Introduction to estimating model input parameters from the required exposure scenarios

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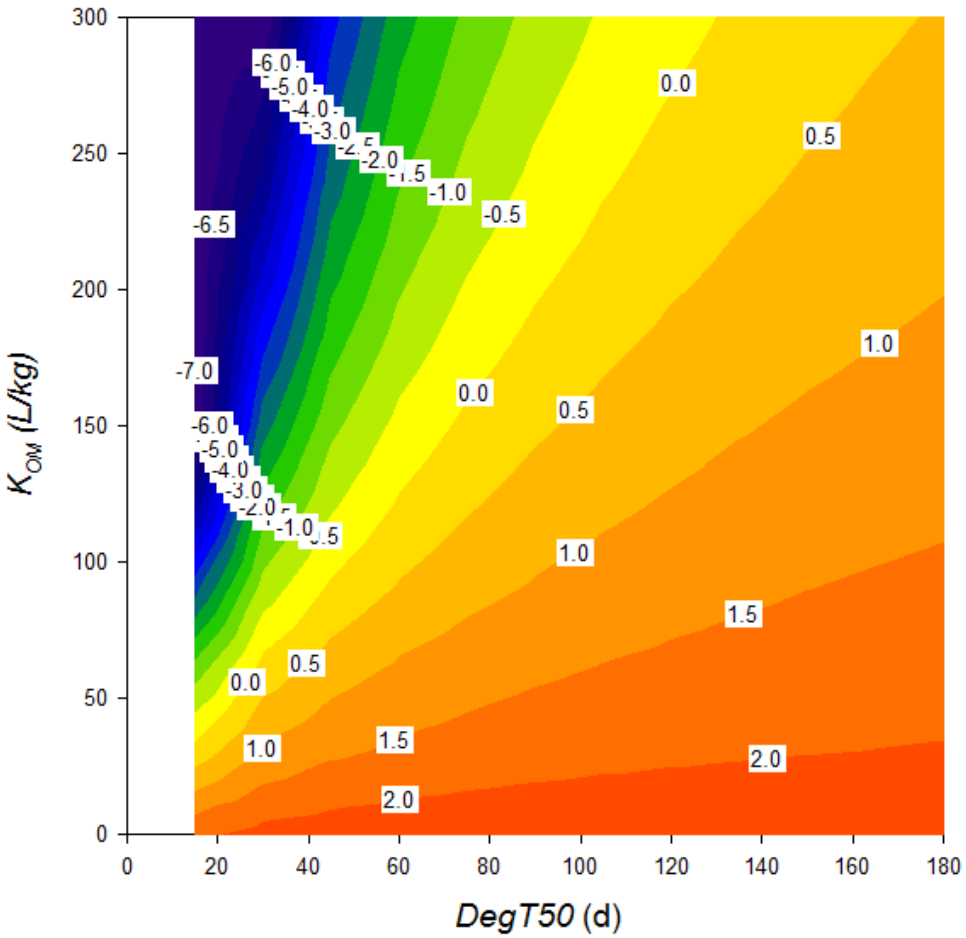
Outline

- Introduction
- Estimating model input for required exposure scenarios
- EFSA endpoint selector

Introduction

Contour plot of FOCUS leaching concentration (µg/L)



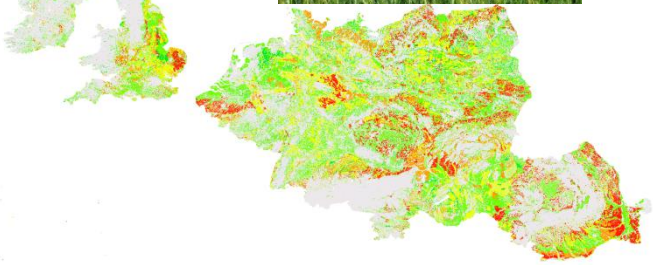
- Okehampton scenario (FOCUSPEARL 4.4.4)
- application of 1 kg/ha in winter cereals

