Based on field data, is the current standard risk assessment for NTTPs at the EU-level sufficiently protective?

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Background

EFSA (2014) Scientific opinion NTTPs

Non-**T**arget **T**errestrial **P**lants

- Protectivity of current Tier1 - Risk Assessment (RA) questioned
- Proposed changes:
  - Additional test on reproductive endpoints (+ use whichever is lower), additional conservatism: Factor 2 (due to additional testing only!)
  - Use ER_{10} in RA (currently ER_{50})
    additional conservatism: Factor 5 – 6, (but additional uncertainty)
  - Make HR_5 - assessment default (same AF?) x Factor 1 – 5 (?) etc…

Total increase in conservatism by a factor of >>20?
(Details see e.g. Christl et al. 2019, 2020)

Do NTTP-field-data indicate a need for such changes?

tier3 solutions

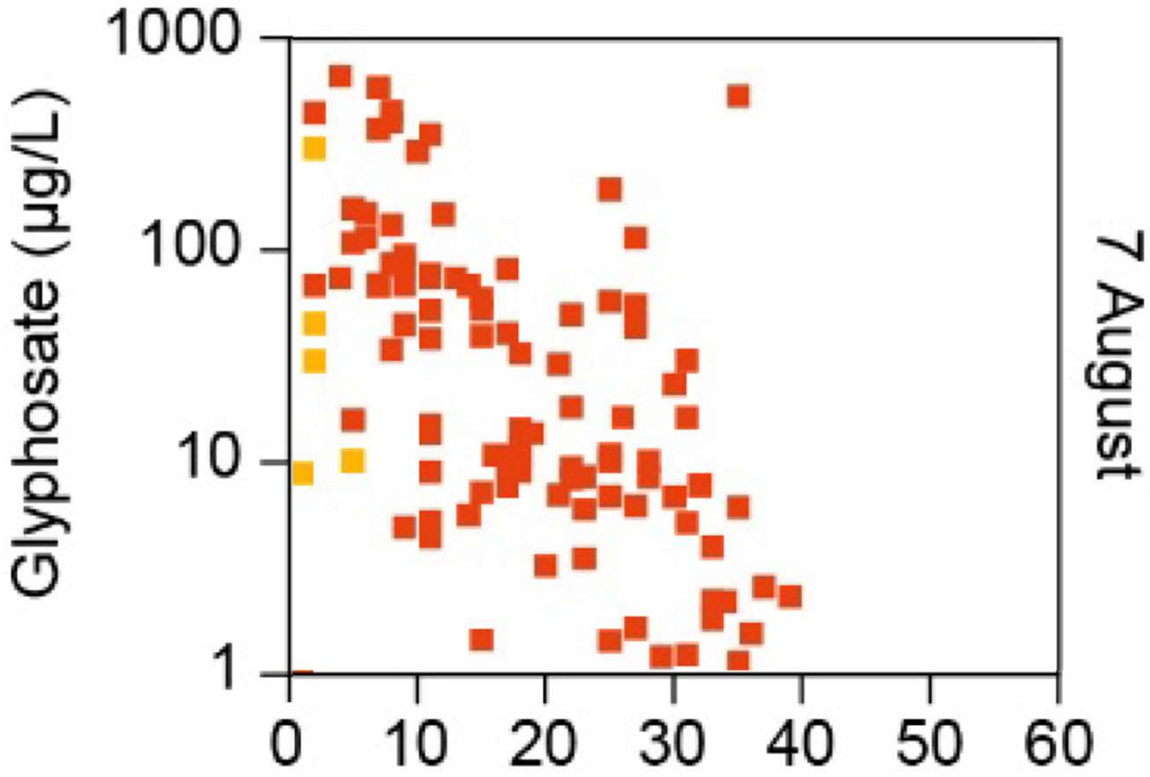
Methods

NTTP semi-field + field study data

- $NOER_{Field}$ if presented, $ER_{25\ field}$ as surrogate
- Lower effect levels (e.g. 5% or 10 %) ?
  - not reliably detectable in field studies (definitely)
  - not relevant for the populations (probably)
- **NOER** – lowest per study or per a.s., or geomean

Methods – retrieving field endpoints

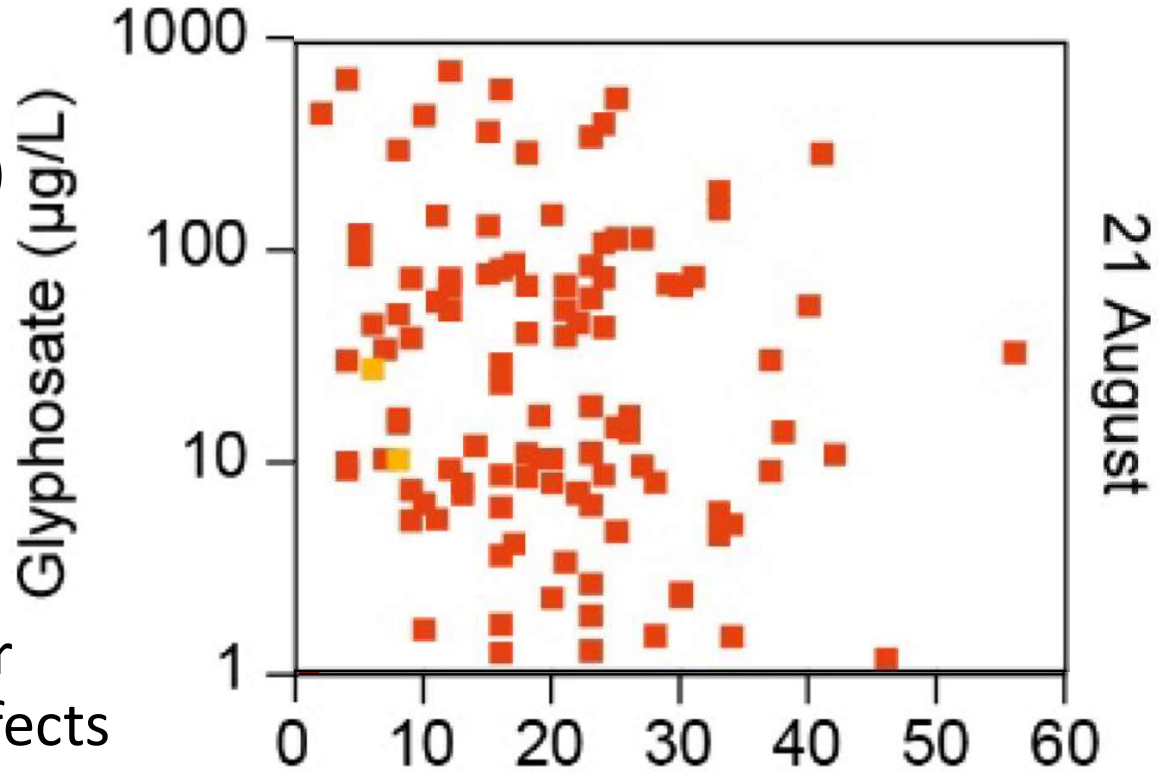
- Flowers (*T. pratense)*
- on abscissa per sample plot; dose on ordinate;
- Here clear effect



