Introduction to use of EFSA DegT50 Endpoint Selector and presentation of Worked examples

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ENDPOINT SELECTOR AND WORKED EXAMPLES

- **Two statistical tests in guidance**

Active Substance	Field DegT50matrix
Soils	DT50 (days) at 20˚C and pF2)
a	59
b	41
c	39
d	54
e	75
f	26
g	26
Geomean	42,7

Active Substance	Laboratory $DegT50_{matrix}$
Soils	DT50 (days) at 20˚C and pF2)
1	112
2	134
	124
	86
5	78
	67
	221
Geomean	109,2

Field= Lab ?

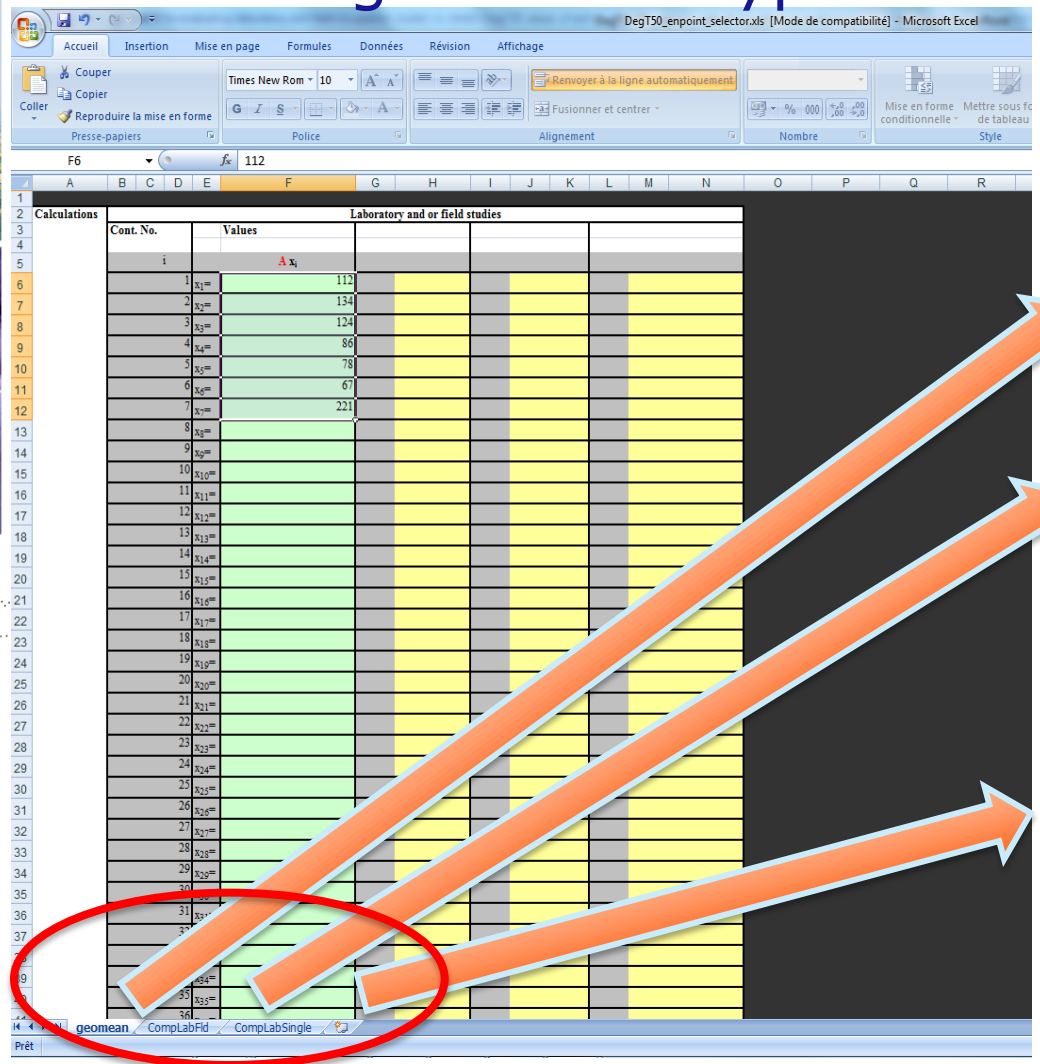
single field> Lab ?