Sensitivity of leaching to DegT50 is extremely large, so guidance important

Introduction

Two-step approach

- assessment of individual field studies to derive a defensible DegT50 from a single field
- estimate median/geomean DegT50 for required exposure scenario considering all relevant DegT50 values from lab plus field studies



Estimating DegT50 for required exposure scenarios

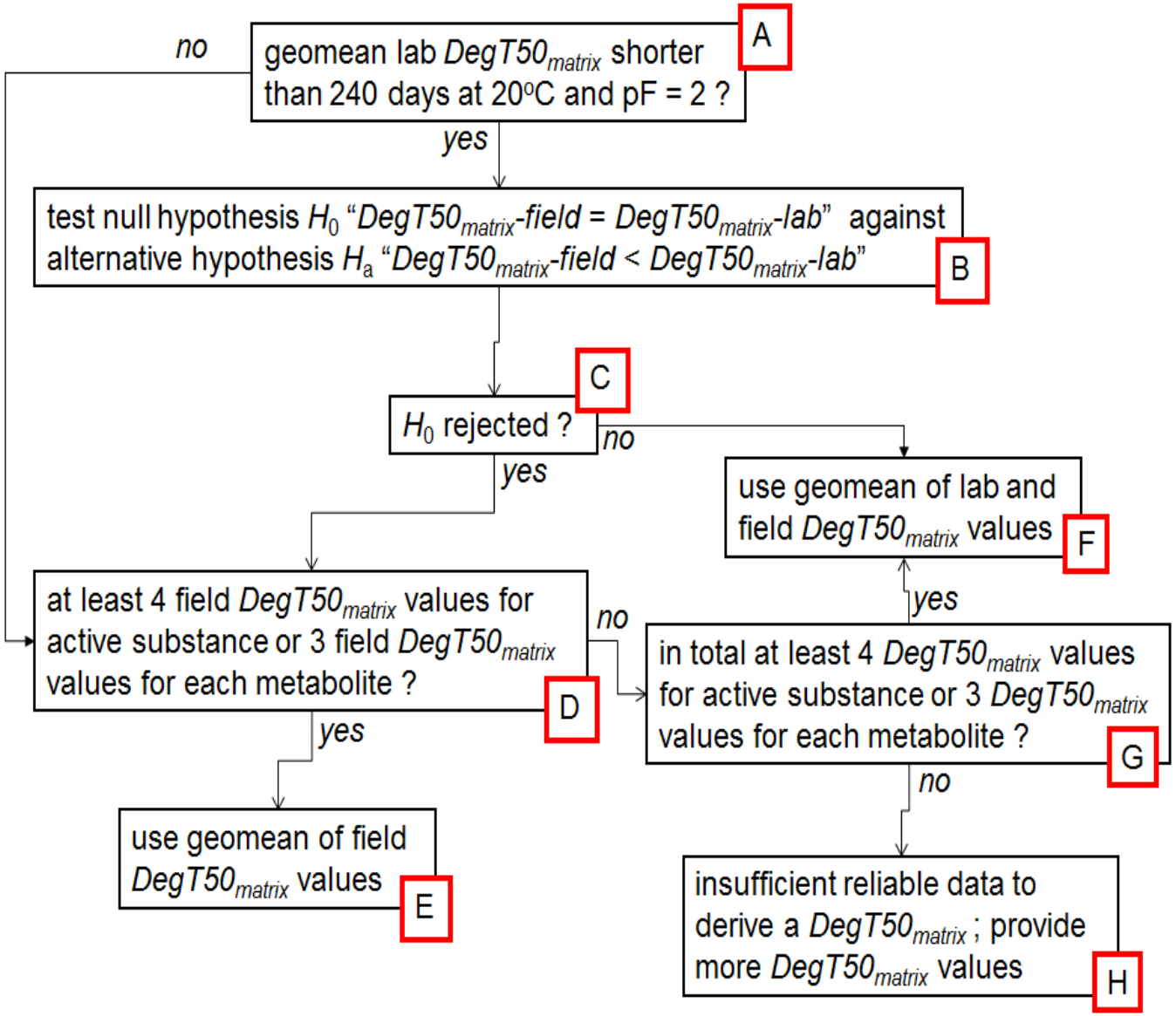
Purpose:
Find the median DegT50 for population of field soils in area of use of substance