- Example Data from Strandberg et al. 2019 (Chapter 5)

Methods – retrieving field endpoints

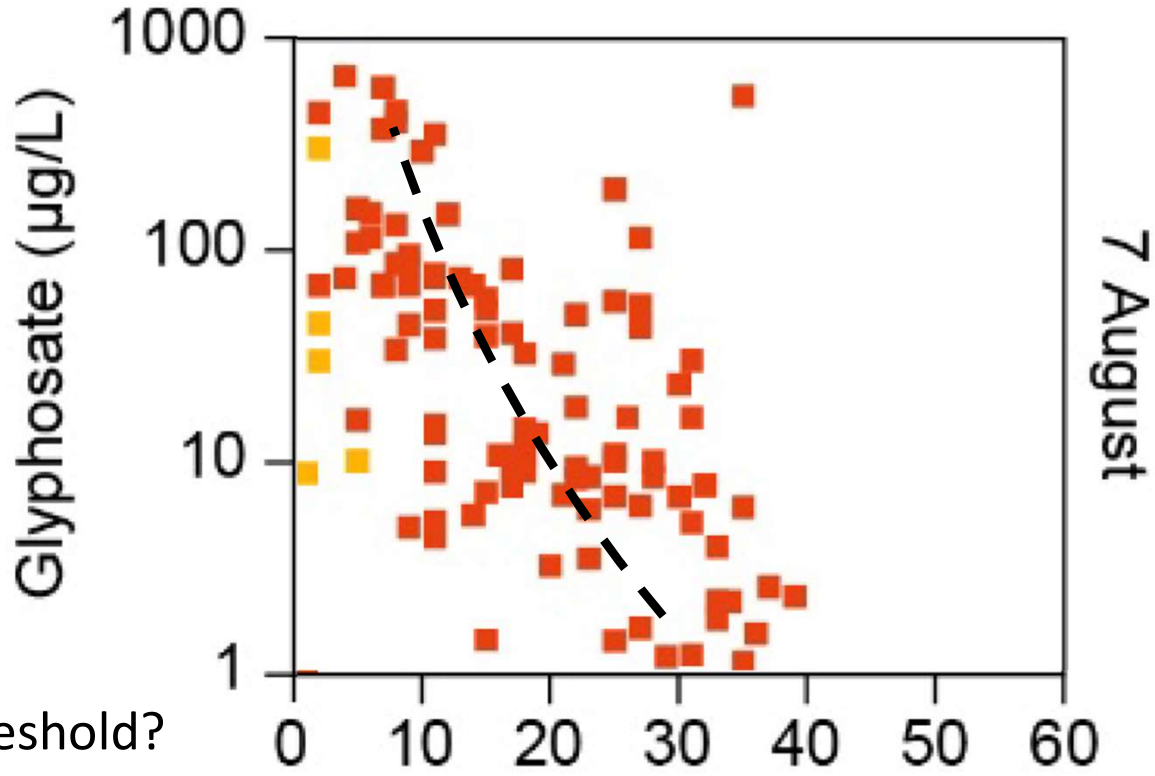
- Flowers (*T. pratense)*
- on abscissa per sample plot; dose on ordinate;
- 14 days later less clear effects



- Example Data from Strandberg et al. 2019 (Chapter 5)

