Industry views on specific regulatory developments

Endocrine Disruption
Pollinator Guidance Document

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Content
Industry view on…

- … EFSA Guidance Document on bee risk assessments

- … EU developments on endocrine disruptors

EFSA Guidance on bee risk assessments*

* European Food Safety Authority Guidance Document on the Risk Assessment of Plant Protection Products on bees (Apis mellifera, Bombus spp. and solitary bees) – EFSA Journal 2013;11(7):3295 – Published July 2013

Bee Guidance Document

Purpose of any guidance document

- Guiding applicants through testing requirements and strategy
- Guiding evaluators through review and risk assessments
- Providing risk managers with reliable basis for decision

Bee Guidance Document

Necessary attributes of a guidance document

- **Consistent**
  - Backed by data and robust science
  - Proportionate to purpose and objectives
- **Workable, effective**
  - Can be followed by applicants and evaluators with reasonable efforts
  - Delivers the right level of information for the right decision

Bee Guidance Document

Built on Uncertainties and Extrapolations

Chronic and larval endpoints for honey bees

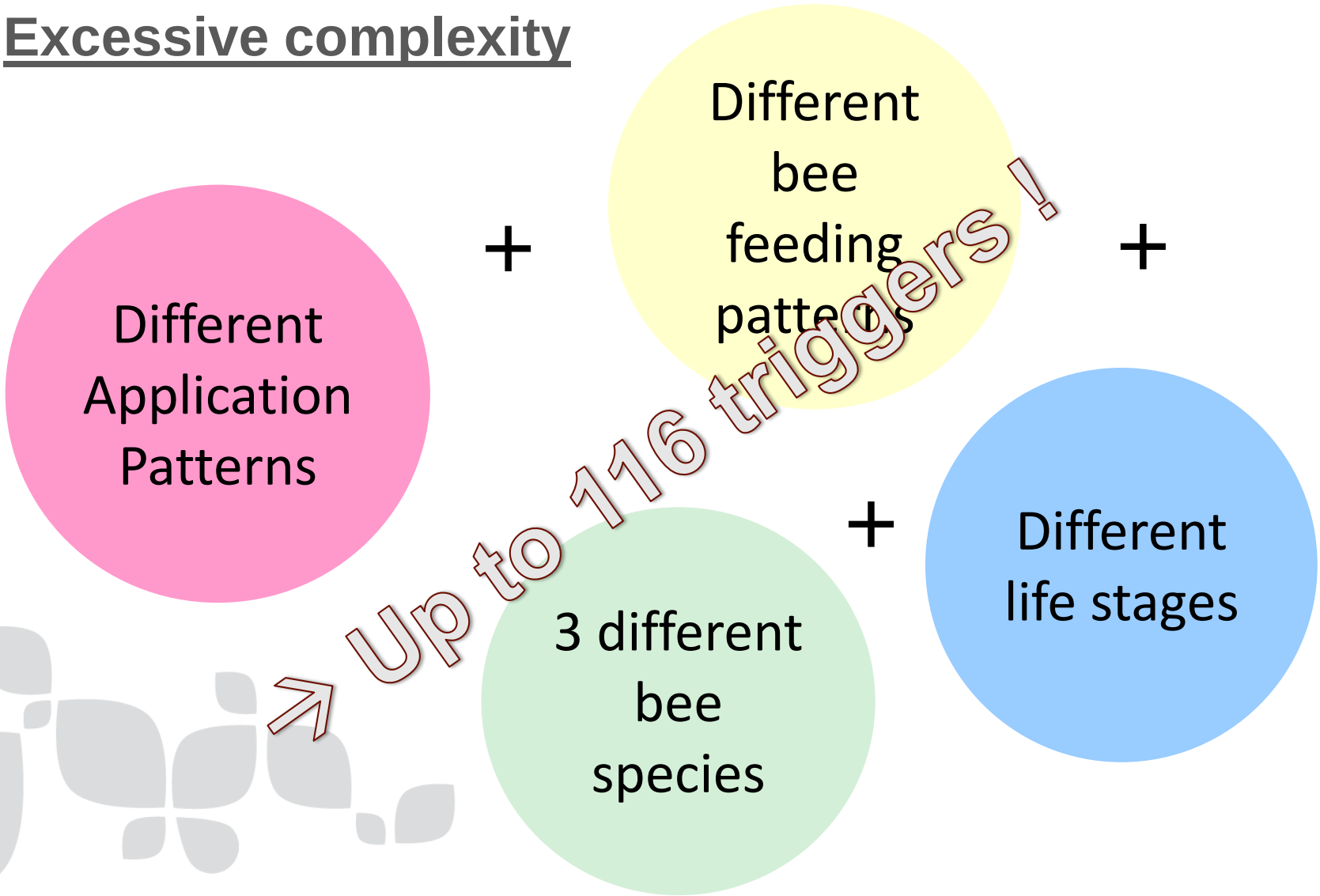
Feeding patterns and toxicity endpoints for bumblebees and solitary bees

Protection goal (max 7% colony size reduction required in GD)

Bee Guidance Document

European Crop Protection

Excessive complexity



Bee Guidance Document

Excessive conservatism (1)

Unlikely and likely exposure situations given equal weight

Background mortality assumption of 4-5% excessively low for free-flying arthropods ?