Pragmatic solution

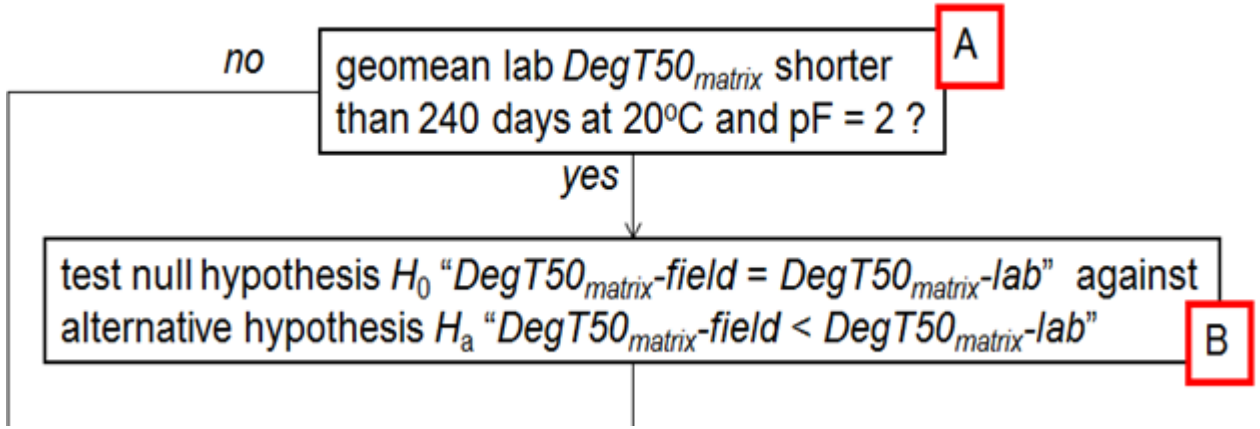
- no volcanic soils because they are different
- studies from temperate regions outside EU are acceptable provided
  - their pH, OM and clay are in EU range
  - their temperature and rainfall are comparable to area of use in EU

very pragmatic:
(e.g. field study in southern France can be used for leaching in Finland)