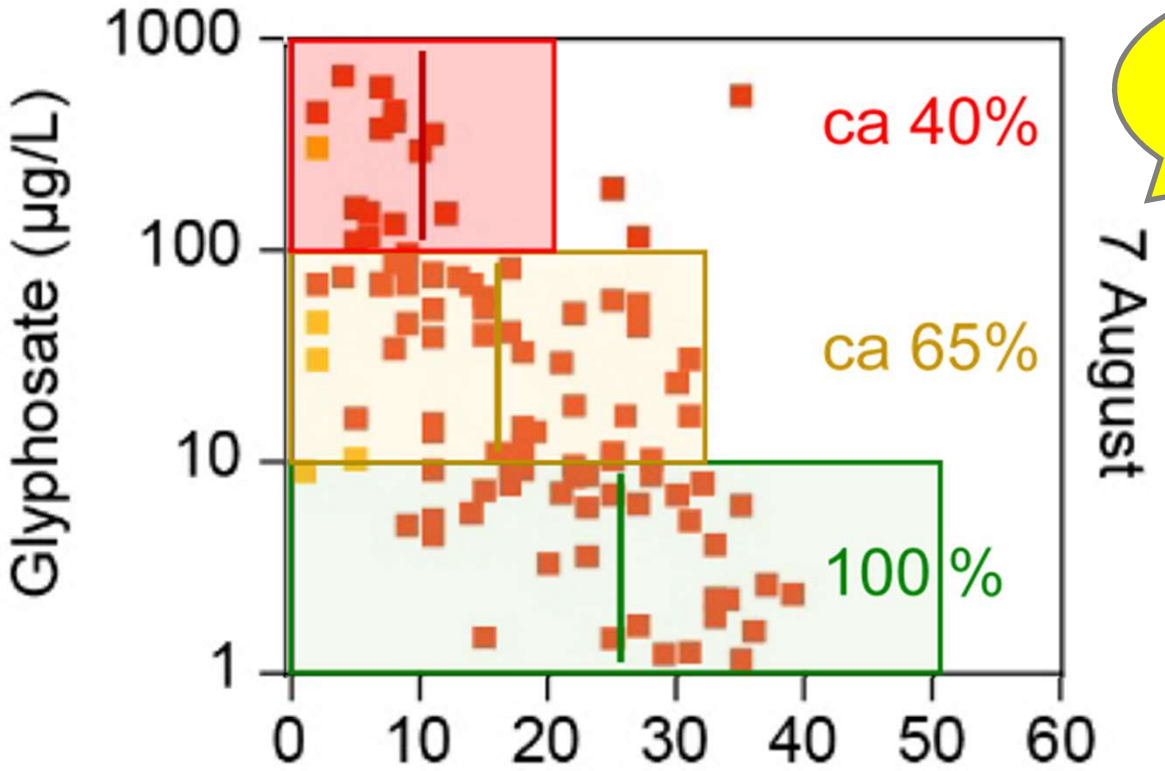
Methods – retrieving field endpoints

- Flowers (*T. pratense)*
- on abscissa per sample plot; dose on ordinate;
- Function?
  - Where threshold?



Methods – retrieving field endpoints

- Flowers (*T. pratense)*
- on abscissa per sample plot; dose on ordinate;
- classify:
  - negligible
  - Moderate
  - pronounced



Effects transient

Data from Strandberg et al. 2019 (Ch. 5)

Threshold ca 10 µg a.s./L (as Roundup Bio®), equals $NOER_{field}$ *ca* 3 g a.s./ha (a bit uncertain)

Methods (RAC Regulatory Acceptable Concentration)

Tier1-RA EU: RAR Regulatory Acceptable Rate

- Lowest endpoint (of two studies w 10 spec.) / AF (5)

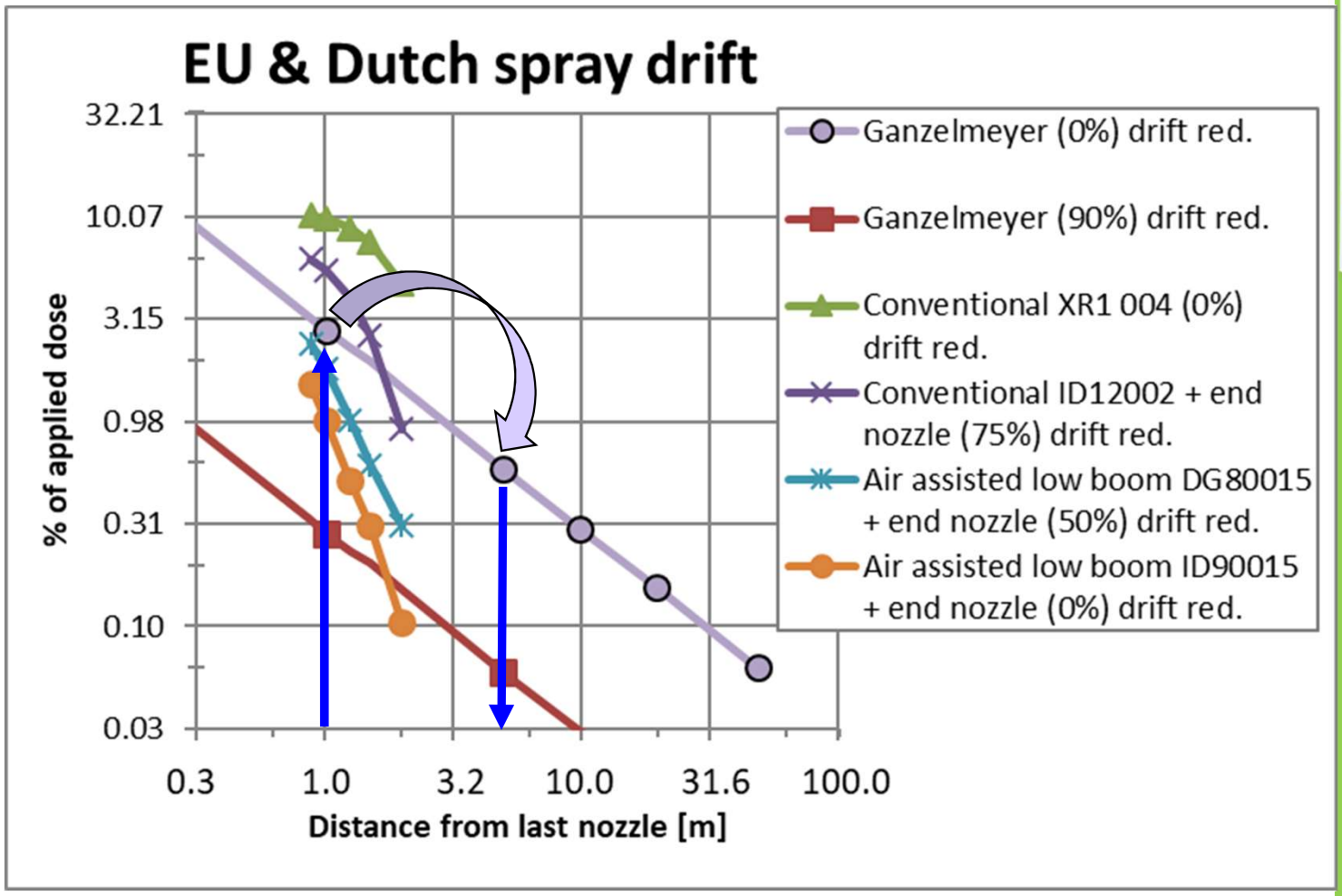
- + random element (stepwise buffer + drift reduction)

  If threshold just not met at 1 m (2.77% drift rate)
  non-spray buffer of 5 m (0.57%) or even lower:
  RAR up to factor 4.86 lower