Active Substance	Field DegT50matrix
Soils	DT50 (days) at 20˚C and pF2)
a	77

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

ENDPOINT SELECTOR AND WORKED EXAMPLES

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



spreadsheets (3)

- « Geomean »:

To derive geomean DT50

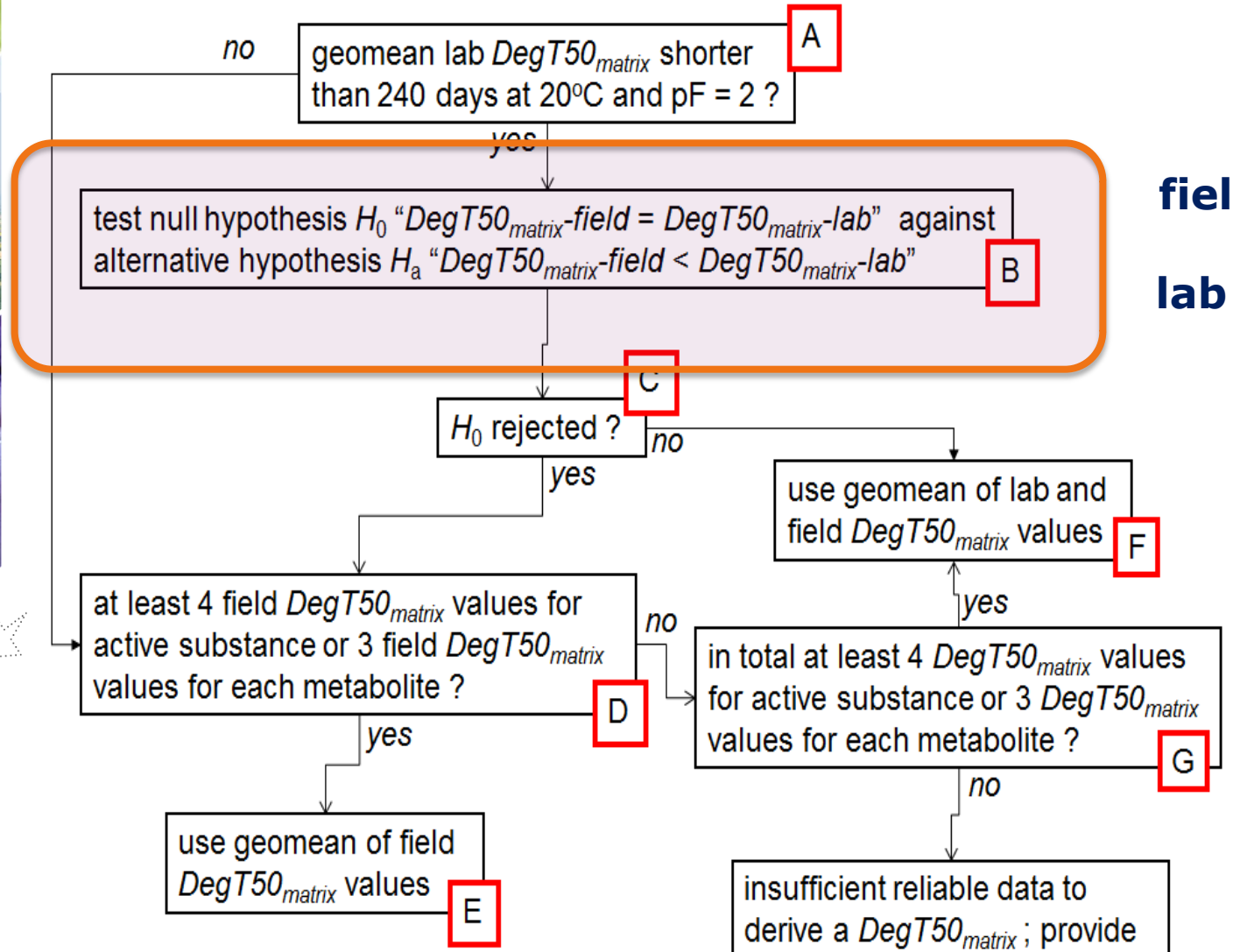
- « Comp LabFld »:

To compare LabDeg T50 vs Field DegT50

- « Comp LabSingle »:

To compare Lab DegT50 vs single Field DegT50

Test of H0 in flow chart: field DegT50s =lab DegT50s ?



field DegT50s
=
lab DegT50s ?

Figure 3: flow chart for assessment of DegT50matrix values from lab and field dissipation studies…

Worked example : field DegT50s = lab DegT50s ?

test null hypothesis H_0 "$DegT50_{matrix}$-field = $DegT50_{matrix}$-lab" against alternative hypothesis H_a "$DegT50_{matrix}$-field < $DegT50_{matrix}$-lab" B

field DegT50s
=
lab DegT50s ?

Tables 2 and 3: Active substance laboratory and field *DegT50*$_{matrix}$

Active Substance	Laboratory *DegT50*$_{matrix}$
Soils	DT50 (days) at 20˚C and pF2)
1	112
2	134
3	124
4	86
5	78
6	67
7	221
Geomean (EFSA DegT50 Endpoint Selector)	109,2

Lab = Field?