Bumble and solitary bee scenarios approx. 60X more conservative than for honey bees!

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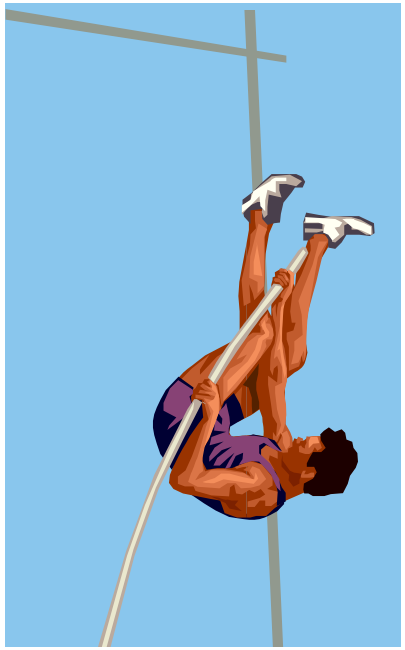
Excessive conservatism (2)

- Combination of extreme exposure assumptions:

  90^{th} percentile residue in nectar/pollen x 90^{th} percentile food from pollen and nectar $\neq$ 90^{th} percentile exposure (edge of field) !

- If ETR triggers changed into regulatory TER triggers, they would range between 5 and ca 2000 (5 to 10 for other arthropods)



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Limited feasibility

No internationally agreed, ring-tested, guidelines for:

- 4 of 6 screening tests on honey bees
- Bumble and solitary bees

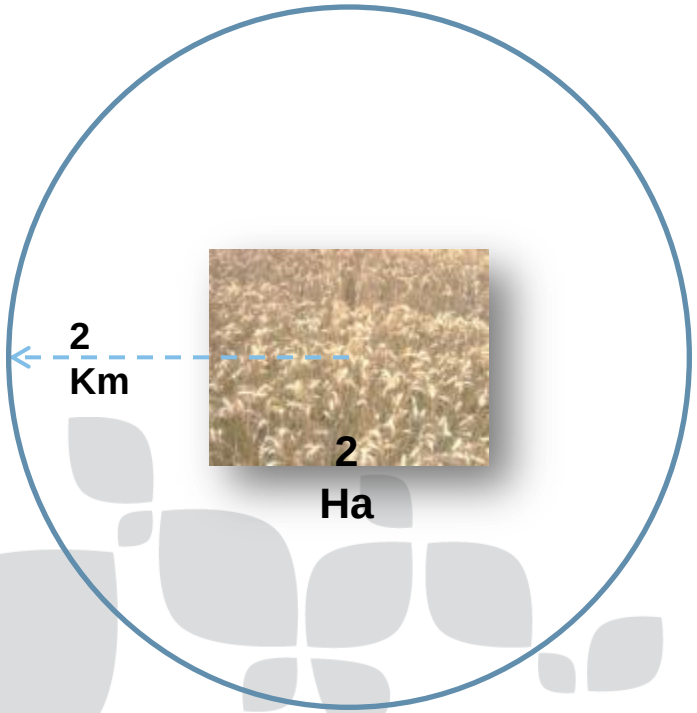
Less than a dozen laboratories in Europe can conduct field tests