Methods – define RARs (steps)

Tier1-RA

- Lowest endpoint
- + random element (buffer stepwise)



Methods - define RARs

Tier1-RA EU: RAR Regulatory Acceptable Rate

- Lowest endpoint (of two studies w 10 spec.) / AF (5)

  ER_{50} Roundup Bio®: *Bellis perennis* ER_{50} 14 g a.s./ha,
  AF = 5, so RAR_{exp} = 2.8 g a.s./ha

- + random element (stepwise buffer)

  If threshold just not met at 1 m (2.77% drift rate) non-spray buffer of 5 m (0.57%) or even lower: RAR up to factor 4.86 lower

  Field rate Roundup26 Bio®: 1440 g a.s./ha
  * 0.15% drift (20 m): RAR_{reg} = 2.16 g a.s./ha
  or 90% drift red. * 0.57% (5 m) RAR_{reg} = 2.05 g as/ha

Methods - define RARs

Tier1-RA EU: RAR Regulatory Acceptable Rate

- Lowest endpoint (of two studies w 10 spec.) / AF (5)
  Experimental starting point
- + random element (stepwise buffer)
  Increases conservatism

(Final RA EU: RAR considering refinements)

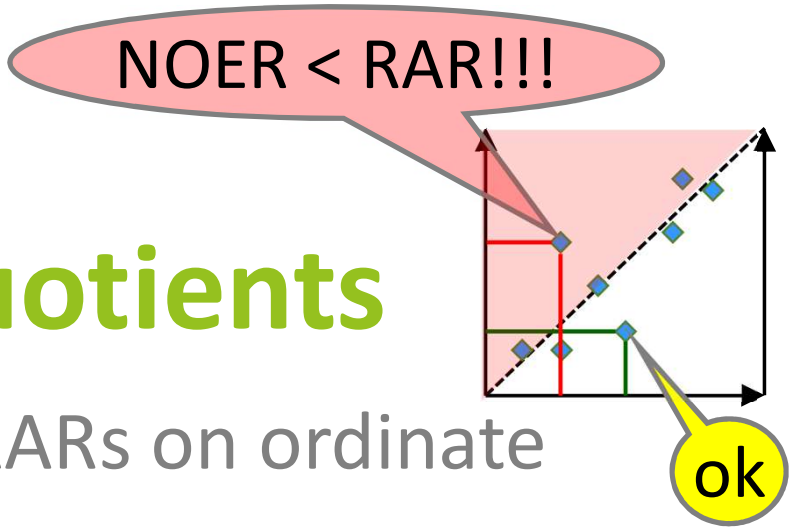
- + refinements (e.g. HR_5, more species tested, less uncertainty, hence lower AF granted (= **RARs in force**)
  reduces conservatism

Assessment 1

Data pairs available

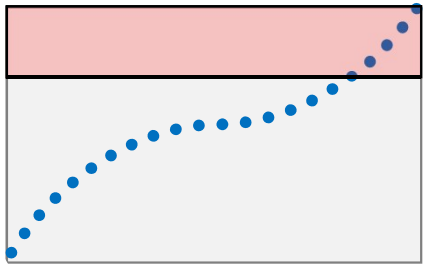
- 36 field studies, many with several experiments in one
- 94 substances / formulations with any NTTP data
- 20 active substances with matching data pair(s):
  T1/T2-NTTP ER_{50} & $NOER_{field}$ endpoints (at least one)
  RAR as detailed in DARs, Review Reports and Conclusions