Active Substance	Field *DegT50*$_{matrix}$
Soils	DT50 (days) at 20˚C and pF2)
a	59
b	41
c	39
d	54
e	75
f	26
g	26
Geomean (EFSA DegT50 Endpoint Selector)	42,7

APPENDIX E.
Worked example of faster degradation in field than in lab

Worked example : field DegT50s = lab DegT50s ?

Laboratory studies

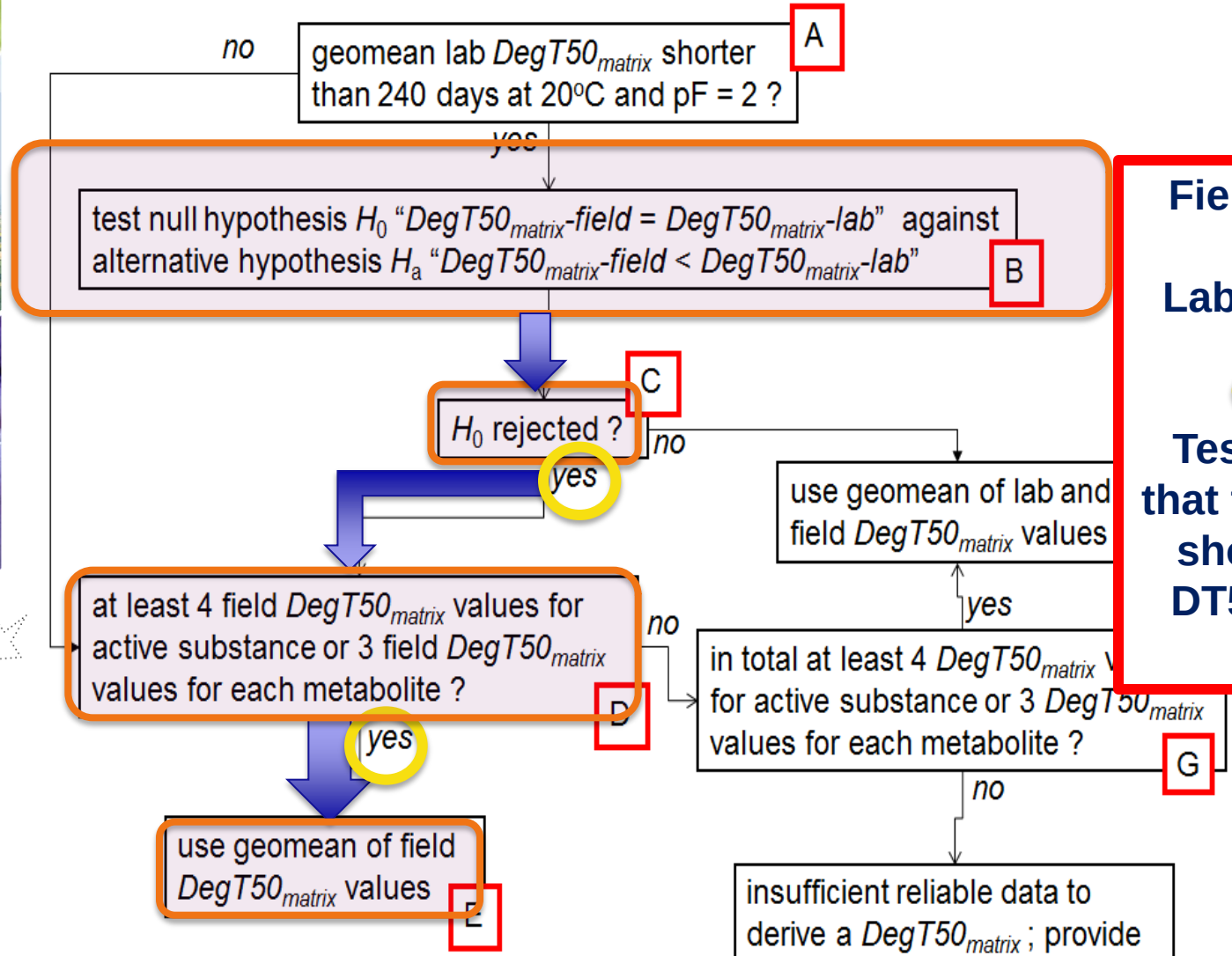
Calculations	Cont. No. i	DegT50 values A x_i	Logarithmic DegT50 values D $l_i = \ln(x_i)$=	deviation from mean μ G $d_i=(l_i-\mu_{lab})$=	squared deviation from mean μ H d_i^2=
		x_1= 112	l_1= 4.718	d_1= 0.026	d_1^2= 0.0007
		x_2= 134	l_2= 4.898	d_2= 0.205	d_2^2= 0.0420
		x_3= 124	l_3= 4.820	d_3= 0.127	d_3^2= 0.0162
		x_4= 86	l_4= 4.454	d_4= -0.239	d_4^2= 0.0569
		x_5= 78	l_5= 4.357	d_5= -0.336	d_5^2= 0.1130
		x_6= 67	l_6= 4.205	d_6= -0.488	d_6^2= 0.2384
		x_7= 221	l_7= 5.398	d_7= 0.705	d_7^2= 0.4973
	8	x_8=	l_8=	d_8=	d_8^2=