Estimating DegT50 for required exposure scenarios



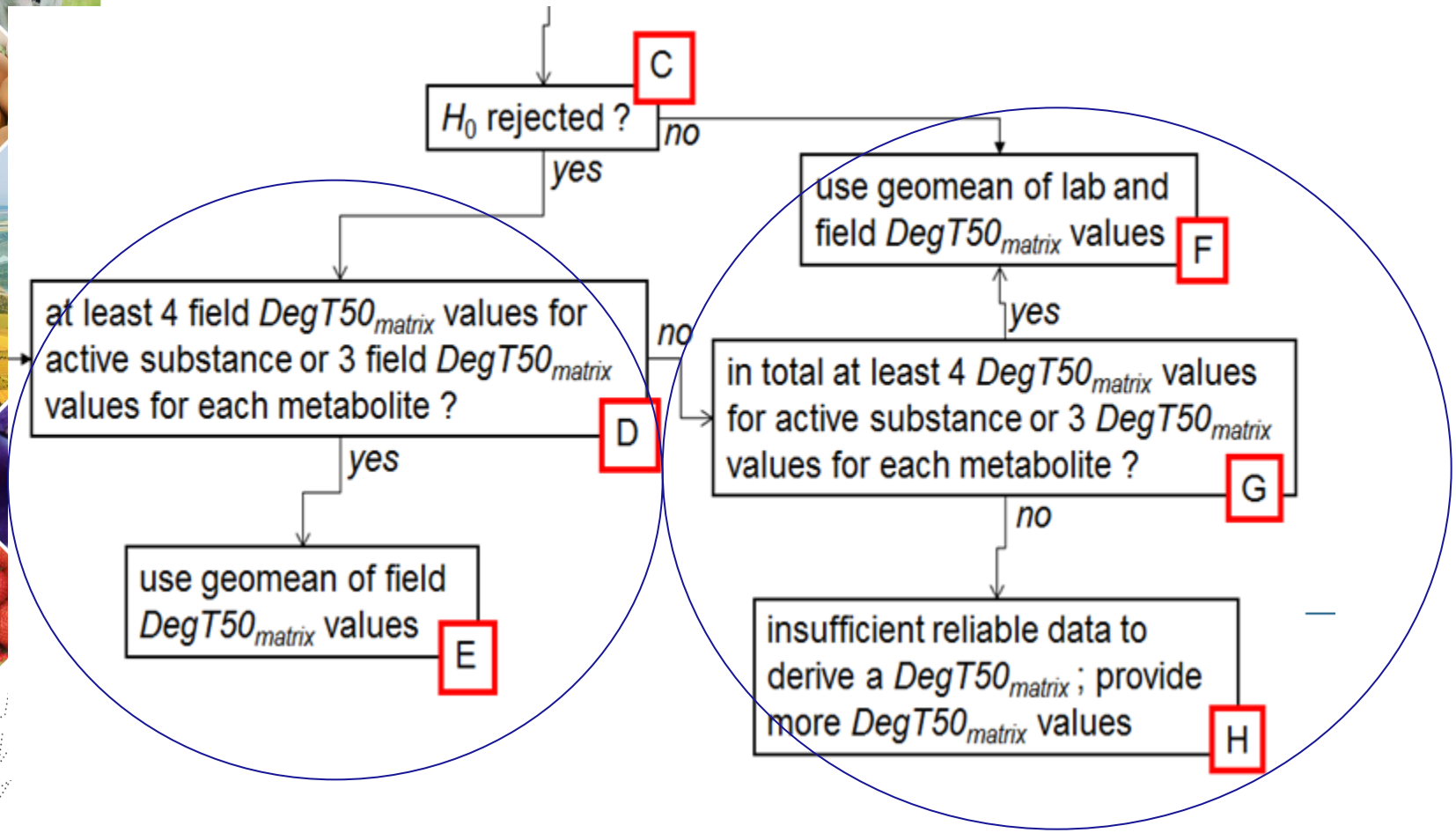
Estimating DegT50 for required exposure scenarios



- Null hypothesis: higher-tier value equal to lower-tier value:
  principle of tiered approach: in each tier, all available relevant scientific information is used (so only reject lower-tier information if justified)

- Very unlikely that lab study with a soil shows faster DegT50 at same temperature and moisture than a field study with this soil, so alternative hypothesis is 'field faster than lab'

Estimating DegT50 for required exposure scenarios



field faster

field and lab equal

Estimating DegT50 for required exposure scenarios

Selection of α-value

- Hypothesis-testing based on α : probability that you accept faster field DegT50 whereas it is not faster in reality
- Usually α = 5%, so 95% probability that field is faster before the lab values are rejected
- Guidance: α = 25%, based on Standing Committee: no clear desire to pursue more conservative risk assessment than current practice where field data are preferred without any statistical test

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Estimating DegT50 for required exposure scenarios

Selection of α-value

- Two statistical tests in guidance
  - Single field DegT50 longer than lab DegT50s ?
  - Test of H0 in flow chart: field DegT50s equal to lab DegT50s ?

- EFSA developed user-friendly spreadsheet for testing of these hypotheses

  (see following presentations)

Thank you !