Assessment options

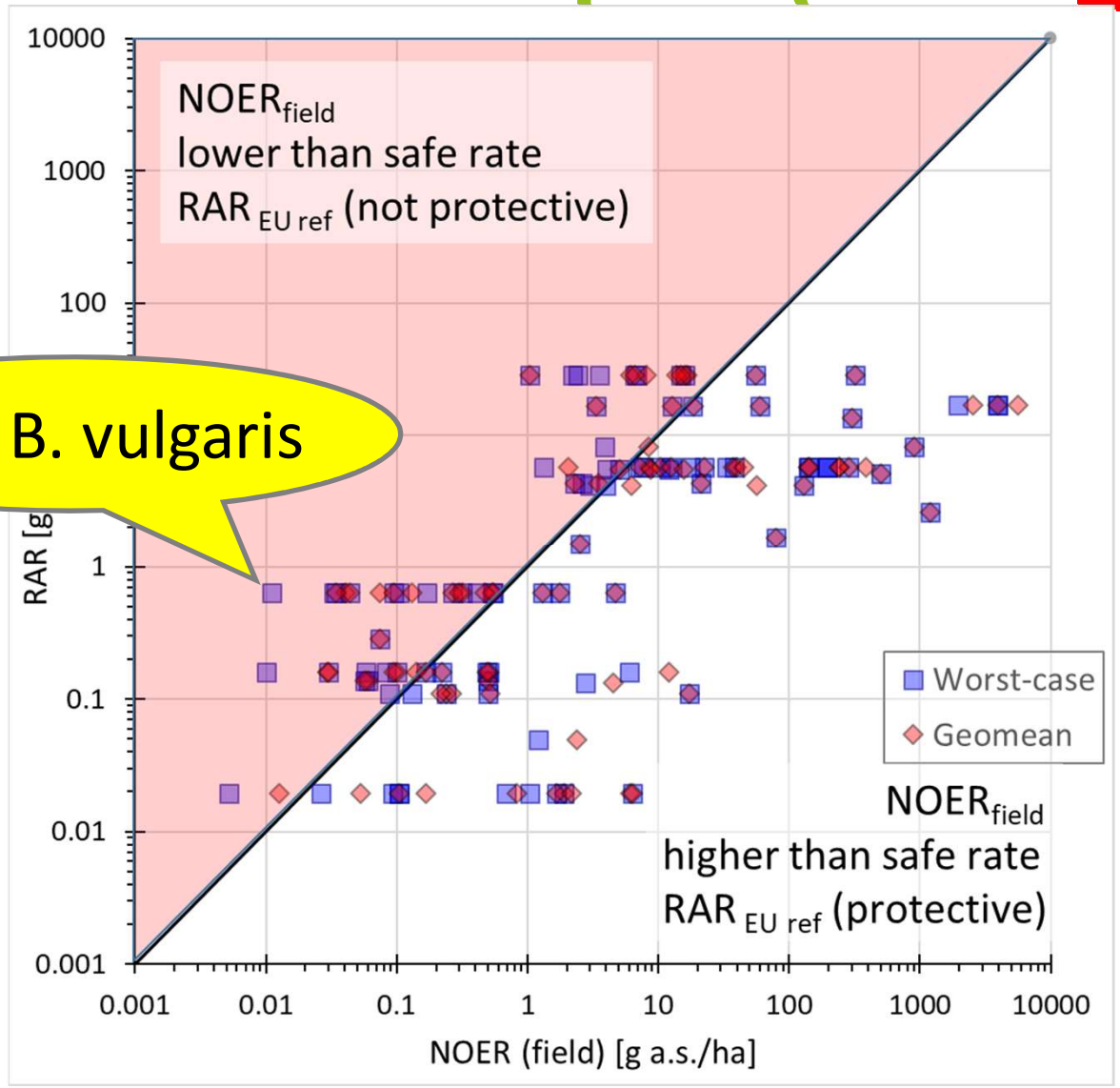


Scatter plots and quotients

- Field studies on abscissa, RARs on ordinate
  - Points bottom-right of diagonal indicate it is protective
- Risk Quotient RQ: $RAR_{Tier\text{-}1}$ / $NOER_{field}$
  - If RQ <1, ok: Tier1-RA protective (RAR lower than $NOER_{field}$)
  - if RQ > 1, NOT protective ($NOER_{field}$ lower than RAR)



Results 1: Scatterplot (RARs in force)



CSF x B. vulgaris

Most data bottom-right of diagonal, RAR_{Tier-1} mostly lower than $NOER_{field}$,

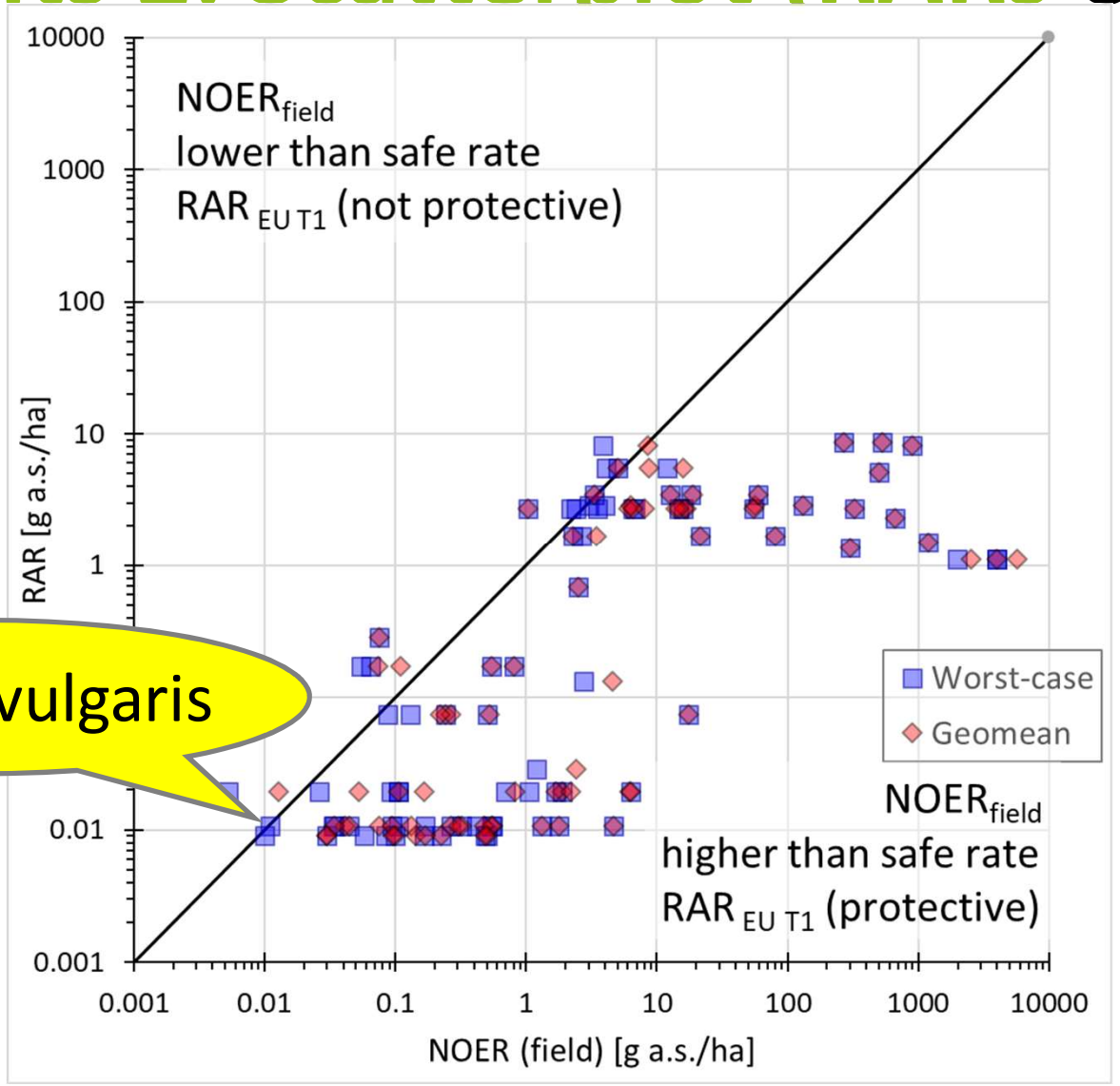
But…

many exceedances.

Which RARs?