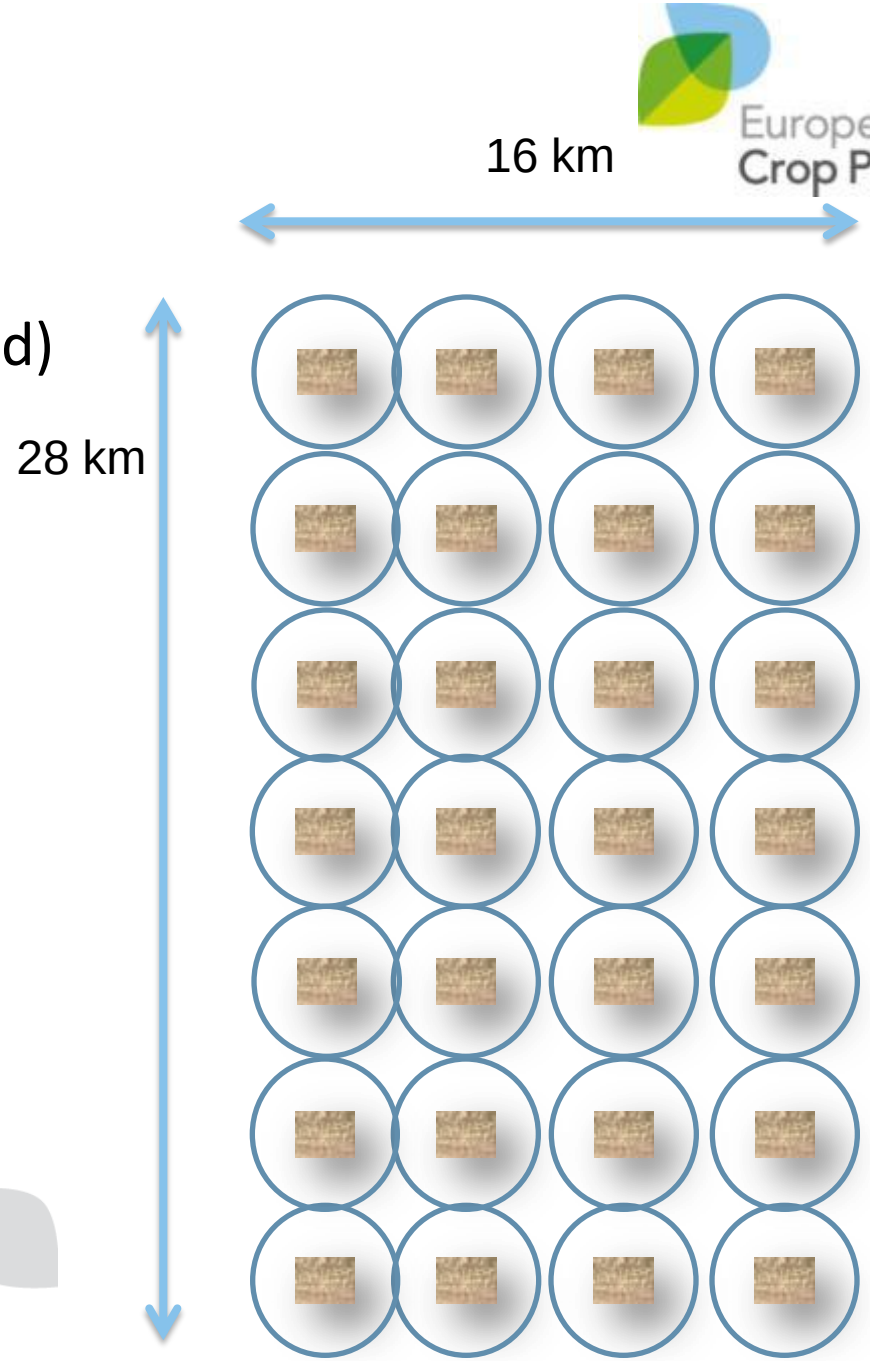
Between (approx.) 180 and 800 colonies required for one higher tier field test

Not possible !

Example: field study

28 Fields 4 km apart
186 colonies (7 colonies/field)





Bee Guidance Document

Consequences if implemented (1)

- High level of screening failure rate for products applied as foliar sprays
- Insufficiently discriminating between (bee) toxic and non-toxic products
- Insufficiently discriminating between likely and unlikely bee exposure situations

→ Does not characterize real risks to bees

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Consequences if implemented (2)

Will any product pass pollinator risk assessments anymore?

Regulatory hurdles unnecessarily high for herbicides and fungicides

Applicants in permanent non-compliance mode

Risk assessors in permanent inconclusive mode

Risk managers in permanent uncertainty mode

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Conclusions

Excessive conservatism + limited workability → **NOT FIT FOR PURPOSE**

Will penalize PPPs and farmers without predictable improvement in bee health

MS urged to oppose adoption of current version - Profound revision required, based on more scientific evidence, justification for changes and greater considerations for feasibility

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Endocrine Disruptors
European Regulatory Developments

Endocrine Disruptors

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Industry supports decisions based on risks assessments, not hazard assessments !

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Regulatory Criteria (1)

- Industry supports impact assessments prior to legislative proposals
- **DG Envi proposed criteria would 'catch broadly'**
- UK CRD study on CP active substances:
  - 56 % not ED (human health)
  - 15% ED (human health, no potency considerations)
  - 28% insufficient information (human health)
  - ?? ED on non-target species

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Regulatory Criteria (2)

- UK CRD study (cont'd):

  Total > 25% ?

→ Potency = critical consideration

Looking at the potential impact…

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- **Potential impact of the ED criteria is extremely high**
  - Triazole family identified as being at risk
  - ***What could that mean?***

Top Ten Products, Poland, Sugarbeet, Fungicides (2011)

Brand	Net Area (000 ha)	Value (€m)
Duett Ultra	105.51	
Eminent 125 SL	9.05	
Alert	11.94	
Yamato	8.63	
Tebu 250 EW	9.34	
Topsin M 500 SC	6.72	
Orius 25 EW	5.76	
Optan 183 SE	2.52	
Horizon	2.94	
Moderator 303 SE	2.39	
Top Ten Total	164.80	2.78
Grand Total	369.72	2.90
Top Ten %	**45%**	**96%**

Key:
No longer authorised
Contains triazoles
Unaffected by ED

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Regulatory Criteria (3)

- 1107 Interim criteria not scientifically robust
- Final ED criteria available before AIR2 renewal decisions?

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Other Developments

- Insufficient scientific evidence behind non-threshold policy
- Threshold/non-threshold decision tightly linked with ED criteria
- Latest draft for revised Commission ED strategy contains unacceptable proposals, e.g. publication of black lists

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Thank you for your attention