hanna Schuster

Questions?

Meet us at Stand 39

Email: Claire.McMillan@cea-res.co.uk

Find more information:
www.cea.adas.co.uk
https://www.linkedin.com/company/cambridge-environmental-assessments



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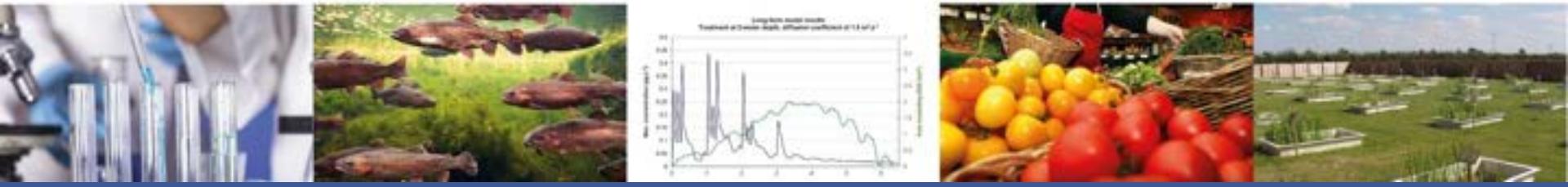
PROVIDING NOVEL SOLUTIONS FOR AN INCREASINGLY DEMANDING REGULATORY WORLD