Those in force…

Results 2: Scatterplot (RARs of Tier-1)



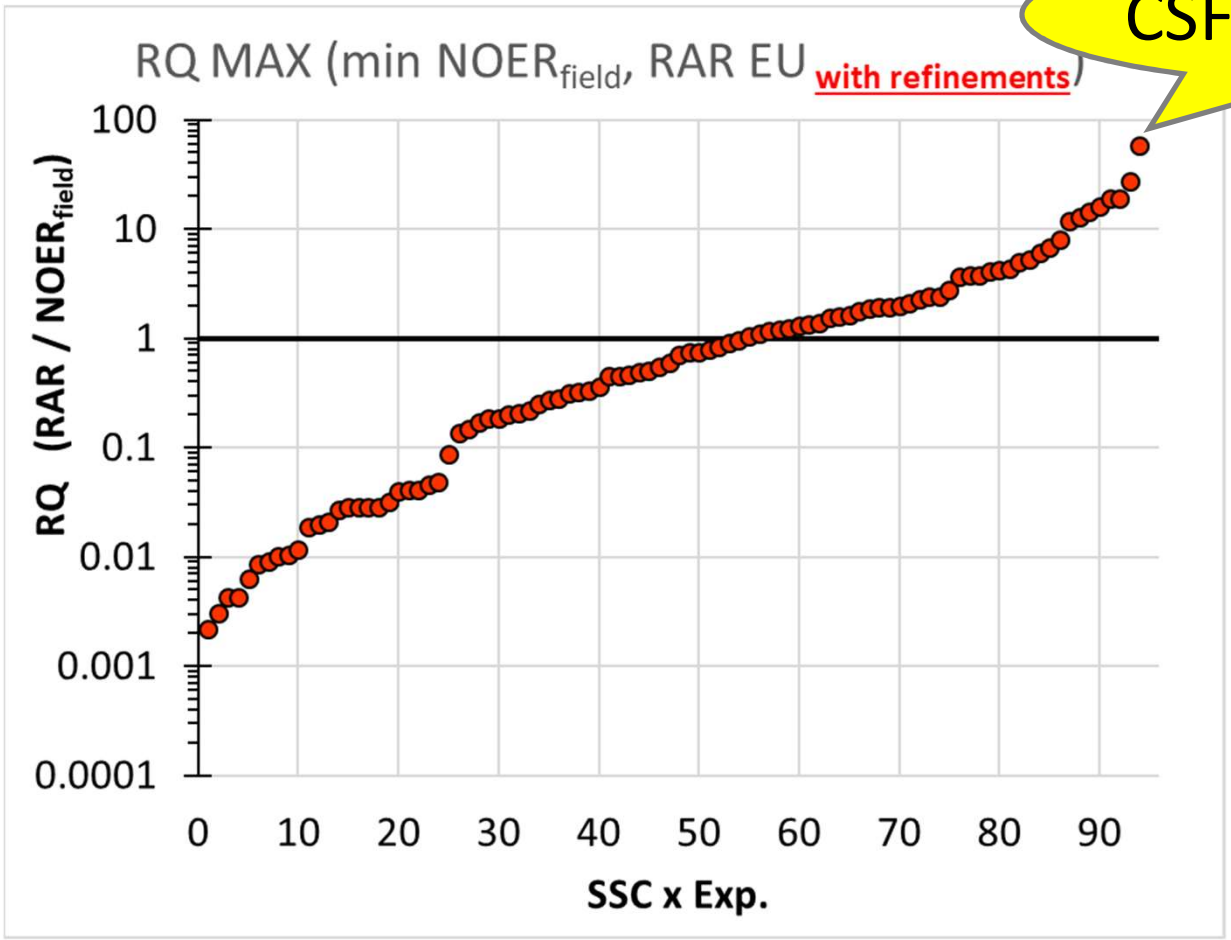
CSF x B. vulgaris

Now good majority bottom-left of diagonal, here RAR$_{Tier-1}$ generally lower than NOER$_{field}$

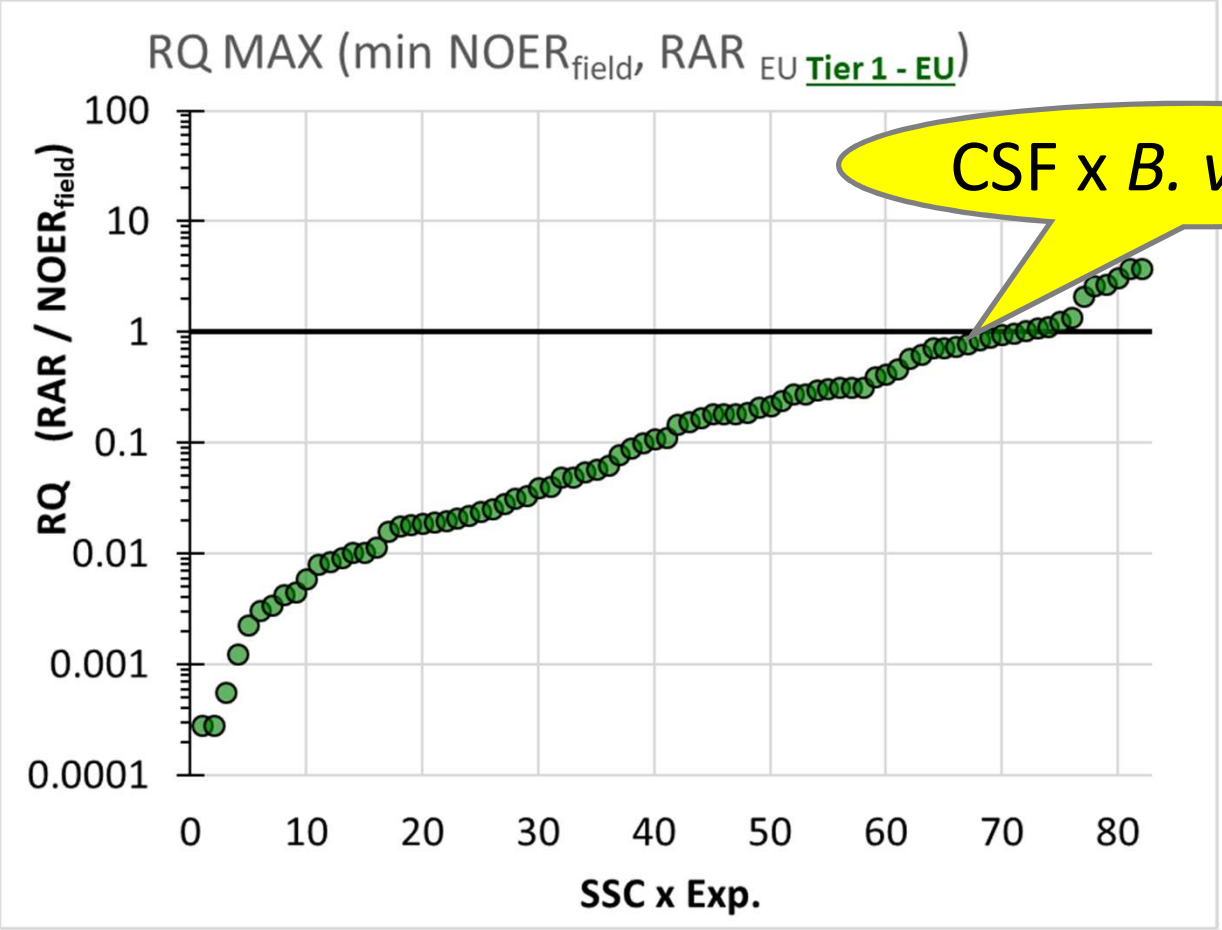
and any exceedances are only minor.