Field studies

Calculations	Cont. No. j	DegT50 values K z_j	Logarithmic DegT50 values N $k_j = \ln(x_j)$=	deviation from mean μ Q $c_j=(l_j-\mu_{fld})$=	squared deviation from mean μ R c_j^2=
		x_1= 59	k_1= 4.078	c_1= 0.324	c_1^2= 0.1047
		x_2= 41	k_2= 3.714	c_2= -0.040	c_2^2= 0.0016
		x_3= 39	k_3= 3.664	c_3= -0.090	c_3^2= 0.0082
		x_4= 54	k_4= 3.989	c_4= 0.235	c_4^2= 0.0553
		x_5= 75	k_5= 4.317	c_5= 0.564	c_5^2= 0.3176
		x_6= 26	k_6= 3.258	c_6= -0.496	c_6^2= 0.2458
		x_7= 26	k_7= 3.258	c_7= -0.496	c_7^2= 0.2458
	8	x_8=	k_8=	c_8=	c_8^2=

Significance level of the test α (as given in the procedure)		AB α =	25%
Upper 1–α quantile of t-distribution with df degrees of freedom		AC $t_{df,1-\alpha}$ =	0.6955
AD Is Student's t-statistic t larger than the t-quantile $t_{...}$?			
YES	→ Test confirms that field studies show shorter DegT50 than laboratory studies	→ Observations do not contradict the hypothesis that field studies show equal DegT50 than laboratory studies	

Worked example : field DegT50s = lab DegT50s ?



Field DegT50s
=
Lab DegT50s ?

!YES!
Test confirms that field studies show shorter DT50 than lab studies

Figure 3: flow chart for assessment of DegT50matrix values from lab and field dissipation studies…

Worked example : Single field DegT50 >> lab DegT50s ?

Metabolites	Laboratory $DegT50_{matrix}$ (days) at 20°C and pF2)	
Soils	Metabolite 1	Metabolite 2
1	303	0.6
2	135	1.9
geomean estimator for the median (From the EFSA DegT50 Endpoint Selector)	202.2	

Metabolites	Field $DegT50_{matrix}$(days) at 20°C and pF2)	
Soils	Metabolite 1	Metabolite 2
a	48	nd
b	24	nd
c	47	1.5
d	58	nd
e	86	nd
geomean estimator for the median (From the EFSA DegT50 Endpoint Selector)	48.6	

Lab = single field ?

Single Field DegT50
>>
Lab DegT50s ?

!NO!
Single value does not contradict the hypothesis that is result from the distribution of laboratory values

Geomean (Lab+field) = 1.1 d

52		→ Test confirms		NO	→ Single value do not contradict the hypothesis that it is result from the distribution of laboratory values
53		that single value shows			
54		longer DegT50 than expected			
55		from laboratory studies			

DegT50 from existing (legacy) field studies : Slower degradation in field than in lab

Special measures for field *DegT50*s that are longer than lab *DegT50*s

- **Check whether any individual field DegT50 is significantly longer than the population of lab DegT50s (statistical test)**
- **Very unlikely that field study with a soil shows longer DegT50 at same temperature and moisture than a lab study with this soil**
- **Much more likely that a longer field DegT50 is caused by systematic errors in inverse modelling procedure**
- **Recommendation:**

  Repeat inverse modelling with Arrhenius activation energy of 115 kJ/mol instead of 65 kJ/mol and with moisture exponent B of 1.5 instead of 0.7

  If new field DegT50 is not anymore significantly longer than DegT50 from lab studies then discard field DegT50

Worked example : slower in degradation in field than in lab

Insecticide (Sub1)**, sprayed on bare soil**

- Dissipation(legacy) field studies > Lab studies
- « What are the possible cause of this ? »
- Sub1: Koc=41 000L/kg (high) ; S=0.06mg/L (Low)
- Slow degradation OR slow dissolution / slow penetration / Photochemical degradation
- Not appropriate for GW / appropriate for PECsoil

APPENDIX F. Worked example of slower degradation in field than in lab

Thank you !