As Risk quotients…

Results 3: risk quotients (RQ) refined



Results 4: Risk quotients (Tier-1 - RA)

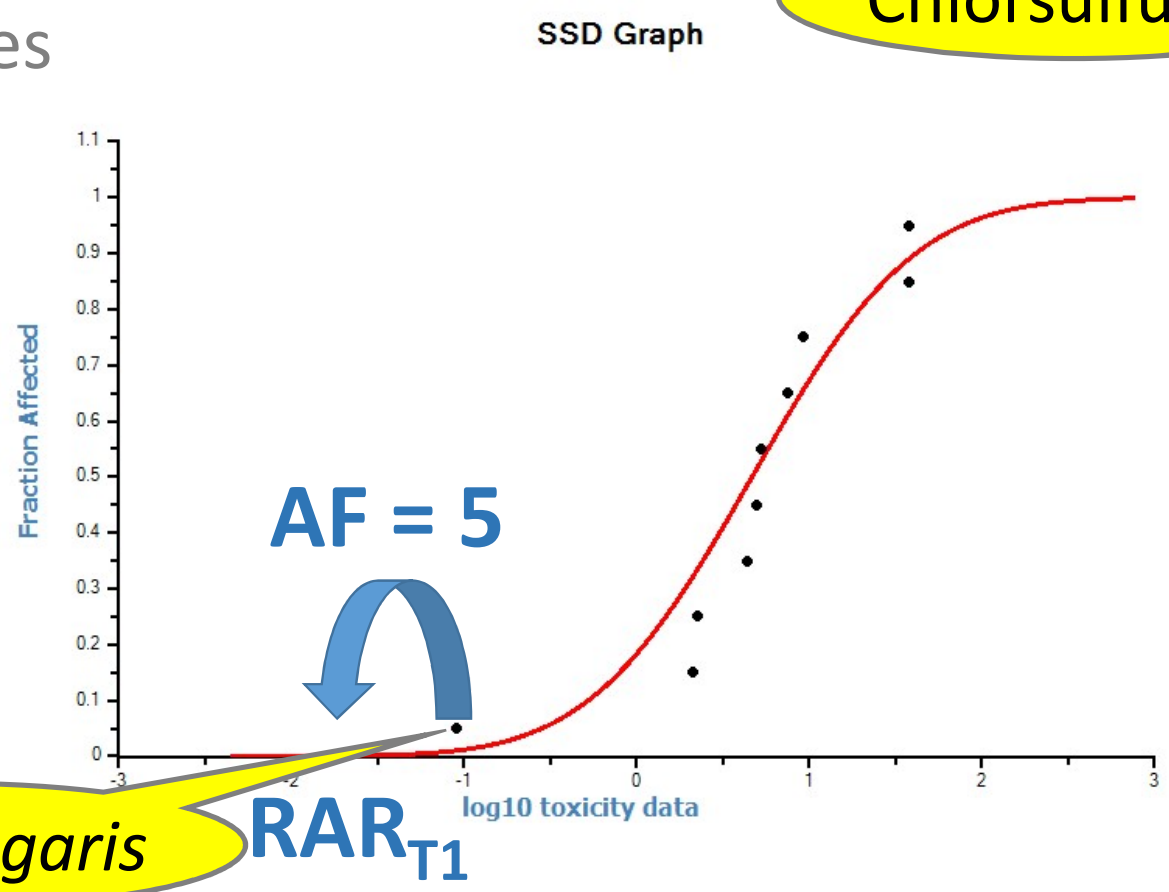


Why such a difference between RAR_{T1} and RAR_{reg}?

Assessment- Tier-1 - RAR Highest RQ - Chlorsulfuron

- SSD: One species very sensitive (*Beta vulgaris*)

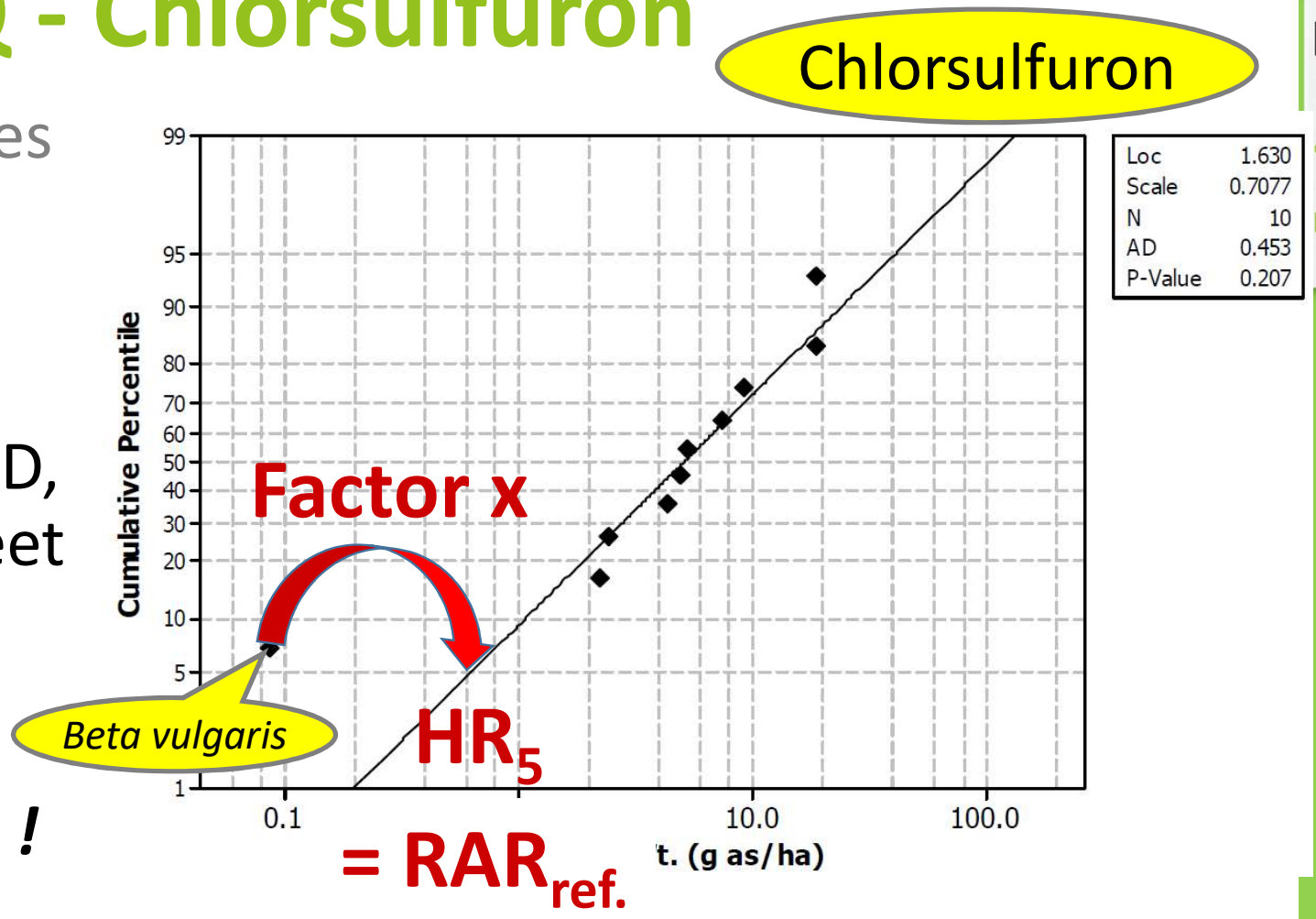
Chlorsulfuron



Assessment - Refined RAR
Highest RQ - Chlorsulfuron

- SSD: One species very sensitive (*Beta vulgaris*)
- Refinement with custom SSD, disregarding beet
- Most sensitive species in field:

Beta vulgaris !



Assessment - Protectivity
Tier1- RA ←→ refined RA

- In this case, the standard RA (EU, Tier1) was protective, also based on the field study:
  Beta vulgaris most sensitive species,
  both in Tier1 – RA and in the field.
- Refinements must consider protection goals:
  Are there NTTP (relatives of beet) as sensitive?
  - (Do they need protection?)
  - (This is a different question.)
- We were interested in the basic Tier-1-RA
  (with mitigation (buffer etc.), but
  without custom refinements)

Conclusion 1
Tier 1-Assesment ok, protective

- Based on available field studies, the European Tier 1-RA for NTTPs:
  - two exposure types (seedling emerg. + vegetat. vigour)
  - 10 species each, lowest ER_{50} of the 20 experiments
  - AF of 5 (+ buffer classes + drift reduction) → RAR
- appears to be protective.
- Conservatism about OK

Conclusion 2
European refinements…

- Based on available field studies, refinements of the past were often less protective
  - but note – relevant for the population?
    25% bleached for a week followed by full recovery – probably not
- Recently assessment became more rigorous though
- Need for Tier-1-changes? (Repro-Test, ER_{10}, HR_5 as default…)?
- Based on field test data: More conservatism is not expedient.
- Frequent fails of Tier1-RA would trigger many field studies, but these would largely only confirm that initial RA was safe…
- If too conservative – loss of filter function
  (filter turns into a bucket…)

References (only those mentioned here)

[EFSA] European Food Safety Authority Panel on Plant Protection Products and their Residues. 2014. Scientific opinion addressing the state of the science on risk assessment of plant protection products for non-target terrestrial plants. EFSA J 12(7): 3800

Christl H, Morilla J, Hoen T, Zumkier U. 2019. Comparative assessment of the intrinsic sensitivity of crop species and wild plant species to plant protection products and their active substances and potential implications for the risk assessment: A literature review. Integr Environ Assess Manag 19(2): 176–189

Christl H, Hoen T, Zumkier U. 2020. Comparative assessment of vegetative and reproductive terrestrial plant species endpoints from exposure to herbicides and potential environmental implications - A review. Integr Environ Assess Manag 16(2): 166-183

Strandberg B, Boutin C, Carpenter D et al. 2019 Pesticide effects on non-target terrestrial plants at individual, population and eco-system level (PENTA). Chapter 5: Effect of glyphosate spray drift on plant flowering (Field test) DANISH EPA Pesticide Research 182: 72 -87 ISBN: 978-87-7038-111-6

The End

Thank you for your attention!

This is Work in Progress…

Wanted: Field data!

Contact me: heino.Christl@tier3.de

More information in the relevant literature, see also our web-page

https:\\ www.tier3.de